



Qualis
LIMS

USER MANUAL

Version 9.0.0.1

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1 Preface

This manual provides instructions about configuring and using Qualis LIMS.

This preface contains these topics:

- [Audience](#)
- [Documentation Accessibility](#)
- [Conventions](#)

1.1 Audience

Qualis LIMS user manual is intended for administrators or anyone using Qualis LIMS application.

To use this document, you need the following:

- Prerequisites mentioned installed and tested on your computer.
- Administrative privileges on the computer.
- Knowledge about the following concepts:
 - Domain Name System (DNS)
 - Connected applications
 - Internet Information Server (IIS)
 - File Transfer Protocol (FTP)

1.2 Documentation Accessibility

Qualis LIMS documentation set consists of the following:

- Qualis LIMS User Manual
- Qualis LIMS Online Help System

1.3 Conventions

The following text conventions are used in this document:

1.3.1 Commands

When a command is referred to in the manual, the following distinctions have been made:

When menu commands are referred to, the manual will refer you to the menu bar – E.g. “Choose File from the menu bar and then Print”.

When dialog field options are referred to, the following style has been used for the text – “In the **Page Range** section of the Print dialog, click the **Current Page** option”

Dialog field buttons are shaded and fielded – “Click **OK** to close the Print dialog and launch the print.”

1.3.2 Keyboard

Keys are referred to throughout the manual in the following way:

[ENTER] – denotes the return or enter key, [DELETE] – denotes the Delete key and so on.

Where a command requires two keys to be pressed, the manual displays this as follows:

[CTRL][P] – this means press the letter “p” while holding down the Control key.

1.3.3 Notes

Within each section, any items that need further explanation or extra attention devoted to them are denoted by shading. For example:

Note: “Qualis LIMS will not let you close a screen or window that you haven’t already saved changes to without prompting you to save.”

1.3.4 Warning

Within each section, any items that need warning or extra attention devoted to them are denoted by shading in yellow. For example:

Warning! : If you click Close before saving will close the FTP Configuration screen without saving the configuration.

1.3.5 Callout

Callouts are used to denote an action or describe something in the interface.



1.3.6 Description

This style denotes the sequence that follows an action. In general, a screen shot appears under the style that denotes the result of an action. For Example: The Add User screen appears as shown in the figure.

1.3.7 Hyperlink

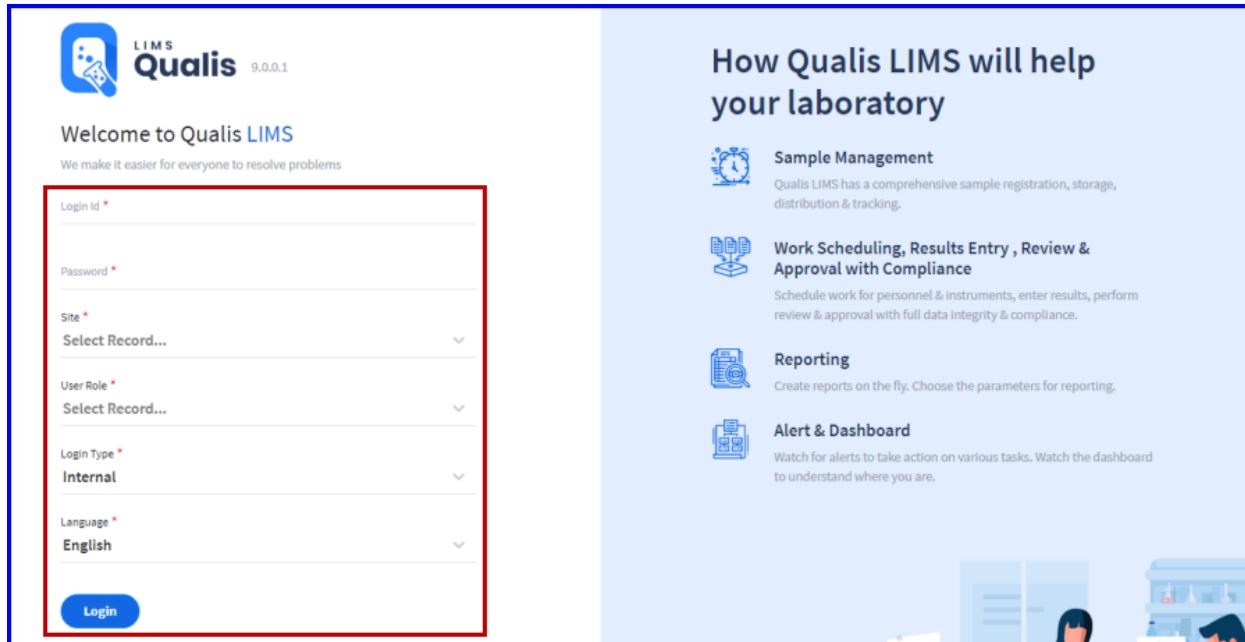
Clicking on hyperlinks will help the user to go to the topic directly in the same document.

Example: [Click here to see how to setup FTP site.](#)

2 Getting Started

2.1 Login

Qualis LIMS login screen appears as shown in the figure:



The image shows the Qualis LIMS login screen. The left side contains the login form with fields for Login Id, Password, Site, User Role, Login Type, and Language, all of which are highlighted with a red box. The right side features a sidebar titled 'How Qualis LIMS will help your laboratory' with four sections: Sample Management, Work Scheduling, Results Entry, Review & Approval with Compliance; Reporting; and Alert & Dashboard. Each section includes an icon and a brief description. The Qualis LIMS logo and version 9.0.0.1 are at the top left, and a small illustration of a laboratory is at the bottom right.

FIGURE: Qualis LIMS – Log in Screen

1. In the **Login Id** field, type the login id received from your administrator.
2. In the **Password** field, type valid password.
3. In the **Site** field, select site to login.
4. In the **User Role** field, select your role.
5. In the **Login Type** fields, select login type: **Internal**
6. In the **Language** field, select language. The application appears in the selected language.
7. Click **Login**.

On successful login, the home screen appears as shown in the figure:

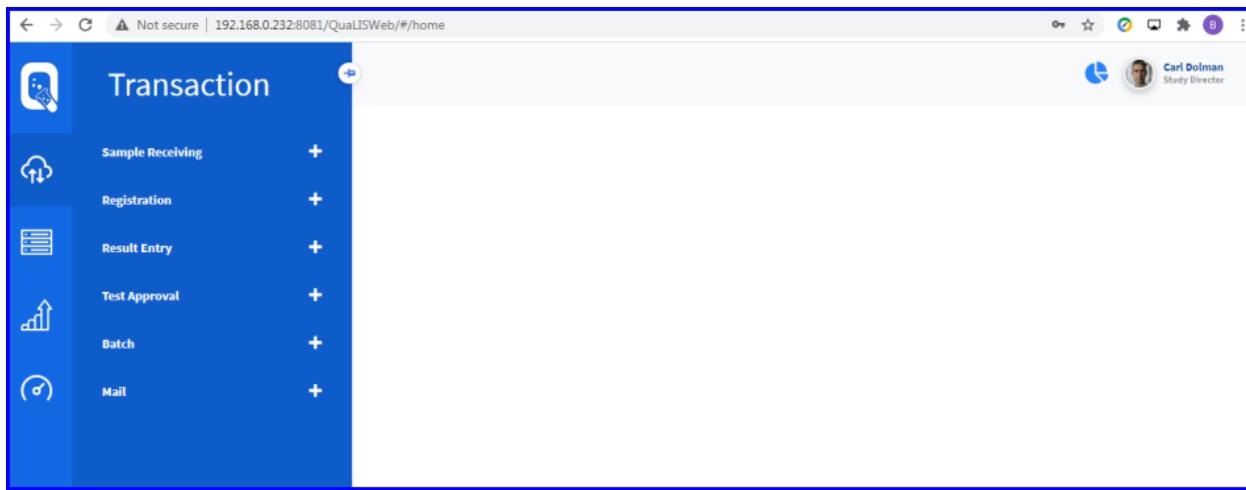


FIGURE: Qualis LIMS Home Page

2.2 Profile Menu

In Qualis LIMS home page, click on the user name/image that appears on the top-right corner of the home page. The profile menu appears as shown in the figure:

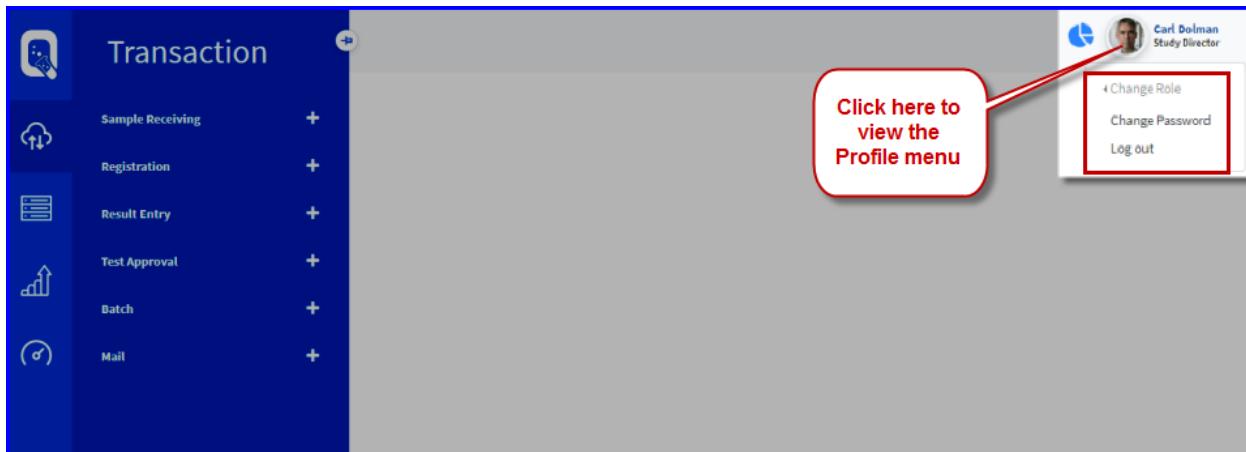


FIGURE: Profile Menu

2.2.1 Change Role

1. On the **Profile** menu, click **Change Role** and then select the role from the list to change the role as shown in the figure:

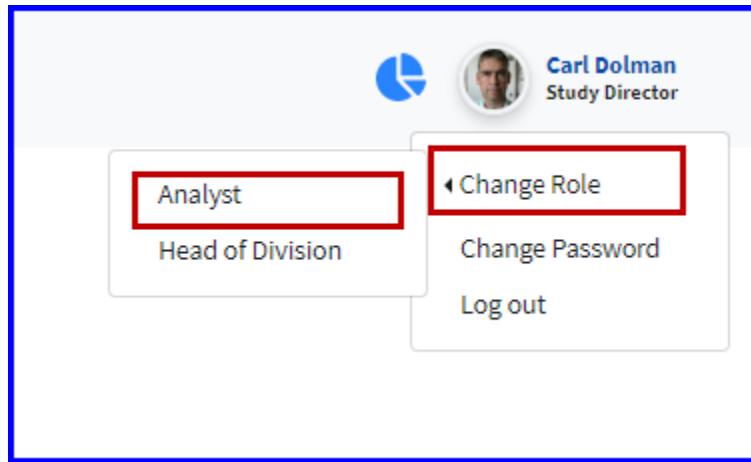


FIGURE: Profile Menu-Change Role Option

The role of the current logged in user is changed to the selected role.

2.2.2 Change Password

1. On the **Profile** menu, click **Change Password**. The Change Password screen appears as shown in the figure:

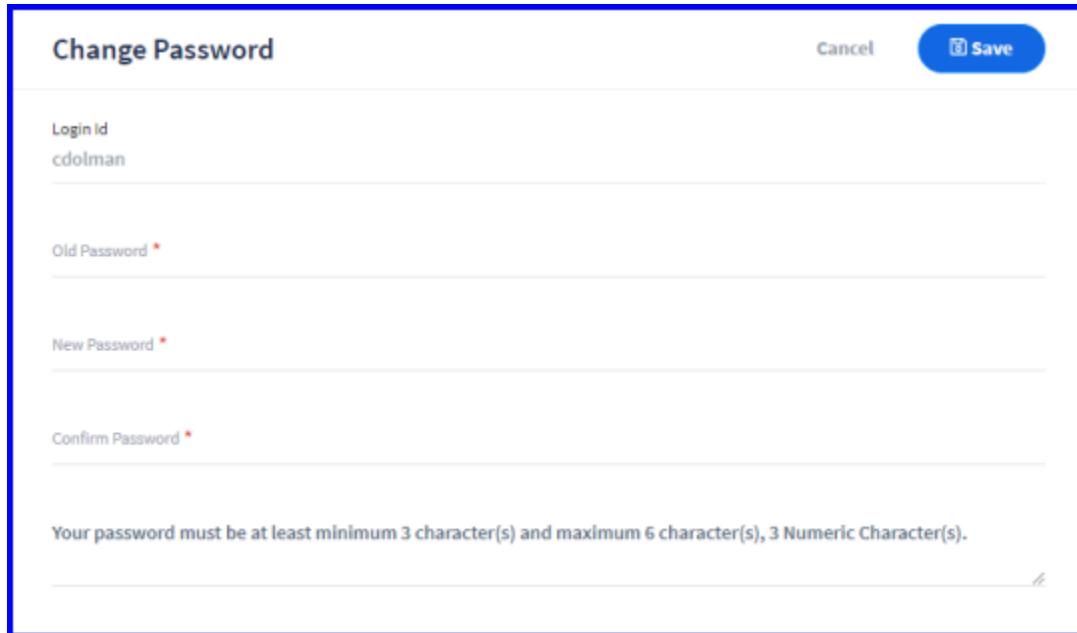
A screenshot of the 'Change Password' screen. The title 'Change Password' is at the top left, and 'Save' is at the top right. The screen contains four input fields: 'Login Id' (cdolman), 'Old Password *', 'New Password *', and 'Confirm Password *'. Below the fields is a note: 'Your password must be at least minimum 3 character(s) and maximum 6 character(s), 3 Numeric Character(s.)'. The 'Old Password' field is currently empty.

FIGURE: Profile Menu-Change Password Screen

2. In the **Login Id** field, you can see the current logged in user name appears.

3. In the **Old Password** field, type your old password.
4. In the **New Password** and **Confirm Password** fields, type the new password. The new password should adhere to the password policy/condition that appears at the bottom of the **Change Password** screen.
5. Click **Save**.

2.2.3 **Logout**

1. On the **Profile** menu, click **Logout** to logout Qualis LIMS application.

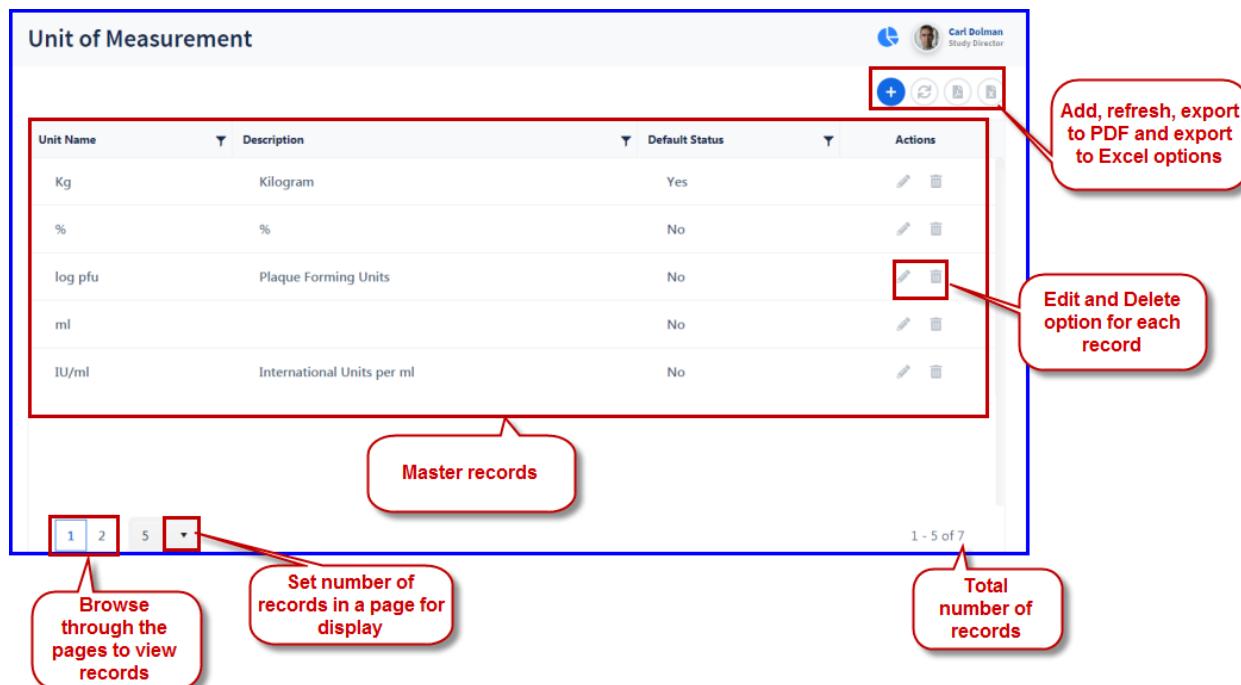
3 Masters

Masters in Qualis LIMS are used to store and maintain data outside a process and refer it in process using "Master" field type in the form. For example, when you store a sample, you may want to look up the storage data such as organisation, division, lab, site, section etc. In this example storage location data can be created and managed as a master. Also customer data can also be created and managed as a master. Other examples are Storage Location Master, Storage Condition Master, and Unit of Measurement Master etc.

In Qualis LIMS, you can add/create masters, edit master details and delete existing masters.

3.1 Common Features

Masters in Qualis LIMS are designed alike to enable the user to understand and use all common features with ease. Following is the list of common features in masters.



Unit Name	Description	Default Status	Actions
Kg	Kilogram	Yes	 
%	%	No	 
log pfu	Plaque Forming Units	No	 
ml		No	 
IU/ml	International Units per ml	No	 

Master records

1 - 5 of 7

Add, refresh, export to PDF and export to Excel options

Edit and Delete option for each record

Browse through the pages to view records

Set number of records in a page for display

Total number of records

FIGURE: Masters – Screen Layout

Masters in Web Method Setup are designed alike to enable the user to understand and use all common features with ease. Following is the list of common features in Method Setup.

3.1.1 List of Common Controls in LIMS

The descriptions of common controls in LIMS are listed below:

Button Name	Image	Description
Home		Goes to the Home page.
Save		Will submit the entries given by the user to perform certain task.
Add		Enables add new records to the masters.
Edit		Enables edit the selected record in the master
Delete		Enables delete the selected record in the master
Default Status	 Default Status	When enabled, the master or feature is loaded in the other modules/masters
Export to PDF		Downloads the master data to PDF
Export to Excel		
Back		Goes back to the previous screen / menu
Cancel		Will clear the entries in the current form for fresh entry
Open		Will open the selected file / folder
Refresh		Will refresh the screen
File Upload		Enables upload files manually

Print		Will print the current form/master/report
Mandatory Fields		All fields marked with a * are mandatory and must be filled to avoid error/alert messages.

3.1.2 Add Records to the Master

To add a new record to the master, follow these steps:

1. Open the master to which you want to add a new record.
2. In the master screen, click . The add screen appears. Fill in mandatory fields and then click **Save**.

3.1.3 Pagination

Set number of records to view in the master screen as shown in the figure:

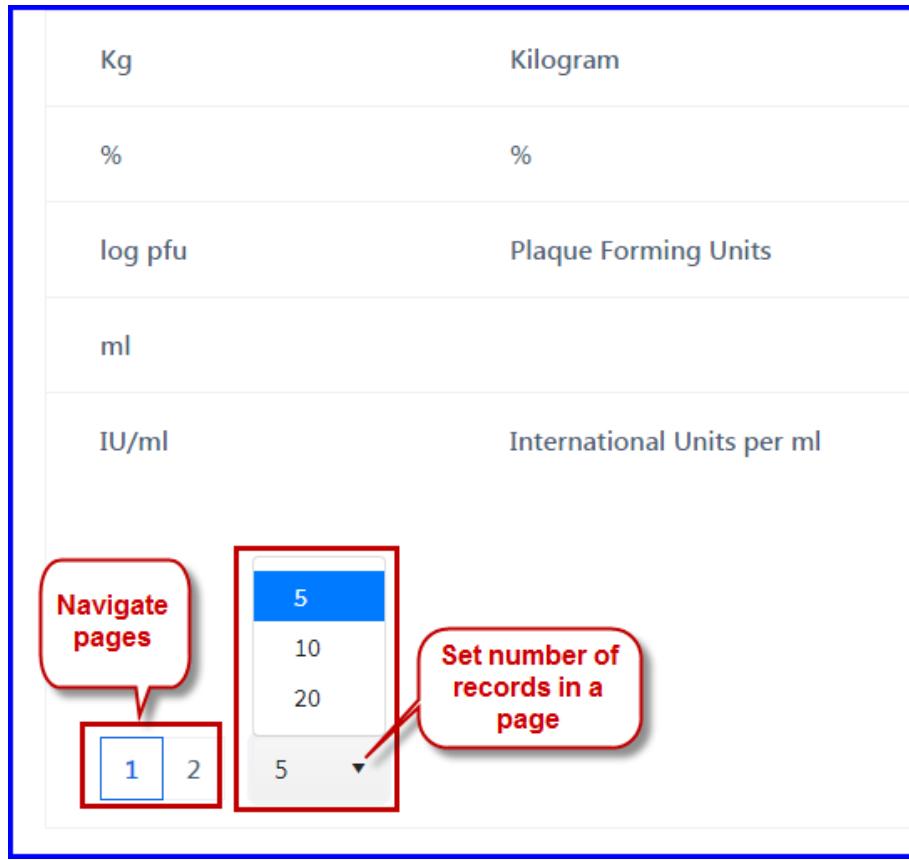


FIGURE: Set Number of Records for View

You can view the selected number of records in the master screen page. For example, if you select 5. Then each page displays 5 records and you can navigate the pages by clicking on the page numbers as shown in the above figure.

3.1.4 Download Master Records to PDF

You can download records in any master to PDF. To do so, follow these steps:

1. In the Master screen, click  as shown in the figure:

Unit of Measurement				
Unit Name	Description	Default Status	Actions	
Kg	Kilogram	Yes		
%	%	No		
log pfu	Plaque Forming Units	No		
ml		No		
IU/ml	International Units per ml	No		

FIGURE: Downloading Master Records to PDF

The records in the UOM master are downloaded to the local storage in PDF. Double-click the downloaded PDF file. The PDF file appears as shown in the figure:

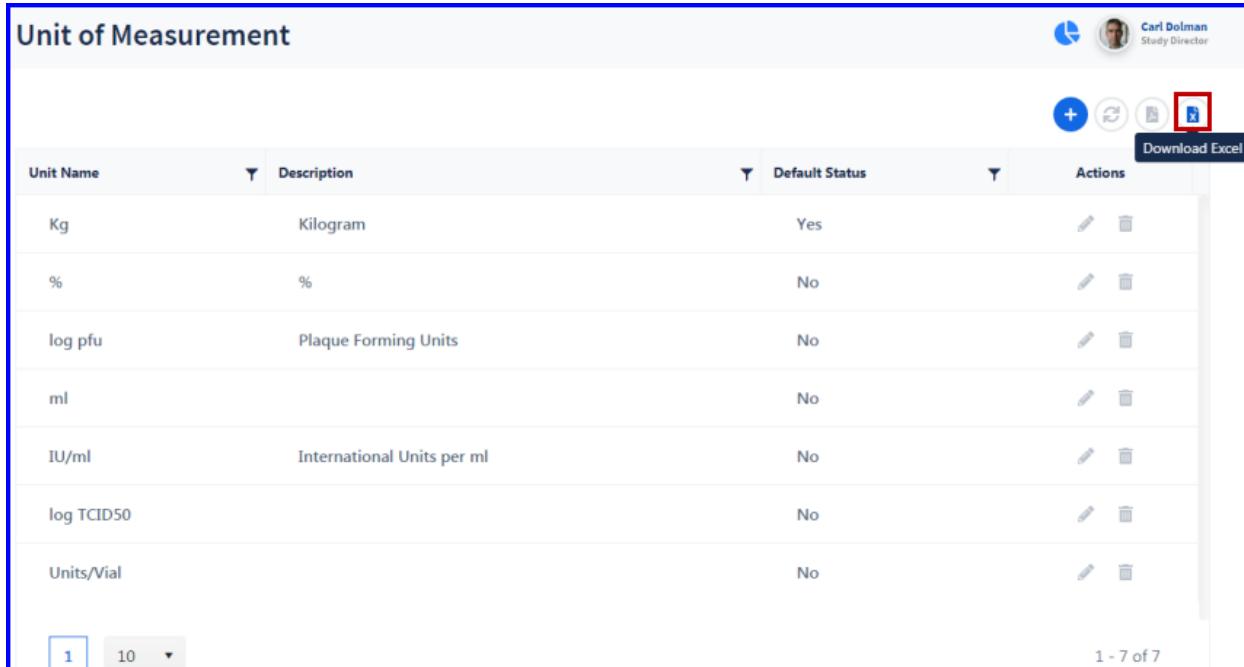
Unit Name	Description	Default Status
Kg	Kilogram	Yes
%	%	No
log pfu	Plaque Forming Units	No
ml		No
IU/ml	International Units per ml	No
log TCID50		No
Units/Vial		No

FIGURE: Downloaded Master Records in PDF

3.1.5 Download Master Records to Excel

You can download records in any master to MS Excel. To do so, follow these steps:

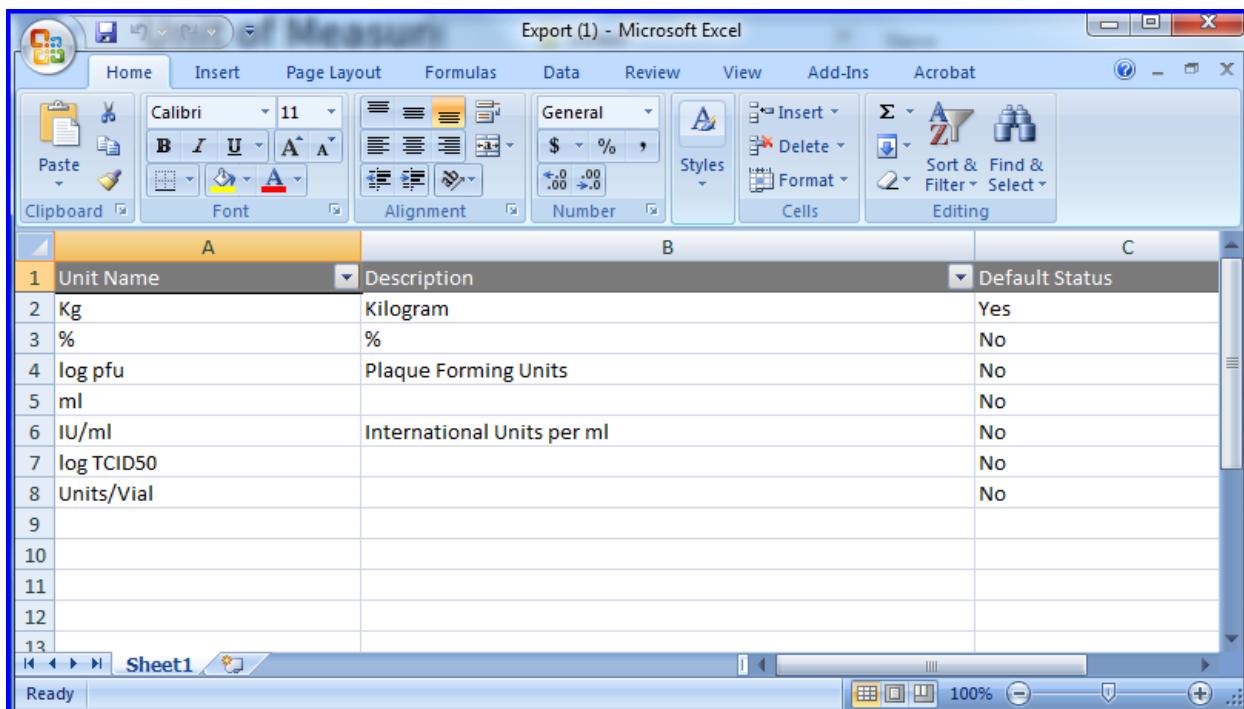
1. In the master screen, click  as shown in the figure:



Unit Name	Description	Default Status	Actions
Kg	Kilogram	Yes	 
%	%	No	 
log pfu	Plaque Forming Units	No	 
ml		No	 
IU/ml	International Units per ml	No	 
log TCID50		No	 
Units/Vial		No	 

FIGURE: Downloading UOM Master Records to Excel

The records in the UOM master are downloaded to the local storage in Excel format. Double-click the downloaded excel file to view the content. The Excel file appears as shown in the figure:



	A	B	C
1	Unit Name	Description	Default Status
2	Kg	Kilogram	Yes
3	%	%	No
4	log pfu	Plaque Forming Units	No
5	ml		No
6	IU/ml	International Units per ml	No
7	log TCID50		No
8	Units/Vial		No
9			
10			
11			
12			
13			

FIGURE: Downloaded Master Records in Excel

3.2 Base Masters

Qualis LIMS allows you to create and manage following masters:

- Unit of Measurement
- Storage Location
- License Authority
- Charge Band
- Container Type
- KPI Band
- Source
- Barcode

- Certificate Type

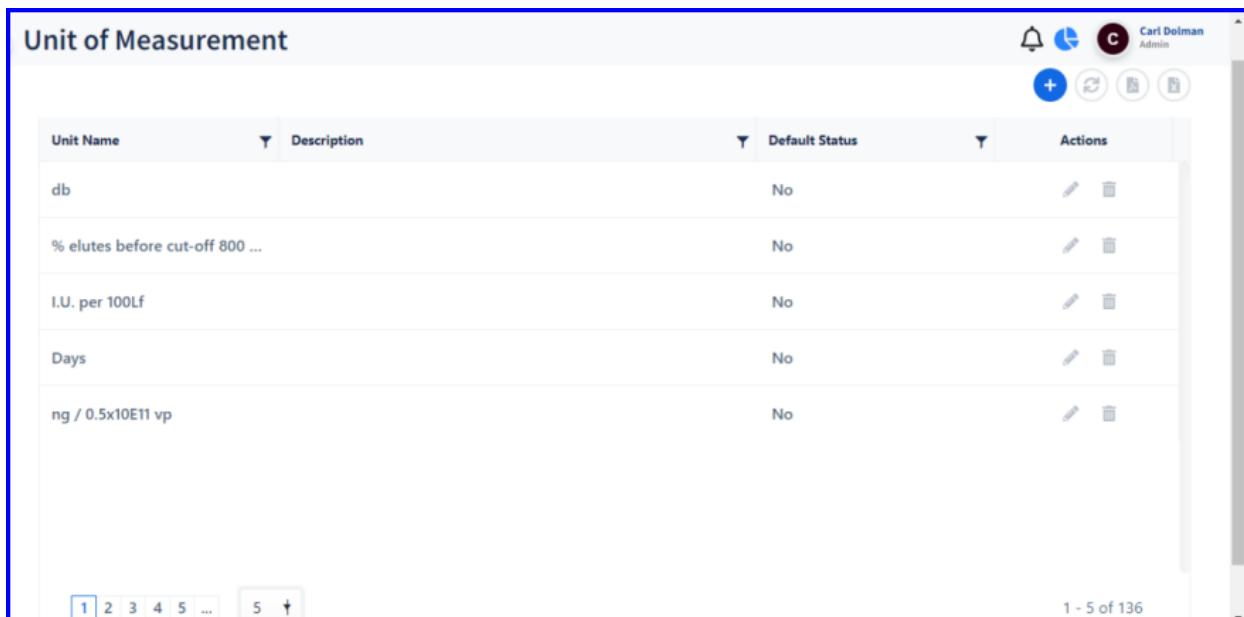
3.2.1 Unit of Measurement

Unit of Measurement master is used to create and manage UOMs (Unit of Measurement) that are used to measure samples.

3.2.1.1 Creating a New Unit of Measurement

To create a UOM, follow these steps:

1. On the main menu, click  **Base Masters** and then click **Unit of Measurement**. The **Unit of Measurement** master screen appears as shown in the figure:



Unit Name	Description	Default Status	Actions
db		No	 
% elutes before cut-off 800 ...		No	 
I.U. per 100Lf		No	 
Days		No	 
ng / 0.5x10E11 vp		No	 

FIGURE: Unit of Measurement Master Screen

In the Unit of Measurement master screen you can see the list of UOMs created. Options to edit and delete UOMs appear in each record.

2. Click  . The **Add** screen appears as shown in the figure:



Add Unit of Measurement

Unit Name *

Min

Description

minutes

Default Status

save

FIGURE: Add Unit of Measurement screen

3. In the **Unit Name** field, type the name for the UOM.
4. In the **Description** field, type description for the UOM.
5. Click to set the **Default Status** button to “Yes”.
6. Click **Save**.

You can see the UOM you created listed in the Unit of Measurement master.

3.2.1.2 Editing Unit of Measurement Record

To edit UOM record, follow these steps:

1. Click  that appears under **Actions** to edit a record.
2. In the **Edit** screen do required changes and then click **Submit**.

3.2.1.3 Deleting Unit of Measurement Record

1. To delete a Unit of Measurement record, in the Unit of Measurements master screen, click  that appears under **Actions**.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

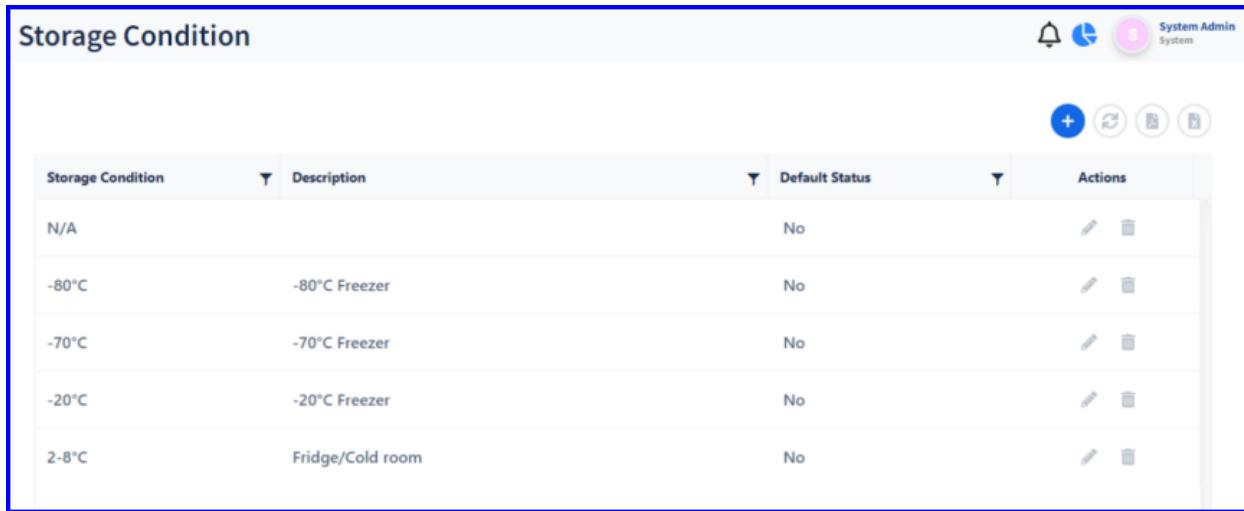
3.2.2 Storage Condition

Storage Condition master is used to create and manage storage conditions that are used to store samples. Storage condition defines the temperature in which the samples are stored.

3.2.2.1 Creating a New Storage Condition

To create a new Storage Condition, follow these steps:

1. On the main menu, click  Base Masters and then click **Storage Condition**. The **Storage Condition** master screen appears as shown in the figure:



Storage Condition	Description	Default Status	Actions
N/A		No	 
-80°C	-80°C Freezer	No	 
-70°C	-70°C Freezer	No	 
-20°C	-20°C Freezer	No	 
2-8°C	Fridge/Cold room	No	 

FIGURE: Storage Condition Master Screen

In the Storage Condition master screen you can see the list of storage conditions created. Options to edit and delete storage conditions appear in each record.

2. Click  . The **Add Storage Condition** dialog appears as shown in the figure:

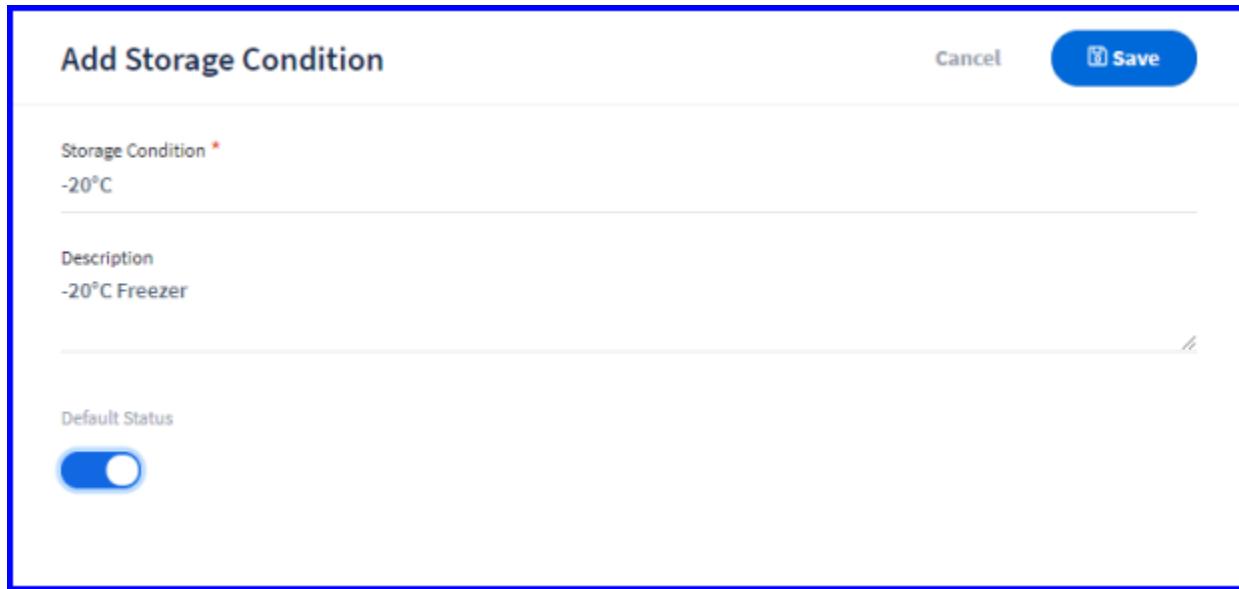


FIGURE: Add Storage Condition Screen

3. In the **Storage Condition** field, type the name for the storage condition.
4. In the **Description** field, type description for the storage condition.
5. By default, the **Default Status** button is set to “**Yes**”. When the default status button is set to “**Yes**” this storage condition will become the default storage condition throughout LIMS in all forms and masters until another storage condition is set to default storage condition. If required, you can set the **Default Status** button to “**No**”.
6. Click **Save**.

You can see the storage condition you created listed in the storage condition master.

3.2.2.2 Editing Storage Condition Record

To edit storage condition record, follow these steps:

1. Click  that appears under **Actions** in the record.
2. In the **Edit** screen do required changes and then click **Submit**.

3.2.2.3 Deleting Storage Condition Record

1. To delete a storage condition record, in the Storage Condition master screen, click  that appears under **Actions** in the record.

2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

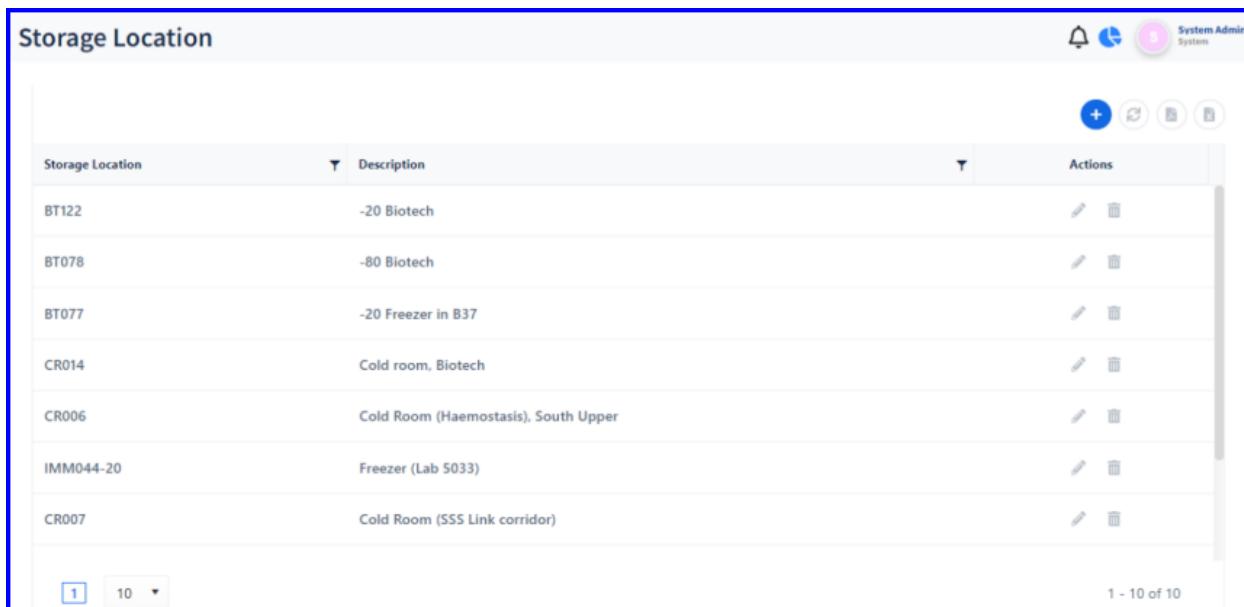
3.2.3 Storage Location

Storage Location master is used to create and manage storage locations that are used to store samples.

3.2.3.1 Creating a New Storage Location

To create a new storage location, follow these steps:

1. On the main menu, click , **Base Masters** and then click **Storage Location**. The **Storage Location** master screen appears as shown in the figure:



Storage Location	Description	Actions
BT122	-20 Biotech	 
BT078	-80 Biotech	 
BT077	-20 Freezer in B37	 
CR014	Cold room, Biotech	 
CR006	Cold Room (Haemostasis), South Upper	 
IMM044-20	Freezer (Lab 5033)	 
CR007	Cold Room (555 Link corridor)	 

FIGURE: Storage Location Master Screen

In the Storage Location master screen you can see the list of storage locations created. Options to edit and delete storage locations appear in each record.

2. Click . The **Add Storage Location** dialog appears as shown in the figure:



The screenshot shows the 'Add Storage Location' screen. At the top, there is a header with the title 'Add Storage Location' and two buttons: 'Cancel' and 'Save'. Below the header is a form with two fields. The first field is labeled 'Storage Location *' and contains the value 'IMMO44+4'. The second field is labeled 'Description' and contains the value 'Fridge (Lab 5033)'. The entire form is enclosed in a blue border.

FIGURE: Add Storage Location Screen

3. In the **Storage Location** field, type the name for the storage Location.
4. In the **Description** field, type description for the storage location.
5. By default, the **Default Status** button is set to “**Yes**”. When the default status button is set to “**Yes**” this storage location will become the default storage location throughout LIMS in all forms and masters until another storage location is set to default storage location. If required, you can set the **Default Status** button to “**No**”.
6. Click **Save**.

You can see the storage location you created listed in the storage location master.

3.2.3.2 Editing Storage Location Record

To edit a storage location record, follow these steps:

1. Click  that appears under **Actions** in the record.
2. In the **Edit** screen do required changes and then click **Submit**.

3.2.3.3 Deleting Storage Location Record

1. To delete a storage location record, in the Storage Location master screen, click  that appears under **Actions** in the record.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

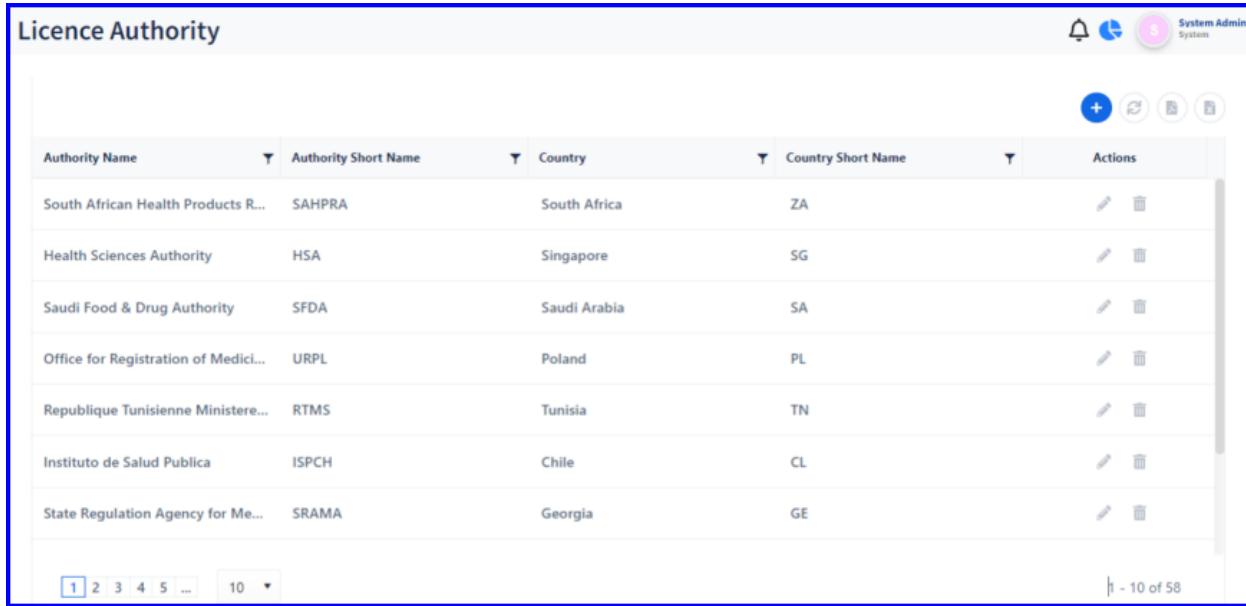
3.2.4 License Authority

License Authority master is used to create and manage license authorities.

3.2.4.1 Creating a New License Authority

To create a new license authority, follow these steps:

1. On the main menu, click  Base Masters and then click License Authority. The License Authority master screen appears as shown in the figure:



Authority Name	Authority Short Name	Country	Country Short Name	Actions
South African Health Products R...	SAHPRA	South Africa	ZA	 
Health Sciences Authority	HSA	Singapore	SG	 
Saudi Food & Drug Authority	SFDA	Saudi Arabia	SA	 
Office for Registration of Medicines...	URPL	Poland	PL	 
Republique Tunisienne Ministere...	RTMS	Tunisia	TN	 
Instituto de Salud Publica	ISPCH	Chile	CL	 
State Regulation Agency for Medical...	SRAMA	Georgia	GE	 

FIGURE: License Authority Master Screen

In the License Authority master screen you can see the list of license authority records created. Options to edit and delete license authority appear in each record.

2. Click  . The Add License Authority dialog appears as shown in the figure:



Add License Authority

Authority Name *

Bulgarian Drug Agency

Authority Short Name *

BG

Country *

Bulgarian

Country Short Name

BG

Cancel

Save

FIGURE: Add License Authority Screen

3. In the **Authority Name** field, type the name of the license authority.
4. In the **Authority Short Name** field, type the short name for the license authority
5. In the **Country** field, select country of the license authority.
6. In the **Country Short Name** field, type short name for the country of the license authority.
7. Click **Save**.

You can see the license authority you created listed in the License Authority master.

3.2.4.2 Editing License Authority Record

To edit a License Authority record, follow these steps:

1. Click  that appears under **Actions** in the record.
2. In the **Edit** screen do required changes and then click **Submit**.

3.2.4.3 Deleting License Authority Record

1. To delete a License Authority record, in the License Authority master screen, click  that appears under **Actions** in the record.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

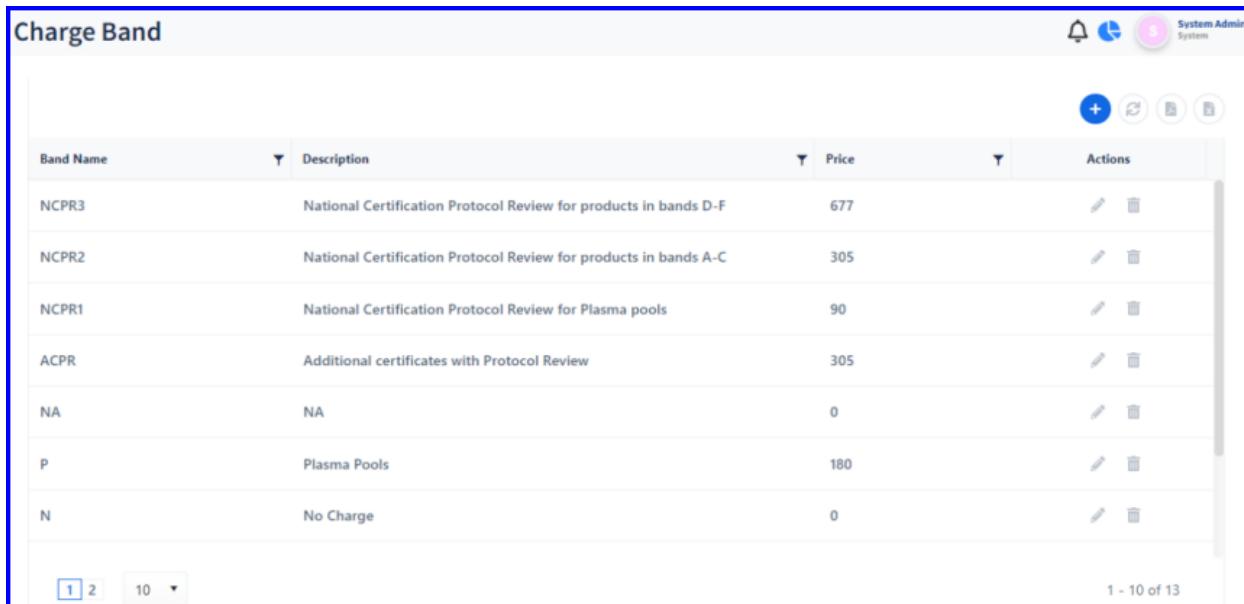
3.2.5 Charge Band

Charge Band master is used to create and manage charge bands. Charge bands are associated with products in Product master.

3.2.5.1 Creating a New Charge Band

To create a new charge band, follow these steps:

1. On the main menu, click , **Base Masters** and then click **Charge Band**. The **Charge Band** master screen appears as shown in the figure:



Band Name	Description	Price	Actions
NCPR3	National Certification Protocol Review for products in bands D-F	677	 
NCPR2	National Certification Protocol Review for products in bands A-C	305	 
NCPR1	National Certification Protocol Review for Plasma pools	90	 
ACPR	Additional certificates with Protocol Review	305	 
NA	NA	0	 
P	Plasma Pools	180	 
N	No Charge	0	 

FIGURE: Charge Band Master Screen

In the Charge Band master screen you can see the list of charge band records created. Options to edit and delete charge band appear in each record.

2. Click . The **Add Charge Band** dialog appears as shown in the figure:



Add Charge Band

Band Name *

Description

Price *

Cancel

Save

FIGURE: Add Charge Band Screen

3. In the **Band Name** field, type the name of the charge band.
4. In the **Description** field, type description of the charge band
5. In the **Price** field, type price for the charge band.
6. Click **Save**.

You can see the charge band you created listed in the Charge Band master.

3.2.5.2 Editing Charge Band Record

To edit a Charge Band record, follow these steps:

1. Click  that appears under **Actions** in the record.
2. In the **Edit** screen do required changes and then click **Submit**.

3.2.5.3 Deleting Charge Band Record

1. To delete a Charge Band record, in the Charge band master screen, click  that appears under **Actions** in the record.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

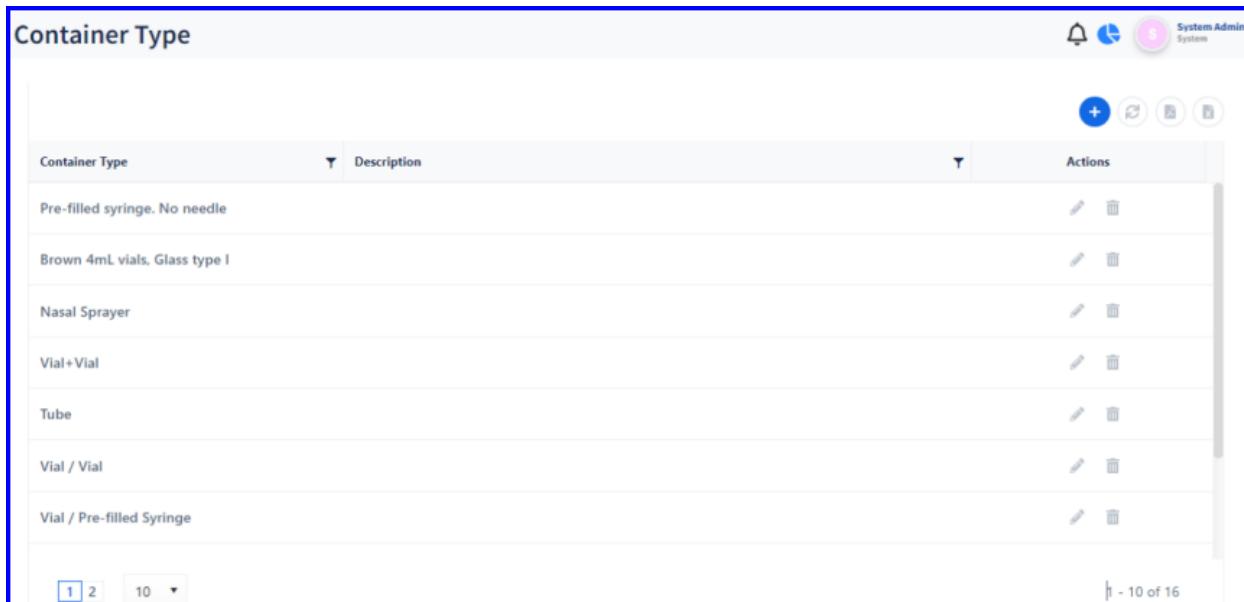
3.2.6 Container Type

Container Type master is used to create and manage container types that are used to store samples.

3.2.6.1 Creating a New Container Type

To create a new Container Type, follow these steps:

1. On the main menu, click , **Base Masters** and then click **Container Type**. The **Container Type** master screen appears as shown in the figure:



Container Type	Description	Actions
Pre-filled syringe. No needle		 
Brown 4mL vials, Glass type I		 
Nasal Sprayer		 
Vial+Vial		 
Tube		 
Vial / Vial		 
Vial / Pre-filled Syringe		 

FIGURE: Container Type Master Screen

In the Container Type master screen you can see the list of Container Type records created. Options to edit and delete Container Type appear in each record.

2. Click  . The **Add Container Type** dialog appears as shown in the figure:



FIGURE: Add Container Type Screen

3. In the **Container Type** field, type the name for the container type.
4. In the **Description** field, type description of the container type
5. Click **Save**.

You can see the Container Type you created listed in the Container Type master.

3.2.6.2 Editing Container Type Record

To edit a Container Type record, follow these steps:

1. Click  that appears under **Actions** in the record.
2. In the **Edit** screen do required changes and then click **Submit**.

3.2.6.3 Deleting Container Type Record

1. To delete a Container Type record, in the Container Type master screen, click  that appears under **Actions** in the record.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

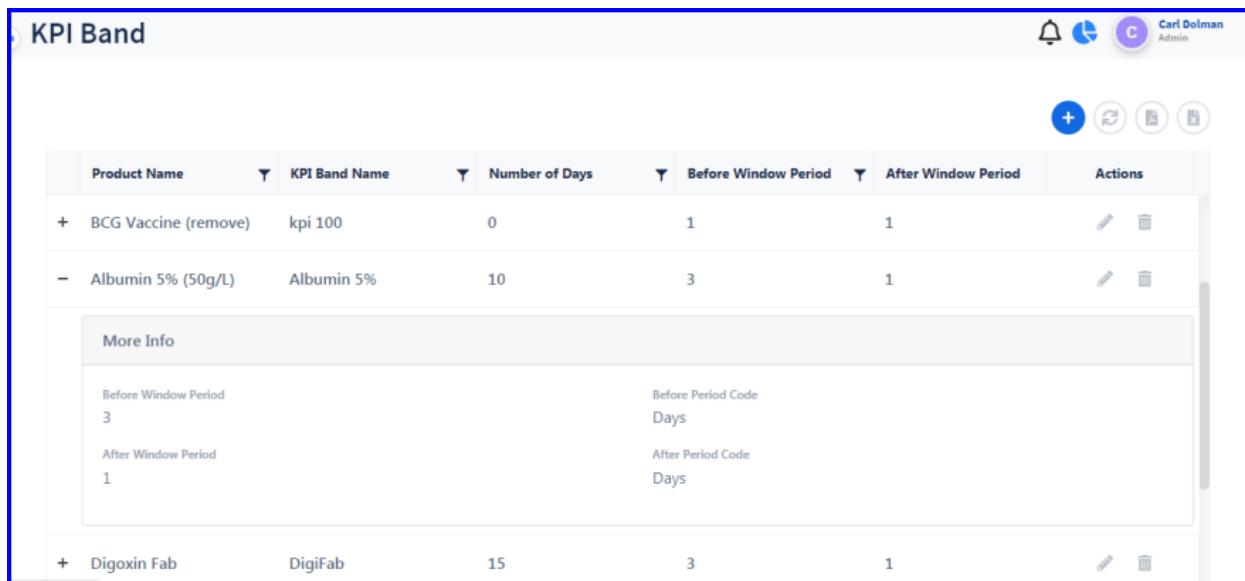
3.2.7 KPI Band

KPI Band master is used to add and manage Key Performance Indicator bands (KPI Band) that are used in clock monitoring.

3.2.7.1 Creating a New KPI Band

To create a new KPI band, follow these steps:

1. On the main menu, click  **Base Masters** and then click **KPI Band**. The **KPI Band** master screen appears as shown in the figure:



Product Name	KPI Band Name	Number of Days	Before Window Period	After Window Period	Actions
+ BCG Vaccine (remove)	kpi 100	0	1	1	 
- Albumin 5% (50g/L)	Albumin 5%	10	3	1	 

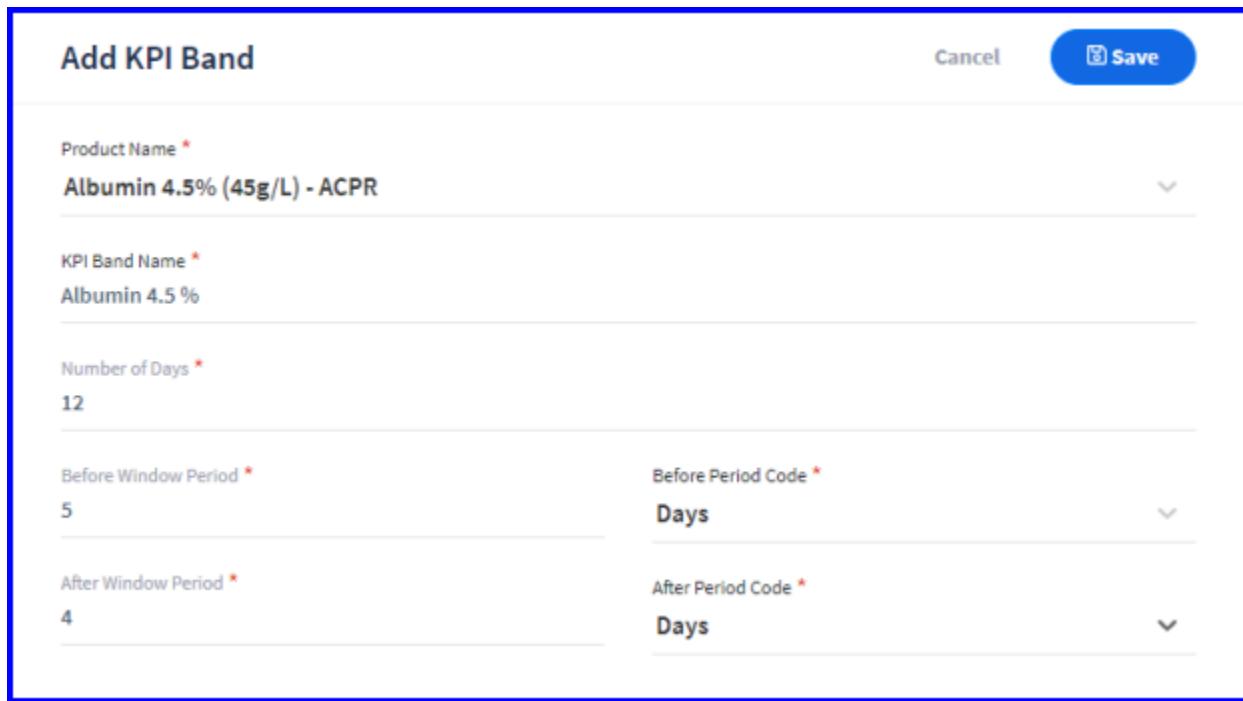
More Info

Before Window Period	Before Period Code
3	Days
After Window Period	After Period Code
1	Days

FIGURE: KPI Band Master Screen

In the KPI Band master screen you can see the list of KPI bands created. Options to edit and delete KPI bands appear in each record.

2. Click  **Add KPI Band**. The **Add KPI Band** screen appears as shown in the figure:



Add KPI Band

Cancel  Save

Product Name *

Albumin 4.5% (45g/L) - ACPR

KPI Band Name *

Albumin 4.5 %

Number of Days *

12

Before Window Period *

5

After Window Period *

4

Before Period Code *

Days

After Period Code *

Days

FIGURE: Add KPI Band screen

3. In the **Product Name** field, select the product to which you want to create KPI band.
4. In the **KPI Band Name** field, type the name for the KPI band.
5. In the **Number of Days** field, type the number of days.
6. In the **Before Window Period** field, type the number of days.
7. In the **After Window Period** field, type the number of days.
8. In the **Before Period Code** field, select unit for the **Before Window Period** field.
9. In the **After Period Code** field, select unit for the **After Window Period** field.
10. Click **Save**.

You can see the KPI Band you created listed in the KPI Band master.

3.2.7.2 Editing KPI Band Record

To edit KPI Band record, follow these steps:

1. Click  that appears under Actions to edit a record.
2. In the **Edit KPI Band** screen do required changes and then click **Save**.

3.2.7.3 Deleting KPI Band Record

1. To delete a KPI Band record, in the KPI Bands master screen, click  that appears under **Actions**.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

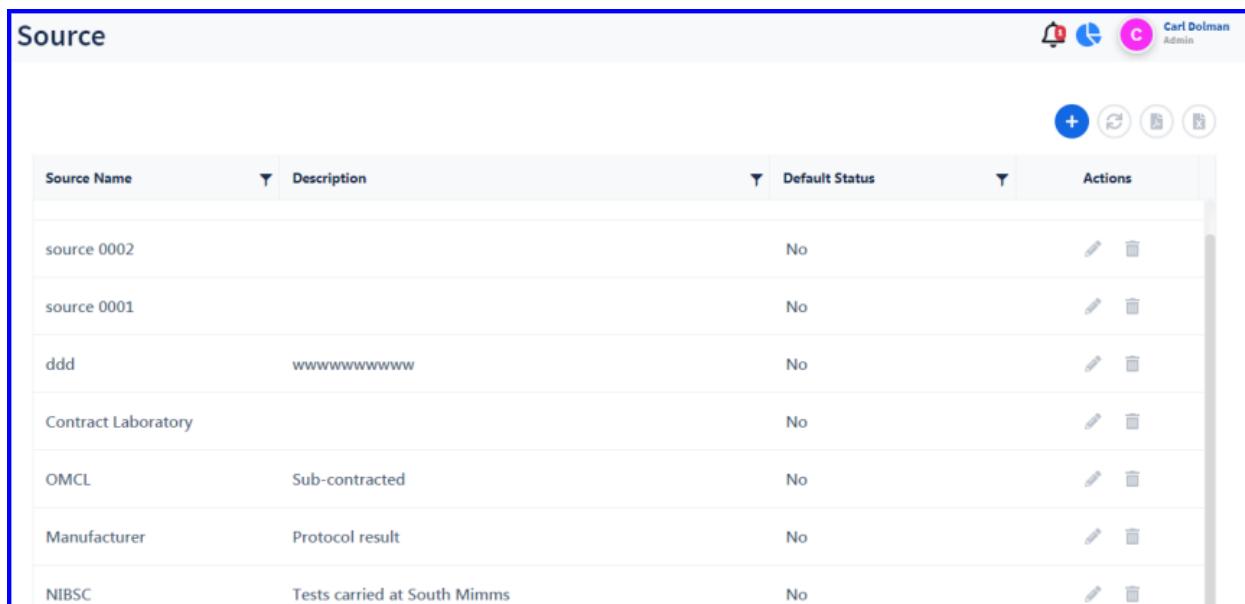
3.2.8 Source

Source master is used to add and manage sources that are used in plasma pool sample registration.

3.2.8.1 Creating a New Source

To create a new source, follow these steps:

1. On the main menu, click , **Base Masters** and then click **Source**. The **Source** master screen appears as shown in the figure:

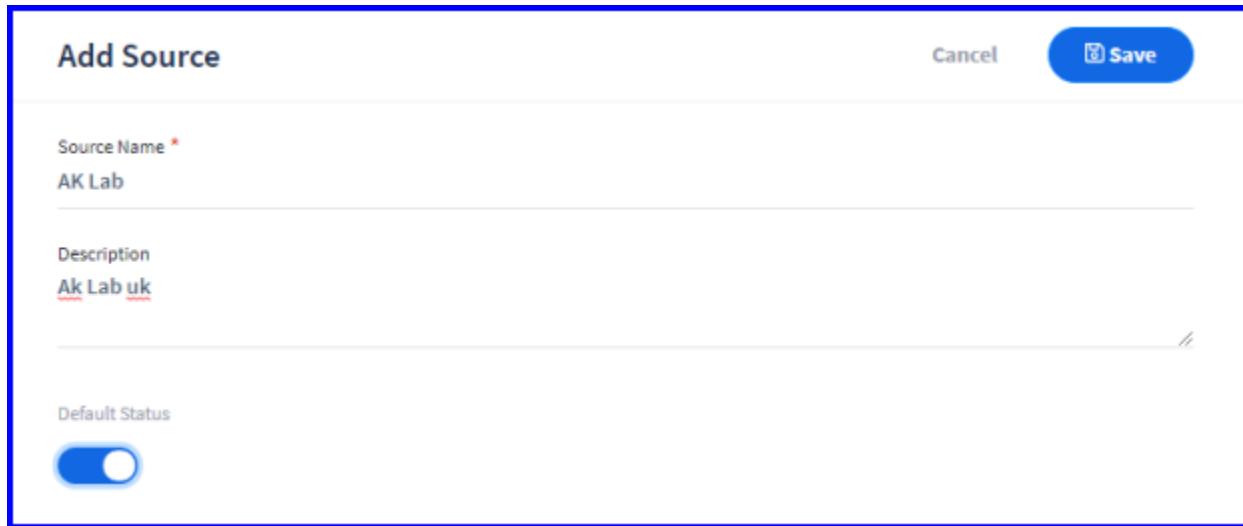


Source Name	Description	Default Status	Actions
source 0002		No	 
source 0001		No	 
ddd	wwwwwwwwww	No	 
Contract Laboratory		No	 
OMCL	Sub-contracted	No	 
Manufacturer	Protocol result	No	 
NIBSC	Tests carried at South Mimms	No	 

FIGURE: Source Master Screen

In the Source master screen you can see the list of Sources created. Options to edit and delete Sources appear in each record.

2. Click  . The **Add Source** screen appears as shown in the figure:



Add Source	
Source Name *	AK Lab
Description	Ak Lab uk
Default Status	<input checked="" type="checkbox"/>

FIGURE: Add Source screen

3. In the **Source Name** field, type the name of the source you want to add.
4. In the **Description** field, type description if any.
5. Click to check the **Default Status** of the source to active.
6. Click **Save**.

You can see the source you created listed in the Source master.

3.2.8.2 Editing Source Record

To edit source record, follow these steps:

1. Click  that appears under **Actions** to edit a record.
2. In the **Edit Source** screen do required changes and then click **Save**.

3.2.8.3 Deleting Source Record

1. To delete a source record, in the sources master screen, click  that appears under **Actions**.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

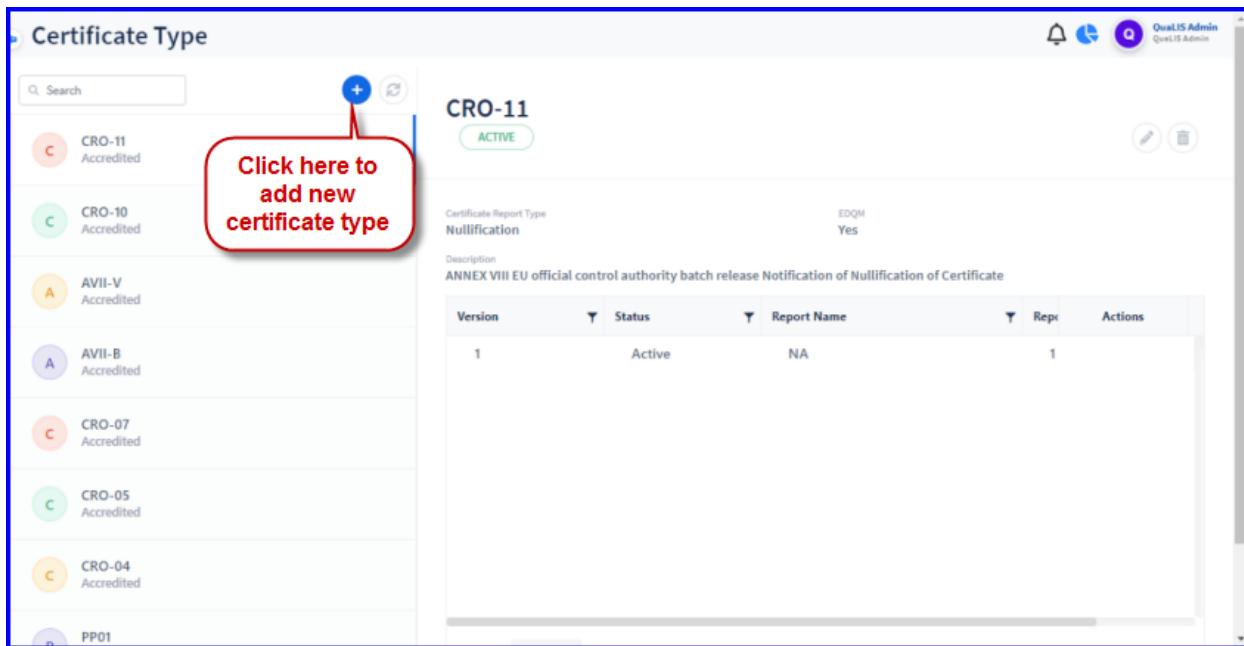
3.2.9 Certificate Type

Certificate Type master is used to create and manage certificate types.

3.2.9.1 Creating a New Certificate Type

To create a new Certificate Type, follow these steps:

1. On the main menu, click  Base Masters and then click Certificate Type. The Certificate Type master screen appears as shown in the figure:

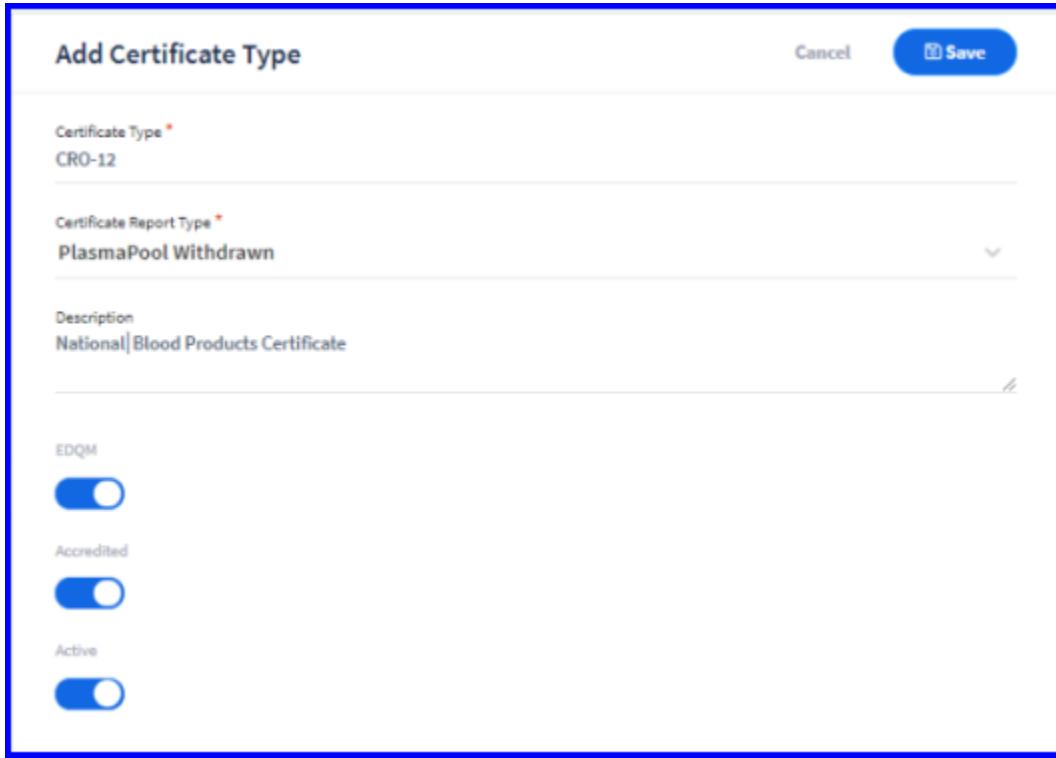


The screenshot shows the 'Certificate Type' master screen. On the left, a list of existing certificate types is displayed in a table format. Each row contains a color-coded icon (red, green, orange, blue, or purple), a code (e.g., CRO-11, CRO-10, AVII-V, AVII-B, CRO-07, CRO-05, CRO-04, PP01), and the word 'Accredited'. A red callout box with the text 'Click here to add new certificate type' points to a blue '+' button located in the top right corner of the list area. On the right, a detailed view of the 'CRO-11' record is shown. The record is marked as 'ACTIVE'. It includes fields for 'Certificate Report Type' (Nullification), 'EDQM' (Yes), and a 'Description' (ANNEX VIII EU official control authority batch release Notification of Nullification of Certificate). Below this, a table lists the version, status, report name, and a column for actions. The table shows one entry: Version 1, Status Active, Report Name NA, and an action button.

FIGURE: Certificate Type Master Screen

In the Certificate Type master screen you can see the list of Certificate Type records created. Options to edit and delete Certificate Type appear in each record.

2. Click  . The Add Certificate Type dialog appears as shown in the figure:



The screenshot shows the 'Add Certificate Type' screen. At the top right are 'Cancel' and 'Save' buttons. The 'Save' button is highlighted with a blue background and white text. The form fields are as follows:

- Certificate Type ***: CRO-12
- Certificate Report Type ***: PlasmaPool Withdrawn
- Description**: National Blood Products Certificate
- EDQM**: Enabled (blue toggle switch)
- Accredited**: Enabled (blue toggle switch)
- Active**: Enabled (blue toggle switch)

FIGURE: Add Certificate Type Screen

3. In the **Certificate Type** field, type the name for the certificate type.
4. In the **Certificate Report Type** field, select the batch type for the certificate type.
5. In the **Description** field, type description of the certificate type
6. Click to enable the **EDQM** option if required. When this option is enabled, product details associated with EDQM will appear.
7. Click to enable the **Accredited** option if required. Enabling this option enables issue the certificate.
8. Click to enable the **Active** option to make the certificate type active.
9. Click **Save**.

You can see the certificate type you created listed in the Certificate Type master.

3.2.9.2 Editing Certificate Type Record

To edit a Certificate Type record, follow these steps:

1. In the Certificate Type master screen, select the certificate type record to edit, and then click  that appears in the record.
2. In the **Edit Certificate Type** screen do required changes and then click **Save**.

3.2.9.3 Deleting Certificate Type Record

To edit a Certificate Type record, follow these steps:

1. In the Certificate Type master screen, select the certificate type record to delete, and then click  that appears in the record.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

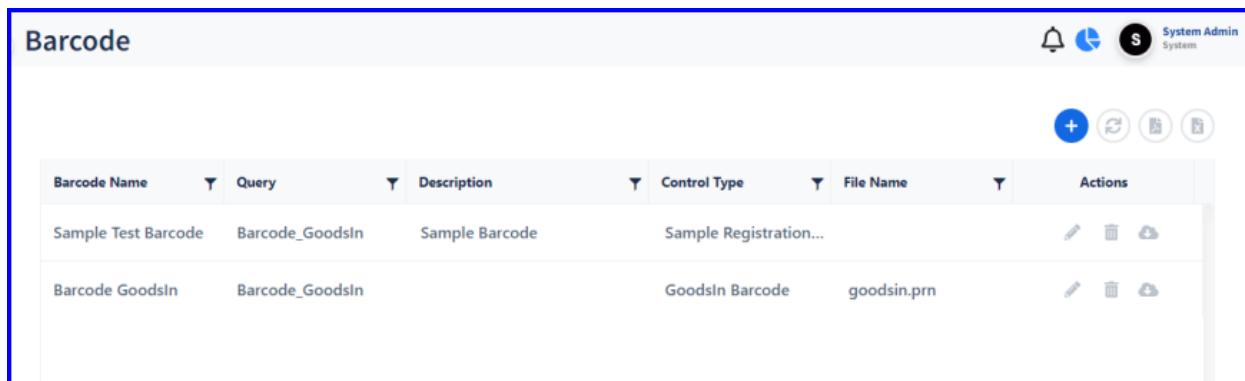
3.2.10 Barcode

Barcode master is used to create and manage Barcodes.

3.2.10.1 Creating a New Barcode

To create a new Barcode, follow these steps:

3. On the main menu, click , **Base Masters** and then click **Barcode**. The **Barcode** master screen appears as shown in the figure:

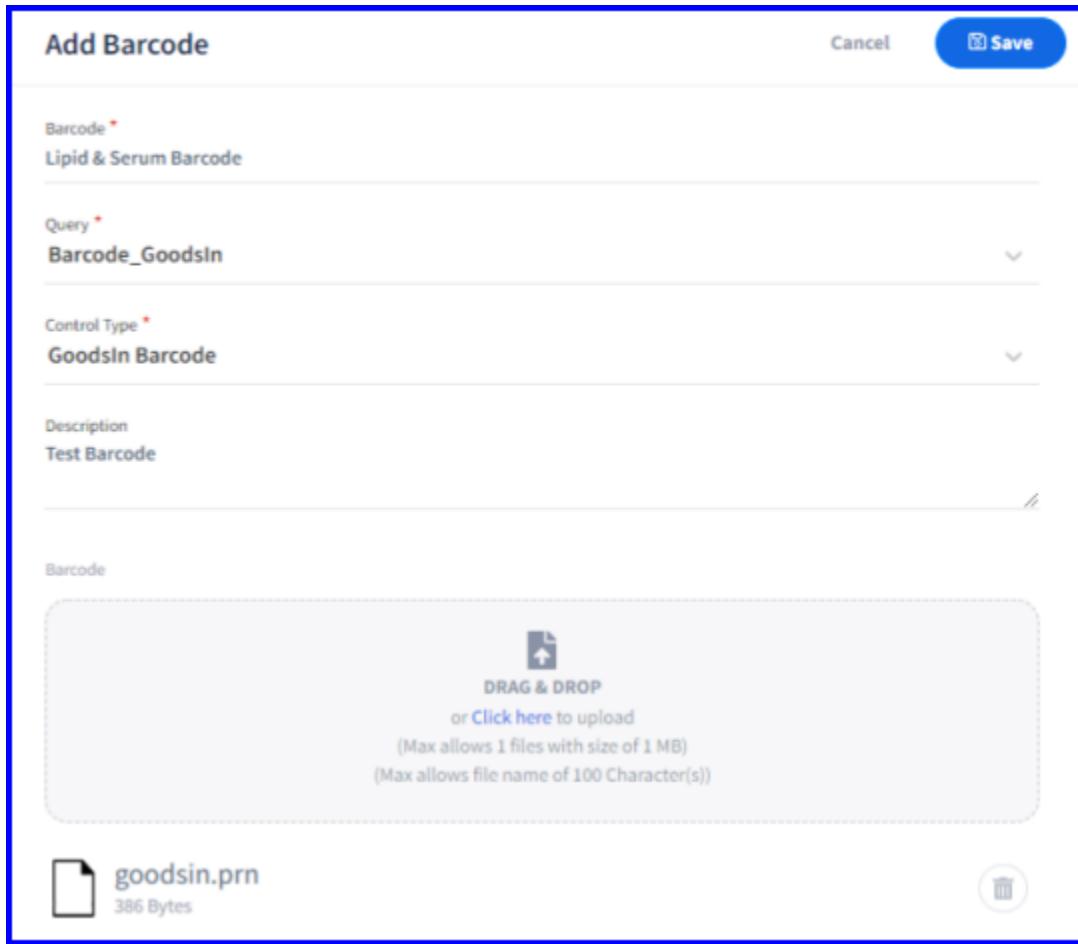


Barcode Name	Query	Description	Control Type	File Name	Actions
Sample Test Barcode	Barcode_GoodsIn	Sample Barcode	Sample Registration...		  
Barcode GoodsIn	Barcode_GoodsIn		GoodsIn Barcode	goodsin.prn	  

FIGURE: Barcode Master Screen

In the Barcode master screen you can see the list of Barcodes created. Options to edit and delete Barcodes appear in each record.

4. Click  . The **Add Barcode** dialog appears as shown in the figure:



The screenshot shows the 'Add Barcode' screen. The form fields are as follows:

- Barcode ***: Lipid & Serum Barcode
- Query ***: Barcode_GoodsIn
- Control Type ***: GoodsIn Barcode
- Description**: Test Barcode

Below the fields is a file upload area:

Barcode

DRAG & DROP
or [Click here](#) to upload
(Max allows 1 files with size of 1 MB)
(Max allows file name of 100 Character(s))

Attached file:

- goodsin.prn (386 Bytes)

Buttons at the top right:

- Cancel
- Save

FIGURE: Add Barcode Screen

5. In the **Barcode** field, type the name for the Barcode.
6. In the **Query** field, select the query for the Barcode.
7. In the **Control Type** field, select control type for the Barcode. The control type should be same as query.
8. In the **Description** field, type description for the Barcode.
9. You drag and drop a PRN file for the barcode. Or click **Click here** to attach the PRN file.
10. Click **Save**.

You can see the Barcode you created listed in the Barcode master.

3.2.10.2 Editing Barcode Record

To edit a Barcode record, follow these steps:

11. Click  that appears under **Actions** in the record.
12. In the **Edit** screen do required changes and then click **Submit**.

3.2.10.3 Deleting Barcode Record

13. To delete a Barcode record, in the Barcode master screen, click  that appears under **Actions** in the record.
14. The **Confirmation** dialog appears. Click **Ok** to delete the record.

3.2.10.4 Downloading PRN File

15. To download the PRN file attached to the Barcode, click  that appears under **Actions** in the record.

3.3 EDQM Master

EDQM information is recorded as masters in EDQM Master. EDQM information is recorded in subsets and is associated to respective product in EDQM Product Master as shown in the figure:

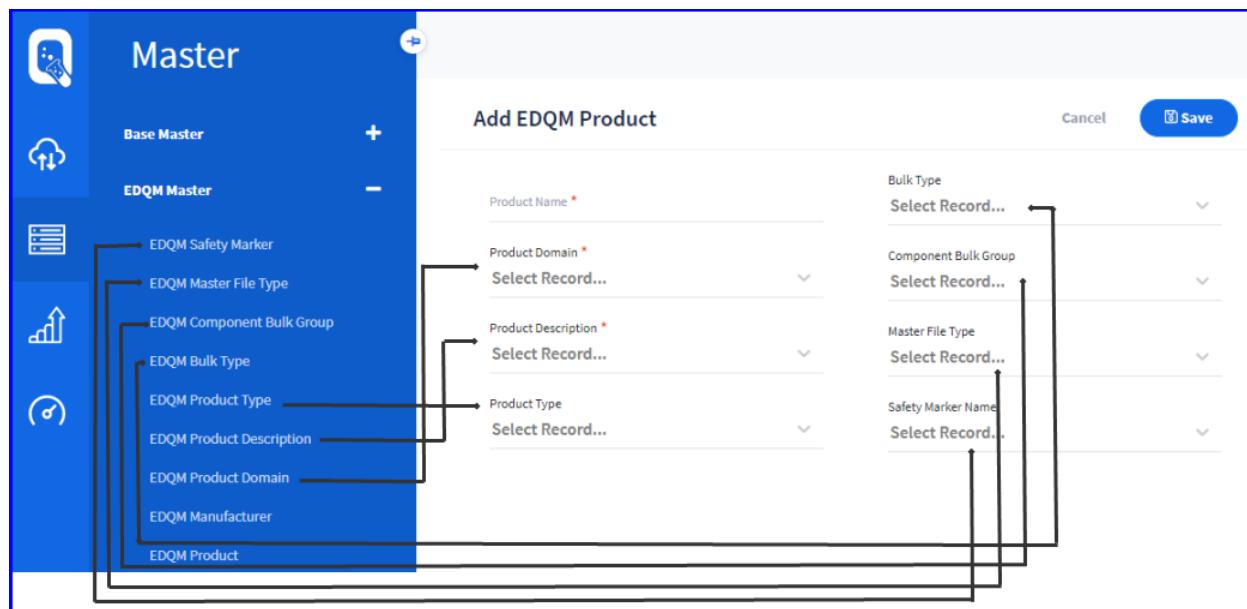


FIGURE: EDQM Master

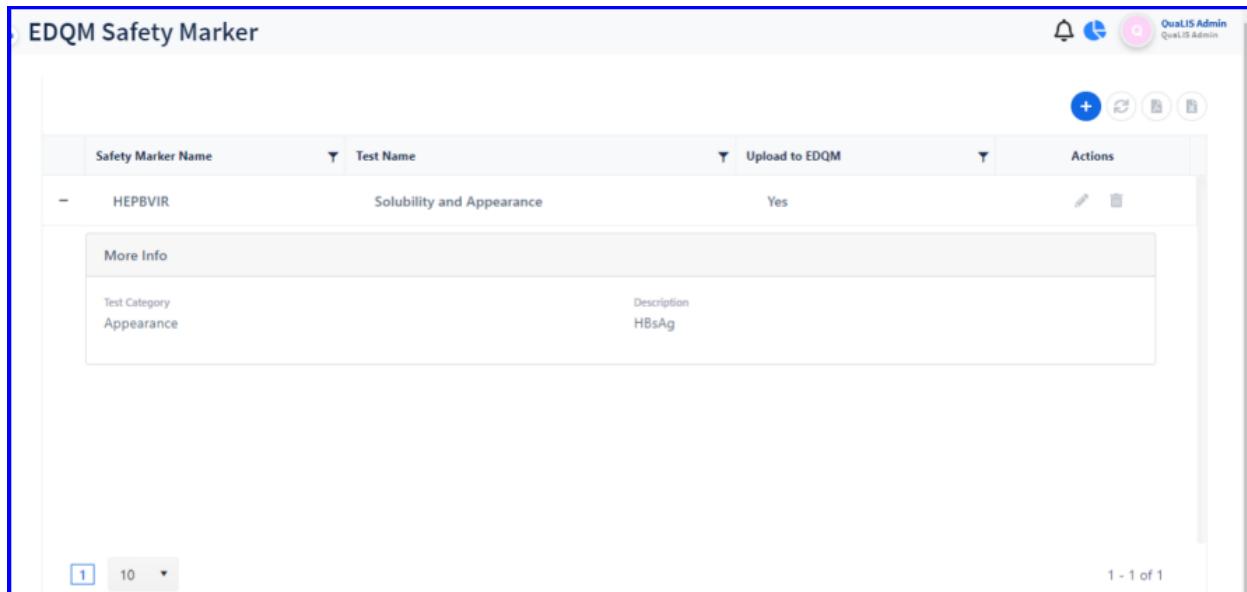
3.3.1 EDQM Safety Marker

EDQM Safety Marker master is used to create and manage EDQM Safety Markers. EDQM Safety Marker is mapped to the EDQM product in EDQM Product master.

3.3.1.1 Creating a New EDQM Safety Marker

To create a new EDQM Safety Marker, follow these steps:

1. On the main menu, click  EDQM Master and then click **EDQM Safety Marker**. The **EDQM Safety Marker** master screen appears as shown in the figure:



Safety Marker Name	Test Name	Upload to EDQM	Actions
HEPBVIR	Solubility and Appearance	Yes	 

More Info

Test Category	Description
Appearance	HBsAg

FIGURE: EDQM Safety Marker Master Screen

In the EDQM Safety Marker master screen you can see the list of EDQM Safety Marker records created. Options to edit and delete EDQM Safety Marker appear in each record.

2. Click  . The **Add EDQM Safety Marker** dialog appears as shown in the figure:



Add EDQM Safety Marker

Safety Marker Name *

HEPAVIR%Y###B19

Description

B19 DNA as determined by NAT, HAV RNA as determined by NAT

Test Category *

Safety

Test Name *

Determination of B19 DNA in Plasma Pools

Upload to EDQM

Save

FIGURE: Add EDQM Safety Marker Screen

3. In the **Safety Marker Name** field, type the name for the EDQM Safety Marker.
4. In the **Description** field, type description of the EDQM Safety Marker
5. In the **Test Category** field, select the test category.
6. In the **Test name** field, select the test name for the EDQM Safety Marker.
7. Click to enable the **Upload to EDQM** option if required.
8. Click **Save**.

You can see the EDQM Safety Marker record you created listed in the EDQM Safety Marker master.

3.3.1.2 Editing EDQM Safety Marker Record

To edit an EDQM Safety Marker record, follow these steps:

1. In the EDQM Safety Marker master screen, click  that appears under **Actions** in the record you want to edit.
2. In the **Edit** screen do required changes and then click **Submit**.

3.3.1.3 Deleting EDQM Safety Marker Record

1. To delete a EDQM Safety Marker record, in the EDQM Safety Marker master screen, click  that appears under **Actions** in the record you want to delete.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

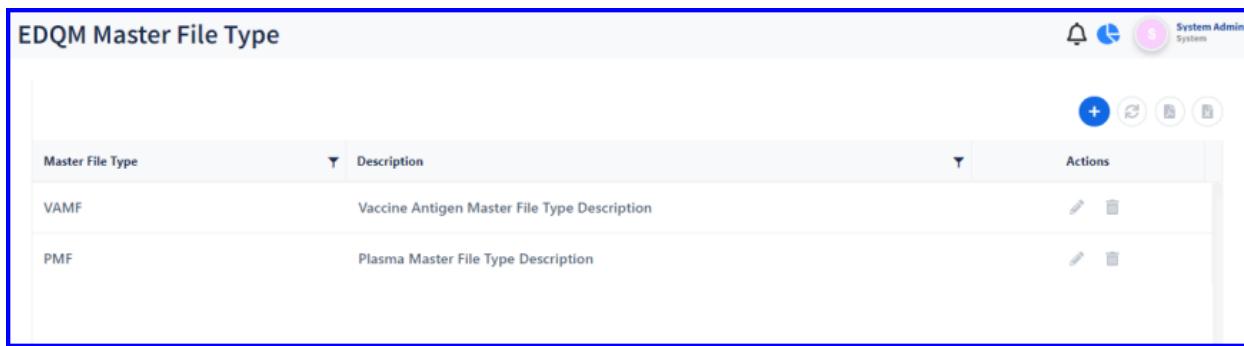
3.3.2 EDQM Master File Type

EDQM Master File Type master is used to create and manage EDQM Master File Types. EDQM Master File Type is mapped to the EDQM product in EDQM Product master.

3.3.2.1 Creating a New EDQM Master File Type

To create a new EDQM Master File Type, follow these steps:

1. On the main menu, click , **EDQM Master** and then click **EDQM Master File Type**. The **EDQM Master File Type** master screen appears as shown in the figure:



Master File Type	Description	Actions
VAMF	Vaccine Antigen Master File Type Description	 
PMF	Plasma Master File Type Description	 

FIGURE: EDQM Master File Type Master Screen

In the EDQM Master File Type master screen you can see the list of EDQM Master File Type records created. Options to edit and delete EDQM Master File Type appear in each record.

2. Click . The **Add EDQM Master File Type** dialog appears as shown in the figure:



Master File Type *

PMF

Description

Plasma Master File Type Description

Save

FIGURE: Add EDQM Master File Type Screen

3. In the **Master File Type** field, type the name for the Master File Type.
4. In the **Description** field, type description of the Master File Type
5. Click **Save**.

You can see the EDQM master file type record you created listed in the EDQM Master File Type master.

3.3.2.2 Editing EDQM Master File Type Record

To edit an EDQM Master File Type record, follow these steps:

1. In the EDQM Master File Type master screen, click  that appears under **Actions** in the record you want to edit.
2. In the **Edit** screen do required changes and then click **Submit**.

3.3.2.3 Deleting EDQM Master File Type Record

1. To delete an EDQM Master File Type record, in the EDQM Master File Type master screen, click  that appears under **Actions** in the record you want to delete.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

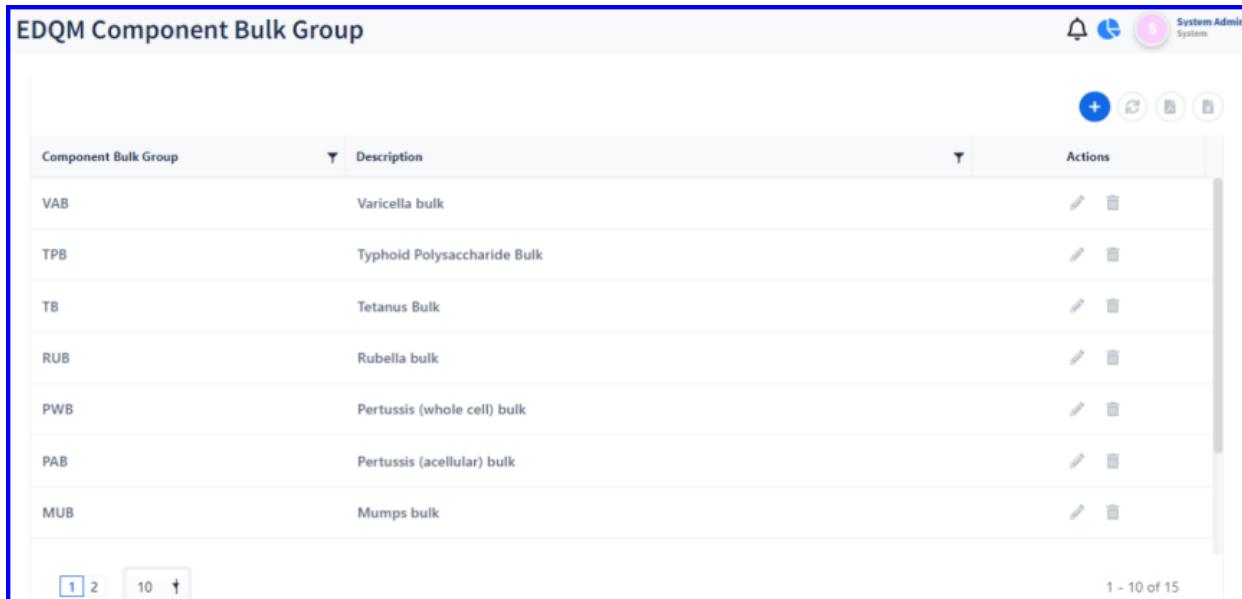
3.3.3 EDQM Component Bulk Group

EDQM Component Bulk Group master is used to create and manage EDQM component bulk groups. EDQM component bulk group is mapped to the EDQM product in EDQM Product master.

3.3.3.1 Creating a New EDQM Component Bulk Group

To create a new EDQM Component Bulk Group, follow these steps:

1. On the main menu, click  EDQM Master and then click **EDQM Component Bulk Group**. The **EDQM Component Bulk Group** master screen appears as shown in the figure:



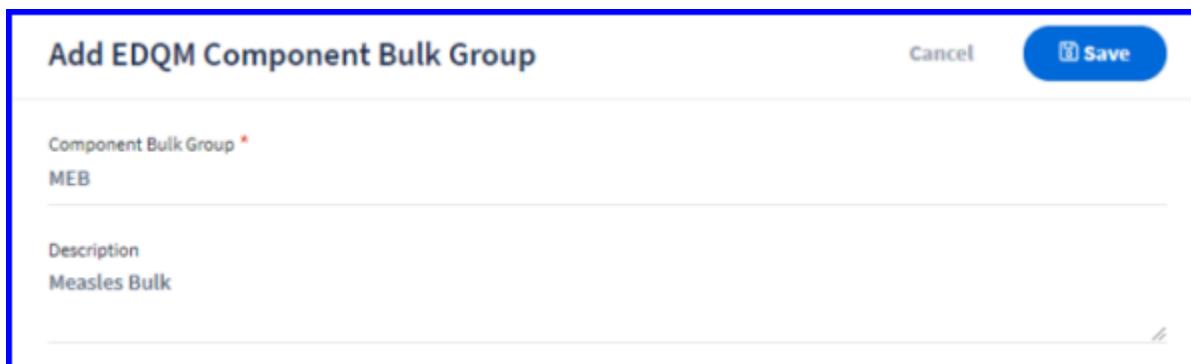
The screenshot shows the 'EDQM Component Bulk Group' master screen. The title bar at the top says 'EDQM Component Bulk Group'. On the right, there are icons for a bell, a gear, and a user profile, and the text 'System Admin' and 'System'. Below the title is a table with columns: 'Component Bulk Group' (containing VAB, TPB, TB, RUB, PWB, PAB, MUB), 'Description' (containing Varicella bulk, Typhoid Polysaccharide Bulk, Tetanus Bulk, Rubella bulk, Pertussis (whole cell) bulk, Pertussis (acellular) bulk, Mumps bulk), and 'Actions' (containing edit and delete icons). At the bottom of the table are navigation buttons (1, 2, 10, †) and the text '1 - 10 of 15'.

Component Bulk Group	Description	Actions
VAB	Varicella bulk	 
TPB	Typhoid Polysaccharide Bulk	 
TB	Tetanus Bulk	 
RUB	Rubella bulk	 
PWB	Pertussis (whole cell) bulk	 
PAB	Pertussis (acellular) bulk	 
MUB	Mumps bulk	 

FIGURE: EDQM Component Bulk Group Master Screen

In the EDQM Component Bulk Group master screen you can see the list of EDQM component bulk group records created. Options to edit and delete EDQM component bulk group appear in each record.

2. Click  . The **Add EDQM Component Bulk Group** dialog appears as shown in the figure:



The screenshot shows the 'Add EDQM Component Bulk Group' dialog. The title bar says 'Add EDQM Component Bulk Group'. On the right are 'Cancel' and 'Save' buttons. The form has two fields: 'Component Bulk Group *' with 'MEB' entered, and 'Description' with 'Measles Bulk' entered.

Component Bulk Group *	MEB
Description	Measles Bulk

FIGURE: Add EDQM Component Bulk Group Screen

3. In the **Component Bulk Group** field, type the name for the EDQM Component Bulk Group.
4. In the **Description** field, type description of the EDQM Component Bulk Group
5. Click **Save**.

You can see the EDQM component bulk group record you created listed in the EDQM Component Bulk Group master.

3.3.3.2 Editing EDQM Component Bulk Group Record

To edit an EDQM Component Bulk Group record, follow these steps:

1. In the EDQM Component Bulk Group master screen, click  that appears under **Actions** in the record you want to edit.
2. In the **Edit** screen do required changes and then click **Submit**.

3.3.3.3 Deleting EDQM Component Bulk Group Record

1. To delete an EDQM component bulk group record, in the EDQM Component Bulk Group master screen, click  that appears under **Actions** in the record you want to delete.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

3.3.4 EDQM Bulk Type

EDQM Bulk Type master is used to create and manage EDQM bulk types. EDQM Bulk Type is mapped to the EDQM product in EDQM Product master.

3.3.4.1 Creating a New EDQM Bulk Type

To create a new EDQM Bulk type, follow these steps:

1. On the main menu, click , **EDQM Master** and then click **EDQM Bulk Type**. The **EDQM Bulk Type** master screen appears as shown in the figure:

EDQM Bulk Type		
Bulk Type	Description	Actions
PPT9V	Pneumo Polysacc serotype 9V	 
PPT7F	Pneumo Polysacc serotype 7F	 
PPT6B	Pneumo Polysacc serotype 6B	 
PPT5	Pneumo Polysacc serotype 5	 
PPT4	Pneumo Polysacc serotype 4	 
PPT23F	Pneumo Polysacc serotype 23F	 
PPT19F	Pneumo Polysacc serotype 19F	 

1 2 10 ▾ 1 - 10 of 13

FIGURE: EDQM Bulk Type Master Screen

In the EDQM Bulk Type master screen you can see the list of EDQM Bulk Type records created. Options to edit and delete EDQM Bulk Type appear in each record.

2. Click . The **Add EDQM Bulk Type** dialog appears as shown in the figure:

Add EDQM Bulk Type

Bulk Type *	PPT23F
Description	Pneumo Polysacc serotype 23F

FIGURE: Add EDQM Bulk Type Dialog

3. In the **Bulk Type** field, type the name for the Bulk Type you want to create.
4. In the **Description** field, type description if any.
5. Click **Save**.

You can see the EDQM Bulk Type record you created listed in the EDQM Bulk Type master.

3.3.4.2 Editing EDQM Bulk Type Record

To edit an EDQM Bulk Type record, follow these steps:

1. In the EDQM Bulk Type master screen, click  that appears under **Actions** in the record you want to edit.
2. In the **Edit** screen do required changes and then click **Submit**.

3.3.4.3 Deleting EDQM Bulk Type Record

1. To delete an EDQM Bulk Type record, in the EDQM Bulk Type master screen, click  that appears under **Actions** in the record you want to delete.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

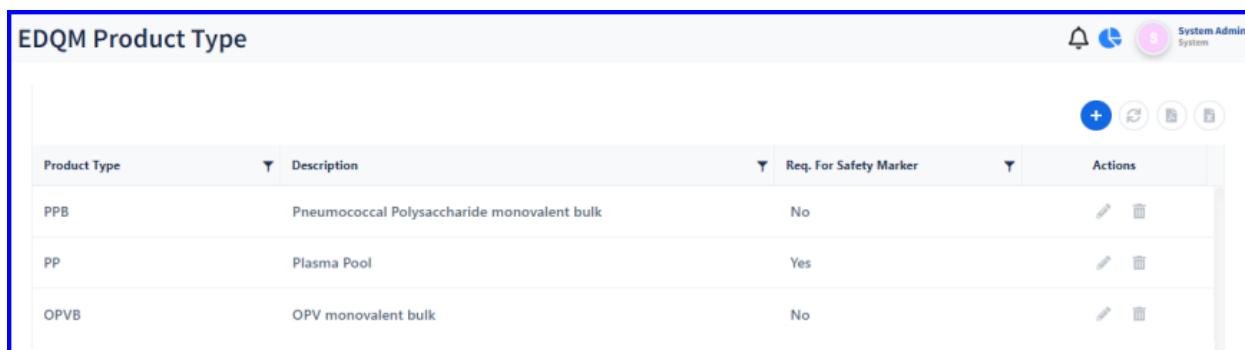
3.3.5 EDQM Product Type

EDQM Product Type master is used to create and manage EDQM Product types.

3.3.5.1 Creating a New EDQM Product Type

To create a new EDQM Product type, follow these steps:

1. On the main menu, click  **EDQM Master** and then click **EDQM Product Type**. The **EDQM Product Type** master screen appears as shown in the figure:



Product Type	Description	Req. For Safety Marker	Actions
PPB	Pneumococcal Polysaccharide monovalent bulk	No	 
PP	Plasma Pool	Yes	 
OPVB	OPV monovalent bulk	No	 

FIGURE: EDQM Product Type Master Screen

In the EDQM Product Type master screen you can see the list of EDQM Product Type records created. Options to edit and delete EDQM Product Type appear in each record.

2. Click  . The **Add EDQM Product Type** dialog appears as shown in the figure:

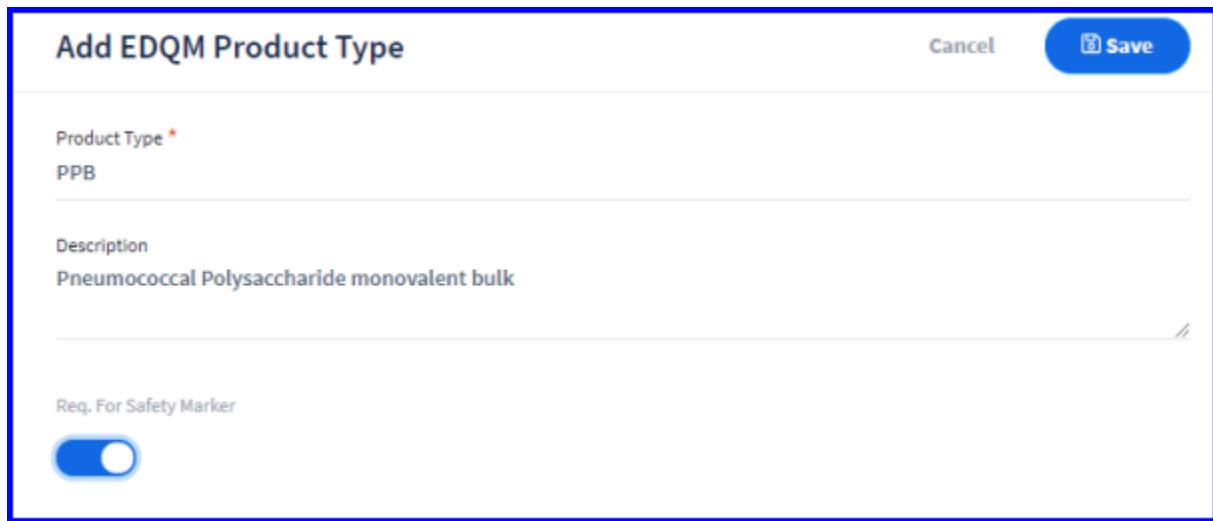


FIGURE: Add EDQM Product Type Dialog

3. In the **Product Type** field, type the name for the Product Type you want to create.
4. In the **Description** field, type description if any.
5. Click to turn on the **Req. For Safety Marker** option if required. When this option is turned on, then selecting the **Safety Marker Name** field becomes mandatory in the **Add EDQM Product** dialog.
6. Click **Save**.

You can see the EDQM product type you created listed in the EDQM Product Type master.

3.3.5.2 Editing EDQM Product Type Record

To edit an EDQM Product Type record, follow these steps:

1. In the EDQM Product Type master screen, click  that appears under **Actions** in the record you want to edit.
2. In the **Edit** screen do required changes and then click **Submit**.

3.3.5.3 Deleting EDQM Product Type Record

1. To delete an EDQM Product Type record, in the EDQM Product Type master screen, click  that appears under **Actions** in the record you want to delete.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

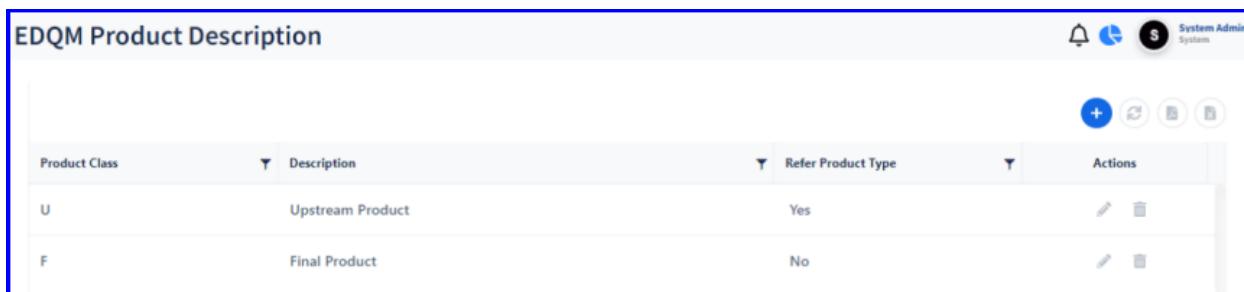
3.3.6 EDQM Product Description

EDQM Product Description master is used to create and manage EDQM Product Descriptions. The EDQM product descriptions help to classify the product in the EDQM Product master.

3.3.6.1 Creating a New EDQM Product Description

To create a new EDQM Product Description, follow these steps:

1. On the main menu, click  **EDQM Master** and then click **EDQM Product Description**. The **EDQM Product Description** master screen appears as shown in the figure:



Product Class	Description	Refer Product Type	Actions
U	Upstream Product	Yes	 
F	Final Product	No	 

FIGURE: EDQM Product Description Master Screen

In the EDQM Product Description master screen you can see the list of EDQM product description records created. Options to edit and delete EDQM product description appear in each record.

2. Click  . The **Add EDQM Product Description** dialog appears as shown in the figure:



The dialog has the following fields:

- Product Class ***: WF-ESC/EPO
- Description**: Downstream product
- Refer Product Type**: (checkbox)

Buttons: **Cancel** and **Save**

FIGURE: Add EDQM Product Description Dialog

3. In the **Product Class** field, type the code to classify the product.
4. In the **Description** field, type description for the class you create.
5. Click to turn on the **Refer Product Type** option if required. When this option is turned on, then selecting the **Product Type** field becomes mandatory in the **Add EDQM Product** dialog.
6. Click **Save**.

You can see the EDQM product description you created listed in the EDQM Product Description master.

3.3.6.2 Editing EDQM Product Description Record

To edit an EDQM Product Description record, follow these steps:

1. In the EDQM Product Description master screen, click  that appears under **Actions** in the record you want to edit.
2. In the **Edit** screen do required changes and then click **Submit**.

3.3.6.3 Deleting EDQM Product Description Record

1. To delete an EDQM Product Description record, in the EDQM Product Description master screen, click  that appears under **Actions** in the record you want to delete.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

3.3.7 EDQM Product Domain

EDQM Product Domain master is used to create and manage EDQM Product Domains.

3.3.7.1 Creating a New EDQM Product Domain

To create a new EDQM Product Domain, follow these steps:

1. On the main menu, click , **EDQM Master** and then click **EDQM Product Domain**. The **EDQM Product Domain** master screen appears as shown in the figure:

EDQM Product Domain		
Product Domain	Description	Actions
HV	Human Vaccine	 
HB	Human Blood Product	 

FIGURE: EDQM Product Domain Master Screen

In the EDQM Product Domain master screen you can see the list of EDQM product domain records created. Options to edit and delete EDQM product domain appear in each record.

2. Click . The **Add EDQM Product Domain** dialog appears as shown in the figure:

Add EDQM Product Domain	
Product Domain *	 
HB	
Domain Description	
Human Blood Product	

FIGURE: Add EDQM Product Domain Dialog

3. In the **Product Domain** field, type the name for the domain you want to create/add.
4. In the **Domain Description** field, type description if any.
5. Click **Save**.

You can see the EDQM product domain you created listed in the EDQM Product Domain master.

3.3.7.2 Editing EDQM Product Domain Record

To edit an EDQM Product Domain record, follow these steps:

1. In the EDQM Product Domain master screen, click  that appears under **Actions** in the record you want to edit.
2. In the **Edit** screen do required changes and then click **Submit**.

3.3.7.3 Deleting EDQM Product Domain Record

1. To delete an EDQM Product Domain record, in the EDQM Product Domain master screen, click  that appears under **Actions** in the record you want to delete.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

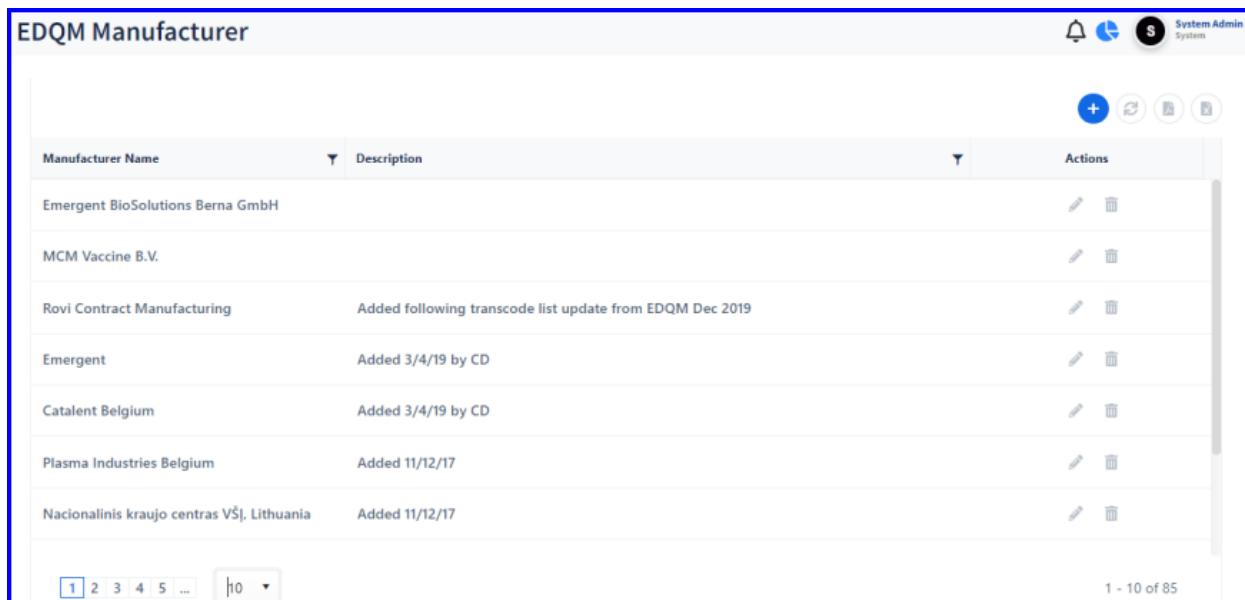
3.3.8 EDQM Manufacturer

EDQM Manufacturer master is used to create and manage EDQM Manufacturers.

3.3.8.1 Creating a New EDQM Manufacturer

To create a new EDQM Manufacturer, follow these steps:

1. On the main menu, click  **EDQM Master** and then click **EDQM Manufacturer**. The **EDQM Manufacturer** master screen appears as shown in the figure:



EDQM Manufacturer		Actions	
Manufacturer Name	Description		
Emergent BioSolutions Berna GmbH			
MCM Vaccine B.V.			
Rovi Contract Manufacturing	Added following transcode list update from EDQM Dec 2019		
Emergent	Added 3/4/19 by CD		
Catalent Belgium	Added 3/4/19 by CD		
Plasma Industries Belgium	Added 11/12/17		
Nacionalinis kraujo centras VSJ, Lithuania	Added 11/12/17		

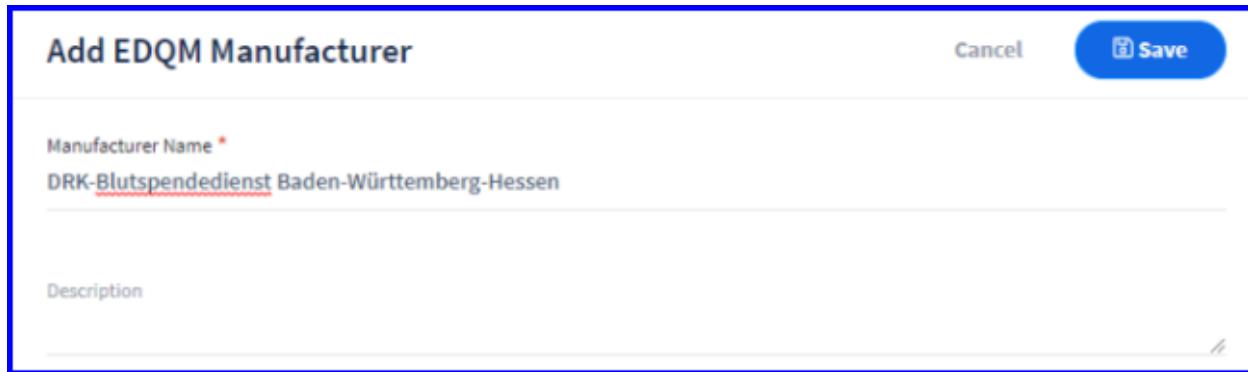
1 2 3 4 5 ... 10 ▾

1 - 10 of 85

FIGURE: EDQM Manufacturer Master Screen

In the EDQM Manufacturer master screen you can see the list of EDQM manufacturer records created. Options to edit and delete EDQM manufacturer appear in each record.

2. Click . The **Add EDQM Manufacturer** dialog appears as shown in the figure:



Add EDQM Manufacturer

Manufacturer Name *

DRK-Blutspendedienst Baden-Württemberg-Hessen

Description

Save

FIGURE: Add EDQM Manufacturer Dialog

3. In the **Manufacturer Name** field, type the name of the manufacturer you want to create/add.
4. In the **Description** field, type description if any.
5. Click **Save**.

You can see the EDQM Manufacturer you created listed in the EDQM Manufacturer master.

3.3.8.2 Editing EDQM Manufacturer Record

To edit an EDQM Manufacturer record, follow these steps:

1. In the EDQM Manufacturer master screen, click  that appears under **Actions** in the record you want to edit.
2. In the **Edit** screen do required changes and then click **Submit**.

3.3.8.3 Deleting EDQM Manufacturer Record

1. To delete an EDQM Manufacturer record, in the EDQM Manufacturer master screen, click  that appears under **Actions** in the record you want to delete.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

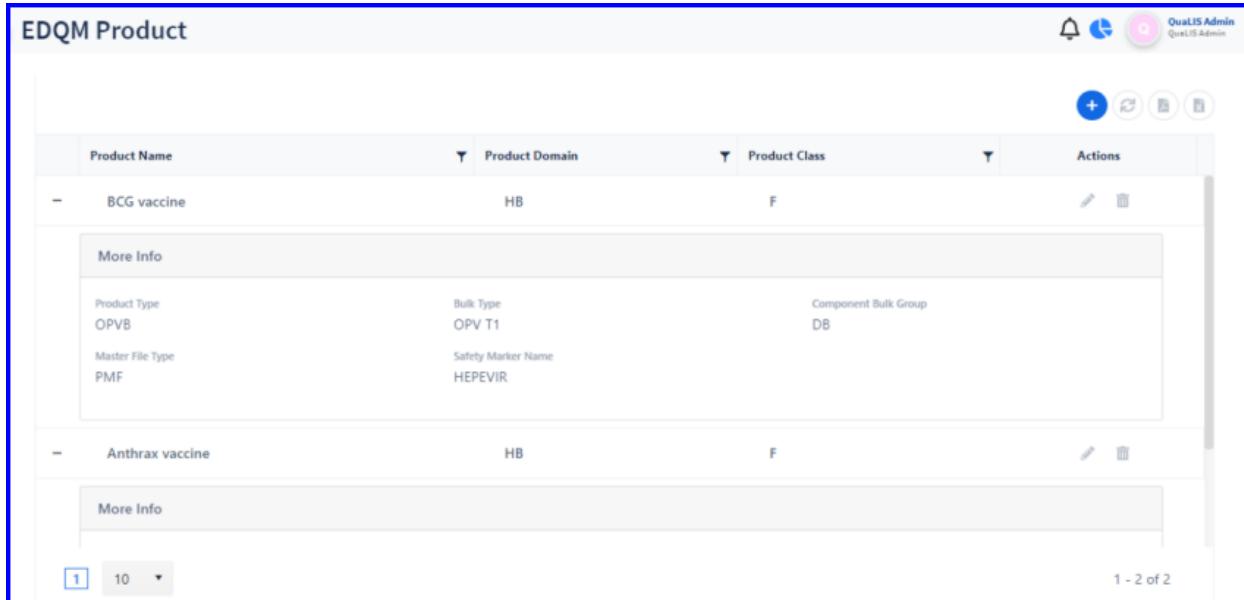
3.3.9 EDQM Product

EDQM Product master is used to create and manage EDQM Products.

3.3.9.1 Creating a New EDQM Product

To create a new EDQM Product, follow these steps:

1. On the main menu, click  **EDQM Master** and then click **EDQM Product**. The **EDQM Product** master screen appears as shown in the figure:



The screenshot shows the 'EDQM Product' master screen. The table lists two products:

Product Name	Product Domain	Product Class	Actions
BCG vaccine	HB	F	 
Anthrax vaccine	HB	F	 

Each product record includes a 'More Info' section with the following details:

Product Type	Bulk Type	Component Bulk Group
OPVB	OPV T1	DB
Master File Type	Safety Marker Name	
PMF	HEPEVIR	

At the bottom left, there is a page number indicator '1 10 ▾' and at the bottom right, it says '1 - 2 of 2'.

FIGURE: EDQM Product Master Screen

In the EDQM Product master screen you can see the list of EDQM products created. Options to edit and delete EDQM product appear in each record.

2. Click  . The **Add EDQM Product** dialog appears as shown in the figure:

Add EDQM Product

Cancel 

Product Name *	Diphtheria, Tetanus and Pertussis (Whole cell) with :	Bulk Type	OPV T2
Product Domain *	HV	Component Bulk Group	DTB
Product Description *	F	Master File Type	VAMF
Product Type	OPVB	Safety Marker Name	B19

FIGURE: Add EDQM Product Dialog

3. In the **Product Name** field, type the name of the product you want to create/add.
4. In the **Product Domain** field, select the domain the product belongs to.
5. In the **Product Description** field, select the class the product is classified. If the **Refer Product Type** option is turned on for the class you selected, then **Product Type** field becomes mandatory field.
6. In the **Product Type** field, select the product type. If the **Req. For Safety Marker** option is turned on for the selected product type then, selecting the **Safety Marker Name** field becomes mandatory here as shown in the figure:

Add EDQM Product

Cancel 

Product Name *	Diphtheria, Tetanus and Pertussis (Whole cell) with :	Bulk Type	OPV T2
Product Domain *	HV	Component Bulk Group	DTB
Product Description *	F	Master File Type	VAMF
Product Type	OPVB	Safety Marker Name	B19

FIGURE: Add EDQM Product Dialog – With Product Type and Safety Marker Name Fields as Mandatory Fields

7. In the **Bulk Type** field, select the bulk type.
8. In the **Component Bulk Group** field, select the component bulk group.
9. In the **Master File Type** field, select the master file type.
10. In the **Safety Marker Name** field, select the safety marker.
11. Click **Save**.

You can see the EDQM product you created listed in the EDQM Product master.

3.3.9.2 Editing EDQM Product Record

To edit an EDQM Product record, follow these steps:

1. In the EDQM Product master screen, click  that appears under **Actions** in the record you want to edit.
2. In the **Edit** screen do required changes and then click **Submit**.

3.3.9.3 Deleting EDQM Product Record

1. To delete an EDQM Product record, in the EDQM Product master screen, click  that appears under **Actions** in the record you want to delete.

2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

3.4 User Management

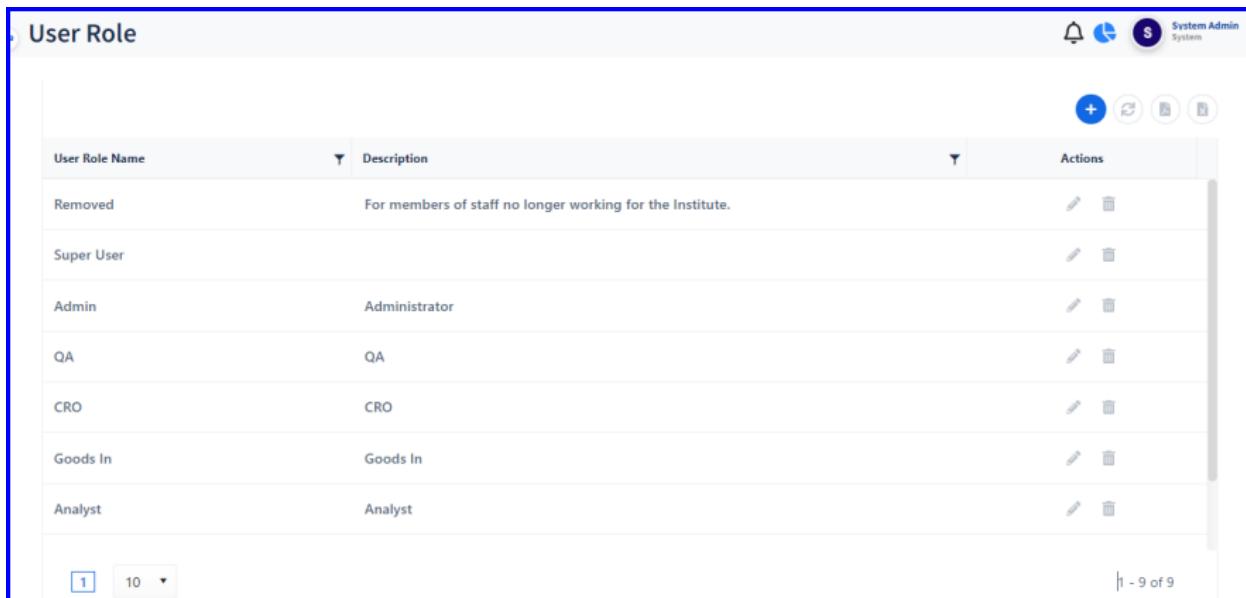
3.4.1 User role Master

User role master is used to create and manage user roles that are used in Password Policy, Screen Rights, User management, Workflows, User Role Template, and approval configuration.

3.4.1.1 Adding a New User role

To create a new User role, follow these steps:

1. On the main menu, click  **User Management** and then click **User Role**. The **User Role** master screen appears as shown in the figure:



The screenshot shows the 'User Role' master screen. At the top, there is a header with the title 'User Role' and a 'System Admin' button. Below the header is a toolbar with icons for adding, deleting, and filtering. The main area is a table with columns: 'User Role Name', 'Description', and 'Actions'. The table contains the following data:

User Role Name	Description	Actions
Removed	For members of staff no longer working for the Institute.	 
Super User		 
Admin	Administrator	 
QA	QA	 
CRO	CRO	 
Goods In	Goods In	 
Analyst	Analyst	 

At the bottom left, there are navigation buttons for page 1, 10, and a dropdown. At the bottom right, it says '1 - 9 of 9'.

FIGURE: User role Master Screen

In the User role master screen, you can see the list of user roles added. Options to edit, and delete appears in each record.

2. Click  . The **Add User Role** screen appears as shown in the figure:



Add User Role

User Role Name *

QA

Description

QA

Cancel

Save

FIGURE: Add User Role Screen

3. In the **User Role Name** field, type the name for the user role.
4. In the **Description** field, type the description.
5. Click **Save**.

You can see the user role you just added listed in the user role master.

3.4.1.2 Editing User Role

To edit user role, follow these steps:

1. Click  that appears under Actions to edit a record.
2. In the **Edit** screen do required changes and then click **Submit**.

3.4.1.3 Deleting User Role

1. To delete a user role, in the User Role master screen, click  that appears under **Actions**.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

3.4.2 Designation Master

Designation master is used to create and manage designations that are used in user management.

3.4.2.1 Adding a New Designation

To create a new Designation, follow these steps:

1. On the main menu, click  **User Management** and then click **Designation**. The **Designation** master screen appears as shown in the figure:



The screenshot shows the 'Designation' master screen. At the top, there is a header with the title 'Designation' and a user profile for 'Carl Dolman, Study Director'. Below the header is a toolbar with icons for 'Add', 'Edit', 'Delete', and 'Search'. The main area is a table with columns: 'Designation Name', 'Description', 'Default Status', and 'Actions'. Two rows of data are visible: 'Study Director' (Yes) and 'HeadOfDivision' (No). Each row has edit and delete icons in the 'Actions' column.

Designation Name	Description	Default Status	Actions
Study Director		Yes	 
HeadOfDivision		No	 

FIGURE: Designation Master Screen

In the Designation master screen, you can see the list of designations added. Options to edit and delete appears in each record.

2. Click action menu and then click **Add**. The **Add** designation screen appears as shown in the figure:



The screenshot shows the 'Add Designation' screen. It has a title bar with 'Add Designation', a 'Cancel' button, and a 'Save' button. The form contains three fields: 'Designation Name *' with the value 'Study Director', 'Description' with a large text area, and 'Default Status' with a toggle switch that is turned on (blue).

FIGURE: Add Designation Screen

3. In the **Designation Name** field, type the name for the designation.
4. In the **Description** field, type the description.
5. Click to turn on the **Default Status** option. When this option is turned on, then this designation will be automatically filled in the **Designation** field in the entire application.

-
6. Click **Save**.

You can see the designation you just added listed in the Designation master.

3.4.2.2 Editing Designation

To edit designation, follow these steps:

1. Click  that appears under Actions to edit a record.
2. In the **Edit** screen do required changes and then click **Submit**.

3.4.2.3 Deleting Designation

1. To delete a designation, in the Designation master screen, click  that appears under **Actions**.
2. The **Confirmation** dialog appears. Click **Ok** to delete the record.

3.4.3 Holiday Planner

Holiday Planner enables to define the days of the year that are to be recognized as holidays by NIBSC LIMS.

You can add holiday plan for each year. For each plan, you can add versions. Versions remain in Draft state until approved. Once approved, the holiday plan will become default holiday schedule for the year and cannot be deleted.

3.4.3.1 Adding a New Holiday Plan

To create a new holiday plan, follow these steps:

1. On the main menu, click , **User Management** and then click **Holiday Planner**. The **Holiday Planner** screen appears as shown in the figure:

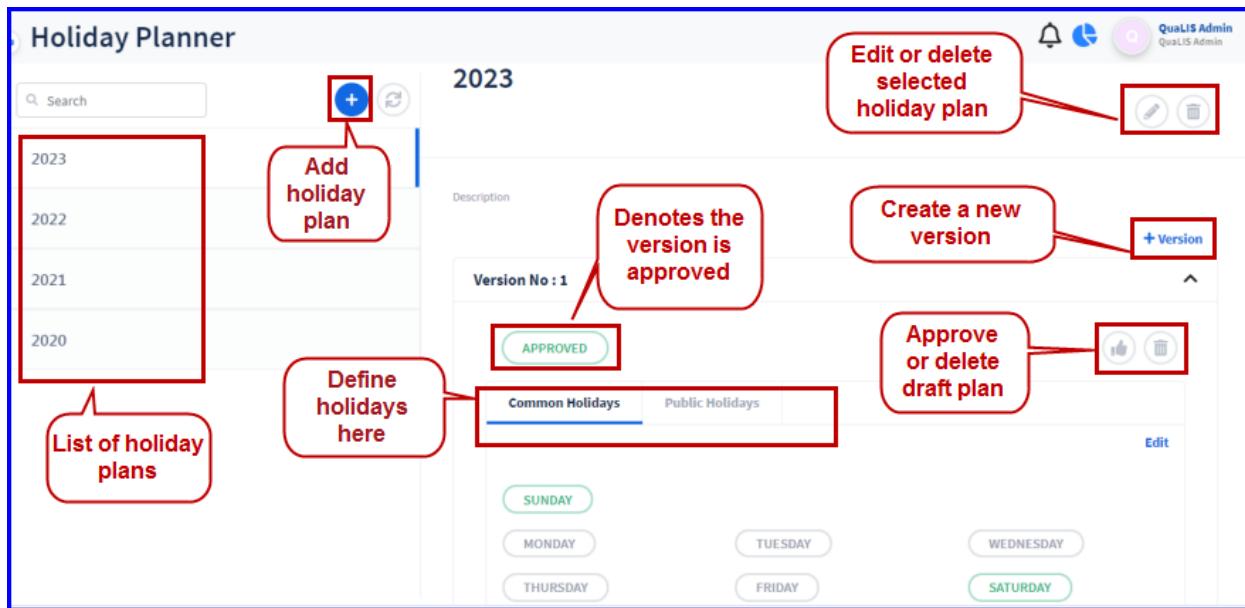


FIGURE: Holiday Planner Screen

In the Holiday Planner screen, you can see the list of holiday plans added. Details of the selected plan appear with the status of the plan version. Options to edit and delete appears for each plan.

2. Click  . The **Add Holiday Planner** screen appears as shown in the figure:

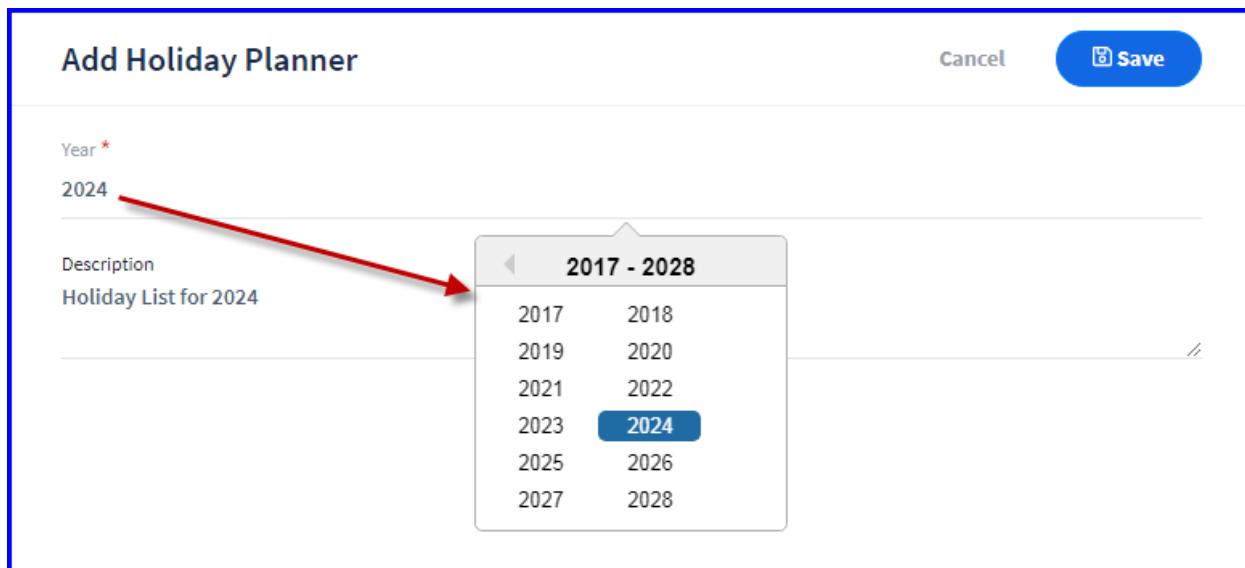


FIGURE: Add Holiday Planner Screen

3. In the **Year** field, click and select the year to plan holidays. You can create only one holiday plan for a year. If a plan is already exists for the selected year, then you will see an alert saying “Already Exists”.

4. In the **Description** field, type description.
5. Click **Save**. The new holiday plan is added and appears as shown in the figure:

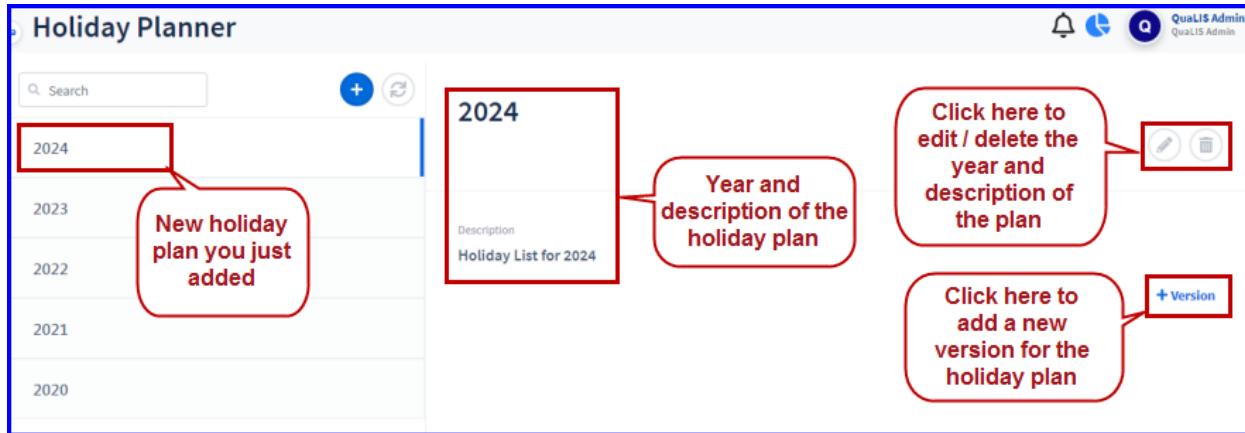


FIGURE: New Holiday Planner Added

3.4.3.2 Adding a New Version

You can add and approve versions to the holiday plan. Until you approve, the version will remain in the draft state. In the draft state, you can edit, approve and delete the version. Once approved, you cannot edit or delete the version. The existing approved holiday plan will retire once you add and approve a new version.

Open the new holiday plan you just added. In the holiday planner screen, click **+ Version**. A new version is added and appears in draft status as shown in the figure with Version No:

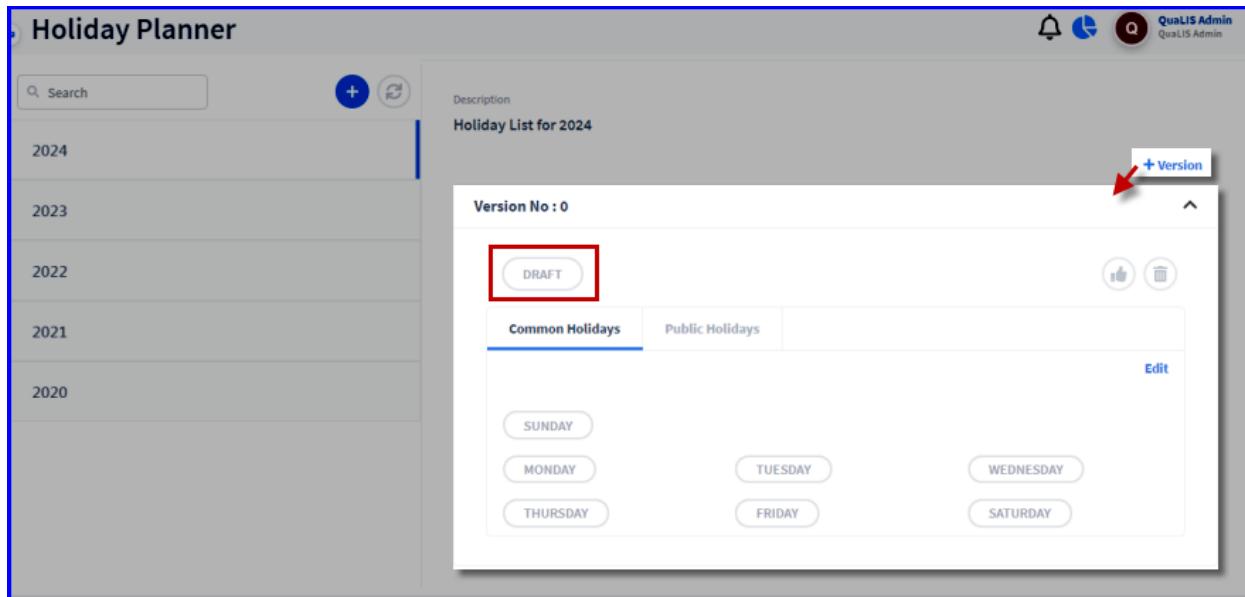


FIGURE: Adding New Version to the Holiday Plan

This section has Common Holidays and Public Holidays tabs.

3.4.3.3 Defining Common Holidays

- In the Common Holiday tab, click Edit. The Edit Common Holidays screen appears as shown in the figure:

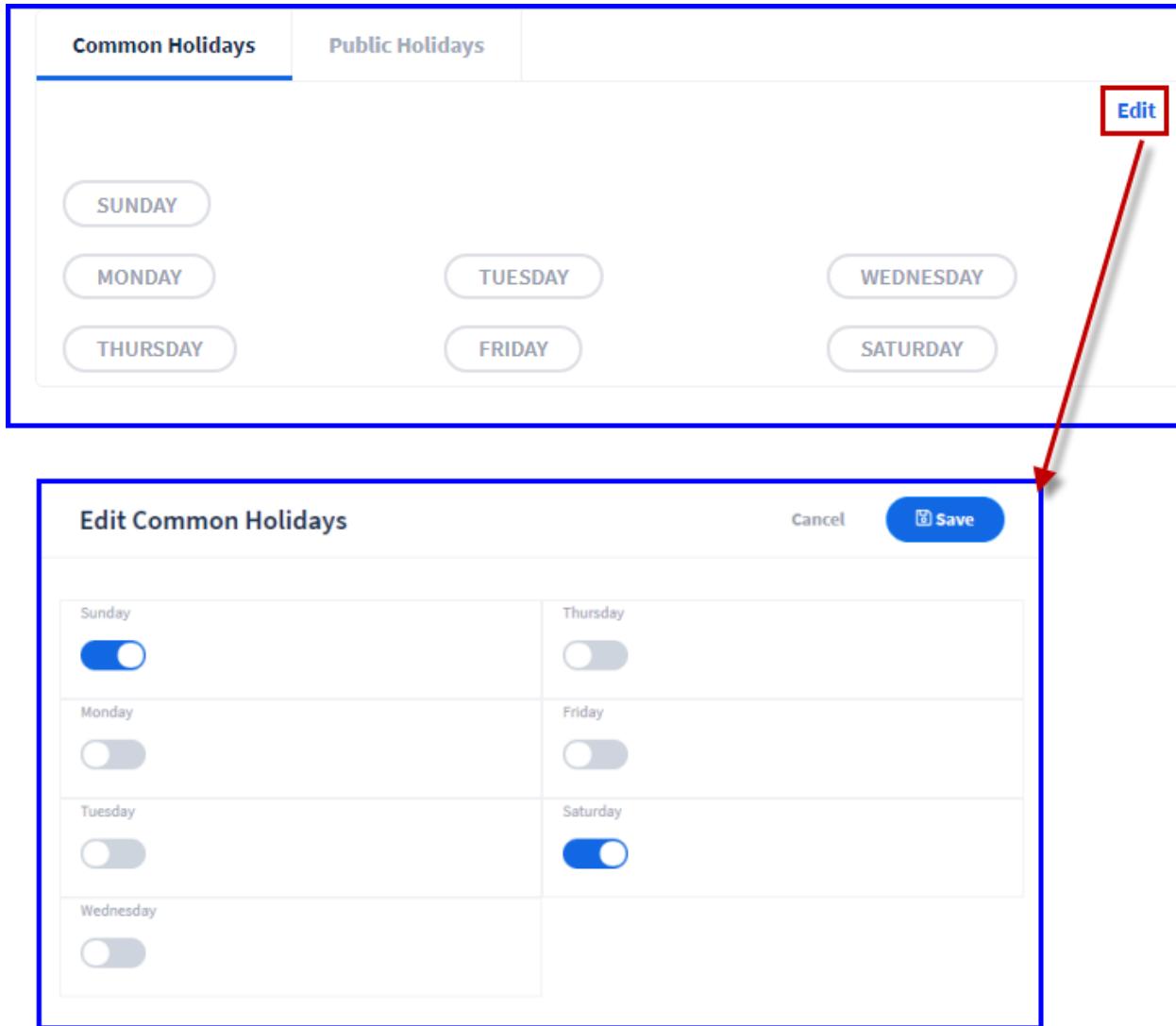


FIGURE: Defining Common Holidays

- In the **Edit Common Holidays** screen, click to define holidays from the list of days in a week. For example, Sunday and Saturday are turned on in the above figure. So, Sunday and Saturdays are defined as common holidays in a week.

3.4.3.4 Defining Public Holidays

Go to the Public Holidays tab. The Public Holidays tab appears as shown in the figure:

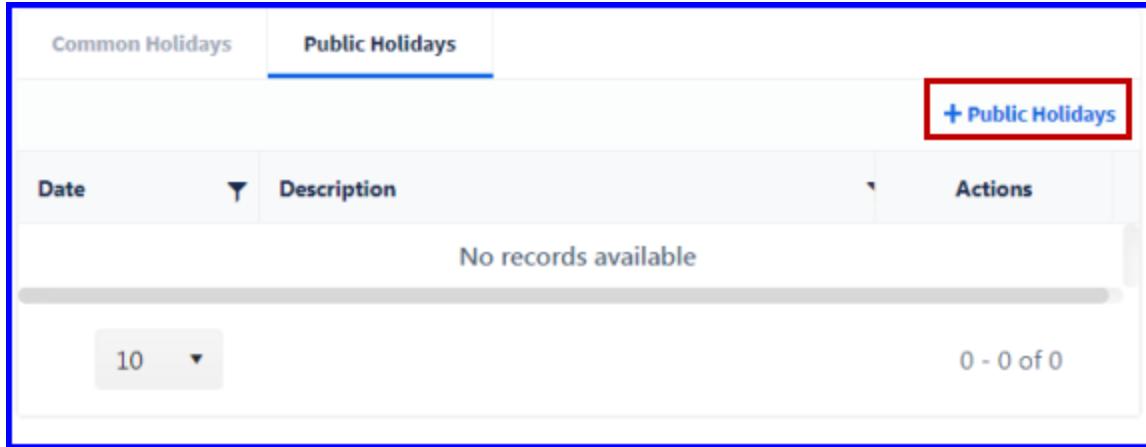


FIGURE: Public Holiday Tab

Click **+ Public Holidays**. The Add Public Holidays screen appears as shown in the figure:

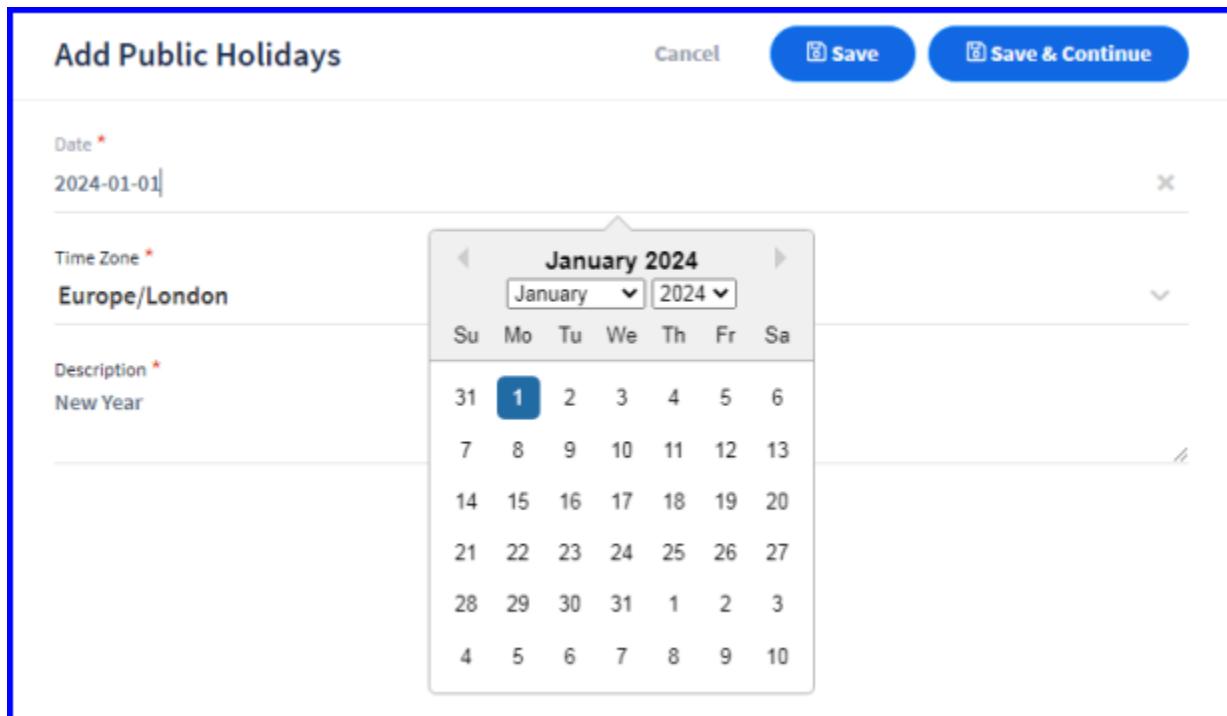
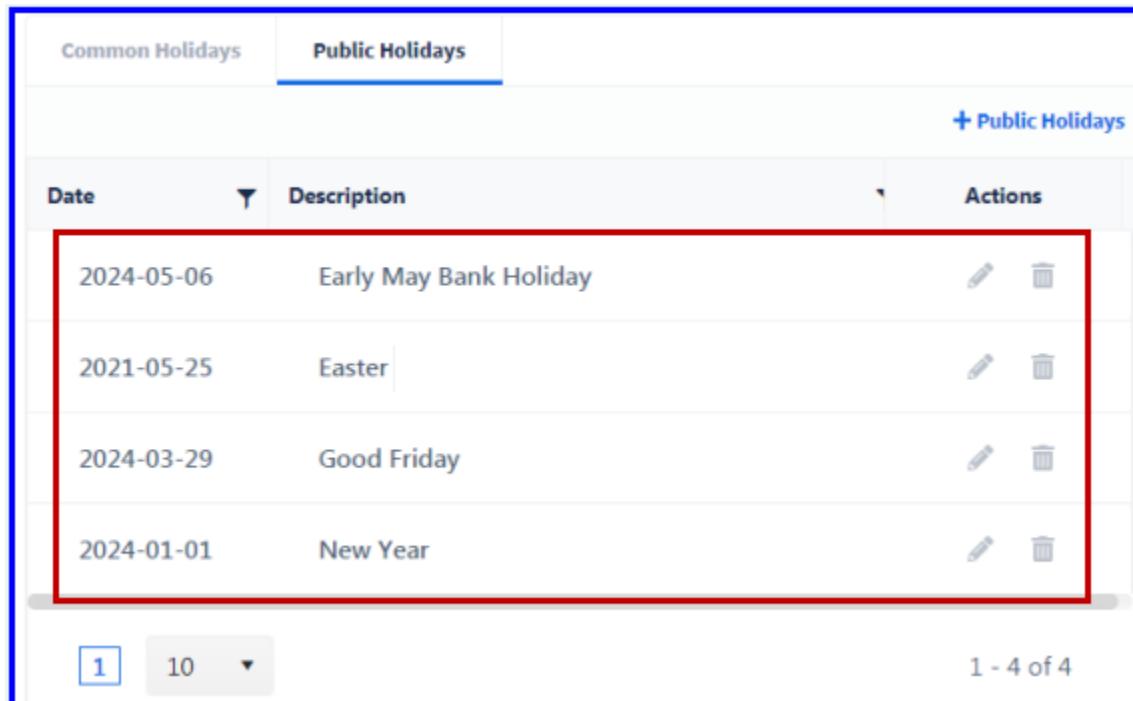


FIGURE: Add Public Holidays

8. In the **Date** field, click and select the day to define as holiday as shown in the above figure.

9. In the **Time Zone** field, select the time zone as applicable.
10. In the **Description** field, type the description for the holiday selected in the **Date** field.
11. Click **Save and Continue** to save and add more holiday(s).
12. Click **Save** to save and exit Add Public Holiday screen.

You can see the public holidays added listed in the **Public Holidays** tab as shown in the figure:



Common Holidays		Public Holidays		
Date	Description	Actions		
2024-05-06	Early May Bank Holiday			
2021-05-25	Easter			
2024-03-29	Good Friday			
2024-01-01	New Year			

1 10 1 - 4 of 4

FIGURE: Public Holidays Added

Each record / public holiday added will have edit and delete options.

13. Click  to edit the record.
14. Click  to delete the record.

3.4.3.5 Approving Version

Once you add a version to the holiday plan, you can approve the version. You can edit or delete the version until you approve it. Once approved you cannot edit or delete the version.

To approve a version, click  as shown in the figure:

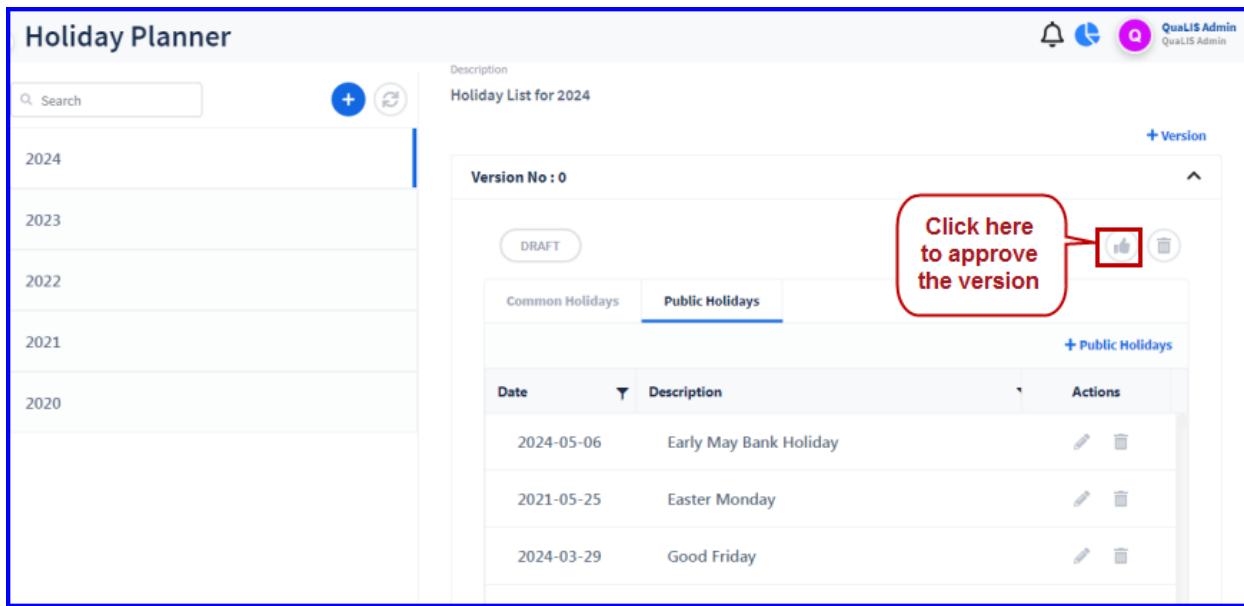


FIGURE: Approving a Version

Once approved, the status of the version turns “**APPROVED**” and appears in green. The version is numbered as **Version No: 1**.

Same way, you can create more versions. But only one version shall be approved and active at a time. When you approve a new version, the previous version gets retired automatically.

You can click  to refresh the Holiday Planner screen.

3.4.4 Password Policy

Password policy can be set to control user authentication behavior. Password policy is must for regulatory compliance and also depends on the organisation policy defined for the individual applications.

Qualis LIMS enables you to create password policies for each role. You can also create multiple password policies for a role.

When you create a policy, it will be in the Draft state. You need to approve the policy to enforce. When a new policy is approved for a role, the existing policy will retire automatically.

Note: When a new password policy is approved for a role, the password of the entire users in that user role will be changed.

Password Policy master is used to create and manage Password Policies.

3.4.4.1 Creating a New Password Policy

To create a new Password Policy, follow these steps:

1. On the main menu, click  **User Management** and then click, **Password Policy**. The **Password Policy** screen appears as shown in the figure:



FIGURE: Password Policy Screen

To filter, click , select the role and then click **Submit**. You can see the list of Password Policies created for the selected role. Options to add, edit, delete, approve and copy policy appear in the action menu.

2. Click  . The **Add Password Policy** screen appears as shown in the figure:

Add Password Policy

Policy Name *
CRO policy

Max Password Length *
6

Min No. of Number Char *
3

No. of Failed Attempt *
9

Min No. of Lower Char *
0

Expiry Required

Min No. of Upper Char *
0

Expiry Policy Days
Expiry Policy Days

Min No. of Special Char *
0

Remainder Days
Remainder Days

Min Password Length *
3

Comments
CRO

FIGURE: Add Password Policy Screen

3. In the **Policy Name** field, type the name for the policy you want to create.
4. Fill in all fields appropriately.
5. Click to turn on the **Expiry Required** option if you want the password to be expired after a period. In the **Expiry Policy Days** field, type number of days after the password should expire. In the **Remainder Days** field, type number of days before expiry of the password the remainder to be sent.
6. Click **Submit**.

You can see the password policy you just created listed in the Password Policy master.

3.4.4.2 Editing and Deleting Password Policy

Note: You can edit or delete a password policy that is in the Draft state and you cannot edit or delete an approved password policy.

1. To edit a password policy, in the Password Policy master screen, select the role, select the password policy, and then click  . In the **Edit Password** screen, do required changes and then click **Save**.

2. To delete a password policy, in the Password Policy master screen, select the role, select the password policy you want to delete, and then click .

3.4.4.3 Approving Password Policy

1. To approve a password policy, in the Password Policy master screen, select the role, select the password policy, click action menu and then click **Approve**.

3.4.4.4 Copying Password Policies

You can copy password policy to multiple roles.

1. To copy a password policy, in the Password Policy master screen, select the role; select the password policy and then click .

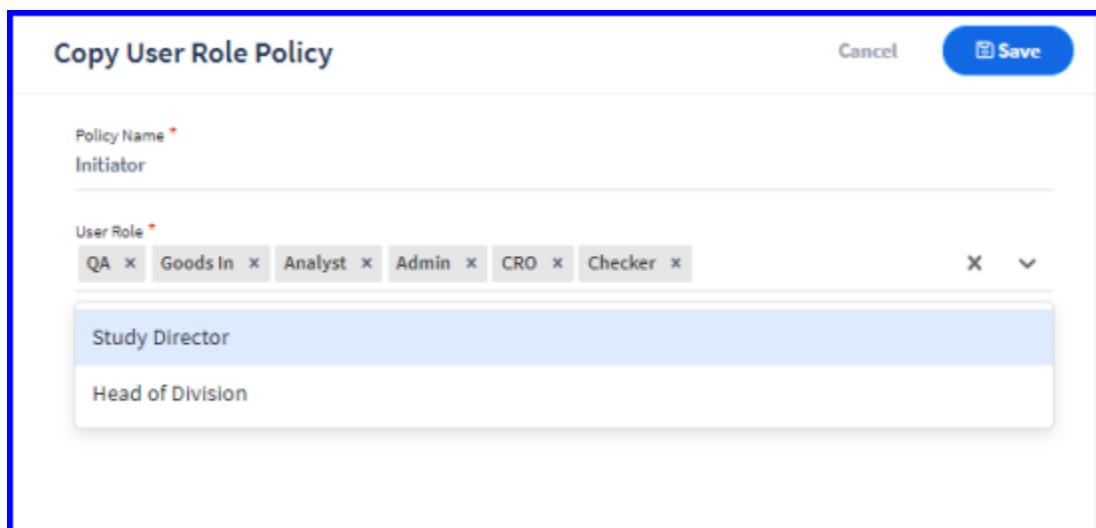


FIGURE: Copy Password Policy Dialog

2. In the **Policy Name** field, type a name for the policy.
3. In the **Copy User Role Policy** dialog, click to select **User Role** to copy the policy. You can select multiple roles.
4. Now the password policy is copied to all the selected roles.

3.4.5 Users

Users screen enables you to do the following in Qualis LIMS:

- Create and manage new user/ user accounts
- Map user roles to the user accounts
- Map Deputy user role to user accounts

3.4.5.1 Adding a New User / User Account

To create a new user account, follow these steps:

1. On the main menu, click  **User Management**, and then click **Users**. The **Users** master screen appears as shown in the figure:



The screenshot shows the Qualis LIMS 'Users' master screen. The left side is a list of users with their names, initials, and status (Active). The right side shows a detailed view of a selected user (User02) and a 'Default' section for managing user roles.

Left Panel (List of users):

- User 02: User02 | Active
- User 01: User01 | Active
- LIMS Admin: LIMSAdmin | Active
- Sathish Kumar: QA | Active
- CRO C: cro | Active
- Head Department: hod | Active
- Study Director: sd | Active
- Jackie O'Brien: Ate153 | Active
- Eilis Moran: ate142 | Active

Right Panel (User02 Details):

Default Section:

Role	Deputy User
Head of Division	Yes

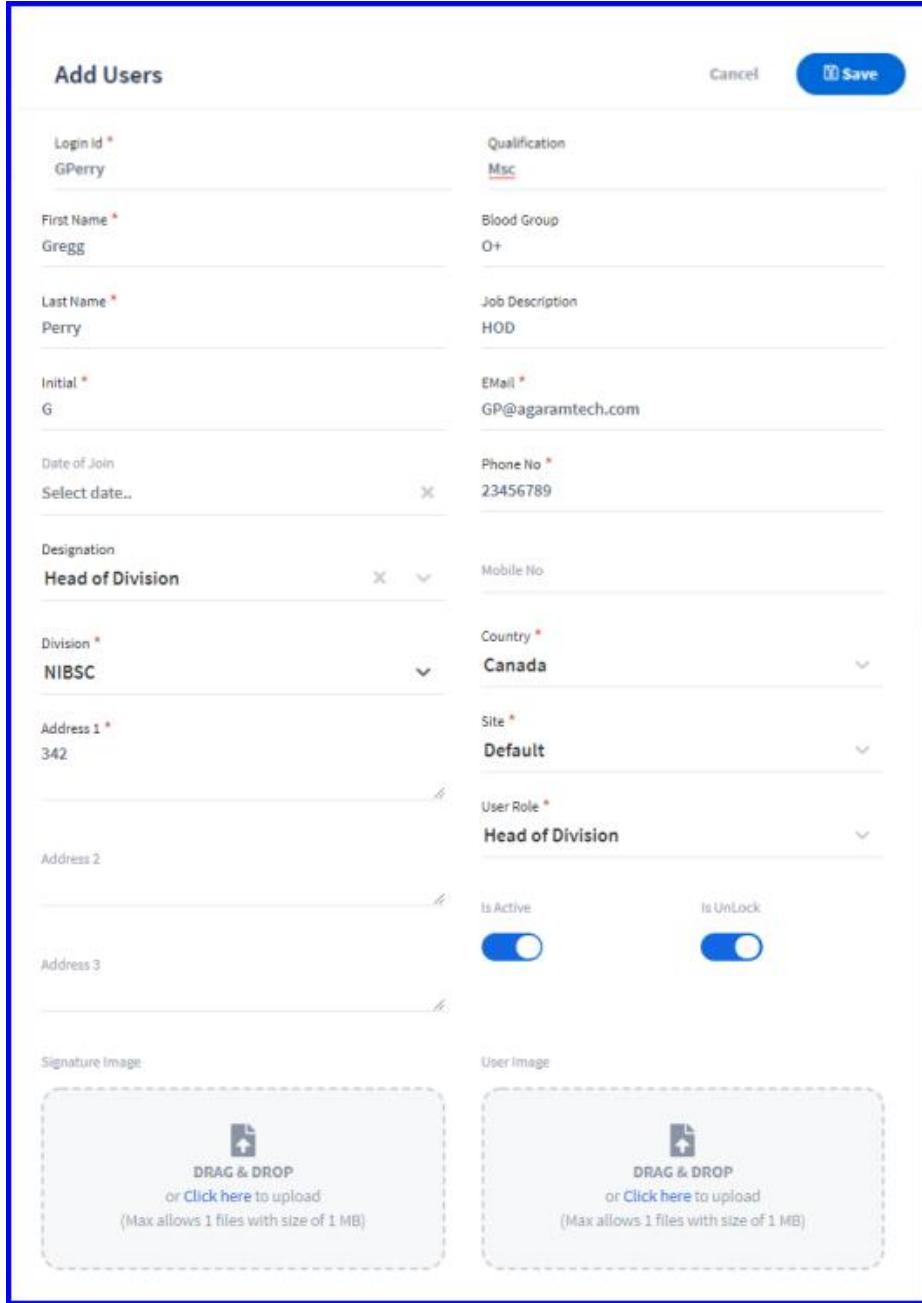
Action Buttons:

- Search user here
- Click here to add new user
- List of users added to the Users master
- View details of the selected user
- Edit, delete or retire user
- Add deputy users to the user here
- Add multiple roles to the user
- Click here to reset password

FIGURE: Users Screen

In the Users screen you can see the list of users added. Options to add, edit, delete, retire users, add role and reset password appears as shown in the above figure. You can also add multiple roles and deputy users to the selected user.

2. In the **Users** screen, click . The **Add** user screen appears as shown in the figure:



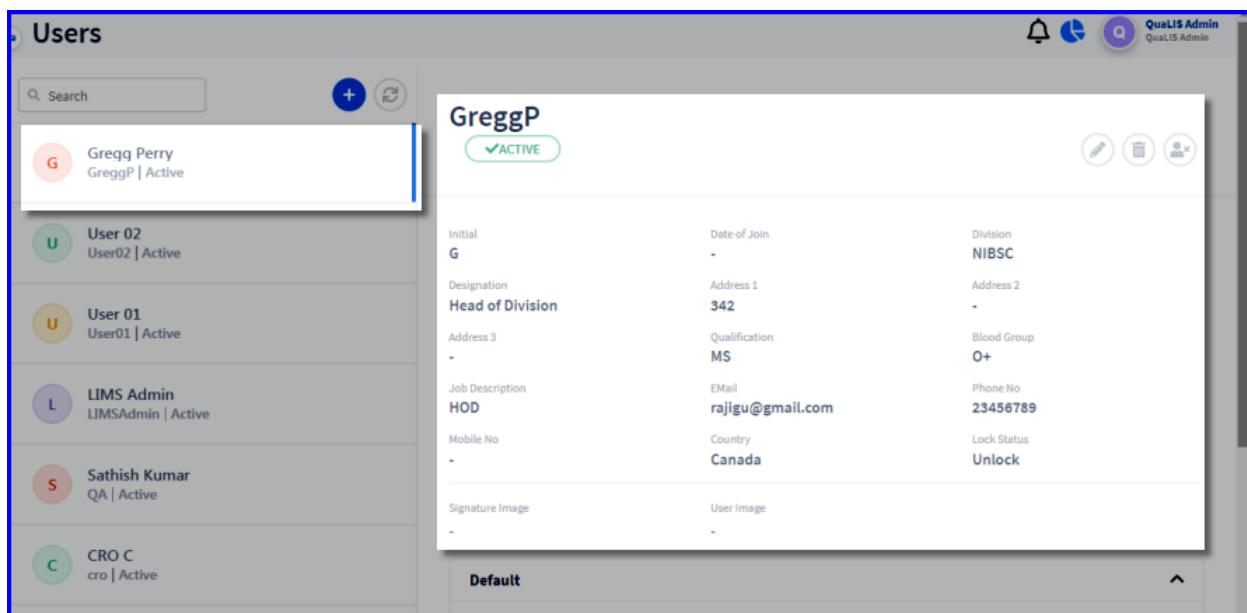
The screenshot shows the 'Add Users' form. The fields and their values are as follows:

- Login Id ***: GPerry
- Qualification**: Msc
- First Name ***: Gregg
- Blood Group**: O+
- Last Name ***: Perry
- Job Description**: HOD
- Initial ***: G
- EMail ***: GP@agaramtech.com
- Date of Join**: Select date..
- Phone No ***: 23456789
- Designation**: Head of Division
- Mobile No**: (dropdown)
- Division ***: NIBSC
- Country ***: Canada
- Address 1 ***: 342
- Site ***: Default
- Address 2**: (dropdown)
- User Role ***: Head of Division
- Address 3**: (dropdown)
- Is Active**:
- Is UnLock**:
- Signature Image**: DRAG & DROP or Click here to upload (Max allows 1 files with size of 1 MB)
- User Image**: DRAG & DROP or Click here to upload (Max allows 1 files with size of 1 MB)

FIGURE: Add Users Screen

3. In the **Login Id** field, type a login name for the user account.
4. Type **First Name, Last Name, Initial, Address1, E-mail** and **Phone No** of the user.
5. Select **Division, Country, Site** and **User Role**.
6. Turn on **Is Active** and **Is Unlock** options to make the user account active and unlocked.
7. Add **Signature Image** and **User Image** if available.
8. Fill in other fields as required.
9. Click **Save**.

You can see the user you just added listed in the User screen as shown in the figure:



The screenshot shows the 'Users' screen in Qualis LIMS. On the left, a list of users is displayed with their initials, names, and status (Active). The user 'GreggP' is selected, and a detailed view is shown on the right. The detailed view includes fields for Initial (G), Date of Join (-), Division (NIBSC), Designation (Head of Division), Address 1 (342), Address 2 (-), Qualification (MS), Blood Group (O+), Job Description (HOD), EMail (rajigu@gmail.com), Phone No (23456789), Mobile No (-), Country (Canada), Lock Status (Unlock), and Signature Image (User Image). There is also a 'Default' button at the bottom.

FIGURE: Users Screen Showing New User Added

3.4.5.2 Editing and Deleting User

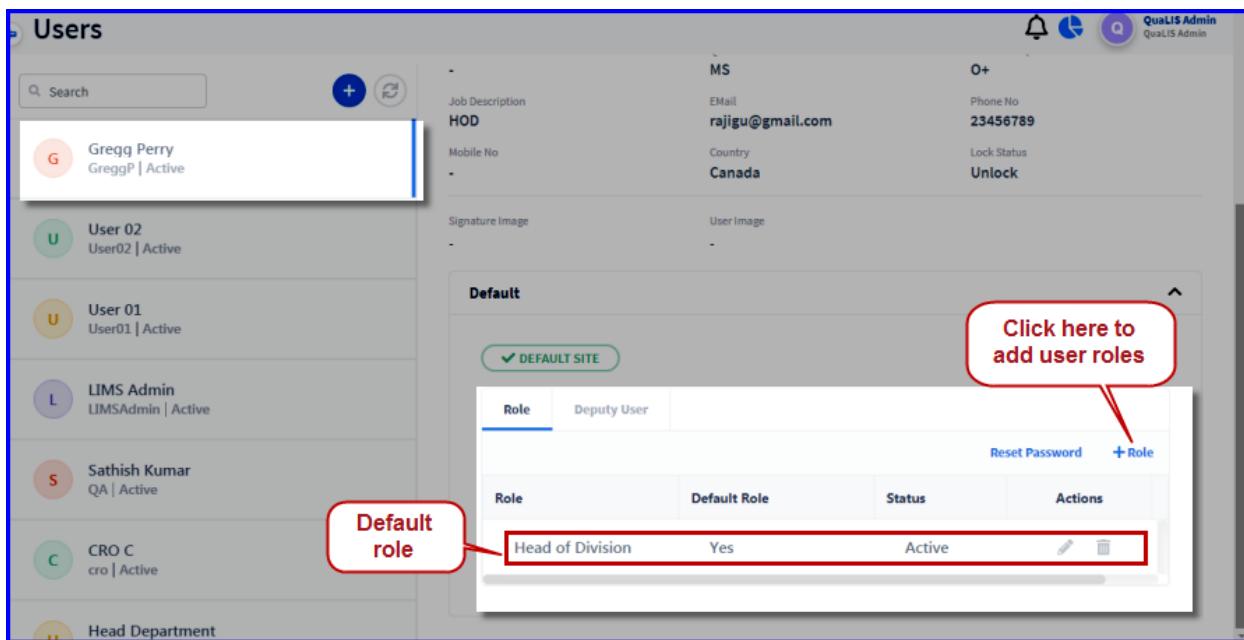
1. To edit user details, in the Users screen, select the user, and then click  . In the **Edit Users** screen, do required changes and then click **Save**.
2. To delete a user, in the Users screen, select the user you want to delete, and then click 

3.4.5.3 Mapping User Role(s) to the User

Once you create a user account, you can map the user account to user role(s). In Qualis LIMS you can map multiple user roles to a user and the user role you added at the time of adding / creating a user account is set as a default user role.

To do so, follow these steps:

1. In the **Users** screen, select a user from the list and then go to the **Role** tab. The **Role** tab appears as shown in the figure:



Role	Default Role	Status	Actions
Head of Division	Yes	Active	Edit Delete

FIGURE: User Role Tab

Here you can see the roles mapped to the selected user account.

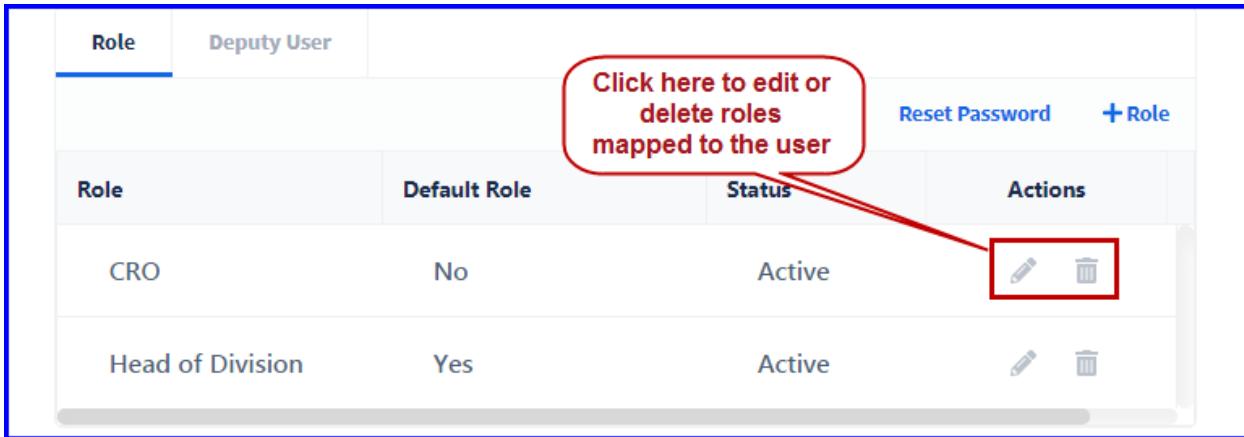
2. To add another role to the selected user, click **+ Role**. The **Add Role** screen appears as shown in the figure:



The screenshot shows the 'Add Role' form. It includes fields for 'Login Id' (GreggP), 'User Role' (QA), 'Default Role' (unchecked), and 'Is Active' (checked). The 'Save' button is visible in the top right corner.

FIGURE: Add Role Screen

3. In the **User Role** field, select the role to map to the login id.
4. Click **Default Role** option to make the role as default role.
5. Click **Save**. The login id is mapped to the selected role and the same appears in the **Role** tab.
6. Repeat steps 1 to 4 to map the selected user to multiple roles. The Role tab appears as shown in the figure with multiple roles mapped to the selected user:



The screenshot shows the 'Role' tab for a user. It has a header with 'Role' and 'Deputy User' tabs. Below is a table with columns: Role, Default Role, Status, and Actions. Two rows are shown: 'CRO' (Default Role: No, Status: Active) and 'Head of Division' (Default Role: Yes, Status: Active). A red callout box with the text 'Click here to edit or delete roles mapped to the user' points to the 'Actions' column for the 'CRO' row. A red box highlights the edit and delete icons in the 'Actions' column for the 'CRO' row.

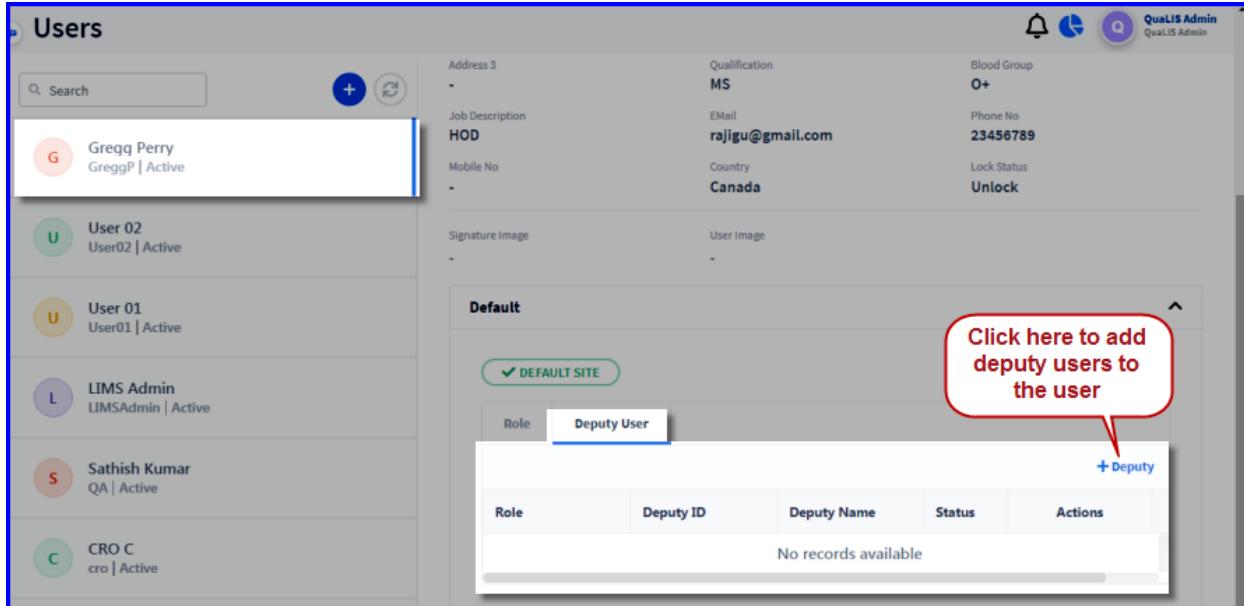
Role	Deputy User			
Role	Default Role	Status	Actions	
CRO	No	Active		
Head of Division	Yes	Active		

FIGURE: Role Tab Showing Roles Mapped to the User

Note: You can edit and delete roles added to the user account. But you cannot delete the default user role.

3.4.5.4 Add Deputy Users to the selected user id/user account

1. In the **Users** screen, select a user from the list and then go to the **Deputy User** tab. The **Deputy User** tab appears as shown in the figure:



The screenshot shows the 'Users' screen with a list of users on the left and a detailed view of a selected user (Gregg Perry) on the right. The 'Deputy User' tab is selected in the 'Default' section. A callout bubble with the text 'Click here to add deputy users to the user' points to the 'Deputy User' tab.

FIGURE: Deputy User Tab

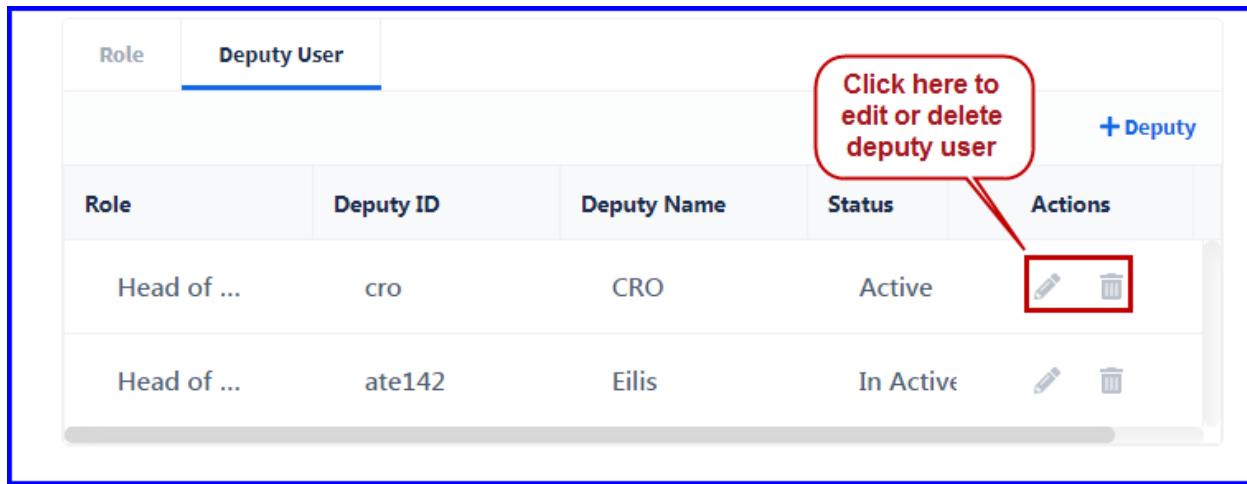
2. Click **+ Deputy**. The **Add Deputy** user screen appears as shown in the figure:



The screenshot shows the 'Add Deputy' user screen. The 'Deputy ID' field is populated with 'ate142'. The 'Deputy Name' field is populated with 'Ellis Moran'. The 'User Role' field is populated with 'Head of Division'. The 'Save' button is visible in the top right corner.

FIGURE: Add Deputy User Role Screen

3. In the **Deputy ID** field, select the user id to map to the selected user as deputy user.
4. In the **Deputy Name** field, the name of the deputy user selected in the **Deputy ID** field appears.
5. In the **User Role** field, select the role for the deputy user.
6. Click **Save**. The user with the selected user role is mapped to the selected user id as deputy user and the same appears in the **Deputy User** tab as shown in the figure:



Deputy User				
Role	Deputy ID	Deputy Name	Status	Actions
Head of ...	cro	CRO	Active	 
Head of ...	ate142	Eilis	In Active	 

FIGURE: Deputy User Tab Showing Added Deputy Users

3.4.6 MIS Rights

The MIS Rights screen enables administrators to grant or revoke access to the reports, dashboard, dashboard home, alerts and alerts home to the selected user role.

1. On the main menu, click , **User Management**, and then click **MIS Rights**. The **MIS Rights** screen appears as shown in the figure:

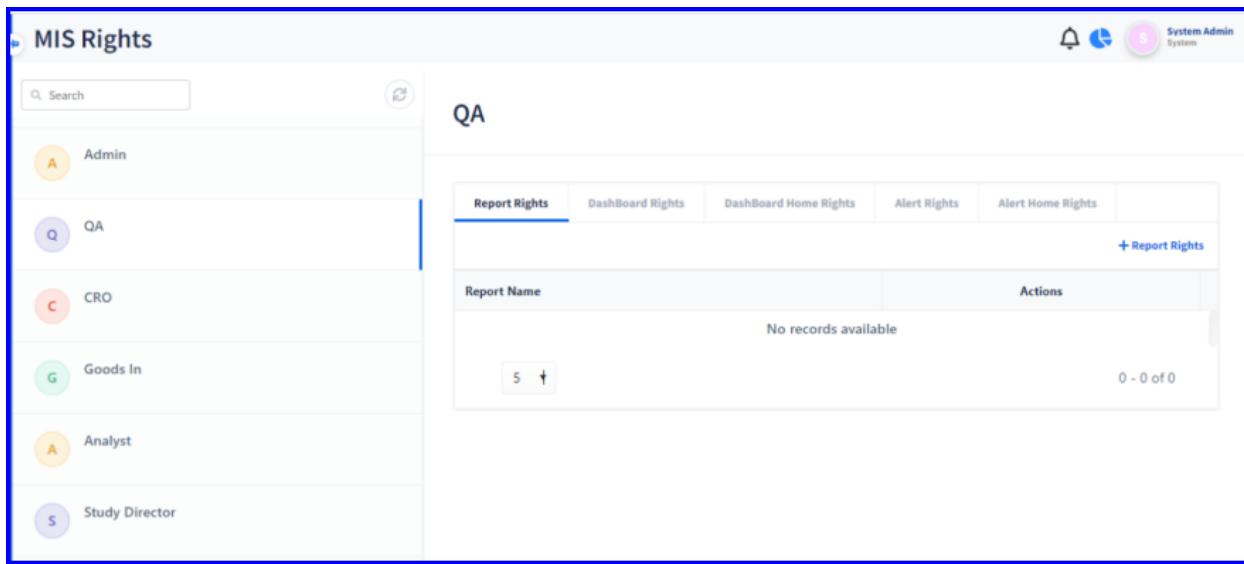


FIGURE: MIS Rights Screen

2. You need to select user role to define MIS rights. Select a user role on the left panel.
3. You can see the **Report Rights**, **Dashboard Rights**, **Dashboard Home Rights**, **Alert Rights** and **Alert Home Rights** tabs as shown in the above figure.
4. By default, the **Report Rights** tab appears as shown in the figure:

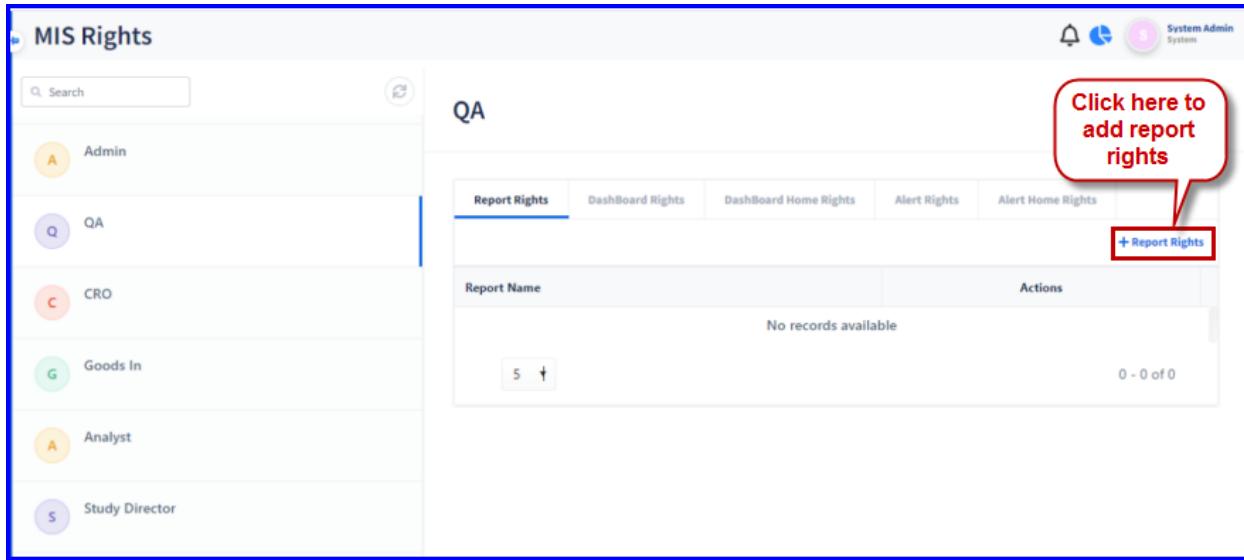


FIGURE: Report Rights Tab

5. In the **Report Rights** tab, click **+ Report Rights**. The **Add Reports Rights** dialog appears as shown in the figure:

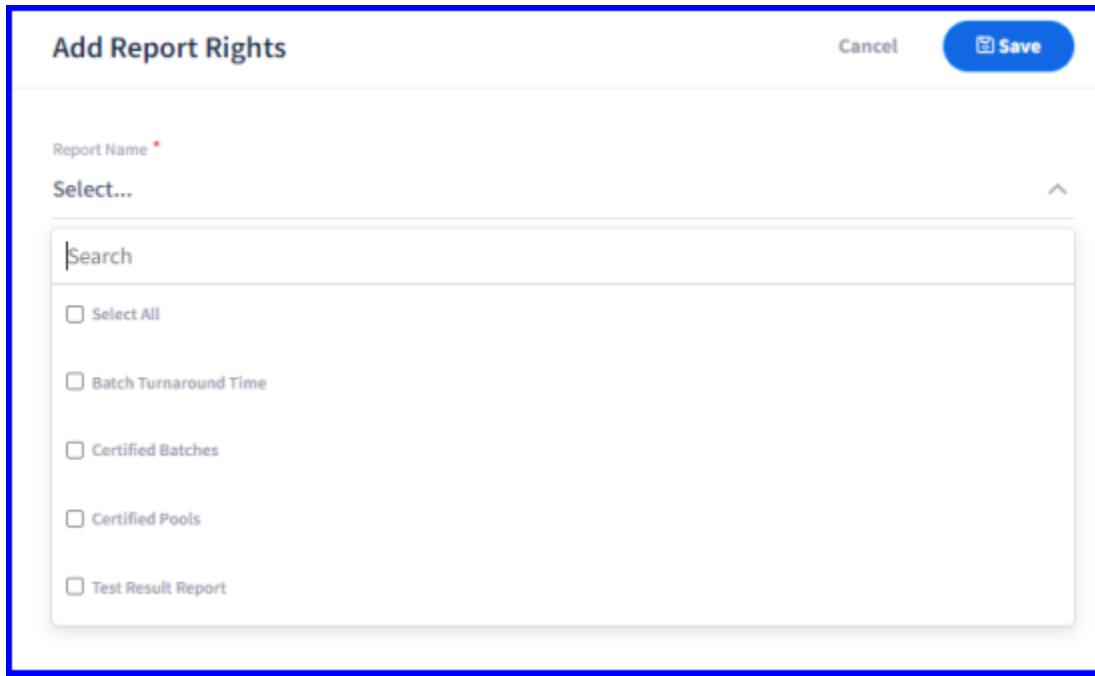


FIGURE: Add Report Rights Dialog

6. In the **Report Name** field click and select reports to grant rights. Click **Select All** to grant rights to all the reports.
7. Click **Save**.
8. Same way, you can grant rights to Dashboard, Dashboard Home, Alert and Alert Home in the respective tabs.

3.4.7 Screen Rights

The Screen Rights screen enables administrators to grant or revoke access to the screens, controls and E-Signature options.

1. On the main menu, click , **User Management**, and then click **Screen Rights**. The **Screen Rights** screen appears as shown in the figure:



FIGURE: Screen Rights Screen

2. You need to select user role to define screen rights. Click , select the User Role and then click **Submit** as shown in the figure:



FIGURE: Selecting User Role to Define Screen Rights

3. To add screens to the selected user role, click  as shown in the figure:

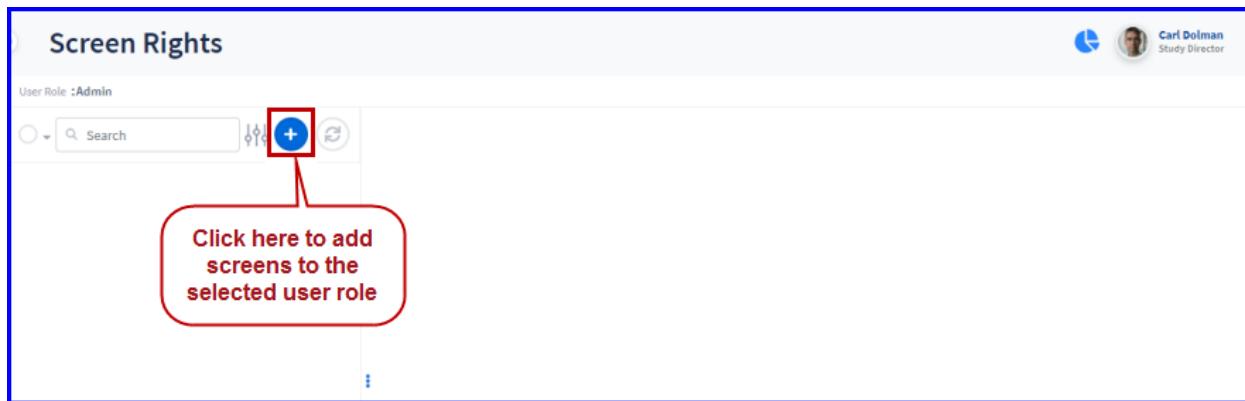


FIGURE: Add Screens to the User Role

- . The **Add Screen Rights** screen appears as shown in the figure:

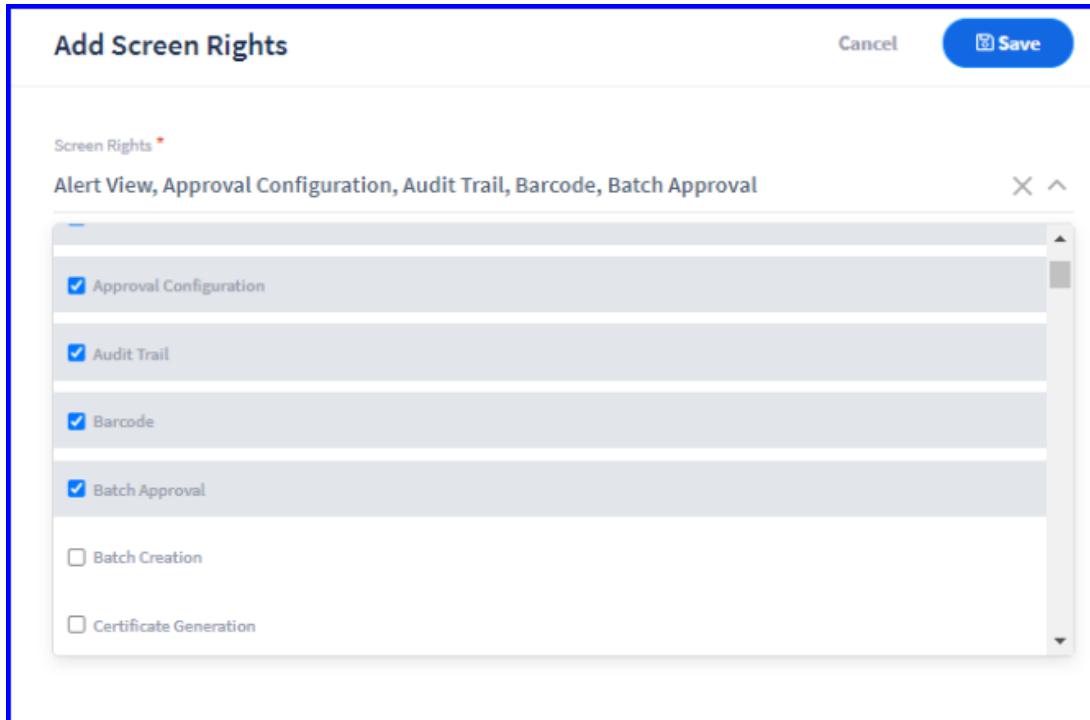


FIGURE: Add Screen Rights Screen

4. In the **Screen Rights** field, click and select screens from the list to grant access as shown in the above figure.
5. Click **Save**. List of screens added to the user role appears in the left panel. And list of controls and E-signature option for the selected screen appears in the right panel as shown in the figure:

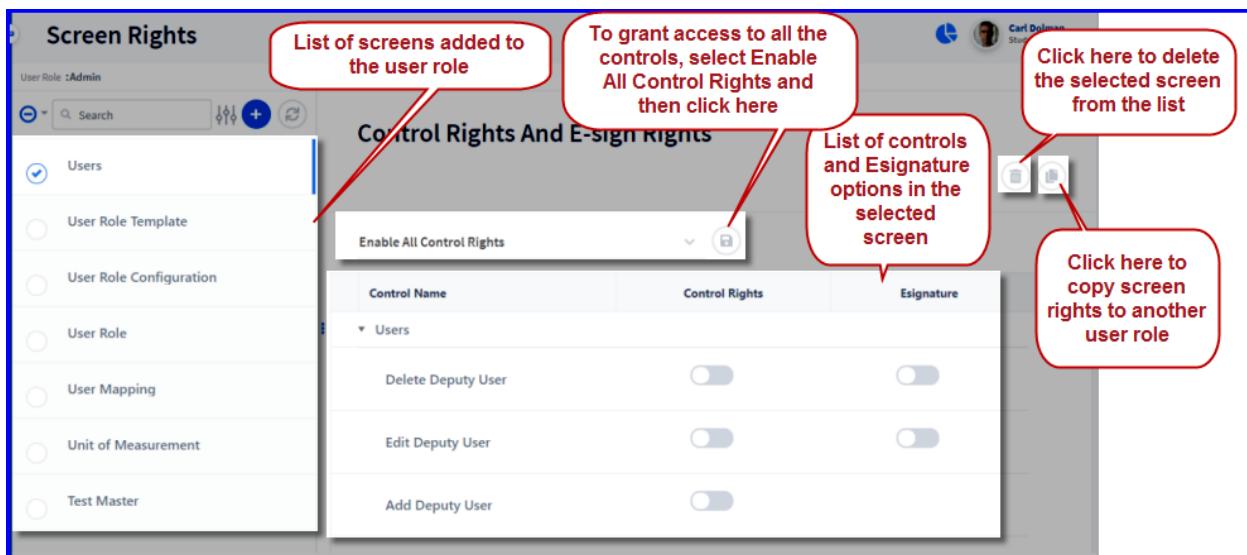
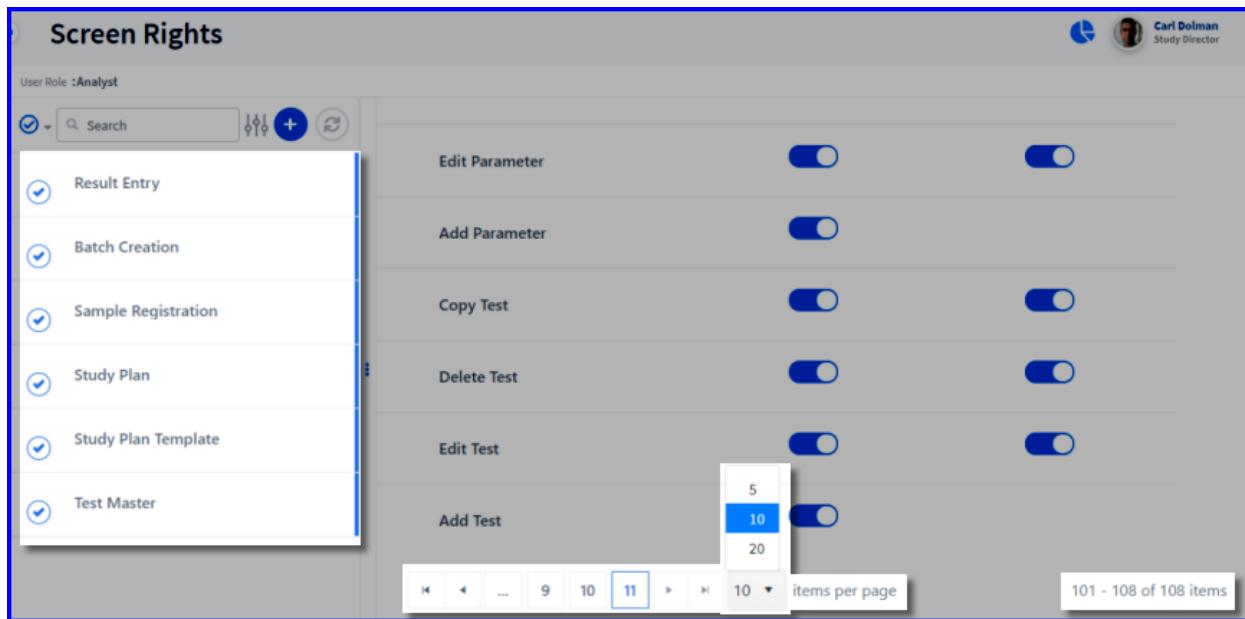


FIGURE: List of Screens, Controls and E-Sign Options

6. To grant control rights, click to turn on the **Control Rights** option for the **Control Name**.
7. To grant E-sign rights, click to turn on the **Esignature** option for the **Control Name**.
8. To grant access to all the controls in the list, select **Enable All Control Rights** and then click .
9. To grant E-sign access to all the controls in the list, select **Enable All Esign Rights** and then click .
10. To revoke access to all controls in the list, select **Disable All Control Rights** and then click .
11. To revoke E-sign access to all controls in the list, select **Disable All Esign Rights** and then click .

3.4.7.1 Pagination

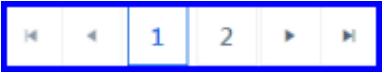
When you select all or more screens in the left panel, controls from the selected screens will appear in the right panel. You can set number of **items per page** for view by selecting 5 / 10 / 20 from the list as shown in the figure:



The screenshot shows the 'Screen Rights' page. On the left, a sidebar lists roles: Result Entry, Batch Creation, Sample Registration, Study Plan, Study Plan Template, and Test Master. Each role has a checkbox next to it. The 'Study Plan' role is selected. The main area displays a table of permissions for the 'Analyst' role. The permissions are: Edit Parameter (on), Add Parameter (on), Copy Test (on), Delete Test (on), Edit Test (on), and Add Test (with a dropdown menu showing 5, 10, 20 items per page, where 10 is selected). At the bottom, there is a navigation bar with page numbers (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108). The current page is 101 of 108 items.

FIGURE: Screen Rights – Pagination

12. Select **items per page** for display: 

13. Use the navigation bar to navigate to the pages: 

3.4.7.2 Copying Screen Rights

You can copy screen rights to multiple roles.

14. To copy screen rights, in the Screen Rights screen, select the role; select the screen(s) and then click .

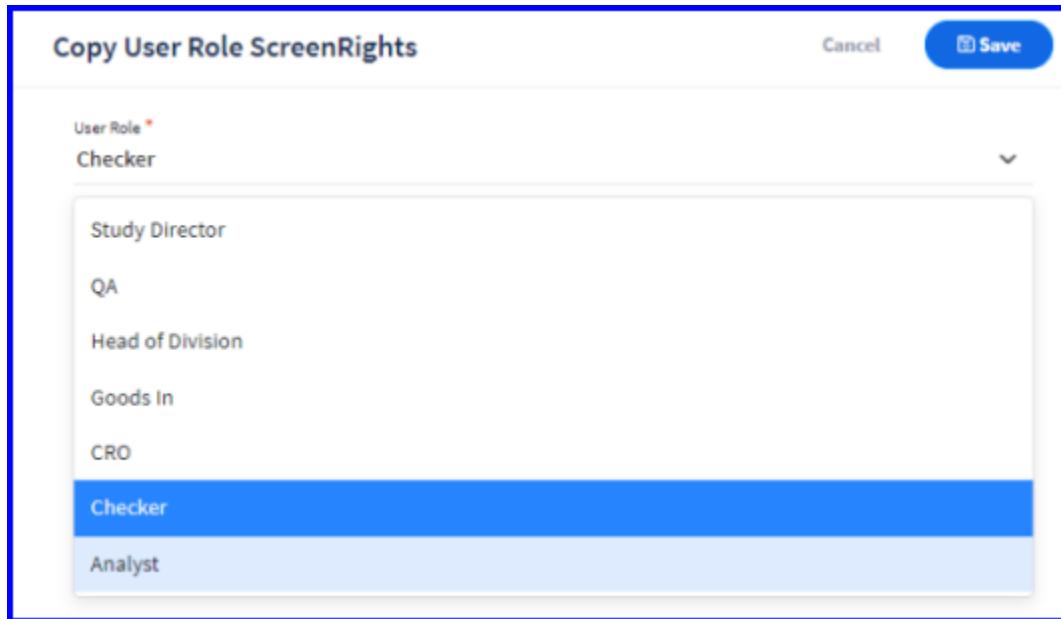


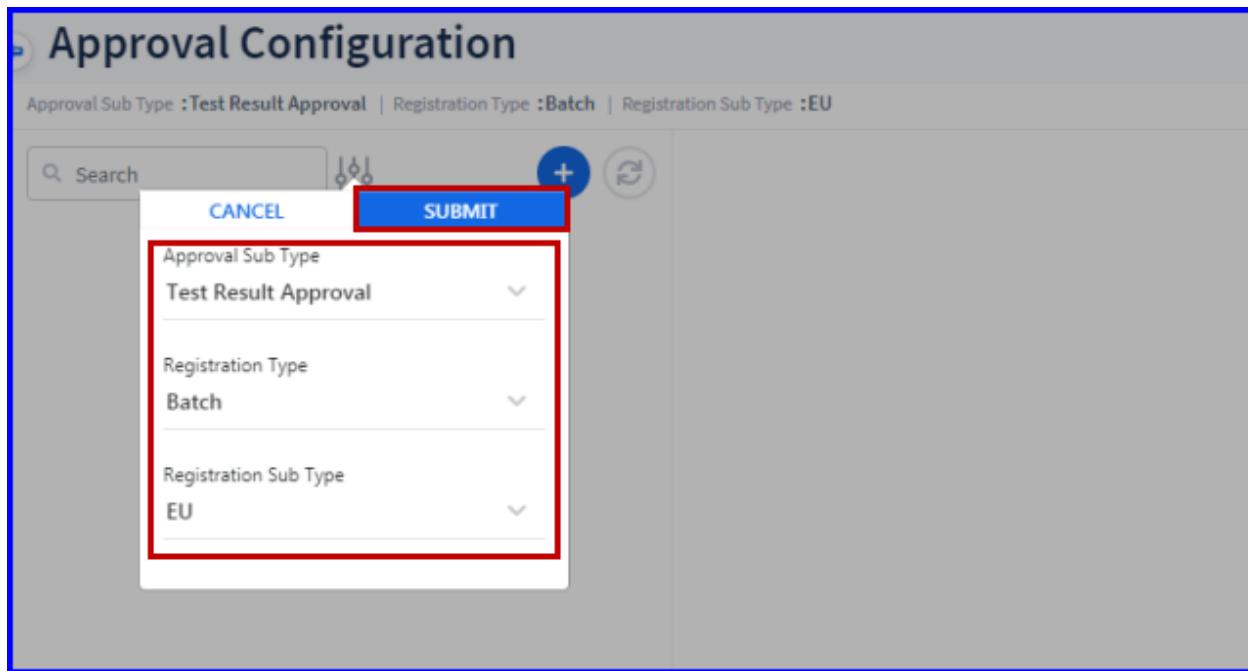
FIGURE: Copy User Role Screen Rights Screen

15. In the **User Role** field, click and select user roles to copy the screen rights. You can select multiple roles.
16. Now the screen rights are copied to all the selected roles.

3.4.8 Approval Configuration

Based on the template designed in the user role template screen you can define the approval flow stages in Approval Configuration screen.

1. On the main menu, click , **User Management**, and then click **Approval Configuration**. The **Approval Configuration** screen appears as shown in the figure:



Approval Sub Type :Test Result Approval | Registration Type :Batch | Registration Sub Type :EU

Search Filter Add Refresh

Cancel Submit

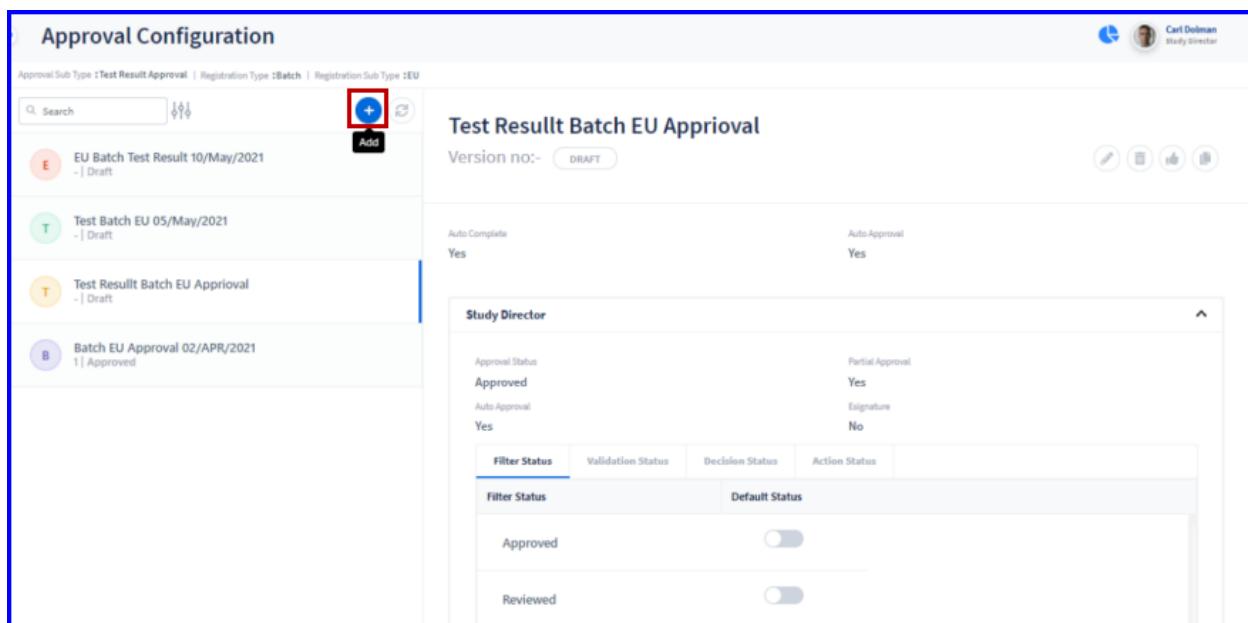
Approval Sub Type
Test Result Approval

Registration Type
Batch

Registration Sub Type
EU

FIGURE: Approval Configuration Screen

2. In the filter Filter, in the **Approval Sub Type** field, select the module you want to create workflow. Select **Registration Type** and **Registration Sub Type** if prompted.
3. Click **Submit**. The approval flow for the selected type and sub types appears as shown in the figure:



Approval Configuration

Approval Sub Type :Test Result Approval | Registration Type :Batch | Registration Sub Type :EU

Search Filter Add Refresh

E EU Batch Test Result 10/May/2021 - Draft

T Test Batch EU 05/May/2021 - Draft

T Test Result Batch EU Approval - Draft

B Batch EU Approval 02/APR/2021 1 Approved

Test Result Batch EU Approval

Version no.: DRAFT

Auto Complete
Yes

Auto-Approval
Yes

Study Director

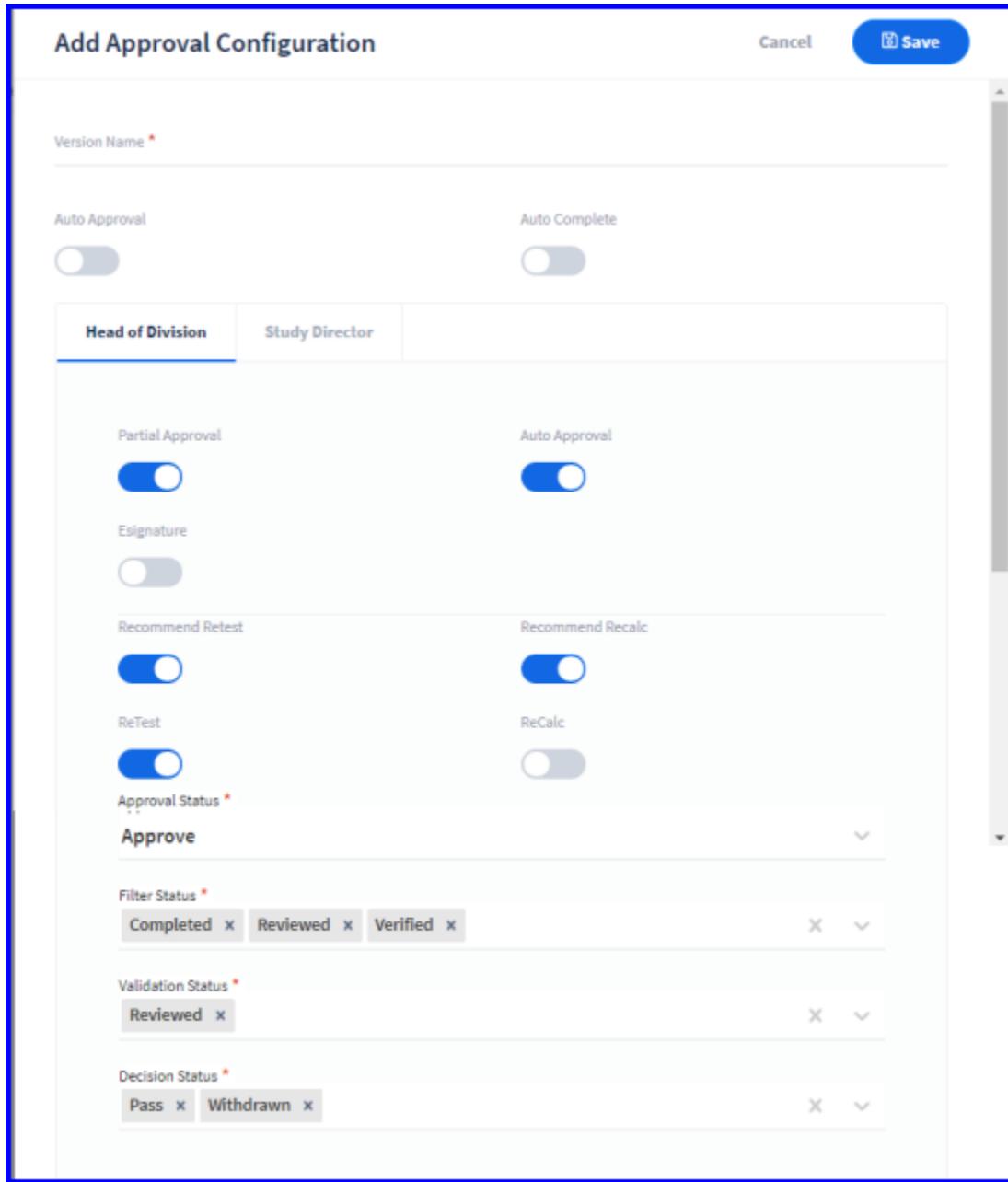
Approval Status	Partial Approval
Approved	Yes
Auto Approval	Signature
Yes	No

Filter Status Validation Status Decision Status Action Status

Filter Status	Default Status
Approved	<input checked="" type="checkbox"/>
Reviewed	<input checked="" type="checkbox"/>

FIGURE: Approval Configuration Screen - Add

4. Click . The **Add Approval Configuration** screen appears as shown in the figure:



The screenshot shows the 'Add Approval Configuration' interface. At the top right are 'Cancel' and 'Save' buttons. The 'Save' button is highlighted with a blue border. The main area contains several configuration sections with toggle switches and dropdown menus. The 'Auto Approval' section has a checked toggle. The 'Partial Approval' section has an unchecked toggle. The 'Recommend Retest' section has a checked toggle. The 'Recommend Recalc' section has a checked toggle. The 'Approval Status' section has a dropdown menu with 'Approve' selected. The 'Filter Status' section has three buttons: 'Completed', 'Reviewed', and 'Verified'. The 'Validation Status' section has a button: 'Reviewed'. The 'Decision Status' section has two buttons: 'Pass' and 'Withdrawn'.

FIGURE: Add Approval Configuration Screen

5. In the **Version Name** field, type a name for the approval flow version.
6. Click to check the **Auto Approval** option to auto approve the sample upon accepting the sample in the Registration screen.
7. Click to check the **Auto Complete** option if required.

The roles available as per the User Role Template will appear as tabs in the approval route.

8. Set the approval flow options as required for the selected type for each role required in approval flow
9. Click to select the **Esignature** check field, if Esignature is required to complete the approval stage.
10. In the **Approval Status** field, click and select the approval status which will be assigned to the sample after completing the approval stage by the selected role.
11. To set the **Filter Status** Details for the selected role in the approval flow, select status values from the list. Selected status values will be available for filtering records for the selected role. Only records with selected status values will be available for the role.
12. To set the **Validation Status** Details for the selected role in the approval flow, select status values from the list. Records with selected status values will be available for taking approval action to the selected role.
13. Repeat the steps for other roles in each tab
14. Click **Save**. The approval configuration is saved as a draft. In the draft state, you can edit or delete the configuration.

3.4.8.1 Approving Approval Configuration

1. After completing settings for all the roles, Click  to approve the Approval Configuration.

Note: If a configuration exists for a particular Sub Type, it will get retired automatically when the new configuration is approved.

3.4.8.2 Copying Approval Configuration

The copy option can be used to replicate the Approval Configuration settings from one type to another type.

1. To copy Approval Configuration, in the Approval Configuration screen, select the configuration and then click .

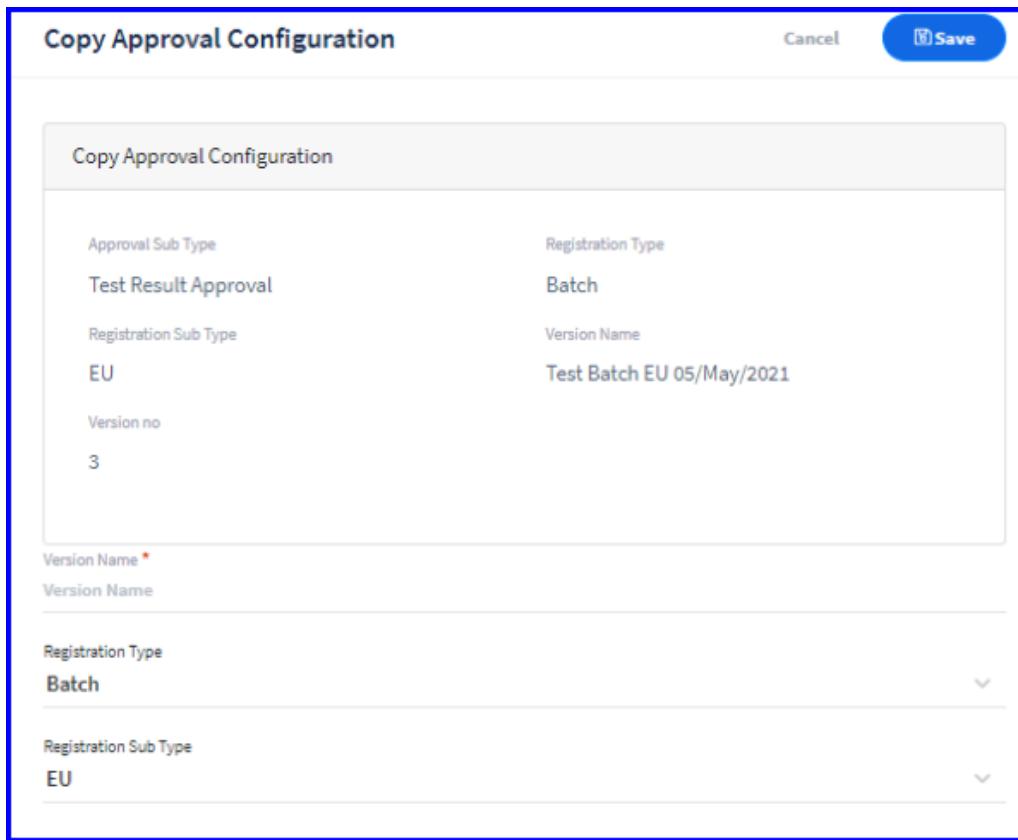


FIGURE: Copy Approval Configuration Screen

2. In the **Version Name** field, type name for the version you copy.
3. In the **registration Type** field, select the registration type.
4. In the **registration Sub Type** field, select the registration sub type.
5. Click **Save**.
6. Now the configuration is copied to the selected type / sub type

3.4.9 User Role Template

User Role Template enables you to create templates to use in the approval configuration screen. You can design the user role template based on the approval stages in the workflows in your organisation. Example for workflows: Test group approval, Registration approval etc. you can add user roles to the stages in the workflow.

Example stages in test group approval workflow: Analyst, Review and Approver.

3.4.9.1 Versioning

You can add and approve versions to the user role template. Until you approve, the version will remain in the draft state. In the draft state, you can edit, approve and delete the version. Once approved, you cannot edit or delete the version. The existing approved template will retire once you add and approve a new version.

To create a user role template, follow these steps:

1. On the main menu, click  **User Management** and then click **User Role Template**. The **User Role Template** screen appears as shown in the figure:

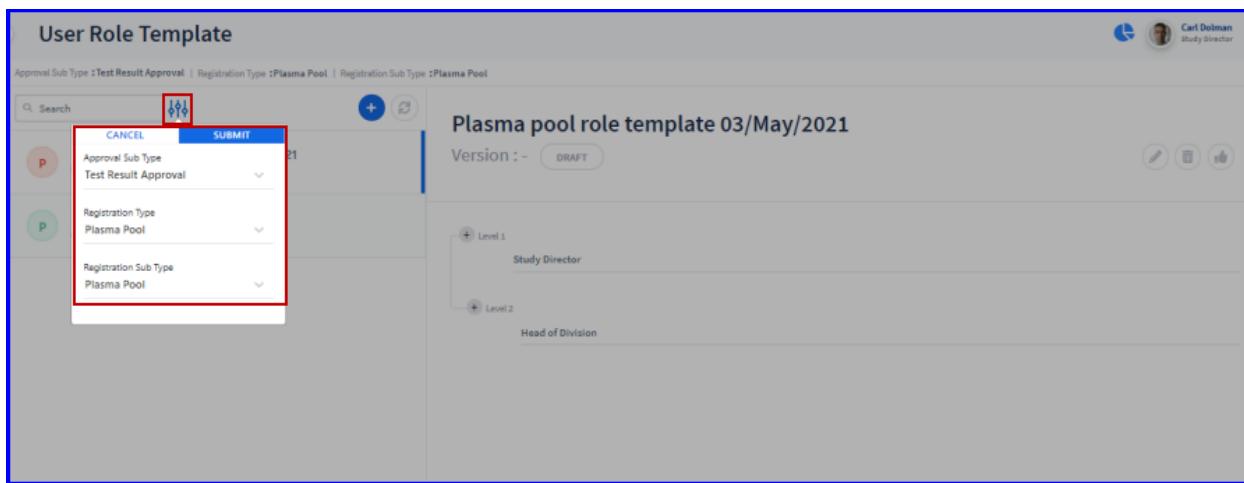


FIGURE: User Role Template Screen Showing Filter

1. In the filter  , in the **Approval Sub Type** field, select the module you want to create template. Select **Registration Type** and **Registration Sub Type** if prompted.
2. Click **Submit**.

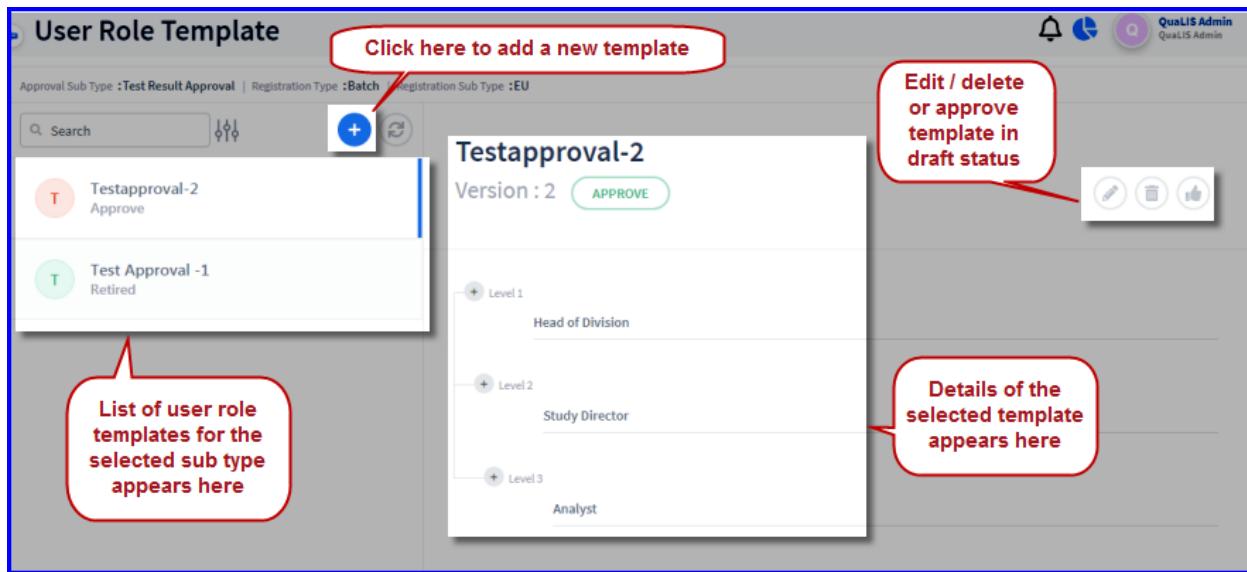


FIGURE: User Role Template Screen Showing List of Templates

Note: If a template exists for a particular sub type, it will get retired automatically when the new template is approved.

3. Click . The **Add User Role Template** screen appears as shown in the figure:

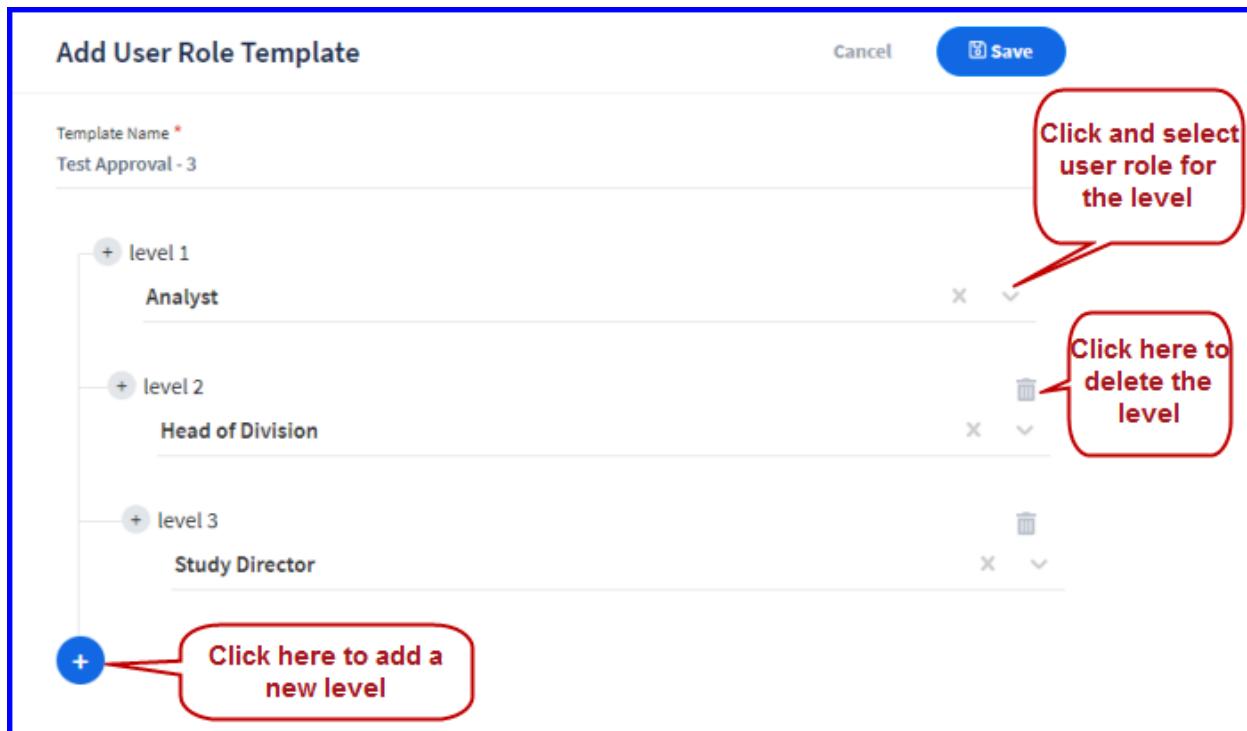
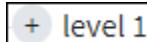


FIGURE: Add User Role Template Screen

4. In the **Template Name** field, type a name for the template.
5.  will appear by default. Click and select user role for the **level 1**. (User roles that are added in the User Role Configuration screen for the workflow type appears here)

Note: Add the roles in the user role approval flow in your organisation in the user role template. Roles that are added can be removed and added again with required correction.

6. Click  to add more levels to the template and select user role for each levels.
7. After creating the required role levels for the approval flow, click **Save**.

You can see the user role template added as a draft in the **User Role Template** screen as shown in the figure:

3.4.9.2 Editing and Deleting User Role Template

You can edit/delete user role templates that are in the draft state. You cannot edit/delete approved templates.

1. To edit a user role template, in the User Role Template master screen, select the template, and then click . In the **Edit User Role Template** screen, do required changes and then click **Submit**. You can change Template Name, add roles and remove roles to the template.
2. To delete a user role template, in the User Role Template master screen, select the template, click and then click .

3.4.9.3 Approving User Role Template

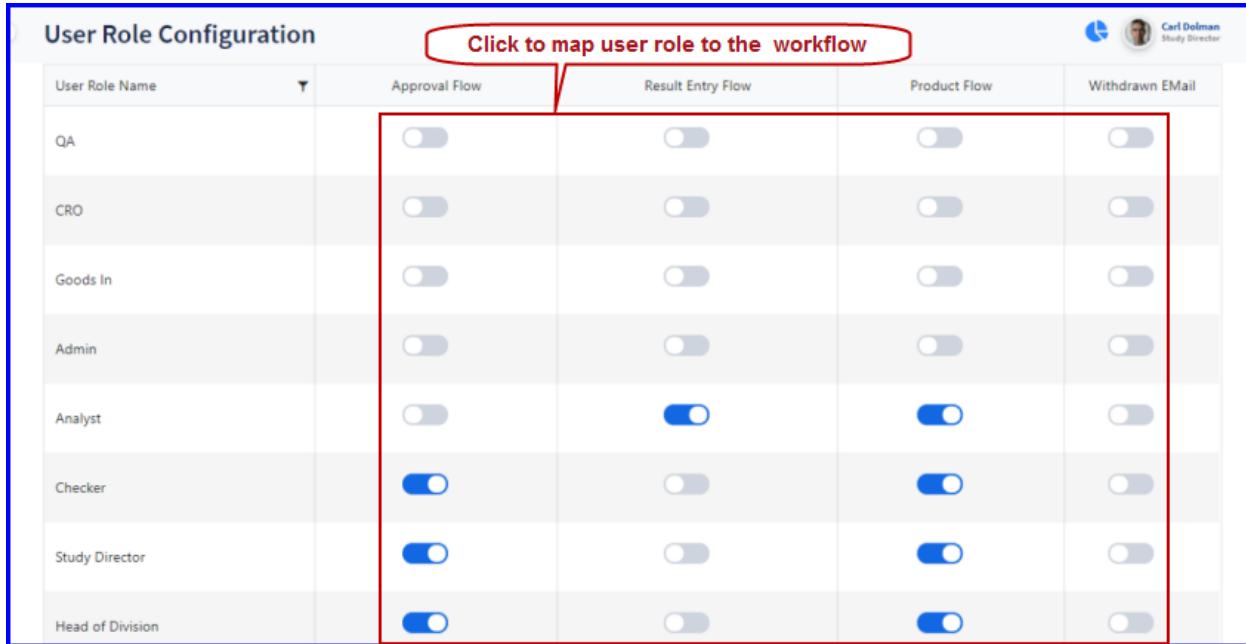
You can approve a template in the draft state.

1. To approve a user role template, in the User Role Template master screen, select the template, and then click . The template is approved and the status appears as **Approved**.

3.4.10 User Role Configuration

User Role Configuration screen helps the administrator to map user roles to the workflows. To do so, follow these steps:

2. On the main menu, click  **User Management** and then click **User Role Configuration**. The **User Role Configuration** screen appears as shown in the figure:



User Role Name	Approval Flow	Result Entry Flow	Product Flow	Withdrawn EMail
QA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CRO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Goods In	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Admin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Analyst	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Checker	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Study Director	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Head of Division	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

FIGURE: User Role Configuration Screen

You can see the list of user role and workflows.

3. Click to map the user roles to the workflow as shown in the above figure.

Note: You can map a user role to either Approval Flow or Result Entry Flow. And you cannot map a user to both Approval Flow and Result Entry Flow.

In the User Role Template screen, user roles mapped to the workflow are listed for selection in the **level** field.

3.4.10.1 Filter User Roles

1. In the User Role Configuration screen, in the **User Role Name** field, click  . the filter appears as shown in the figure:

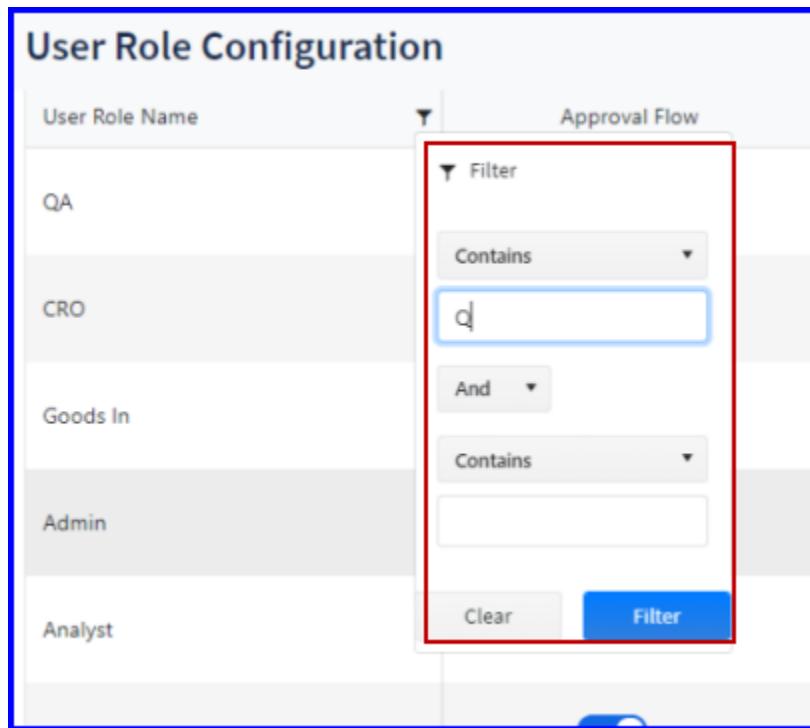


FIGURE: Filter User Role Name

2. Use the filter to search for the user role names and then click **Filter**.

3.4.11 FTP Configuration

FTP Configuration master is used to create and manage FTP locations for file upload.

3.4.11.1 Adding FTP Configuration

To create a new FTP Configuration, follow these steps:

1. On the main menu, click  **User Management** and then click **FTP Configuration**.
The **FTP Configuration** screen appears as shown in the figure:



FIGURE: FTP Configuration Screen

In the FTP Configuration master screen, you can see the list of FTP locations configured. Options to add, edit and delete FTP Configurations appears as shown in the above figure.

2. To add a new FTP location, click . The **Add FTP Config** screen appears as shown in the figure:

Add FTP Configuration

User Name *
FTP1

Password *

Host *
192.168.0.232

Port No *
26

Physical Path *
C:\LIMSFTP\LIMSPATH

Default Status

SSL

Checksum

Save

Cancel

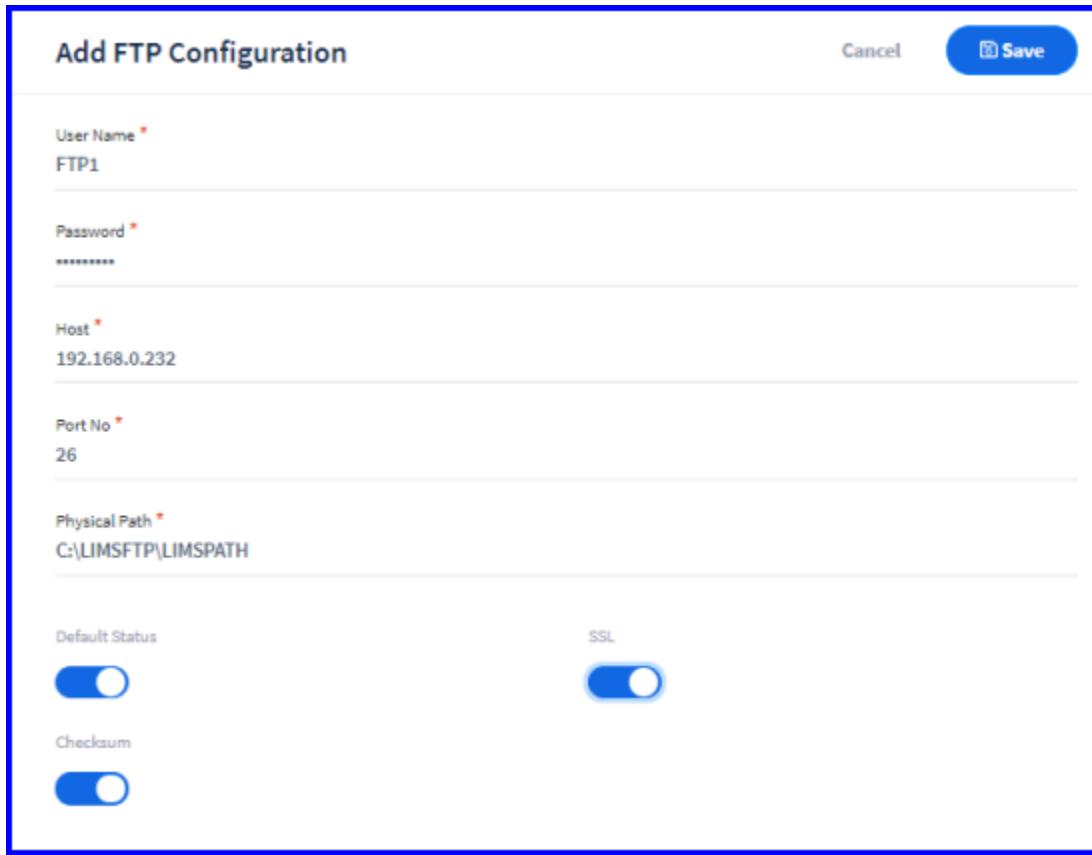


FIGURE: Add FTP Configuration Screen

3. In the **User Name** field, type the name of the machine/server where you want to upload the files.
4. In the **Password** field, type the password of the machine/server.
5. In the **Host** field, type the IP address of the machine/server.
6. In the **Port** field, type the port number.
7. In the **Physical Path** field, type the physical path of the location.
8. Click to select **Default Status** option to make the default status of the FTP location active.
9. Click to select the **SSL** option if applicable.
10. Click **Save**.

You can see the FTP location you created listed in the FTP Configuration master.

3.4.11.2 Editing and Deleting FTP Configurations

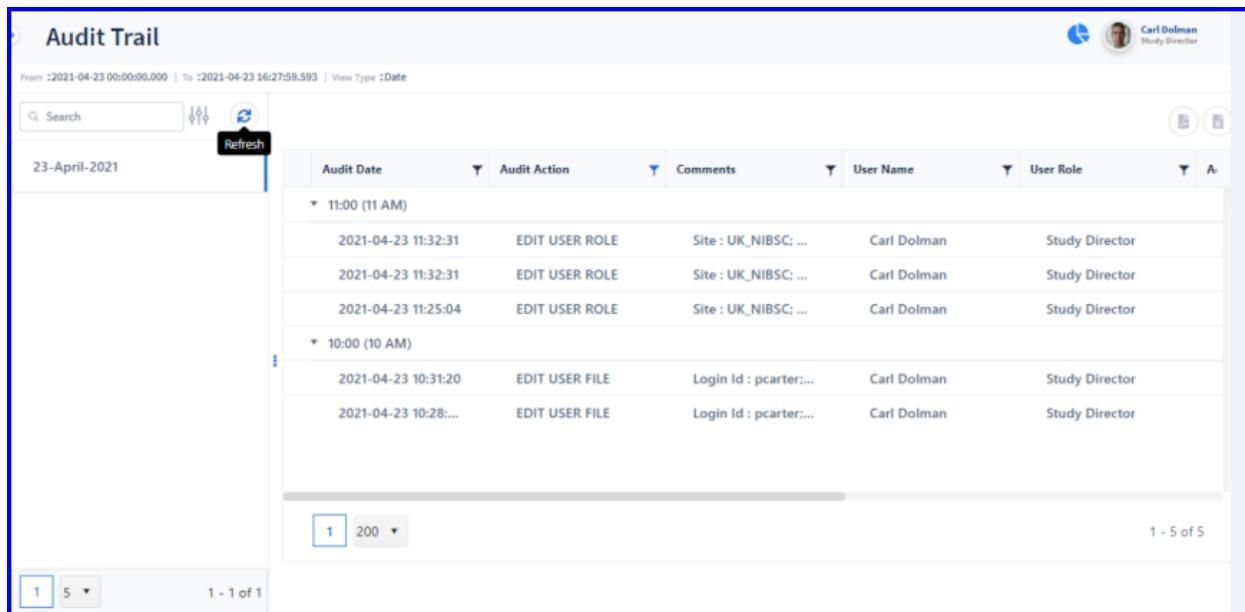
1. To edit a FTP Configuration, in the FTP Configuration master screen, select the FTP Configuration, and then click  . In the **Edit FTP Configuration** screen, do required changes and then click **Save**.
2. To delete a FTP Configuration, in the FTP Configuration master screen, select the FTP Configuration you want to delete, and then click .

3.4.12 Audit Trail

Audit Trail screen enables you to filter and view audit trail log.

To do so, follow these steps:

1. On the main menu, click , **User Management** and then click **Audit Trail**. The **Audit Trail** screen appears as shown in the figure:

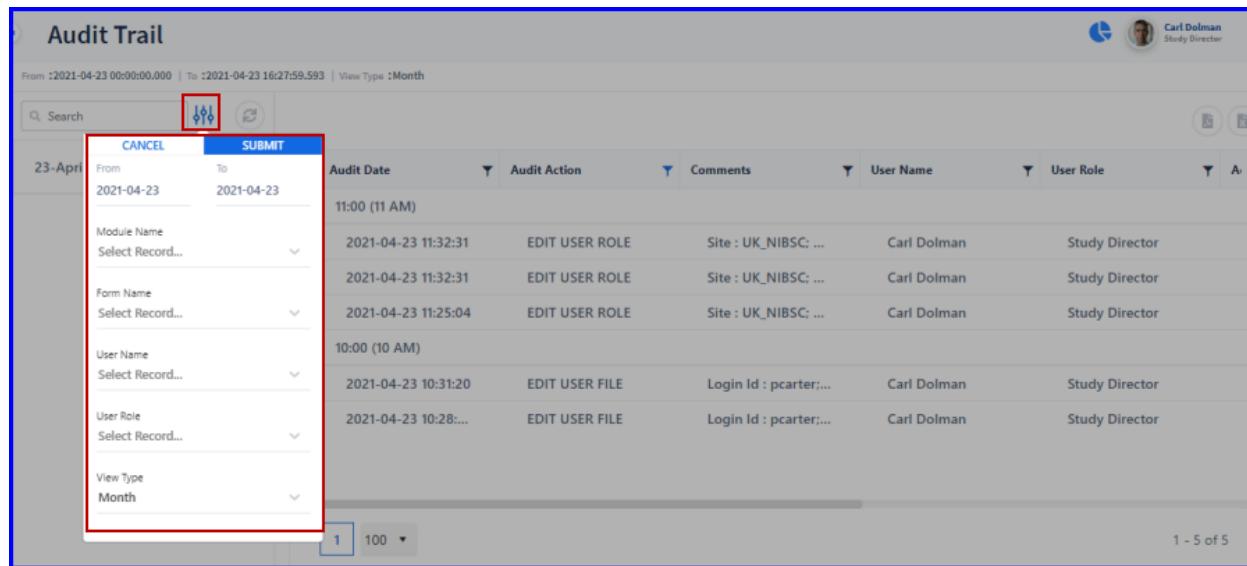


The screenshot shows the Audit Trail screen with a blue border. At the top, there is a search bar and a date range selector set to '23-April-2021'. Below the search bar is a 'Refresh' button. The main area is a table with the following columns: Audit Date, Audit Action, Comments, User Name, and User Role. The table is sorted by Audit Date. The data is grouped by time intervals: '11:00 (11 AM)' and '10:00 (10 AM)'. Each group contains two rows of audit logs. At the bottom of the table, there is a page number '1 200' and a total count '1 - 5 of 5'. The top right corner of the screen shows a user profile for 'Carl Dolman'.

Audit Date	Audit Action	Comments	User Name	User Role
2021-04-23 11:32:31	EDIT USER ROLE	Site : UK_NIBSC: ...	Carl Dolman	Study Director
2021-04-23 11:32:31	EDIT USER ROLE	Site : UK_NIBSC: ...	Carl Dolman	Study Director
2021-04-23 11:25:04	EDIT USER ROLE	Site : UK_NIBSC: ...	Carl Dolman	Study Director
2021-04-23 10:31:20	EDIT USER FILE	Login Id : pcarter:...	Carl Dolman	Study Director
2021-04-23 10:28:...	EDIT USER FILE	Login Id : pcarter:...	Carl Dolman	Study Director

FIGURE: Audit Trail Screen

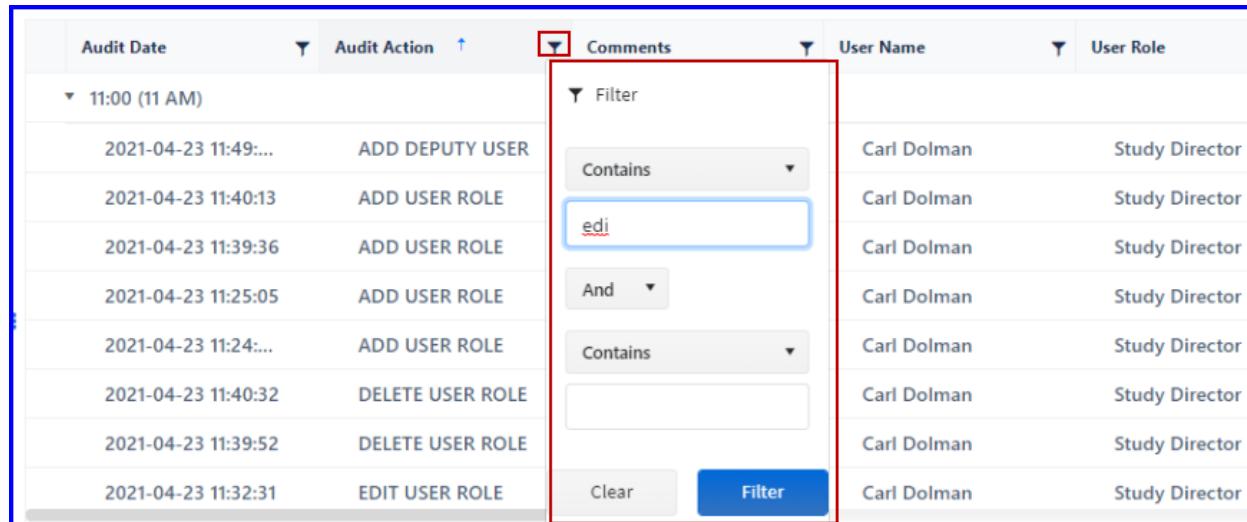
2. To filter click , specify duration by selecting date in the **From** and **To** field, **Module Name** and **Form Name**, **User Name**, **User Role** and then click **Submit** as shown in the figure:



The screenshot shows the Audit Trail page with a filter dialog open. The filter dialog has fields for 'From' (2021-04-23), 'To' (2021-04-23), 'Module Name' (Select Record...), 'Form Name' (Select Record...), 'User Name' (Select Record...), 'User Role' (Select Record...), and 'View Type' (Month). A red box highlights the 'Filter' button in the dialog. The main table shows audit records for the selected date and duration. The first record is for 'EDIT USER ROLE' at 11:00 (11 AM) on 2021-04-23, performed by Carl Dolman as Study Director. The table includes columns for Audit Date, Audit Action, Comments, User Name, and User Role.

FIGURE: Filter audit Trail Records

Audits for the selected screen and duration appear. You can also filter audit records based on the content in each field as shown in the figure:



The screenshot shows the Audit Trail page with a detailed filter dialog for the 'Comments' field. The filter dialog has a 'Contains' dropdown with 'edi' selected, an 'And' operator, and an empty 'Contains' dropdown. A red box highlights the 'Comments' column header and the filter dialog. The main table shows audit records for the selected date and duration. The first record is for 'ADD DEPUTY USER' at 2021-04-23 11:49:... by Carl Dolman as Study Director. The table includes columns for Audit Date, Audit Action, Comments, User Name, and User Role.

FIGURE: Filter audit Records Based on Fields

3.5 Organisation

Organisation in Qualis LIMS consists of the following:

Site: Added and managed in the back end.

Division: Consists of sections.

Section: Consists of labs.

Lab: Consists of users

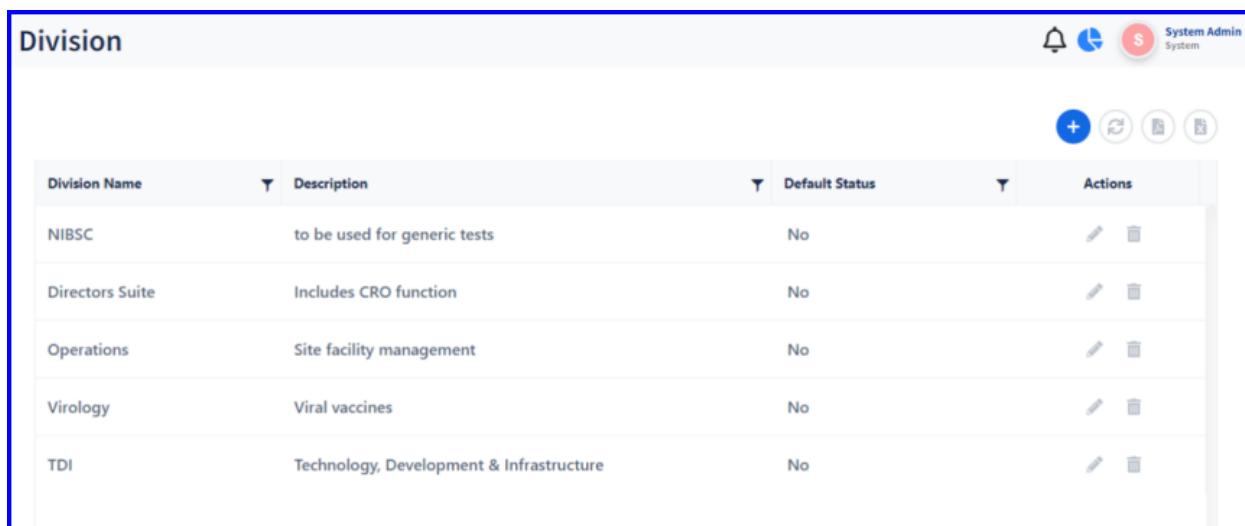
3.5.1 Division Master

Division master is used to create and manage divisions that are used to add sections and user mapping screens.

3.5.1.1 Adding a New Division

To create a new division, follow these steps:

1. On the main menu, click , **Organisation** and then click **Division**. The **Division master** screen appears as shown in the figure:



The screenshot shows the 'Division' master screen. At the top, there is a header with the title 'Division' and a 'System Admin' button. Below the header is a toolbar with icons for adding a new division, deleting, and other actions. The main area is a table with the following data:

Division Name	Description	Default Status	Actions
NIBSC	to be used for generic tests	No	 
Directors Suite	Includes CRO function	No	 
Operations	Site facility management	No	 
Virology	Viral vaccines	No	 
TDI	Technology, Development & Infrastructure	No	 

FIGURE: Division Master Screen

In the Division master screen you can see the list of divisions added. Options to edit, and delete divisions appear in each record.

2. Click . The **Add Division** screen appears as shown in the figure:

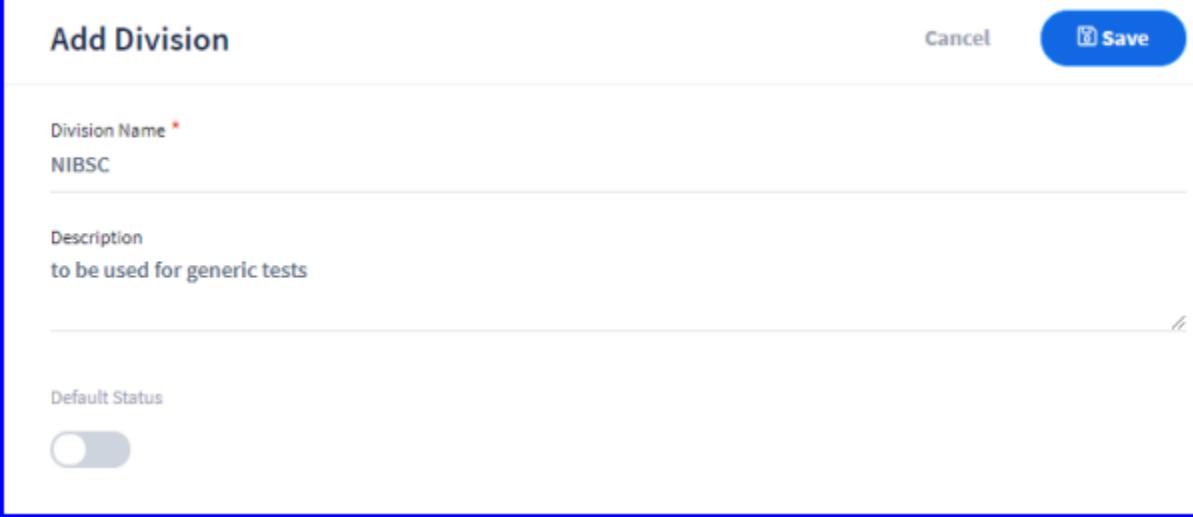


FIGURE: Add Division Screen

3. In the **Division Name** field, type the name for the division.
4. In the **Description** field, type the description.
5. Click to turn on the **Default Status** option to make status of the division active.
6. Click **Save**.

You can see the division you just added listed in the Division master.

3.5.1.2 Editing and Deleting Division

Options to edit and delete divisions appear in each record in the division master.

1. To edit a division details, in the Division master screen, select the division, and then click . In the **Edit Division** screen, do required changes and then click **Save**.
2. To delete a division, in the Division master screen, select the division you want to delete, and then click .

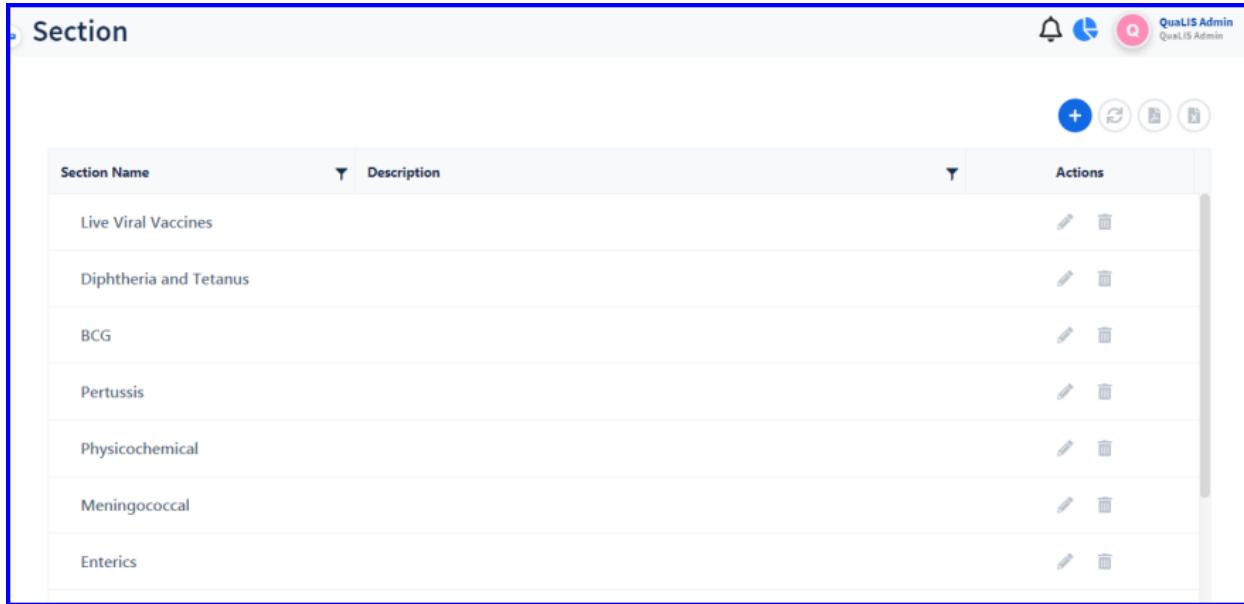
3.5.2 Section Master

Section master is used to create and manage sections that are used in the organisation setup. Labs are grouped under sections.

3.5.2.1 Adding a New Section

To create a new section, follow these steps:

3. On the main menu, click  Organisation and then click Section. The Section master screen appears as shown in the figure:



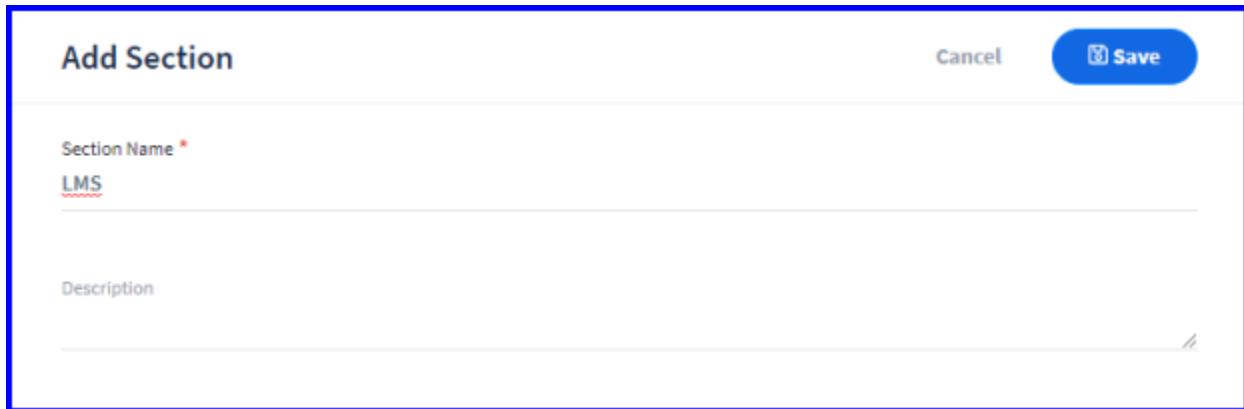
The screenshot shows the 'Section' master screen. At the top, there is a header with the title 'Section' and a user icon for 'QualIS Admin'. Below the header is a toolbar with icons for adding, deleting, and filtering. The main area is a table with columns: 'Section Name', 'Description', and 'Actions'. The 'Actions' column contains edit and delete icons. The table lists the following sections:

Section Name	Description	Actions
Live Viral Vaccines		 
Diphtheria and Tetanus		 
BCG		 
Pertussis		 
Physicochemical		 
Meningococcal		 
Enterics		 

FIGURE: Section Master Screen

In the Section master screen you can see the list of sections added. Options to add, edit, and delete appear in the action menu.

4. Click  . The Add Section screen appears as shown in the figure:



The screenshot shows the 'Add Section' screen. At the top, there is a title 'Add Section' and a 'Cancel' button. On the right is a blue 'Save' button with a checkmark icon. The form has two fields: 'Section Name *' and 'Description'. The 'Section Name' field contains the text 'LMS'. The 'Description' field is empty.

FIGURE: Add Section Screen

5. In the **Section Name** field, type the name for the section.
6. In the **Description** field, type the description.
7. Click **Save**.

You can see the section you just added listed in the Section master.

3.5.2.2 Editing and Deleting Section

Options to edit and delete sections appear in each record in the Section master.

1. To edit section details, in the Section master screen, select the section, and then click . In the **Edit Section** dialog, do required changes and then click **Save**.
2. To delete a section, in the Section master screen, select the section you want to delete, and then click .

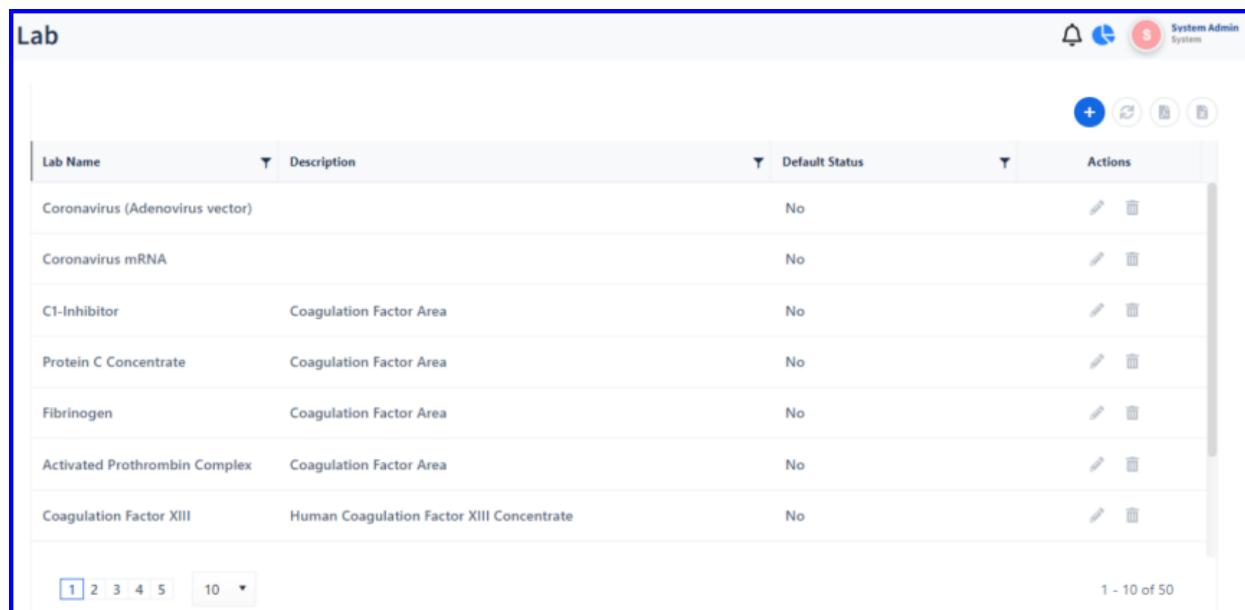
3.5.3 Lab Master

Lab master is used to create and manage labs that are used in the organisation setup. Users are mapped to labs.

3.5.3.1 Adding a New Lab

To create a new lab, follow these steps:

1. On the main menu, click , **Organisation** and then click **Lab**. The **Lab** master screen appears as shown in the figure:



Lab Name	Description	Default Status	Actions
Coronavirus (Adenovirus vector)		No	 
Coronavirus mRNA		No	 
C1-Inhibitor	Coagulation Factor Area	No	 
Protein C Concentrate	Coagulation Factor Area	No	 
Fibrinogen	Coagulation Factor Area	No	 
Activated Prothrombin Complex	Coagulation Factor Area	No	 
Coagulation Factor XIII	Human Coagulation Factor XIII Concentrate	No	 

1 2 3 4 5 10 ▾ 1 - 10 of 50

FIGURE: Lab Master Screen

In the Lab master screen you can see the list of labs added. Options to edit and delete appear in each record.

2. Click  . The **Add Lab** screen appears as shown in the figure:



Add Lab

Lab Name *

Description

Default Status

Cancel 

FIGURE: Add Lab Screen

3. In the **Lab Name** field, type the name for the Lab.
4. In the **Description** field, type the description.

5. Click to turn on the **Default Status** option to make status of the lab active.
6. Click **Save**.

You can see the lab you just added listed in the Lab master.

3.5.3.2 Editing and Deleting Lab

Options to edit and delete labs appear in each record in the lab master.

1. To edit a lab details, in the Lab master screen, select the lab, and then click . In the **Edit Lab** screen, do required changes and then click **Save**.
2. To delete a lab, in the Lab master screen, select the lab you want to delete, and then click .

3.5.4 Organisation Master

Organisation master is used to setup organisation hierarchy in Qualis LIMS. You can do the following in the organisation master screen:

- Add divisions to site
- Add sections to divisions
- Add labs to sections
- Map users to labs

3.5.4.1 View Organisation Hierarchy

1. On the main menu, click , **Organisation** and then click **Organisation**. The **Organisation** master screen appears as shown in the figure:

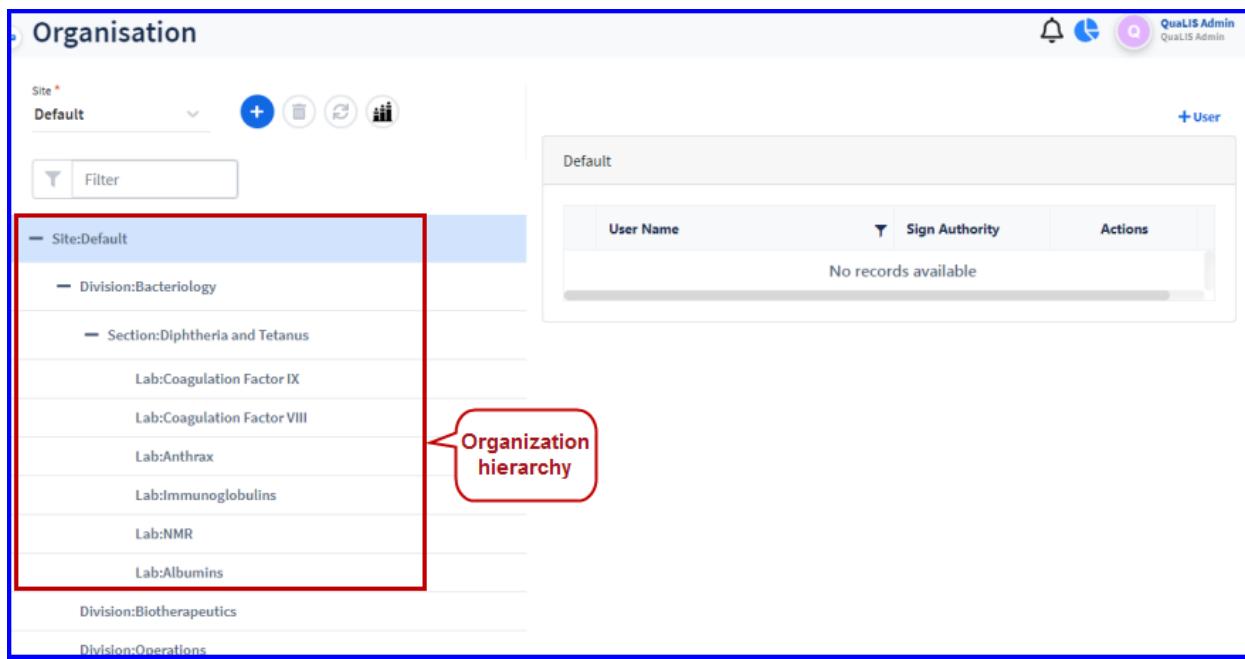


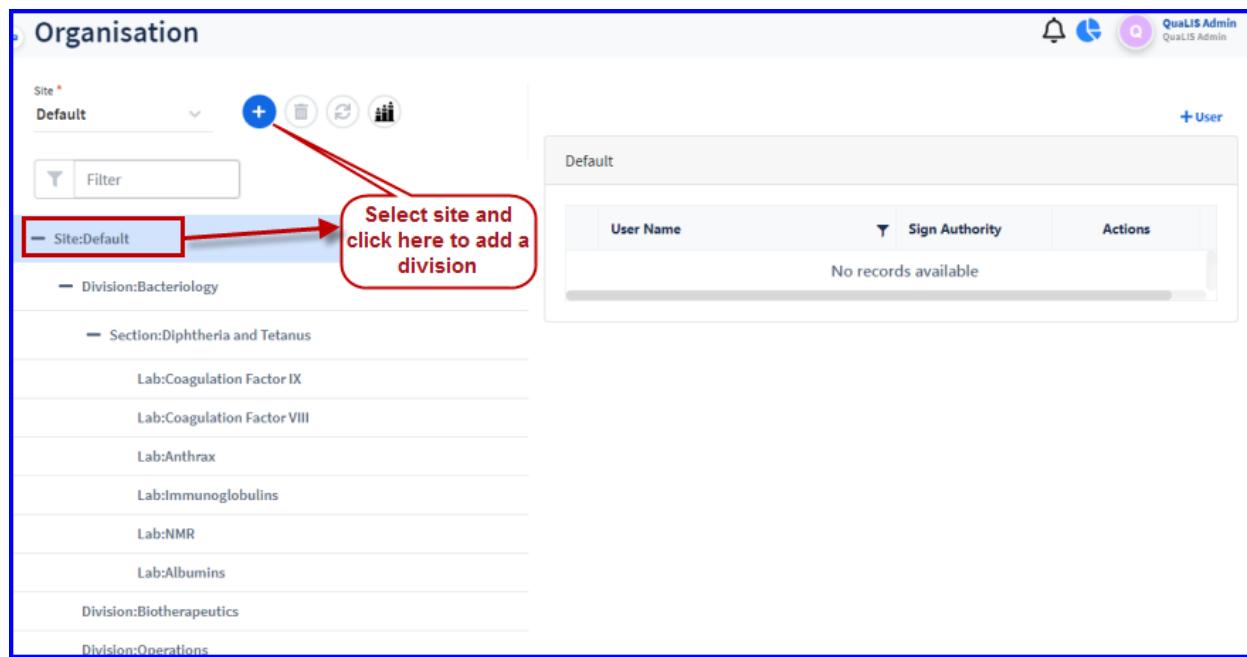
FIGURE: Organisation Master

Organisation master is used to setup organisation hierarchy in Qualis LIMS.

3.5.4.2 Add Division to Site

To add divisions to site, follow these steps:

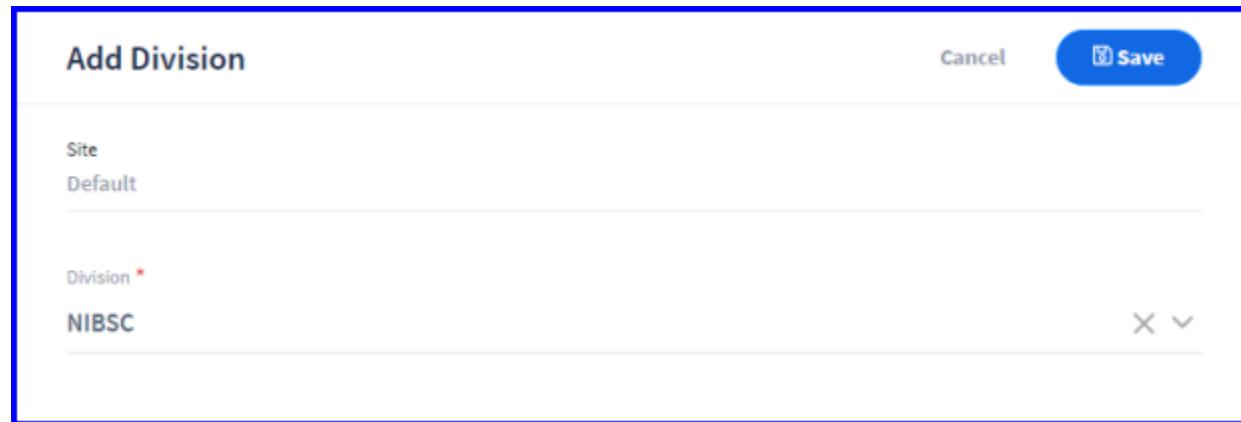
2. In the Organisation master screen, select a site and then click  as shown in the figure:



The screenshot shows the 'Organisation' page in Qualis LIMS. On the left, a tree view lists sites and divisions. A red box highlights the 'Site:Default' node. A red arrow points from this node to a callout box containing the text: 'Select site and click here to add a division'. On the right, a table titled 'Default' shows user information with a note: 'No records available'. The top right corner shows user navigation icons.

FIGURE: Adding Division to Site

3. The **Add Division** dialog appears as shown in the figure:



The screenshot shows the 'Add Division' dialog. It has a 'Site' field set to 'Default'. Below it is a 'Division' field with a dropdown menu containing the option 'NIBSC'. A 'Save' button is visible in the top right corner.

FIGURE: Add Division Dialog

4. In the **Division** field, click and select division from the list to add.
5. Click **Save**. The division will be added to the selected site.

3.5.4.3 Add Section to Division

To add section to divisions, follow these steps:

6. In the Organisation master screen, select a division you want to add section and then click  as shown in the figure:

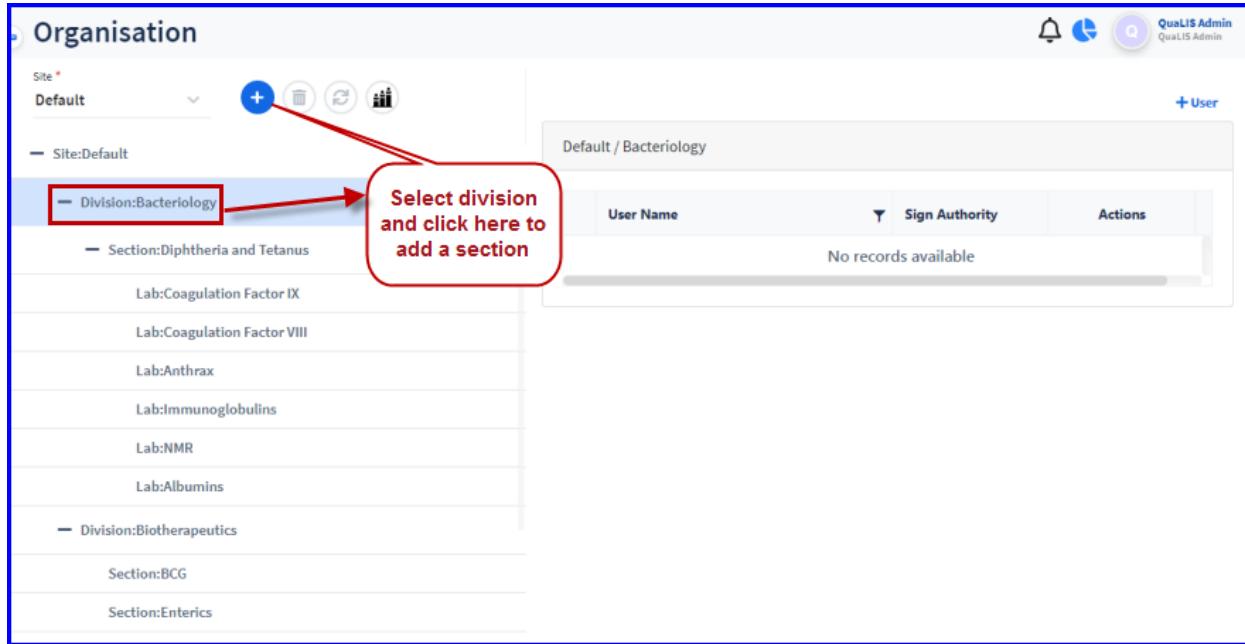


FIGURE: Adding Section to Division

7. The **Add Section** dialog appears as shown in the figure:

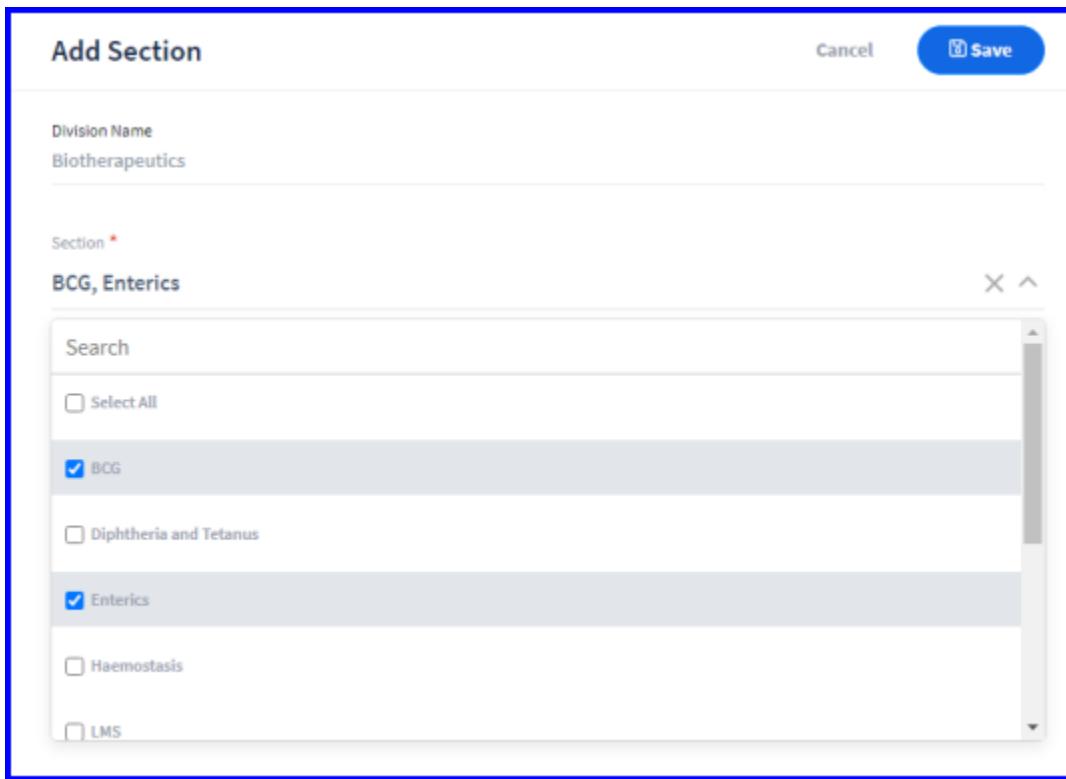


FIGURE: Add Section Dialog

8. In the **Section** field, click and select sections from the list to add. You can click **Select All** to select all the sections to add to the division.
9. Click **Save**. The section(s) will be added to the selected division.

3.5.4.4 Add Labs to Sections

To add labs to section, follow these steps:

In the Organisation master screen, select a section you want to add labs and then click  as shown in the figure:

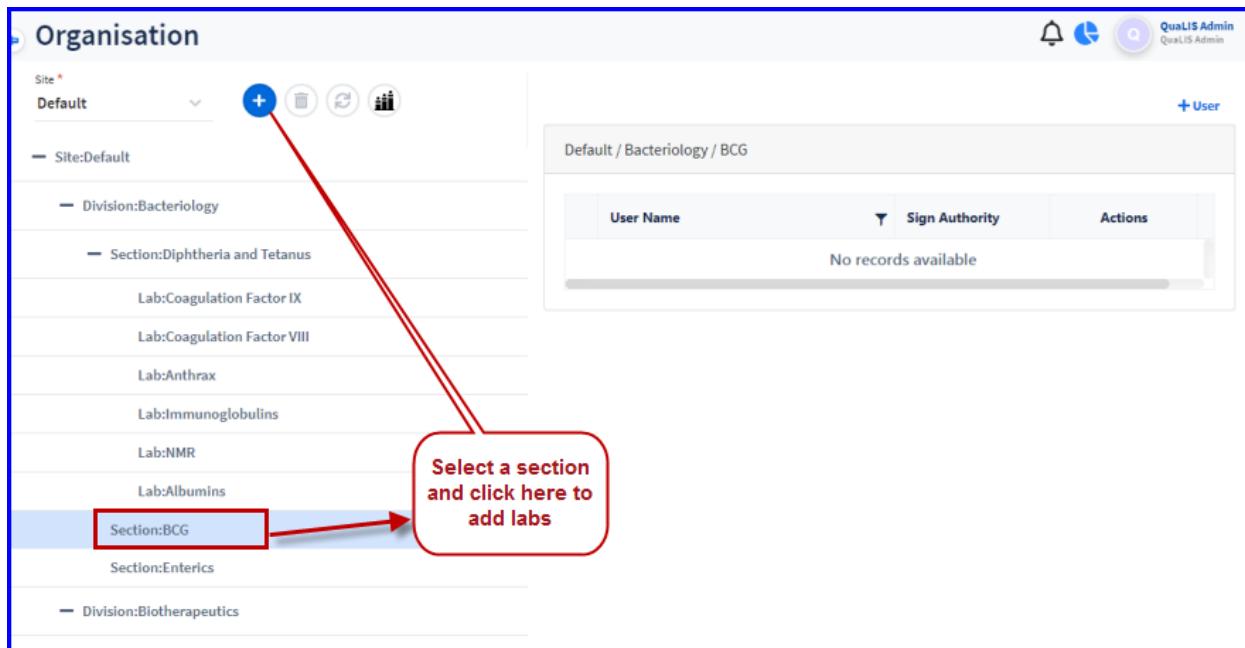


FIGURE: Adding Labs to Section

10. The **Add Lab** dialog appears as shown in the figure:

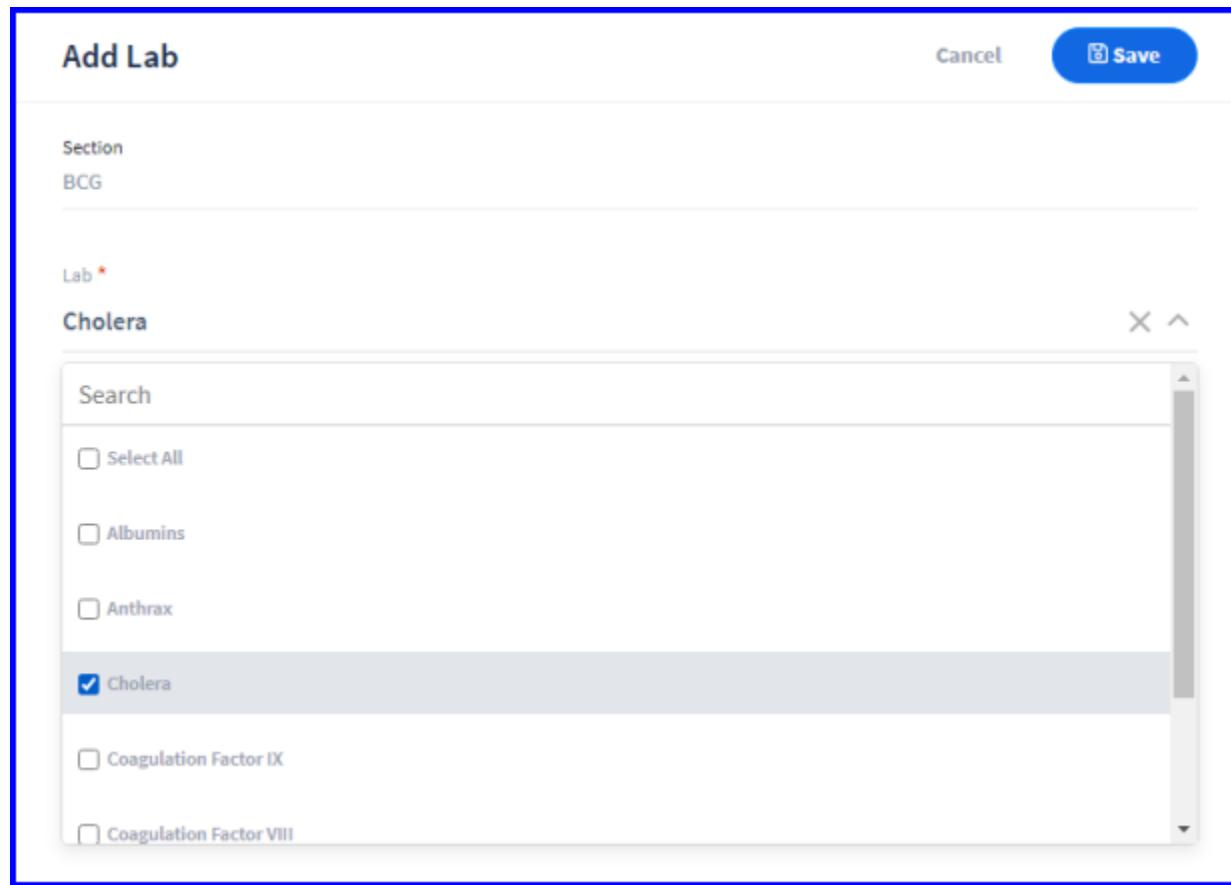


FIGURE: Add Lab Dialog

11. In the **Lab** field, click and select labs from the list to add. You can click **Select All** to select all the labs to add to the section.
12. Click **Save**. The labs(s) will be added to the section.

3.5.4.5 Add User

To add users to lab, follow these steps:

In the Organisation master screen, select a lab you want to add users and then click **+ User** as shown in the figure:

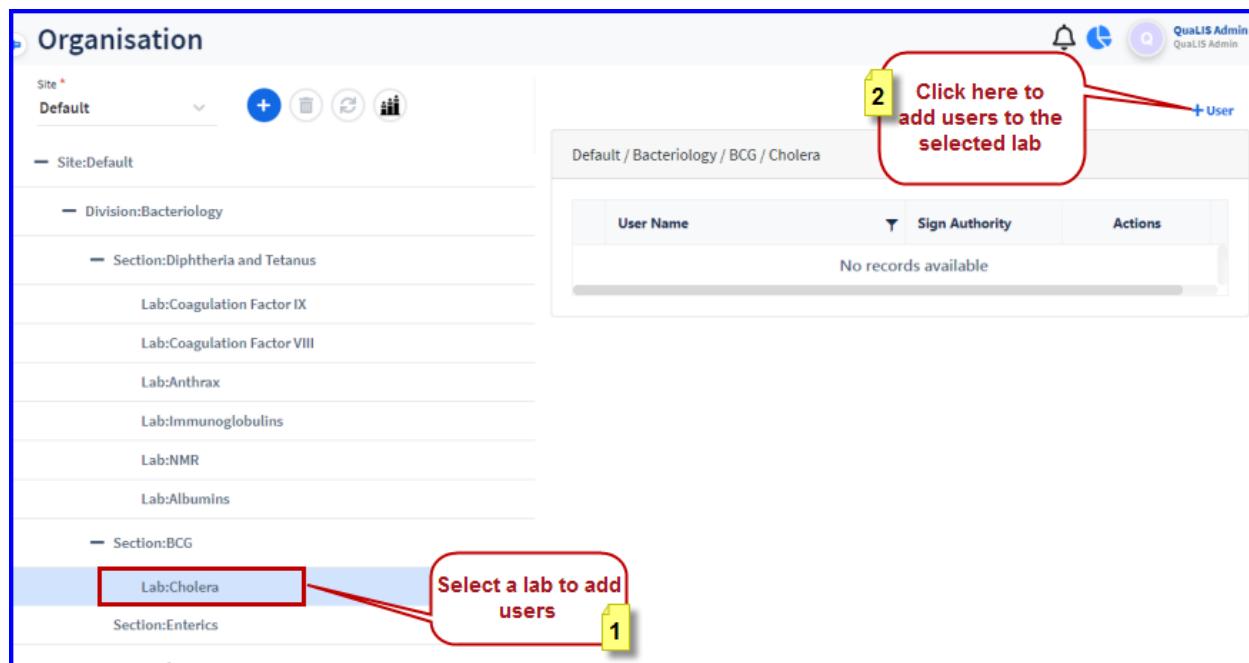
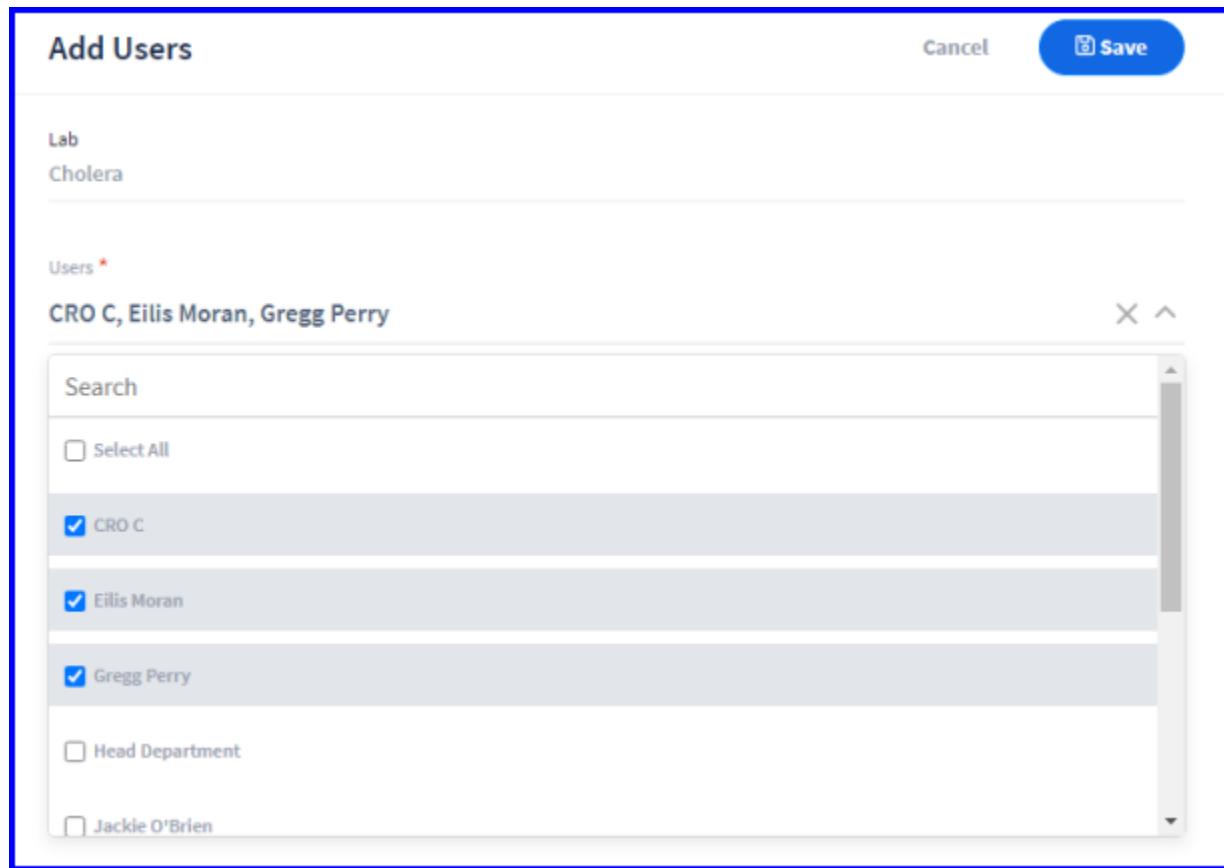


FIGURE: Adding Users to Lab

13. The **Add Users** dialog appears as shown in the figure:



Lab
Cholera

Users *

CRO C, Eilis Moran, Gregg Perry

Search

Select All

CRO C

Eilis Moran

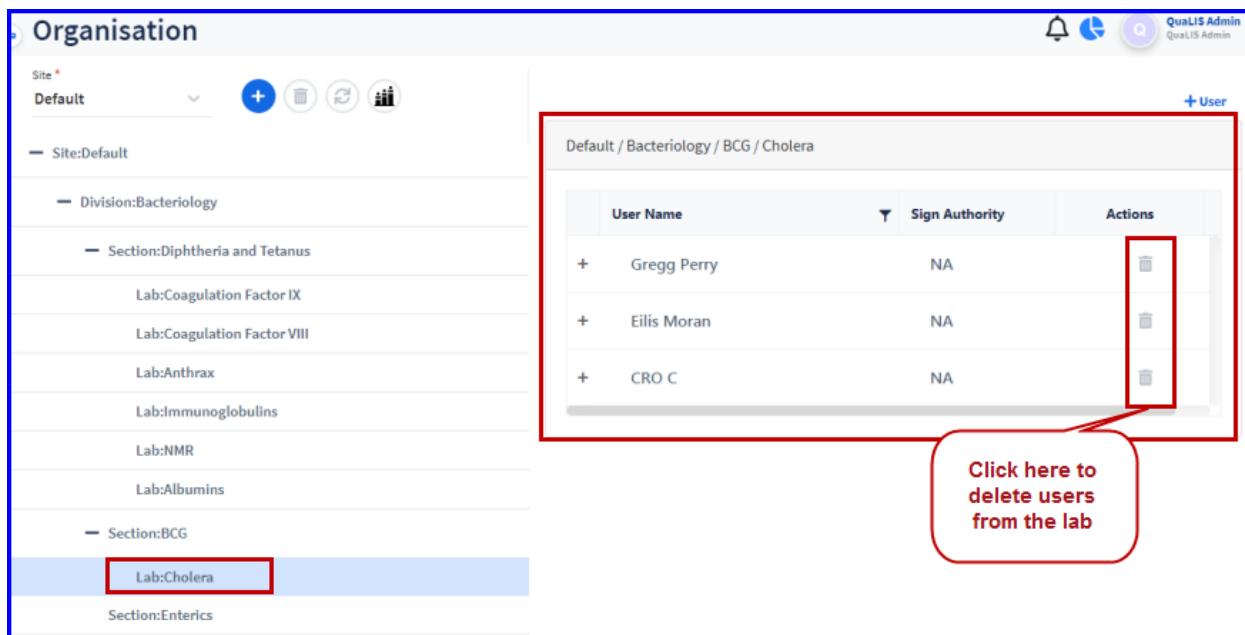
Gregg Perry

Head Department

Jackie O'Brien

FIGURE: Add Users Dialog

14. In the **Users** field, click and select users from the list to add. You can click **Select All** to select all the users to add to the lab.
15. Click **Save**. The selected users will be added to the lab and appears as shown in the figure:



The screenshot shows the 'Organisation' module in Qualis LIMS. On the left, a tree view shows the site structure: Default > Site:Default > Division:Bacteriology > Section:Diphtheria and Tetanus > Lab:Coagulation Factor IX, Lab:Coagulation Factor VIII, Lab:Anthrax, Lab:Immunoglobulins, Lab:NMR, Lab:Albumins > Section:BCG > Lab:Cholera (highlighted with a red box) > Section:Enterics. On the right, a table lists users assigned to 'Default / Bacteriology / BCG / Cholera':

User Name	Sign Authority	Actions
Gregg Perry	NA	
Eilis Moran	NA	
CRO C	NA	

A red box highlights the 'Actions' column, and a callout bubble with the text 'Click here to delete users from the lab' points to the delete icon in the first row.

FIGURE: Users Added to the Lab

You can click  to delete users from the lab as shown in the above figure.

3.5.4.6 View Graphical Representation of Organisation

1. To view graphical representation of the organisation set up, in the Organisation master screen, click . The graphical view of the organisation appears as shown in the figure:

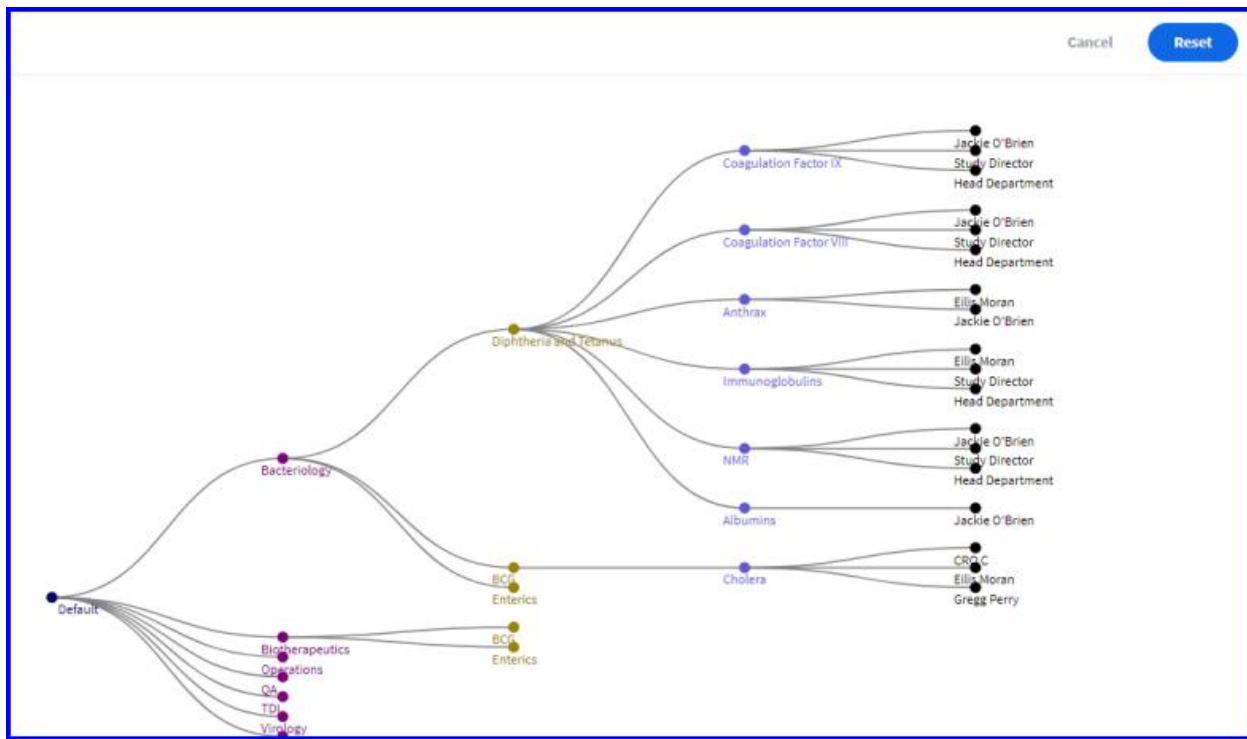


FIGURE: Graphical View of Organisation Setup

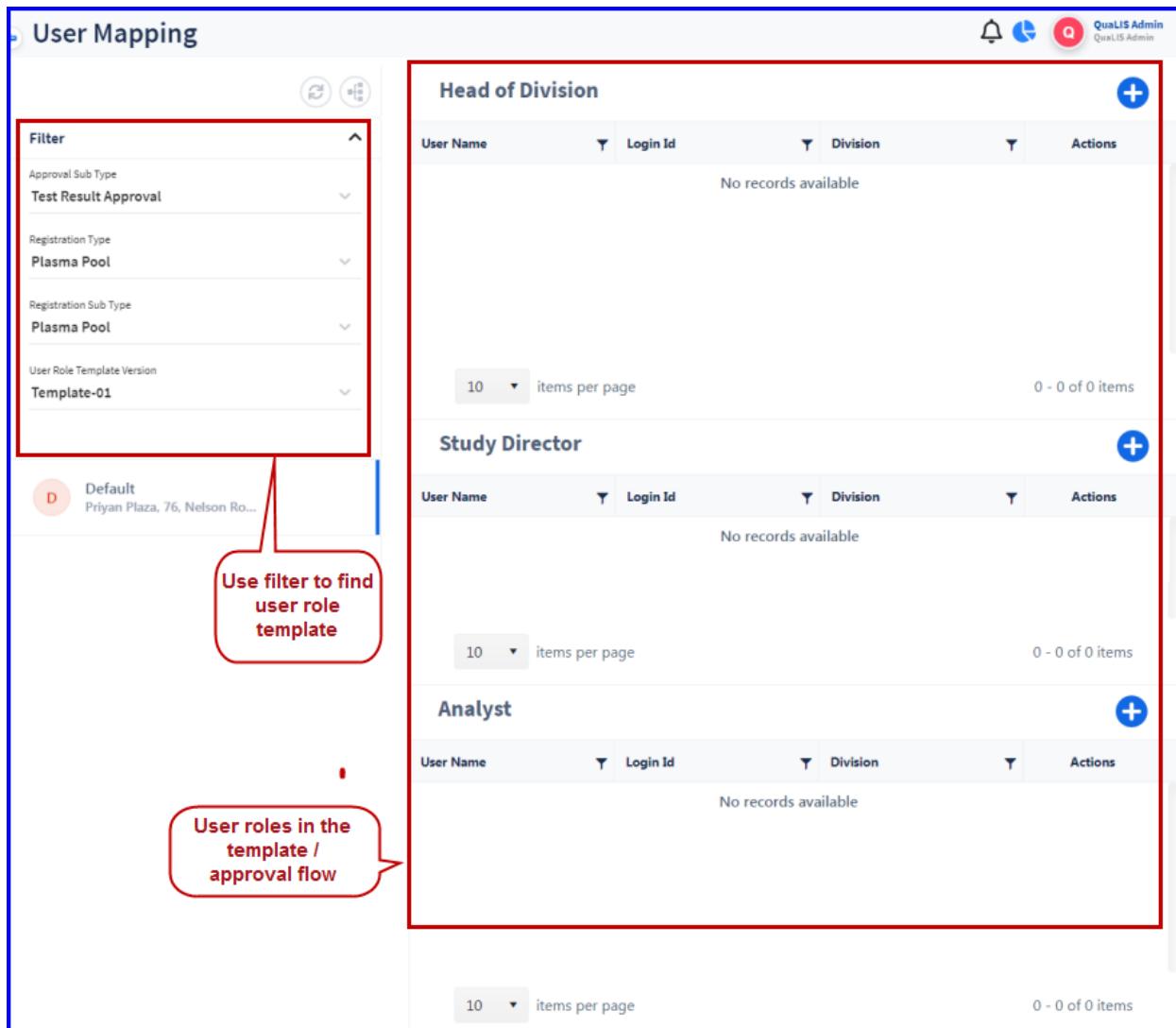
2. Click **Reset** to refresh the graph.
3. Click **Cancel** to close the graph screen.

3.5.5 User Mapping

User Mapping screen enables you to define the approval hierarchy for the selected approval flow. You can add approver and then add analysts for the selected approver.

To set approval hierarchy, follow these steps:

1. On the main menu, click  **Organisation** and then click **User Mapping**. The **User Mapping** screen appears as shown in the figure:



The screenshot shows the 'User Mapping' screen in the Qualis LIMS application. The left side features a 'Filter' panel with dropdown menus for 'Approval Sub Type' (set to 'Test Result Approval'), 'Registration Type' (set to 'Plasma Pool'), 'Registration Sub Type' (set to 'Plasma Pool'), and 'User Role Template Version' (set to 'Template-01'). A red box highlights this filter area, and a callout bubble points to it with the text 'Use filter to find user role template'. The main content area is divided into three sections: 'Head of Division', 'Study Director', and 'Analyst'. Each section has a table with columns for 'User Name', 'Login Id', 'Division', and 'Actions'. All three tables show 'No records available'. Each table has a '10' dropdown for 'items per page' and a '0 - 0 of 0 items' indicator. A red box highlights the 'Head of Division' section, and a callout bubble points to it with the text 'User roles in the template / approval flow'.

FIGURE: User Mapping Screen

2. In the filter, select **Approval Sub type**, **Registration Type**, **Registration Sub Type** and **User Role Template Version**.
3. List of user roles for the selected user role template version appears as shown in the figure:

Head of Division						
User Name	▼	Login Id	▼	Division	▼	Actions
No records available						
10 ▾ items per page 0 - 0 of 0 items						
Study Director						
User Name	▼	Login Id	▼	Division	▼	Actions
No records available						
10 ▾ items per page 0 - 0 of 0 items						
Analyst						
User Name	▼	Login Id	▼	Division	▼	Actions
No records available						

FIGURE: User Mapping Screen

Based on the selected approval flow, sections appear for each role as shown in the above figure.

4. In each section, click . The **Add User** screen appears as shown in the figure:



FIGURE: User Mapping – Add User Screen

5. Click to select the users and then click **Save**.
6. Select a user in the first level and go to the next section. Click **+** as shown in the figure:



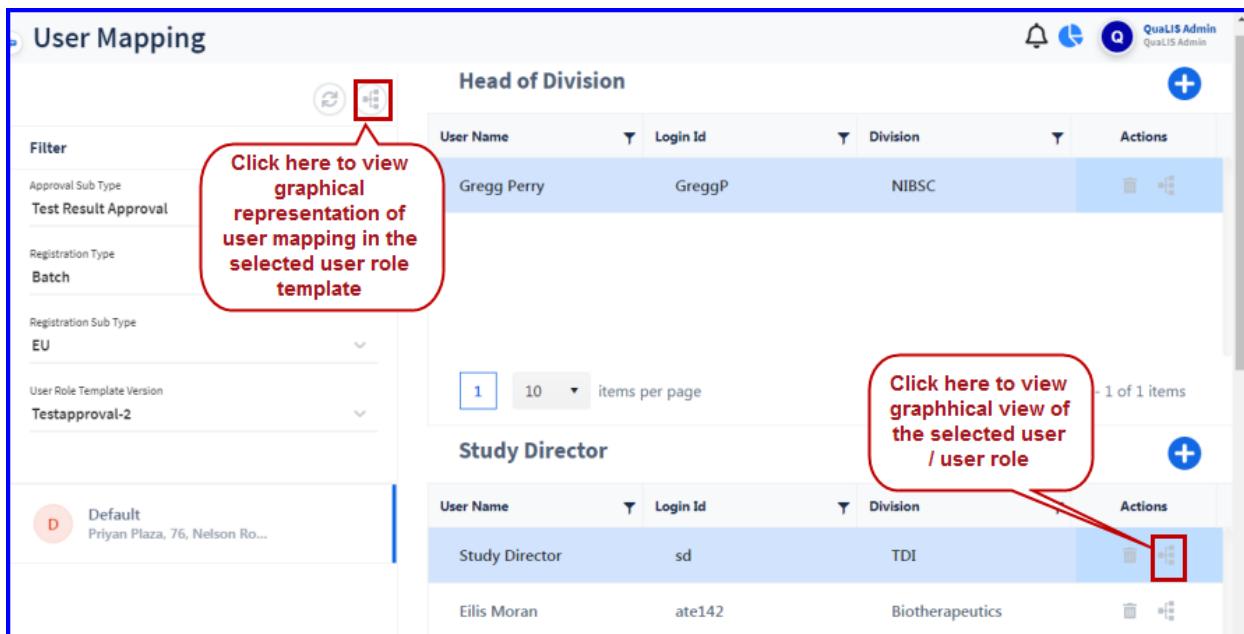
FIGURE: Mapping User to the Next Level

1. Click to select the users and then click **Save**.

2. Repeat steps to add users to the next level.
3. Now you can see the users mapped to each stage in the approval flow.

3.5.5.1 Graphical view of User Mapping

1. In the User Mapping screen, click  as shown in the figure:



User Mapping

Head of Division			
User Name	Login Id	Division	Actions
Gregg Perry	GreggP	NIBSC	 

Filter: Approval Sub Type - Test Result Approval, Registration Type - Batch, Registration Sub Type - EU, User Role Template Version - Testapproval-2

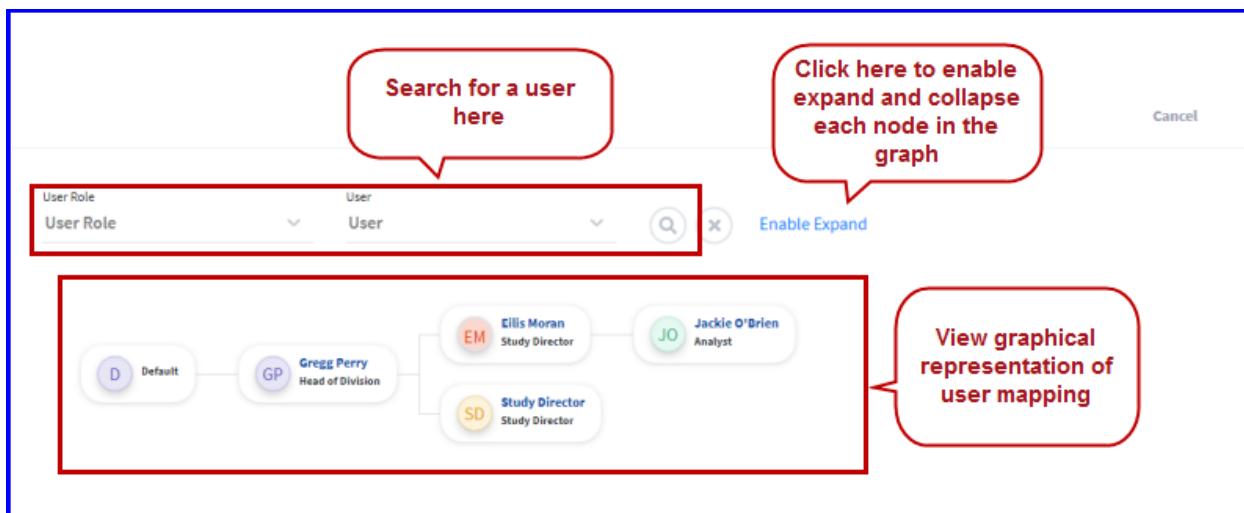
Items per page: 10

Study Director			
User Name	Login Id	Division	Actions
Study Director	sd	TDI	 
Eilis Moran	ate142	Biotherapeutics	 

1 of 1 items

FIGURE: Graphical View of User Mapping - 1

The graphical view of user mapping for the selected user role template appears as shown in the figure:



Search for a user here

User Role: User Role

User: User

Enable Expand

Default -> Gregg Perry (Head of Division) -> EM (Ellis Moran, Study Director) -> SD (Study Director) -> JO (Jackie O'Brien, Analyst)

Click here to enable expand and collapse each node in the graph

View graphical representation of user mapping

FIGURE: Graphical view of User Mapping – 2

2. In the **User Role** field, select user role, in the **User** field, select user to search in the hierarchy and then click . The screen appears as shown in the figure showing the selected user in the hierarchy:

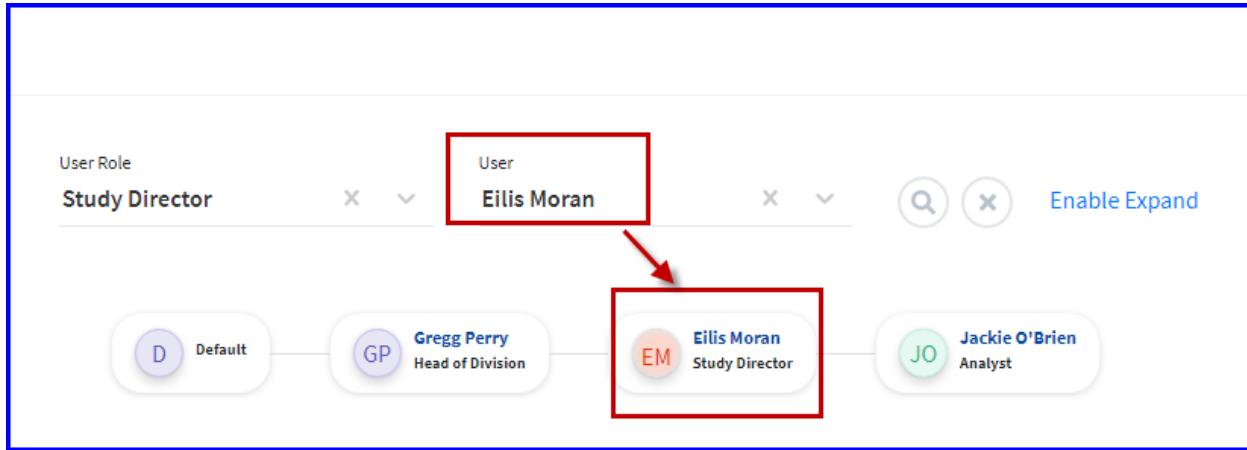


FIGURE: Graphical View - Search User

3. You can see the static graph of the user mapping hierarchy. Click to view **Enable Expand** to expand or collapse the nodes in the hierarchy as shown in the figure:

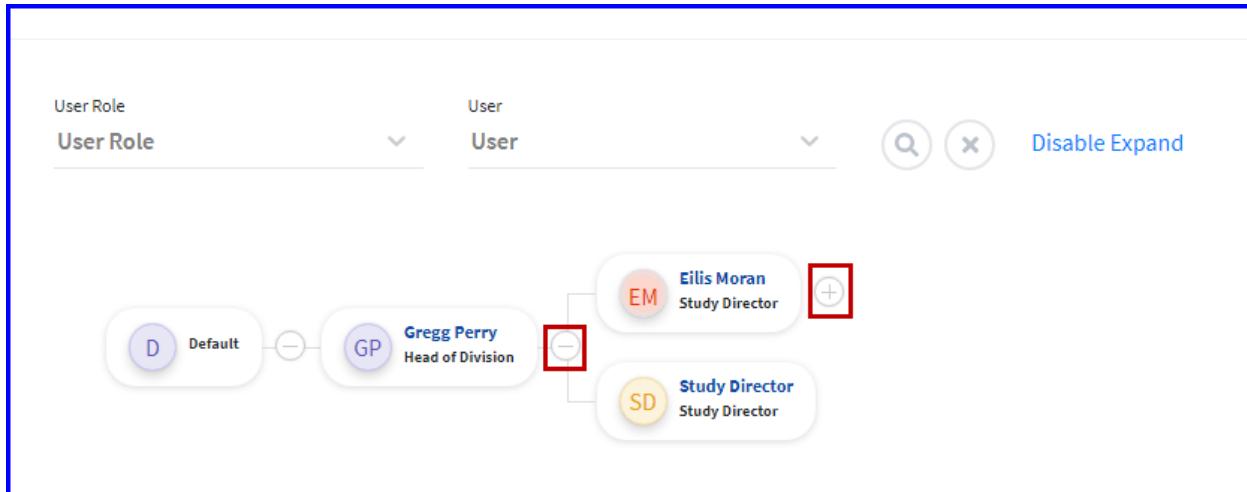


FIGURE: Graphical View of User Mapping – Enable Expand View

You can also view graphical view of the individual user / user role by clicking  as shown in the figure:

Head of Division

User Name	Login Id	Division	Actions
Gregg Perry	GreggP	NIBSC	  

items per page

Study Director

User Name	Login Id	Division	Actions
Study Director	sd	TDI	  
Eilis Moran	ate142	Biotherapeutics	  

Click here to view graphical view of the selected user / user role

Enable Expand



```

graph LR
    EM((EM)) --- JO((JO))
    subgraph "User Roles"
        EM
        JO
    end
    
```

FIGURE: Graphical View of a Selected User

3.6 Contacts

3.6.1 Supplier Category Master

Supplier Category master is used to add and manage supplier categories. Supplier category is used in supplier master to group suppliers.

3.6.1.1 Adding a New Supplier Category

To create a new supplier category, follow these steps:

1. On the main menu, click  Contacts and then click **Supplier Category**. The **Supplier Category** master screen appears as shown in the figure:

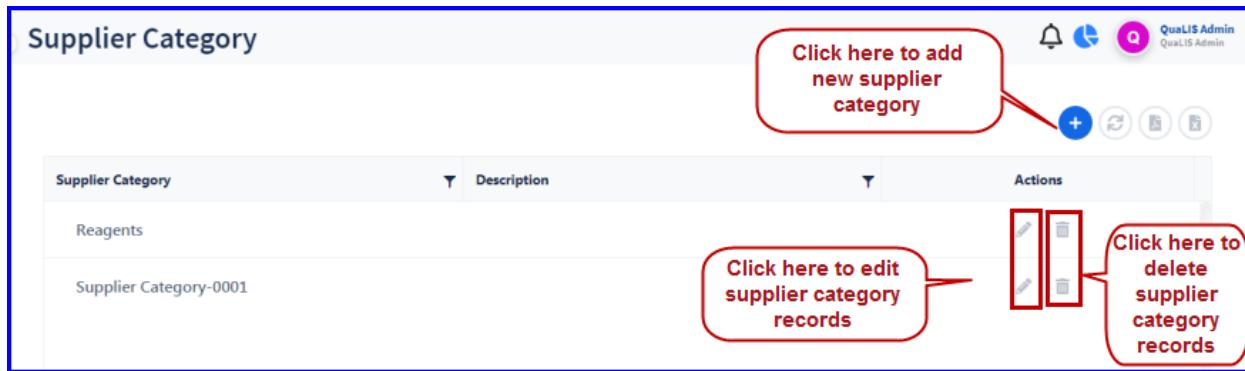


FIGURE: Supplier Category Master Screen

In the Supplier Category master screen you can see the list of supplier categories created. Options to edit and delete supplier categories appear in each record.

2. Click  . The **Add Supplier Category** screen appears as shown in the figure:



FIGURE: Add Supplier Category Dialog

3. In the **Supplier Category Name** field, type the category name.
4. In the **Description** field, type the description.
5. Click **Save**.

You can see the supplier category you just created listed in the Supplier Category master.

3.6.1.2 Editing and Deleting Supplier Category

Options to edit and delete supplier category appear in each record in the supplier category master.

1. To edit supplier category details, in the supplier category master screen, click  to edit the supplier category record. In the **Edit Supplier Category** screen, do required changes and then click **Save**.
2. To delete a supplier category, in the supplier category master screen, click  to delete the supplier category record.

3.6.2 Supplier Master

Supplier master is used to add and manage supplier details.

3.6.2.1 Adding a New Supplier

Once the supplier is created it will be in draft state, you need to approve the supplier. If the supplier is no longer required then you can blacklist the supplier. In case, you need the supplier back in future then you can again approve the blacklisted supplier.

To create a new supplier, follow these steps:

1. On the main menu, click  **Contacts** and then click **Supplier**. The **Supplier** master screen appears as shown in the figure:

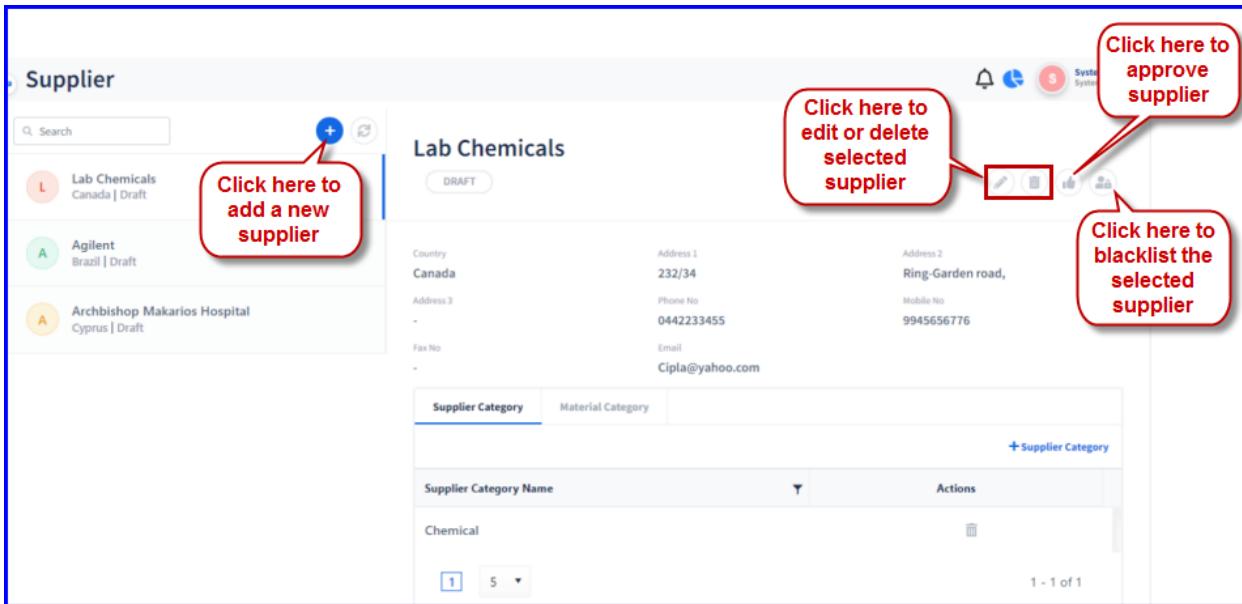
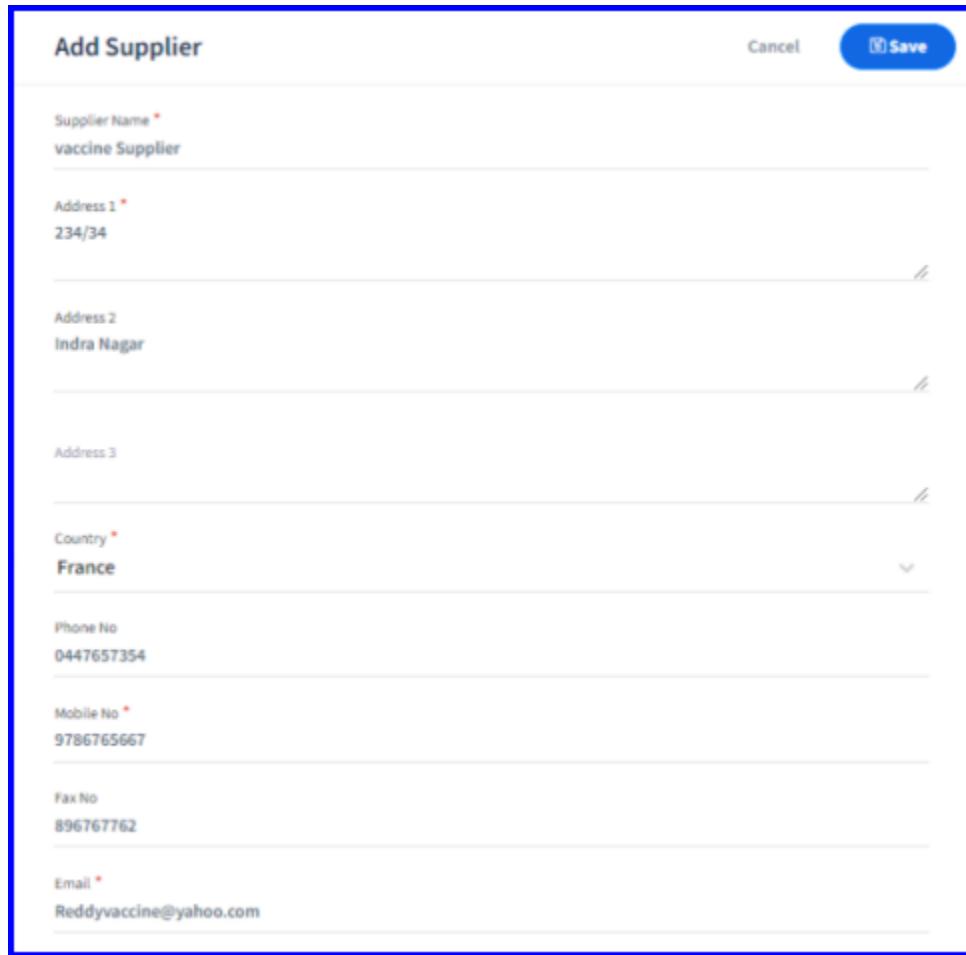


FIGURE: Supplier Master Screen

In the Supplier master screen, you can see the list of suppliers added. Options to edit, delete and blacklist supplier appears in each supplier screen.

2. Click  **Add Supplier**. The **Add Supplier** screen appears as shown in the figure:



Supplier Name *
vaccine Supplier

Address 1 *
234/34

Address 2
Indra Nagar

Address 3

Country *
France

Phone No
0447657354

Mobile No *
9786765667

Fax No
896767762

Email *
Reddyvaccine@yahoo.com

FIGURE: Add Supplier Screen

3. In the **Supplier Name** field, type the supplier name.
4. Fill in **Address1**, **Address2**, **Address3**, **Phone No**, **Mobile No**, **Fax No**, and **Email** fields.
5. In the **Country** field, select the country.
6. Click **Save**.

You can see the supplier you just added listed in the Supplier master.

3.6.2.2 Editing and Deleting Supplier

Options to edit and delete supplier appear in each supplier record in the supplier master.

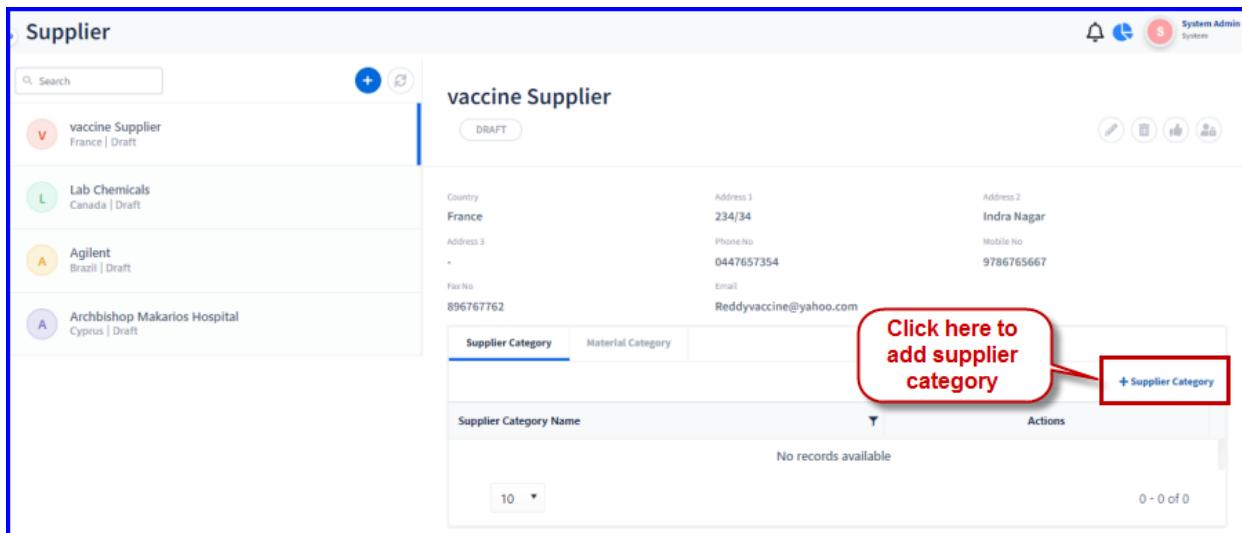
1. To edit supplier details, in the supplier master screen, select the supplier and then click  to edit the supplier record. In the **Edit Supplier** screen, do required changes and then click **Save**.

2. To delete a supplier in the supplier master screen, click  to delete the supplier record.

3.6.2.3 Adding Supplier Category to Supplier

Once you add supplier, you can map supplier category(s) to the supplier. To do so, follow these steps:

1. In the Supplier master screen, select the supplier, go to the **Supplier Category** tab and then click  as shown in the figure:



The screenshot shows the Supplier master screen for 'vaccine Supplier' (Draft). The 'Supplier Category' tab is selected. A callout box with the text 'Click here to add supplier category' points to the '+ Supplier Category' button, which is highlighted with a red box.

FIGURE: Adding Supplier Category to Supplier

The **Add Supplier Category** dialog appears as shown in the figure:



The screenshot shows the 'Add SupplierCategory' dialog. It has a 'Supplier Category Name *' field with a dropdown menu containing 'Select Record...' and 'Chemical'. A 'Save' button is visible in the top right corner.

FIGURE: Add Supplier Category Dialog

2. In the **Supplier Category Name** field, select the supplier category(s) to map with the selected supplier. You can select multiple supplier categories.
3. Click **Save**.

You can see the supplier categories added to the supplier as shown in the figure:

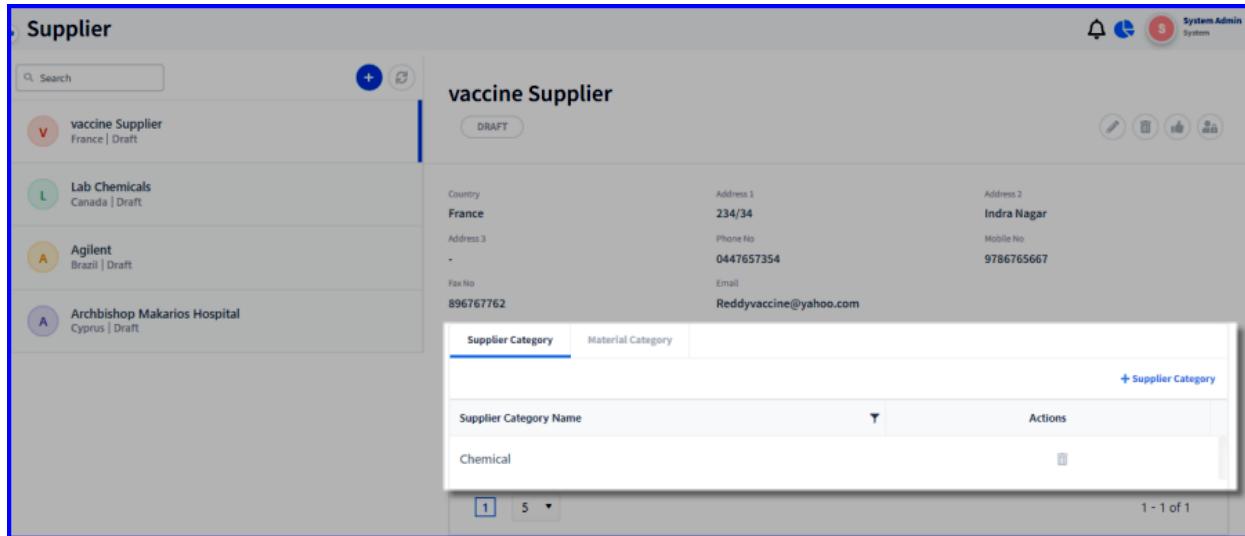


FIGURE: Supplier Categories Added to the Supplier

4. You can delete supplier categories. Option to delete appears in each record.

3.6.2.4 Adding Material Category to Supplier

Once you add supplier, you can map material category(s) to the supplier. To do so, follow these steps:

1. In the Supplier master screen, select the supplier, go to the **Material Category** tab and then click **+ Material Category** as shown in the figure:

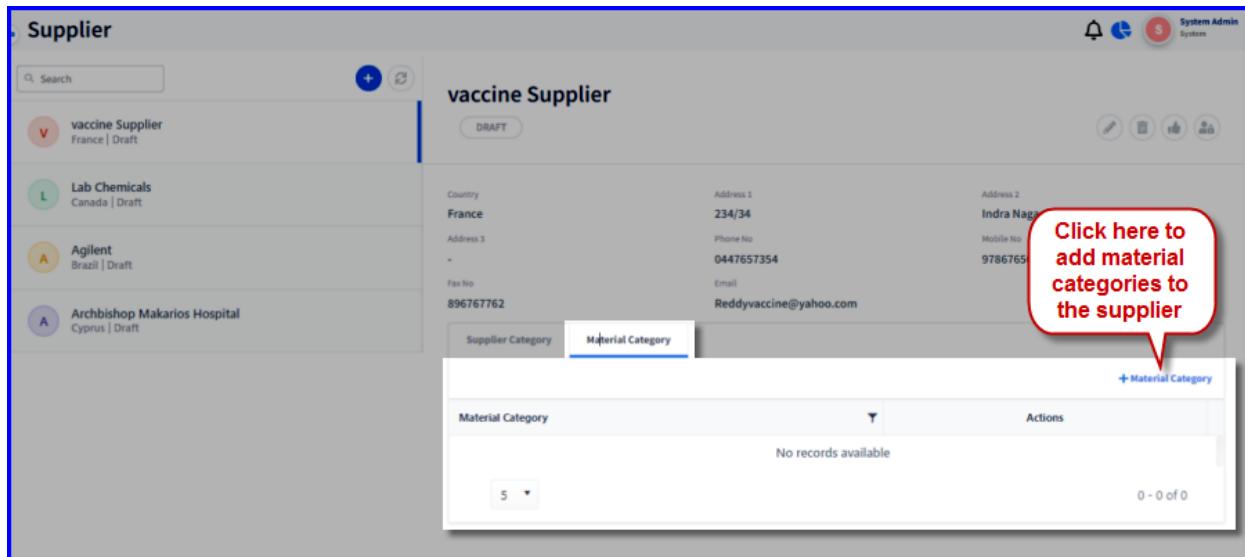


FIGURE: Adding Material Category to Supplier

The **Add Material Category** dialog appears as shown in the figure:

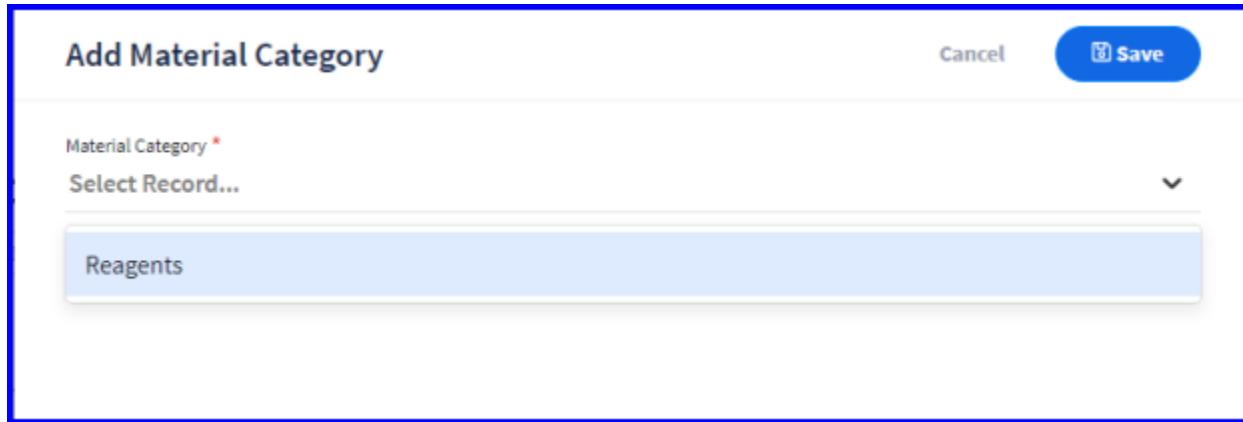


FIGURE: Add Material Category Dialog

2. In the **Material Category Name** field, select the material category(s) to map with the selected supplier. You can select multiple material categories.
3. Click **Save**.

You can see the selected material categories added to the supplier.

4. You can delete material categories. Option to delete appears in each record.

3.6.2.5 Approving Selected Supplier

Once you add a supplier and details, you can approve the supplier. Select a supplier from the list and then click  to approve the supplier.

3.6.2.6 Blacklist Selected Supplier

Select a supplier from the list and then click  to blacklist the supplier.

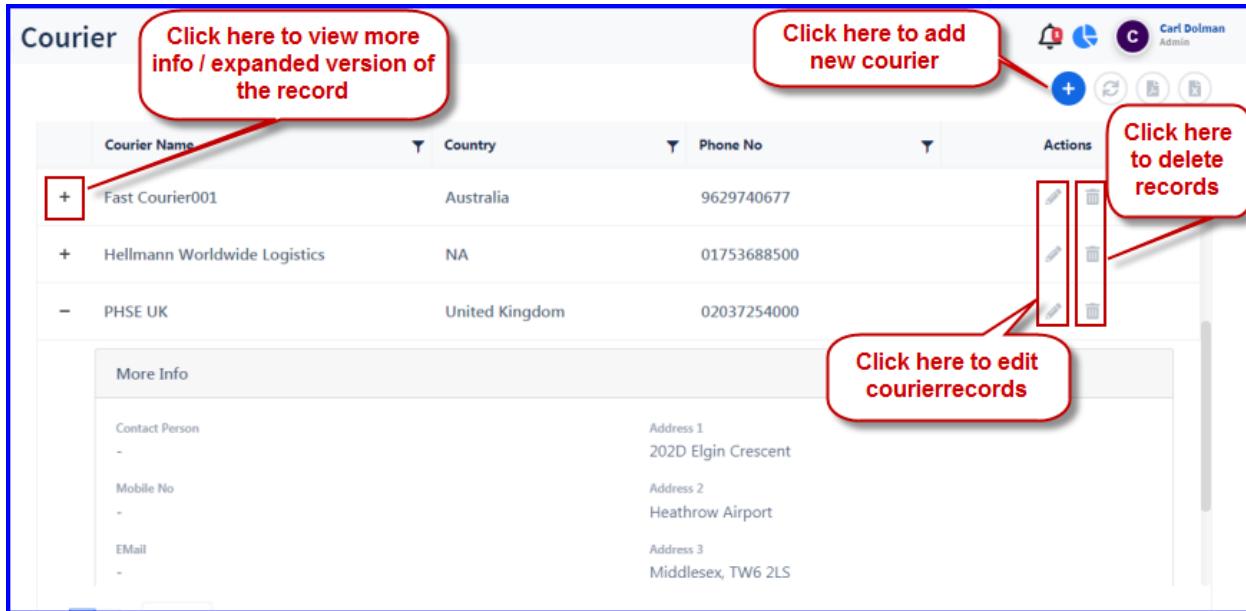
3.6.3 Courier Master

Courier master is used to add and manage couriers to Qualis LIMS. You can store information of a courier company.

3.6.3.1 Adding a New Courier

To create a new courier record, follow these steps:

1. On the main menu, click **Masters, Contact** and then click **Courier**. The Courier master screen appears as shown in the figure:



The screenshot shows a table of couriers with columns: Courier Name, Country, Phone No, and Actions. The Actions column contains icons for edit, add, and delete. Red callout boxes with text overlays are placed over these elements:

- Click here to view more info / expanded version of the record** (over the edit icon for the first row).
- Click here to add new courier** (over the add icon in the Actions column).
- Click here to delete records** (over the delete icon in the Actions column).
- Click here to edit courierrecords** (over the edit icon in the Actions column).

Courier

Courier Name	Country	Phone No	Actions
Fast Courier001	Australia	9629740677	  
Hellmann Worldwide Logistics	NA	01753688500	  
PHSE UK	United Kingdom	02037254000	  

More Info

Contact Person	Address 1
-	202D Elgin Crescent
Mobile No	Address 2
-	Heathrow Airport
EMail	Address 3
-	Middlesex, TW6 2LS

FIGURE: Courier Master Screen

In the Courier master screen you can see the list of couriers created. Options to add, edit and delete couriers appear in the action menu.

2. Click  . The **Add Courier** screen appears as shown in the figure:

Add Courier

Courier Name *	Country *
Professional	Spain
Contact Person	Phone No
Alan	+324 987 453
Address 1	Mobile No
321	
Address 2	Fax No
II main road	
Address 3	EMail
	alan@hotmail.com

FIGURE: Add Courier Screen

3. In the **Courier Name** field, type the courier name.
4. In the **Country** field, select the country.
5. Fill in **Contact Person**, **Phone No**, **Address1**, **Address2**, **Address3**, **Mobile No**, **Fax**, and **Email** fields.
6. Click **Save**.

You can see the courier you just created listed in the courier master.

3.6.3.2 Editing and Deleting Courier

Options to edit and delete courier appear in each record in the Courier master.

1. To edit courier details, in the Courier master screen, click  to edit the courier record. In the **Edit Courier** screen, do required changes and then click **Save**.
2. To delete a courier, in the Courier master screen, click  to delete the courier record.

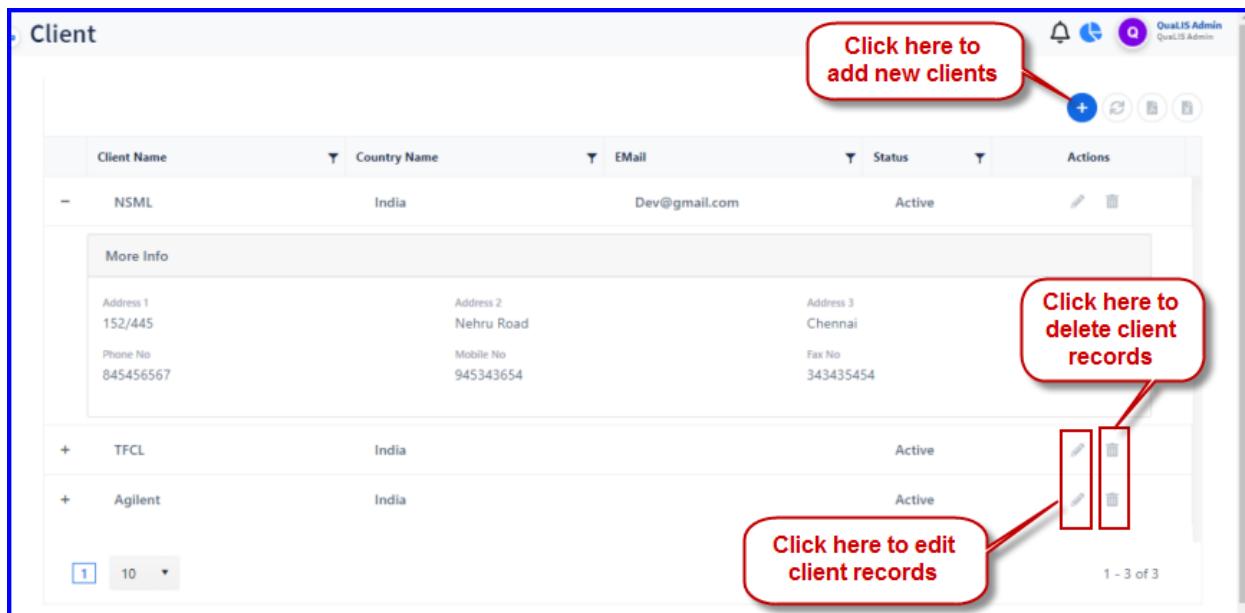
3.6.4 Client Master

Client master is used to add and manage clients to Qualis LIMS. You can store information of a person or company.

3.6.4.1 Adding a New Client

To create a new client, follow these steps:

1. On the main menu, click  **Contacts** and then click **Client**. The Client master screen appears as shown in the figure:



The screenshot shows the 'Client' master screen in Qualis LIMS. The top navigation bar includes a bell icon, a blue gear icon, and a purple user icon labeled 'Qualis Admin'. The main title is 'Client'. The table header includes columns for 'Client Name', 'Country Name', 'EMail', 'Status', and 'Actions'. The table contains three records:

Client Name	Country Name	EMail	Status	Actions
NSML	India	Dev@gmail.com	Active	 
TFCL	India		Active	 
Agilent	India		Active	 

Below the table, a 'More Info' section displays address details for each client. Red callout boxes with arrows point to specific actions: 'Click here to add new clients' points to the 'Add' button in the top right; 'Click here to delete client records' points to the delete icons in the 'Actions' column; and 'Click here to edit client records' points to the edit icons in the 'Actions' column.

FIGURE: Client Master Screen

In the Client master screen you can see the list of clients created. Options to edit and delete clients appear in each record.

2. Click  . The **Add Client** screen appears as shown in the figure:

Add Client

Client Name *
ABC Pvt Ltd

Address 1 *
456

Address 2
Park

Address 3

Phone No
456 987 234

Mobile No

Fax No

Email
abc@abc.com

Country *
Canada

Is Active

Cancel **Save**

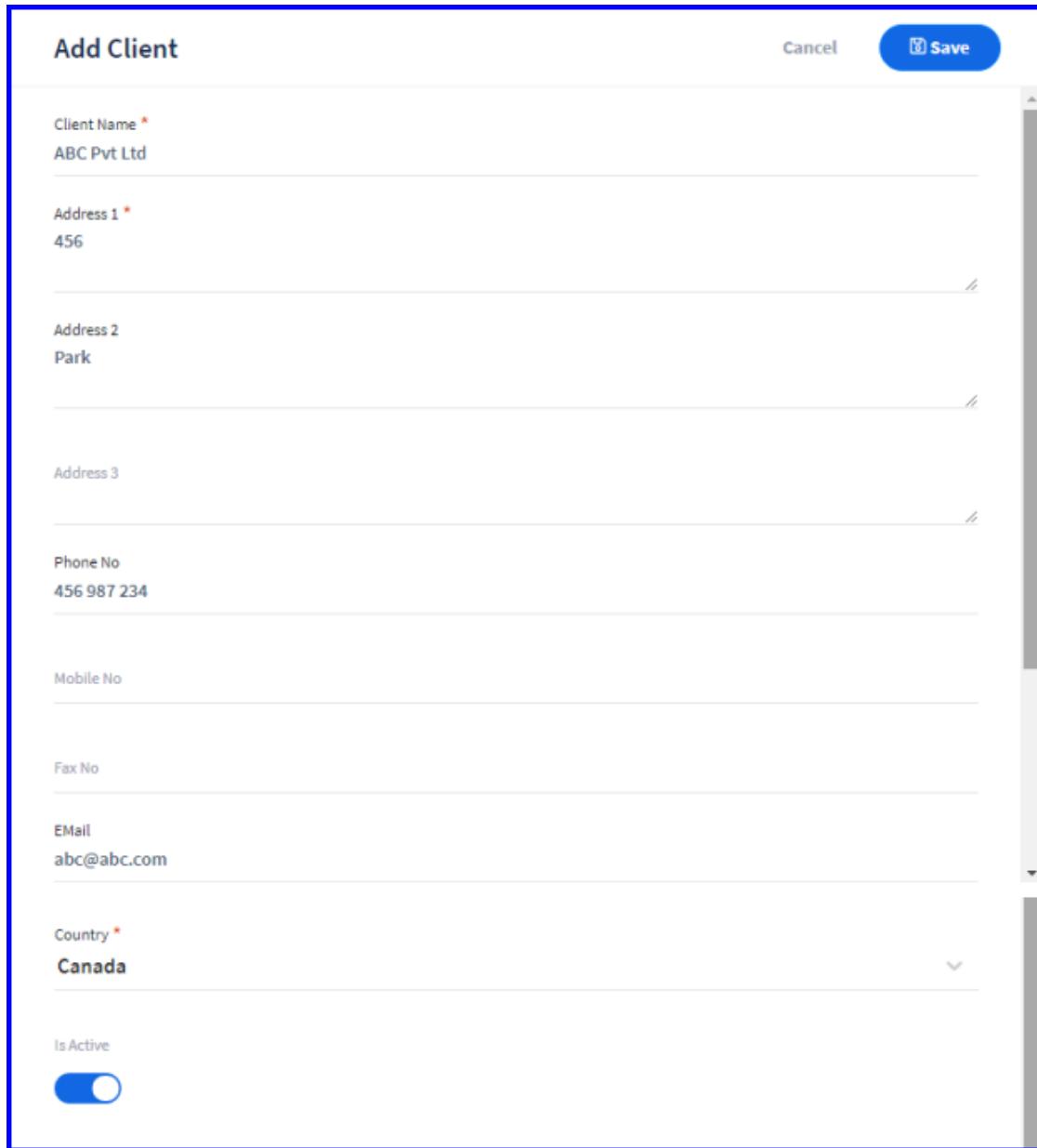


FIGURE: Add Client Screen

3. In the **Client Name** field, type the client name.
4. Fill in **Address1**, **Address2**, **Address3**, **Phone No**, **Mobile No**, **Fax**, and **Email** fields.
5. In the **Country** field, select the country.
6. Click to turn on the **Is Active** option to make the client active.
7. Click **Save**.

You can see the client you just created listed in the client master.

3.6.4.2 Editing and Deleting Client

Options to edit and delete client appear in each record in the Client master.

1. To edit client details, in the Client master screen, click  to edit the client record. In the **Edit Client** screen, do required changes and then click **Save**.
2. To delete a client, in the Client master screen, click  to delete the client record.

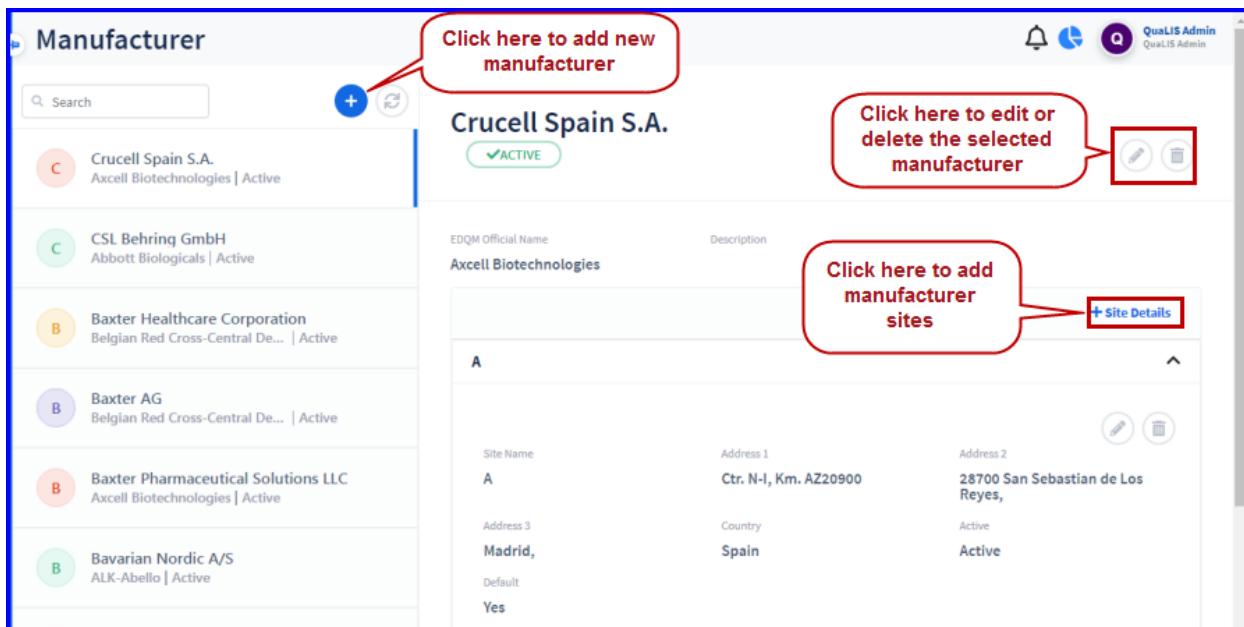
3.6.5 Manufacturer Master

Manufacturer master is used to add and manage manufacturer details.

3.6.5.1 Adding a New Manufacturer

To create a new manufacturer, follow these steps:

1. On the main menu, click , **Contacts** and then click **Manufacturer**. The **Manufacturer** master screen appears as shown in the figure:



The screenshot shows the Manufacturer master screen. On the left, a list of manufacturers is displayed with columns for Name, EDQM Official Name, and Description. The first item in the list is 'Crucell Spain S.A.' with 'Axcell Biotechnologies | Active'. On the right, a detailed view of 'Crucell Spain S.A.' is shown, marked as 'ACTIVE'. The view includes fields for EDQM Official Name (Axcell Biotechnologies), Description (Axcell Biotechnologies), Site Name (A), Address 1 (Ctra. N-1, Km. AZ220900), Address 2 (28700 San Sebastian de Los Reyes,), Country (Spain), and Active (Active). There are buttons for 'Site Details' and 'Edit/Delete'. A callout points to the 'Edit/Delete' buttons with the text 'Click here to edit or delete the selected manufacturer'. Another callout points to the 'Site Details' button with the text 'Click here to add manufacturer sites'. A third callout points to the '+' icon in the top left of the list with the text 'Click here to add new manufacturer'.

FIGURE: Manufacturer Master Screen

In the Manufacturer master screen, you can see the list of manufacturers added. Options to edit and delete appears in the each record.

2. Click . The **Add Manufacturer** screen appears as shown in the figure:



Add Manufacturer

Manufacturer Name *

ALK-Abello A/s

EDQM Official Name *

Abbott Biologicals

Description

Is Active

Save

FIGURE: Add Manufacturer Screen

3. In the **Manufacturer Name** field, type the manufacturer name.
4. In the **EDQM Official Name** field, select the EDQM official name of the manufacturer.
5. In the **Description** field, type the description if any.
6. Click to check the **Is Active** check field if you want to make the manufacturer an active manufacturer.
7. Click **Save**.

You can see the manufacturer you just added listed in the Manufacturer master.

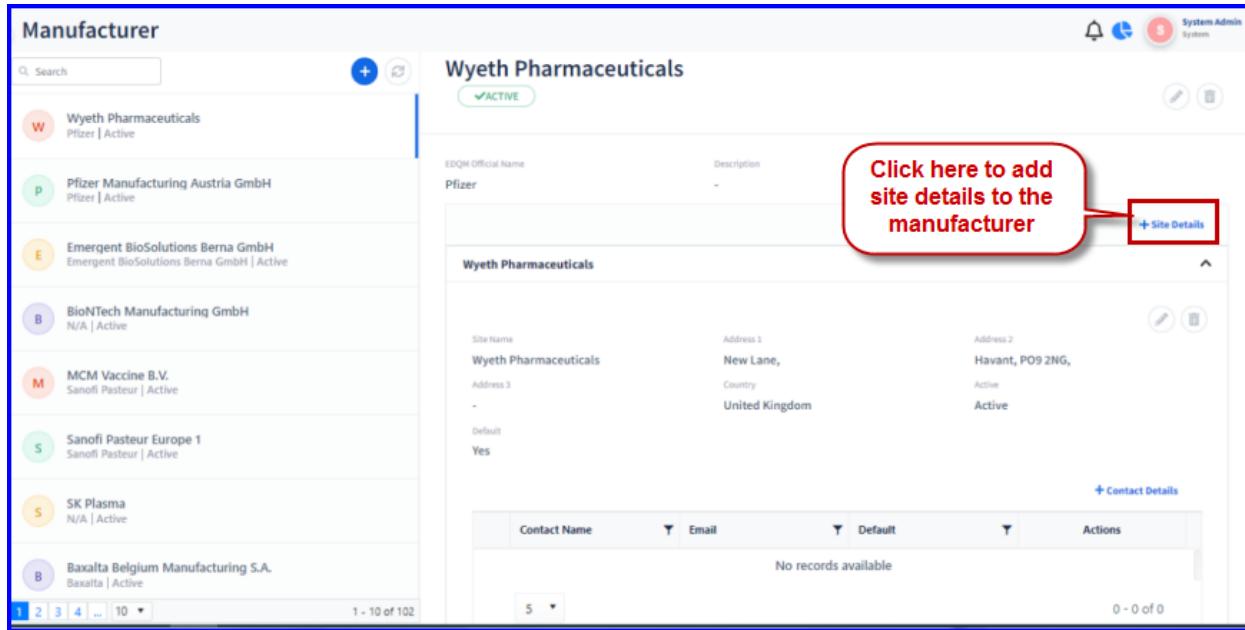
3.6.5.2 Editing and Deleting Manufacturer

1. To edit manufacturer details, in the Manufacturer master screen, select the manufacturer and then click . In the **Edit Manufacturer** screen, do required changes and then click **Save**.
2. To delete a manufacturer, in the Manufacturer master screen, select the manufacturer you want to delete and then click .

3.6.5.3 Adding Sites to the Manufacturer

Once you add a manufacturer, you can add site details of the manufacturer along with the contact details in each site. To do so, follow these steps:

1. In the Manufacturer master screen, select the manufacturer you want to add site(s) and then click **+ Site Details** as shown in the figure:



The screenshot shows the Manufacturer master screen. On the left, a list of manufacturers is displayed, including Wyeth Pharmaceuticals (selected), Pfizer Manufacturing Austria GmbH, Emergent BioSolutions Berna GmbH, BioNTech Manufacturing GmbH, MCM Vaccine B.V., Sanofi Pasteur Europe 1, SK Plasma, and Baxalta Belgium Manufacturing S.A. On the right, the detailed view for Wyeth Pharmaceuticals is shown. The manufacturer is listed as 'Wyeth Pharmaceuticals' (EDQM Official Name: Pfizer). The address is 'New Lane, Havant, PO9 2NG, United Kingdom'. The status is 'Active'. Below this, a table for 'Contact Details' is shown with no records available. A red callout box with the text 'Click here to add site details to the manufacturer' points to the '+ Site Details' button on the right side of the screen.

FIGURE: Adding Sites to the Manufacturer

The **Add Site Details** dialog appears as shown in the figure:

Add Site Details

Cancel 

Site Name *
Vancouver

Address 1 *
305

Address 2
ave 34

Address 3

Country Name *
Canada

Active 

Default 

FIGURE: Add Site Details Dialog

1. In the **Site Name** field, type the name of the site of the manufacturer.
2. Fill in **Address 1**, **Address 2** and **Address 3** fields.
3. In the **Country** field, select the country the site is located.
4. Click to turn on the **Active** option to make the site active.
5. Click to turn on the **Default** option to make the site default site of the manufacturer in Qualis LIMS.
6. Click **Save**.

You can see the site you just added listed under Site Details as shown in the figure:

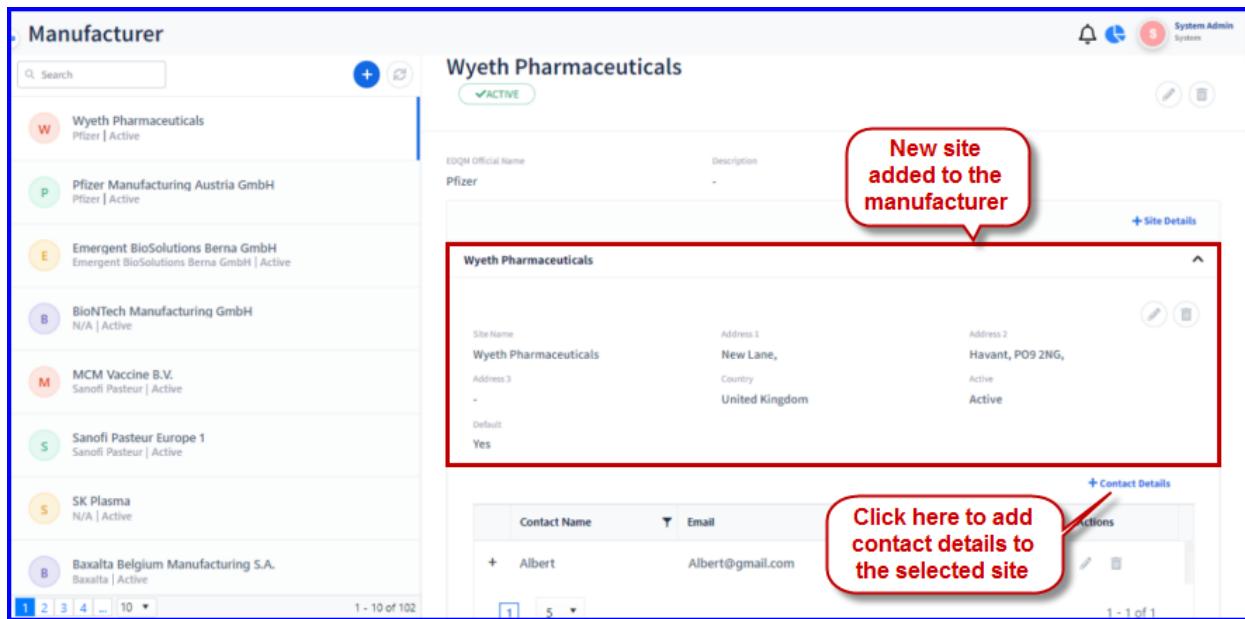


FIGURE: Adding Contact Details to the Selected Site

Same way, you can add more sites to the manufacturer. For each site added you can add contact details. To do so, follow these steps:

1. In the Manufacturer master screen, select the manufacturer, select the site to add contact details and then click **+ Contact Details** as shown in the figure:

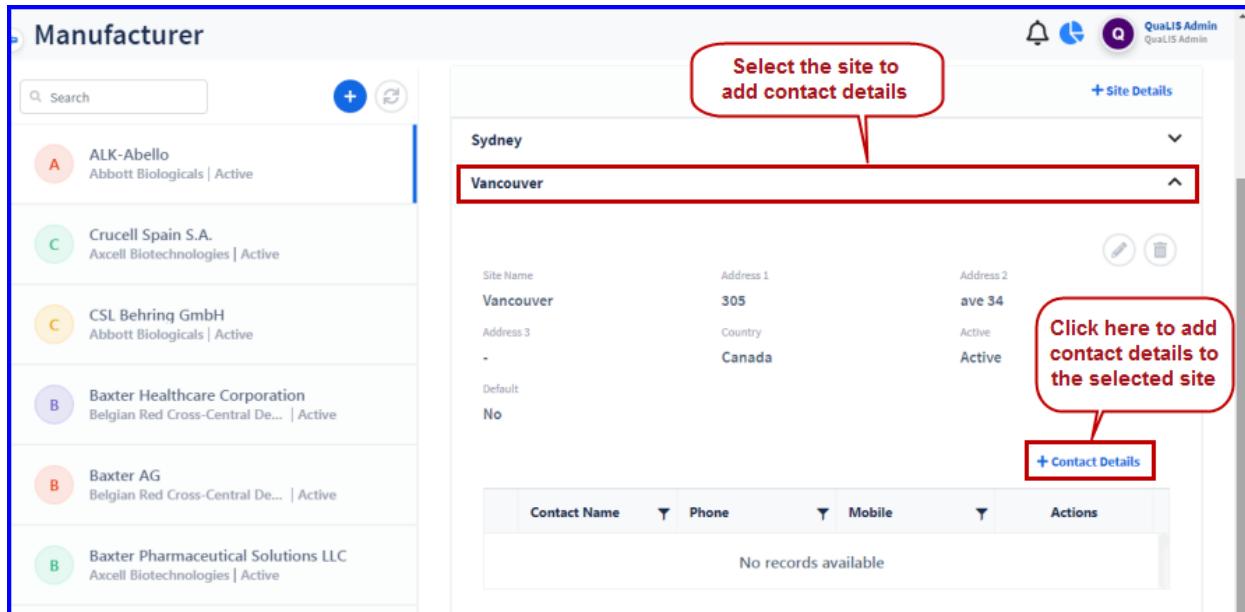
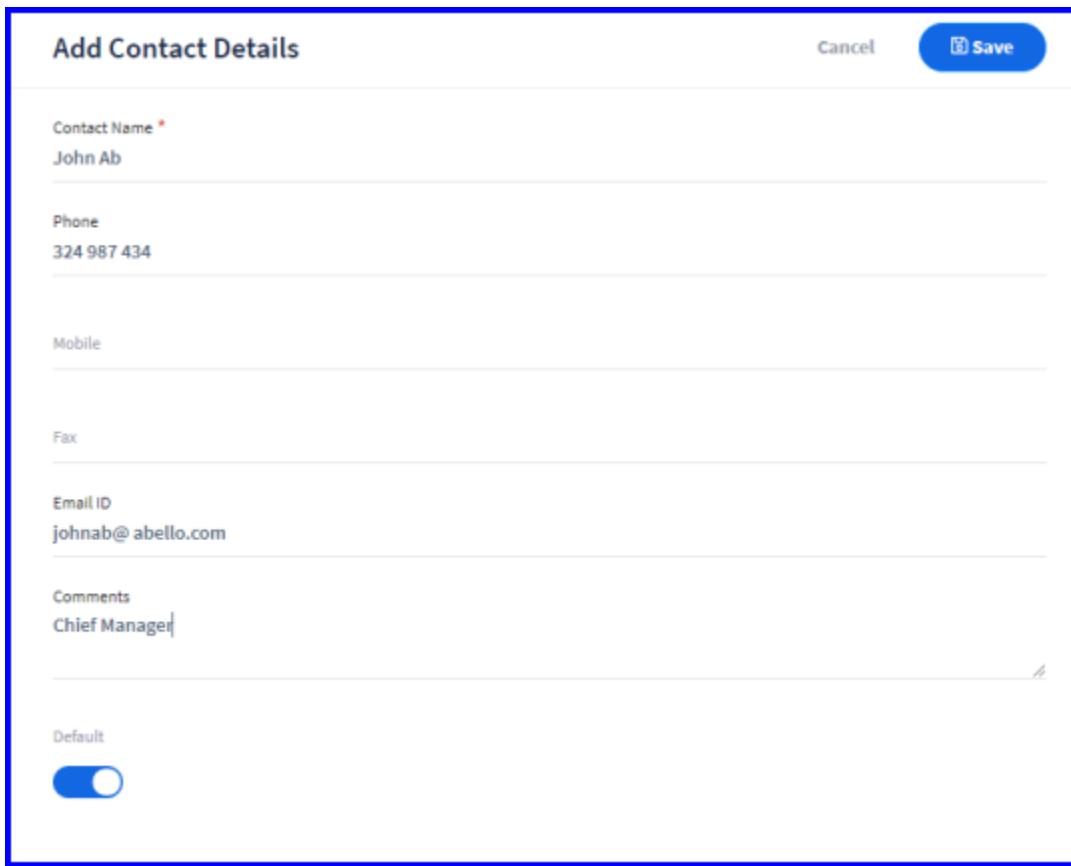


FIGURE: Adding Contact Details to the Site

The **Add Contact Details** dialog appears as shown in the figure:



Contact Name *

John Ab

Phone

324 987 434

Mobile

Fax

Email ID

johnab@ abello.com

Comments

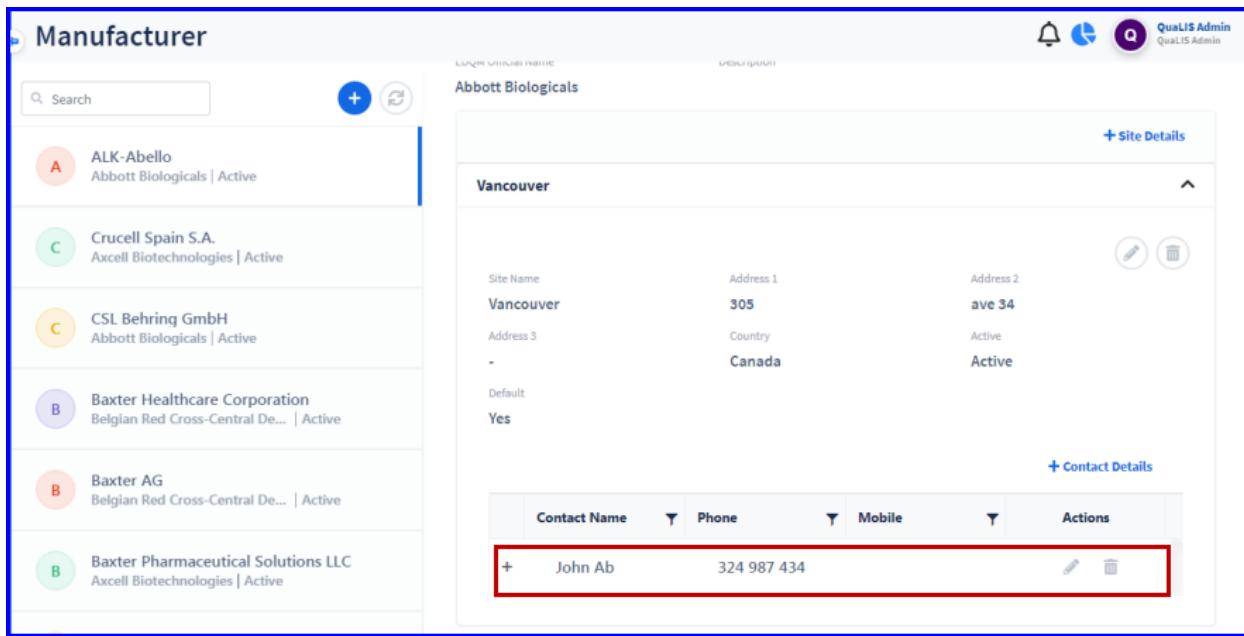
Chief Manager

Default

FIGURE: Add Contact Details Dialog

1. In the **Contact Name** field, type the contact name for the selected site.
2. In the **Country** field, select the country.
3. Fill in **Phone**, **Mobile**, **Fax**, and **Email ID** fields.
4. Click to turn on the **Default** option to make the contact default contact of the site.
5. Click **Save**.

You can see the contact you just added listed under Contact Details as shown in the figure:



The screenshot shows the Qualis LIMS interface for managing manufacturers. On the left, a sidebar lists various manufacturers with their names and status (e.g., Active). The main panel displays the details for 'Abbott Biologicals' with a site named 'Vancouver'. The site details include address (305), country (Canada), and status (Active). A contact list is shown at the bottom, with one contact, 'John Ab', highlighted in a red box.

FIGURE: Added Contact Details

Same way, you can add multiple contacts to a site.

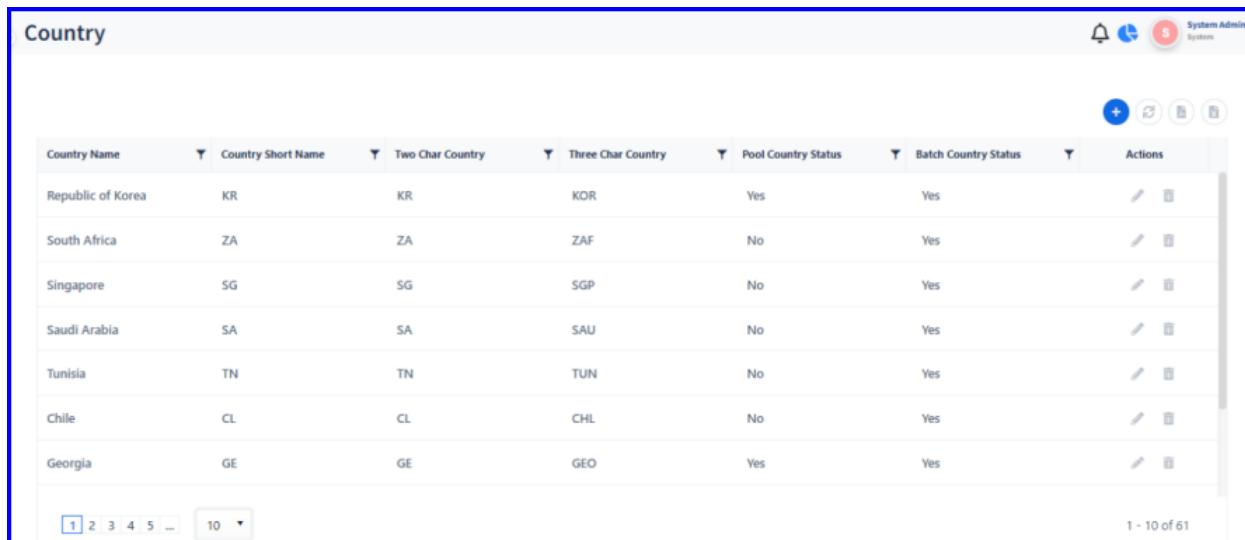
3.6.6 Country Master

Country master is used to add and manage countries. Country details are used in client, supplier and manufacturer masters.

3.6.6.1 Adding a New Country

To create a new country, follow these steps:

1. On the main menu, click , click **Contacts** and then click **Country**. The **Country** master screen appears as shown in the figure:



The screenshot shows a table titled 'Country' with a blue border. The table has columns: Country Name, Country Short Name, Two Char Country, Three Char Country, Pool Country Status, Batch Country Status, and Actions. The data includes:

Country Name	Country Short Name	Two Char Country	Three Char Country	Pool Country Status	Batch Country Status	Actions	
Republic of Korea	KR	KR	KOR	Yes	Yes		
South Africa	ZA	ZA	ZAF	No	Yes		
Singapore	SG	SG	SGP	No	Yes		
Saudi Arabia	SA	SA	SAU	No	Yes		
Tunisia	TN	TN	TUN	No	Yes		
Chile	CL	CL	CHL	No	Yes		
Georgia	GE	GE	GEO	Yes	Yes		

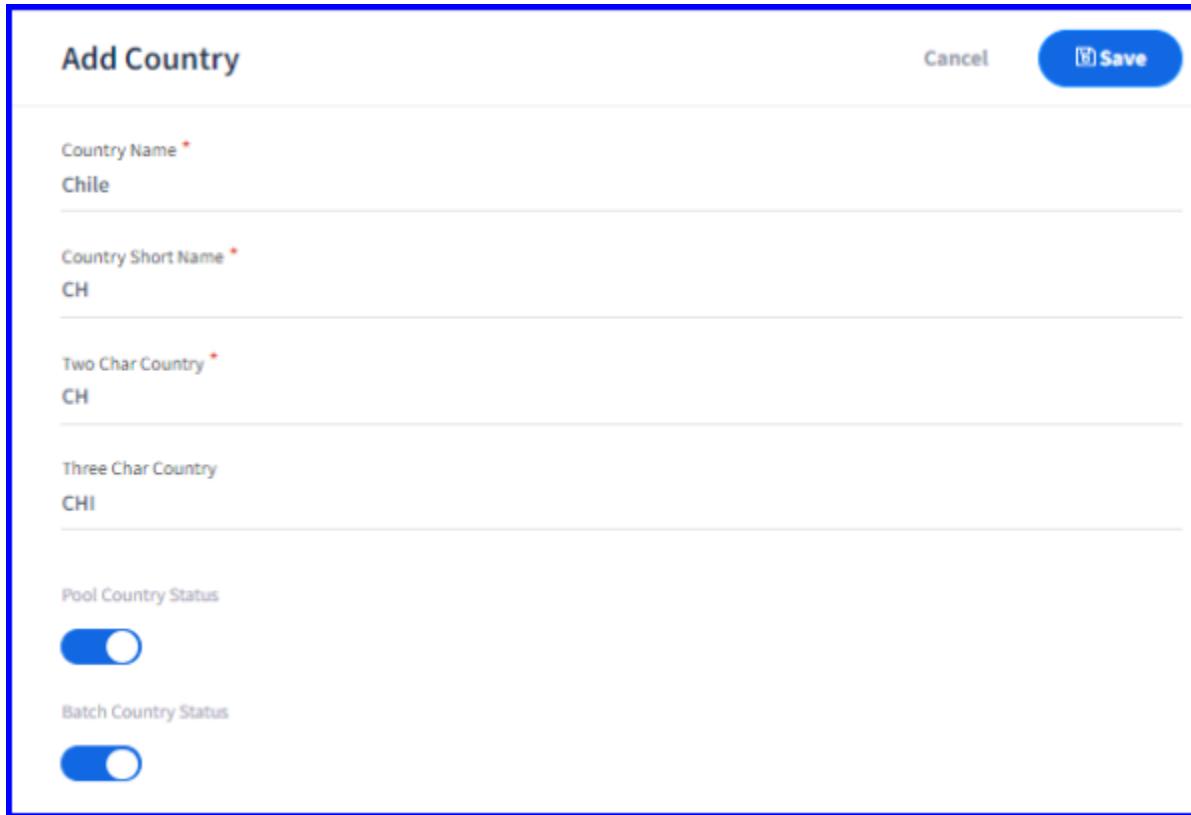
Page navigation: 1 2 3 4 5 ... 10

1 - 10 of 61

FIGURE: Country Master Screen

In the country master screen, you can see the list of countries added. Options to edit and delete countries appear in each record.

2. Click . The **Add Country** screen appears as shown in the figure:



The screenshot shows the 'Add Country' form with a blue border. It has fields for Country Name, Country Short Name, Two Char Country, Three Char Country, Pool Country Status, and Batch Country Status. The 'Save' button is highlighted.

Country Name *	Country Short Name *	Two Char Country *	Three Char Country	Pool Country Status	Batch Country Status
Chile	CH	CH	CHI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Save button:

FIGURE: Add Country Screen

3. In the **Country Name** field, type the country name.
4. In the **Country Short Name** field, type short name of the country.
5. In the **Two Char Country** field, type two letter code of the country.
6. In the **Three Char Country** field, type three letter code of the country.
7. Click to turn on the **Pool Country Status** if required.
8. Click To turn on the **Batch Country Status** if required.
9. Click **Save**.

You can see the country you just added listed in the country master.

3.6.6.2 Editing and Deleting Country

Options to edit and delete country appear in each record in the country master.

1. To edit country details, in the country master screen, click  to edit the country record. In the **Edit Country** screen, do required changes and then click **Save**.
2. To delete a country, in the country master screen, click  to delete the country record.

3.6.7 MA Holder Master

MA Holder master is used to add and manage Marketing Authorization Holder(MAH) details.

3.6.7.1 Adding a New MA Holder

To create a new MA Holder, follow these steps:

1. On the main menu, click , **Contacts** and then click **MA Holder**. The **MA Holder** master screen appears as shown in the figure:

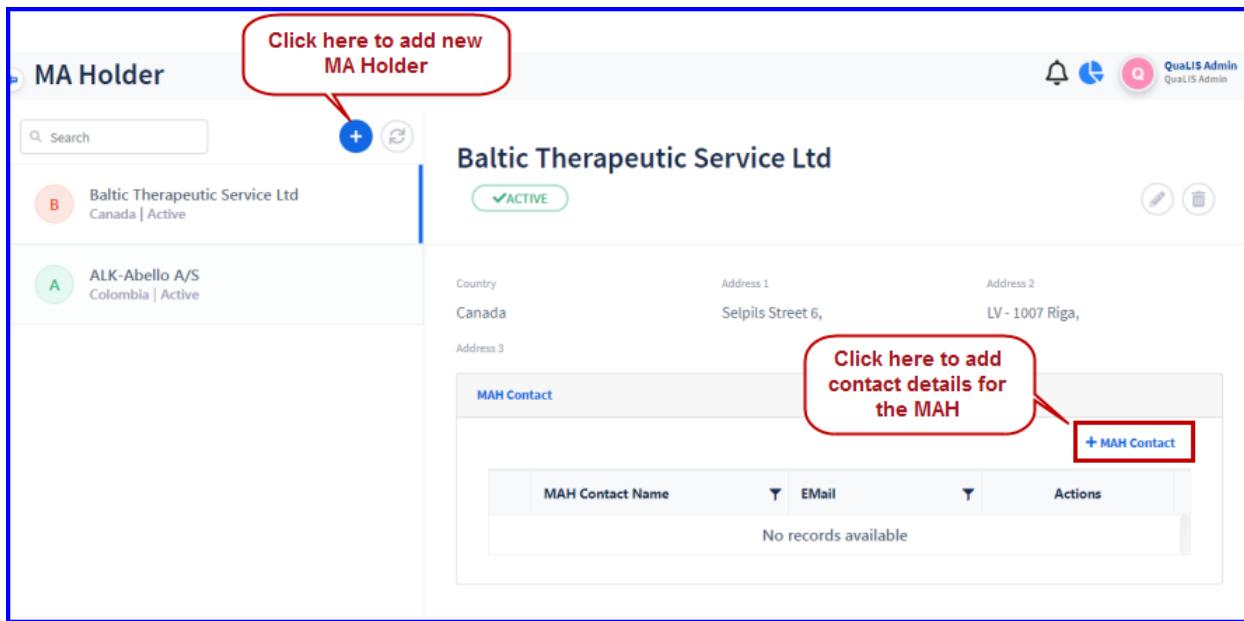
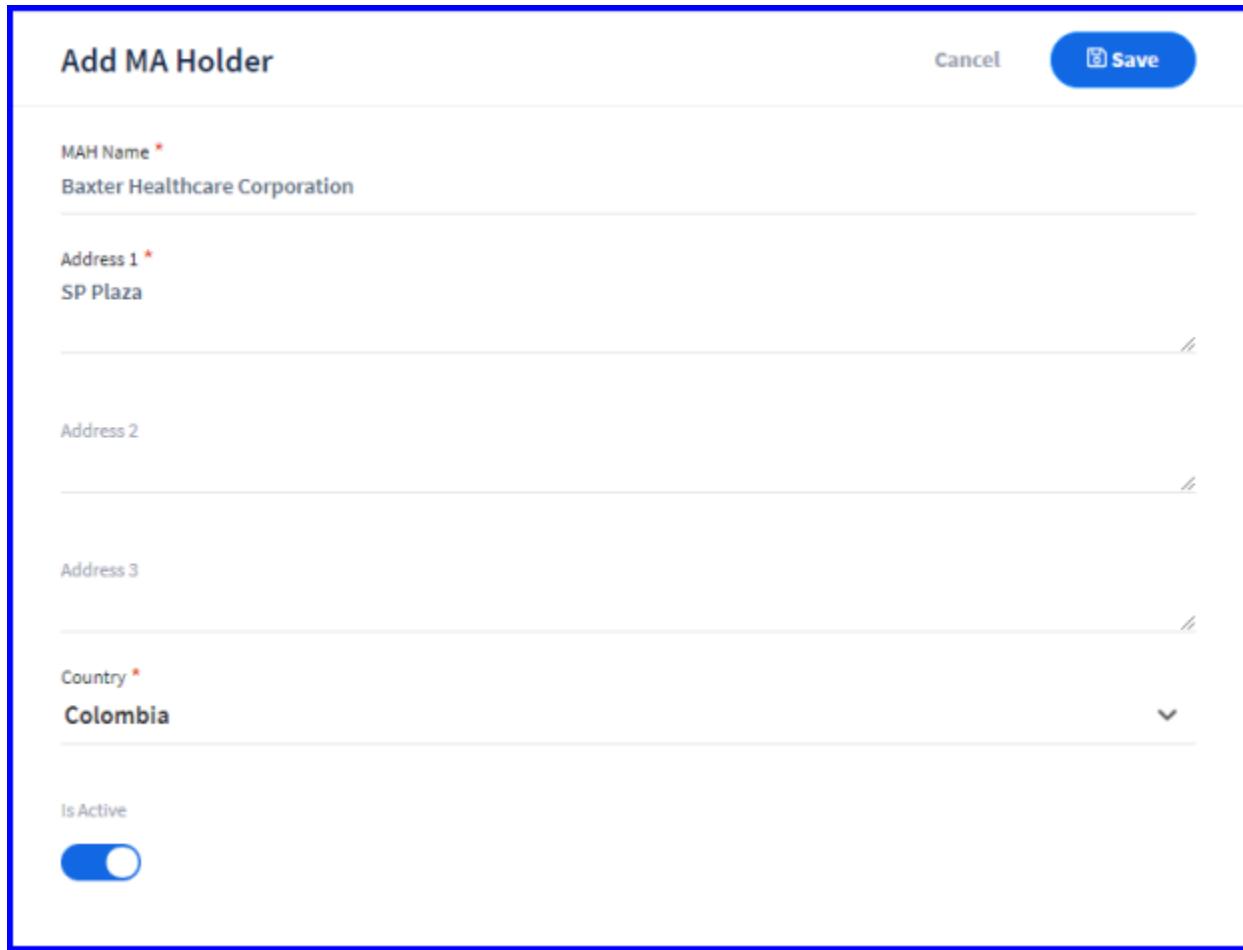


FIGURE: MA Holder Master Screen

In the MA Holder master screen, you can see the list of MA Holders added. Options to edit and delete appears in the each record.

2. Click . The **Add MA Holder** screen appears as shown in the figure:



MAH Name *

Baxter Healthcare Corporation

Address 1 *

SP Plaza

Address 2

Address 3

Country *

Colombia

Is Active

FIGURE: Add MA Holder Screen

3. In the **MAH Name** field, type the Marketing Authorization Holder name.
4. In the **Address 1**, **Address 2** and **Address 3** fields type address of the MA Holder.
5. In the **Country** field, select country of the MAH
6. Click to check the **IsActive** check field to make the MA Holder an active MA Holder.
7. Click **Save**.

You can see the MA Holder you just added listed in the MA Holder master.

3.6.7.2 Editing and Deleting MA Holder

1. To edit MA Holder details, in the MA Holder master screen, select the MA Holder and then click . In the **Edit MA Holder** screen, do required changes and then click **Save**.

2. To delete a MA Holder, in the MA Holder master screen, select the MA Holder you want to delete and then click .

3.6.7.3 Adding Contacts to MA Holder

Once you add MAH, you can add contact details for the MAH. To do so, follow these steps:

1. In the MA Holder master screen, select the MA Holder, and then click  **MAH Contact** as shown in the figure:



FIGURE: Adding Contact Details to the MAH

The **Add MAH Contact** dialog appears as shown in the figure:

Add MAH Contact

Cancel 

MAH Contact Name *

Emegent

Phone No

0442277667

Mobile No

879564532

Fax No

89787788

Email *

Emegent@gmail.com

Default Status

FIGURE: Add MAH Contact Dialog

2. In the **MAH Contact Name** field, type the contact name for the selected site.
3. In the **Country** field, select the country.
4. Fill in **Phone**, **Mobile No**, **Fax No**, and **Email** fields.
5. Click to turn on the **Default Status** option to make the contact default contact of the MAH.
6. Click **Save**.

You can see the contact you just added listed under **MAH Contact** as shown in the figure:



MAH Contact Name	Email	Default	Actions
Emergent	Emegent@gmail.com	Yes	

FIGURE: Contact Added to the MA Holder

7. Same way, you can add more contacts to a MAH. You can also edit and delete contacts. Options to edit and delete appears in each contact record.

3.7 Product

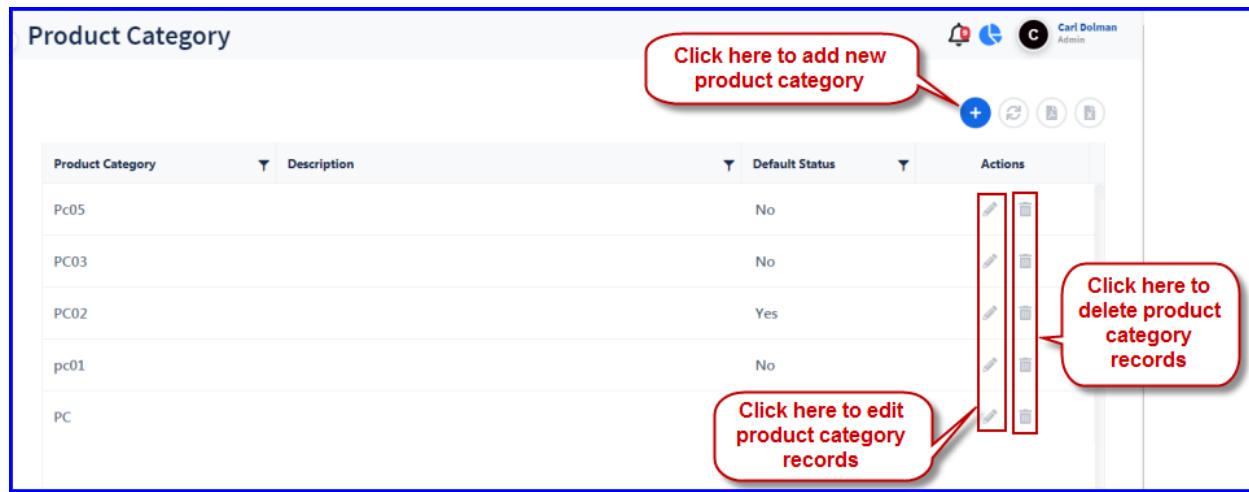
3.7.1 Product Category Master

Product Category master is used to add and manage product categories. Product category is used in product master to group products.

3.7.1.1 Adding a New Product Category

To create a new product category, follow these steps:

1. On the main menu, click **Product** and then click **Product Category**. The **Product Category** master screen appears as shown in the figure:



The screenshot shows a table titled 'Product Category' with columns: 'Product Category', 'Description', 'Default Status', and 'Actions'. The data rows are:

Product Category	Description	Default Status	Actions
Pc05		No	   
PC03		No	   
PC02		Yes	   
pc01		No	   
PC			   

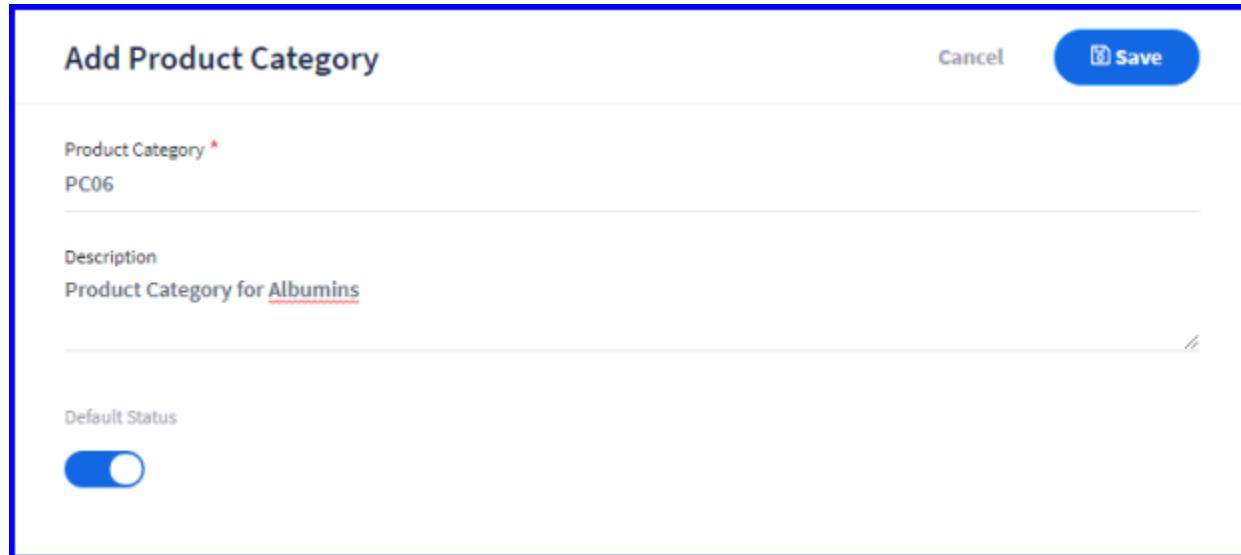
Annotations on the right side of the table:

- A red callout bubble points to the top right corner of the table with the text: 'Click here to add new product category'.
- A red callout bubble points to the 'Edit' icon in the 'Actions' column of the first row with the text: 'Click here to edit product category records'.
- A red callout bubble points to the 'Delete' icon in the 'Actions' column of the first row with the text: 'Click here to delete product category records'.

FIGURE: Product Category Master Screen

In the Product Category master screen you can see the list of product categories created. Options to edit and delete product categories appear in each record.

2. Click . The **Add Product Category** screen appears as shown in the figure:



The dialog has the following fields:

- Product Category ***: PC06
- Description**: Product Category for Albumins
- Default Status**: A toggle switch is set to **On**.

Buttons at the top right: **Cancel** and **Save**.

FIGURE: Add Product Category Dialog

3. In the **Product Category Name** field, type the category name.
4. In the **Description** field, type the description.
5. Click **Save**.

You can see the product category you just created listed in the Product Category master.

3.7.1.2 Editing and Deleting Product Category

Options to edit and delete product category appear in each record in the product category master.

1. To edit product category details, in the product category master screen, click  to edit the product category record. In the **Edit Product Category** screen, do required changes and then click **Save**.
2. To delete a product category, in the product category master screen, click  to delete the product category record.

3.7.2 Product Master

Product master is used to add and manage products to Qualis LIMS. When you add a product it will be in the Draft state. You can edit, delete, complete or approve the product. Once approved, you cannot edit or delete the product. The product is assigned to an user and the assigned user can correct or approve the product.

3.7.2.1 Adding a New Product

To create a new product, follow these steps:

1. On the main menu, click , **Product** and then click **Product**. The **Product** master screen appears as shown in the figure:

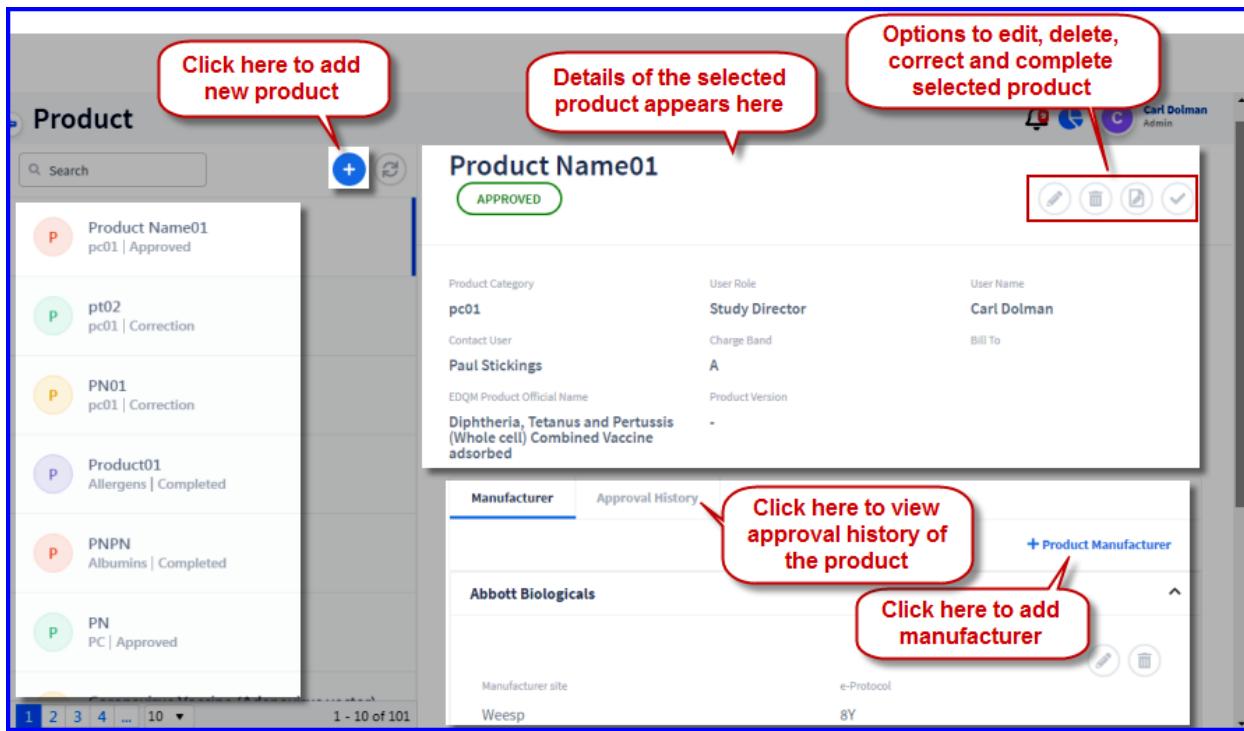


FIGURE: Product Master Screen

In the Product master screen, you can see the list of products added. Options to edit, delete, correct and complete product appears in the each record.

2. Click . The **Add Product** screen appears as shown in the figure:

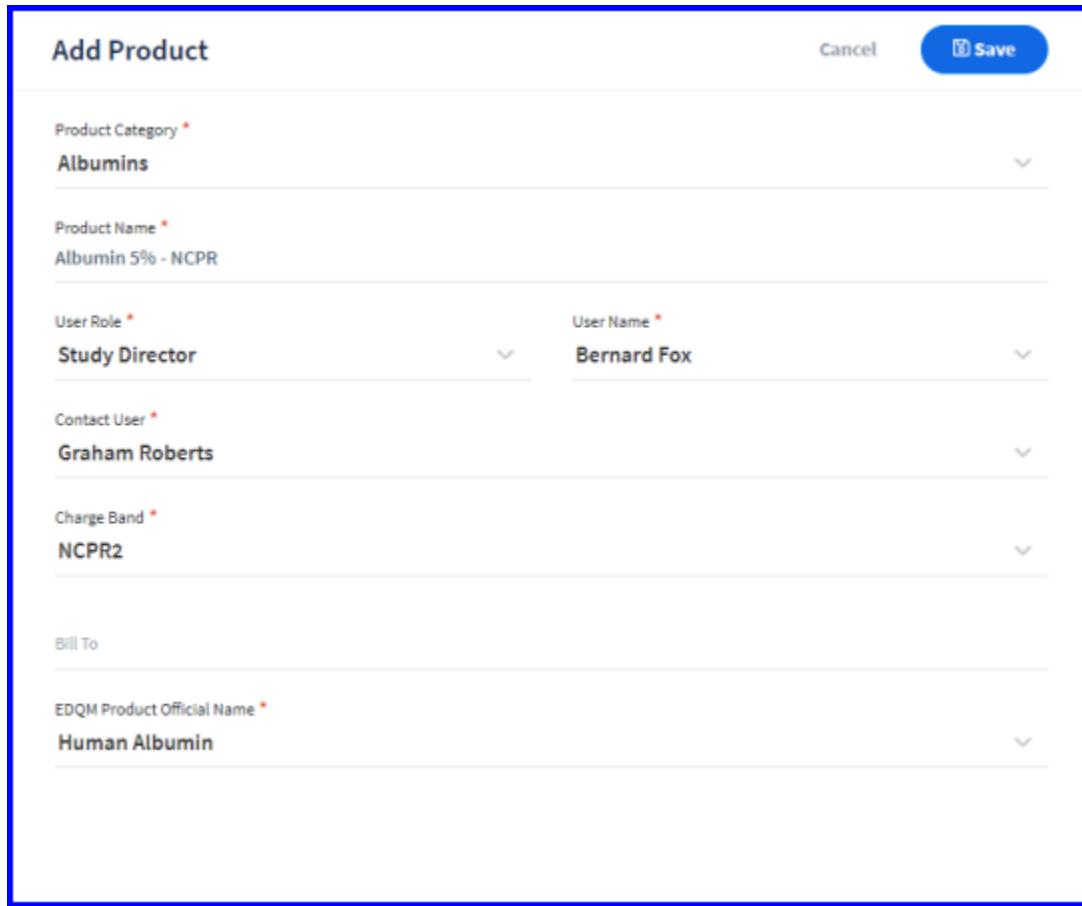


FIGURE: Add Product Screen

3. In the **Product Category** field, select the product category. Categories added to the Product Category master appears here.
4. In the **Product Name** field, type the product name you want to add.
5. In the **User Role** field, select a user role to assign the product. User roles that has rights to the Product Flow option in the User Role Configuration screen appears here.
6. In the **User Name** field, select a user to assign the product. This user will have rights to correct and approve the product.
7. In the **Contact User** field, select a user to assign as contact to the product
8. In the **Charge Band** field, select the charge band to assign to the product. Charge bands added to the Charge Band master appears here.
9. In the **Bill To** field, type the contact /number for billing.
10. In the **EDQM Product Official Name** field, select the official name of the product.

11. Click **Save**.

You can see the product you just added listed in the Product master.

3.7.2.2 Editing and Deleting Product

You can edit or delete a product in the Draft state. You cannot edit or delete a product in Completed

1. To edit product details, in the Product master screen, select the product and then click . In the **Edit Product** screen, do required changes and then click **Save**.
2. To delete a product, in the Product master screen, select the product you want to delete and then click .

3.7.2.3 Change Product Record Status to COMPLETED

Records in the DRAFT state should be COMPLETED. Only records in the COMPLETED state shall be approved. To complete a record, follow these steps:

1. In the Product master screen, select the product you want to complete and then click  as shown in the figure:

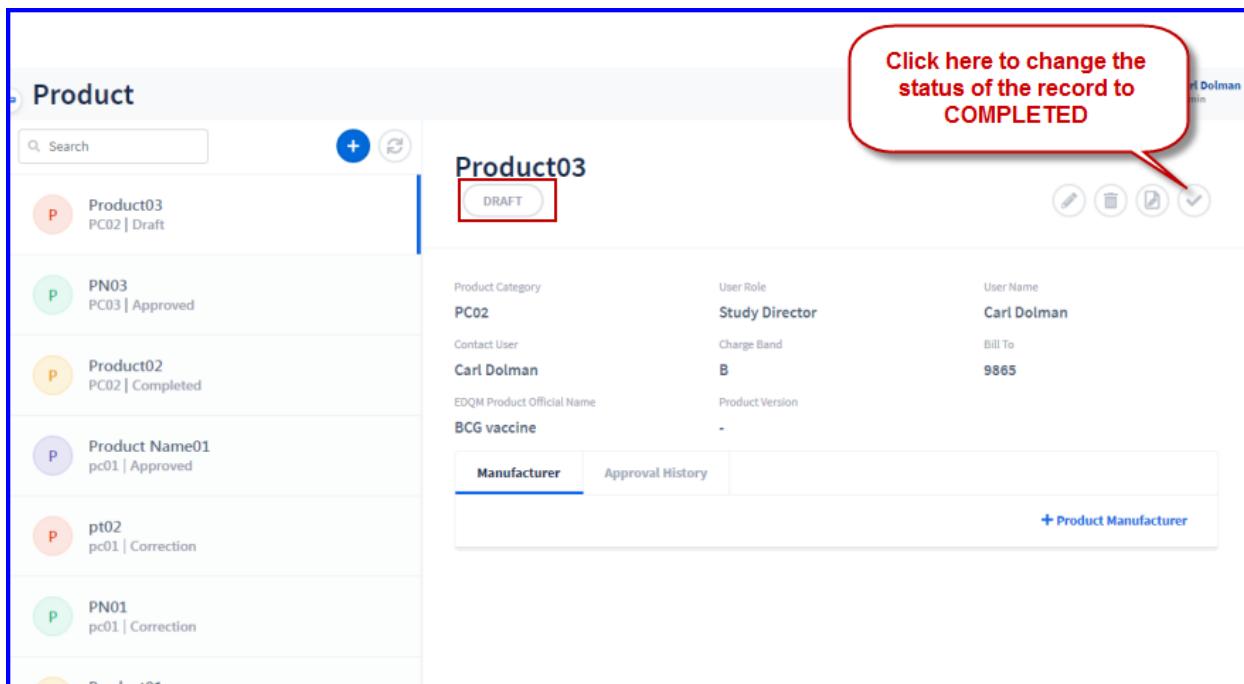
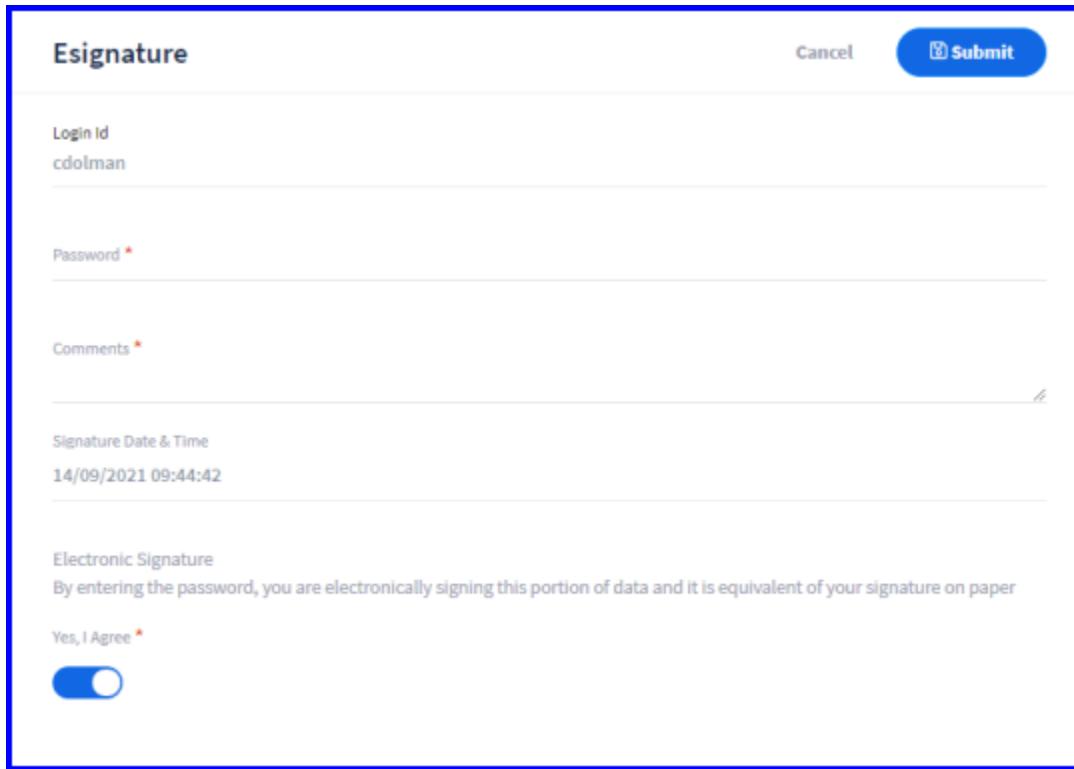


FIGURE: Changing the Status of the Product Record to COMPLETED

The **Esignature** dialog appears for authentication as shown in the figure:



Esignature

Cancel **Submit**

Login Id
cdolman

Password *

Comments *

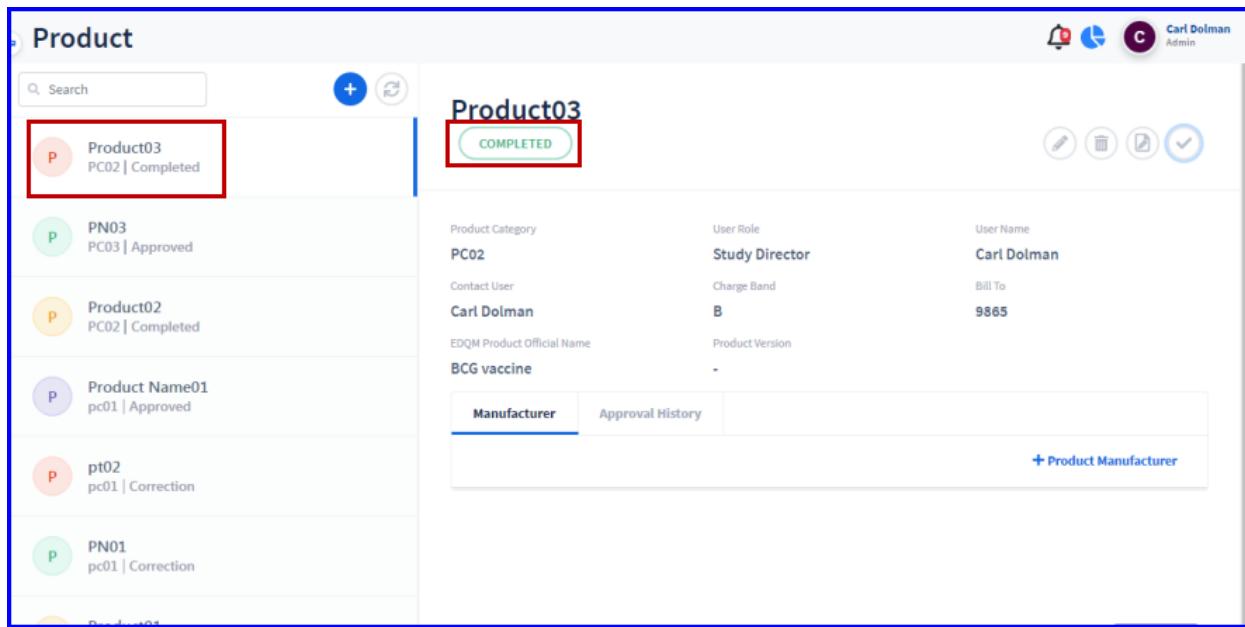
Signature Date & Time
14/09/2021 09:44:42

Electronic Signature
By entering the password, you are electronically signing this portion of data and it is equivalent of your signature on paper

Yes, I Agree *

FIGURE: Esignature Dialog

2. In the **Login Id** field, your user name will appear.
3. In the **Password** field type valid password.
4. In the **Comments** field, type your comments and then click **Submit**.
5. Now the product record goes to the **COMPLETED** state as shown in the figure:



The screenshot shows the Product master screen. On the left, a list of products is displayed, with 'Product03' selected and highlighted with a red box. On the right, the detailed view for 'Product03' is shown, also with a red box around the 'COMPLETED' status indicator. The product details include: Product Category (PC02), User Role (Study Director), User Name (Carl Dolman); Contact User (Carl Dolman), Charge Band (B), Bill To (9865); EDQM Product Official Name (BCG vaccine), Product Version (-); and a Manufacturer section with a 'Product Manufacturer' button. The top right corner shows the user profile of 'Carl Dolman Admin'.

FIGURE: Product Record in the COMPLETED State

3.7.2.4 Approving Product Record

You can approve a product record that is in the COMPLETED state.

Note: Once you approve a product, you cannot edit product details. Instead, you can correct product details.

To approve a product record, follow these steps:

1. In the Product master screen, select the product you want to approve, click  and then click  as shown in the figure:

Product

Product02
PC02 | Completed

Product Name01
pc01 | Approved

pt02
pc01 | Correction

PN01
pc01 | Correction

Product01
Allergens | Completed

PNPN
Albumins | Completed

1 2 3 4 ... 10 1 - 10 of 102

Product02
COMPLETED

Product Category: PC02
User Role: Study Director
Contact User: Carl Dolman
EDQM Product Official Name: BCG vaccine
Charge Band: A
Product Version: -

Manufacturer Approval History

Click here to approve the product

Correction Approve Carl Dolman 2344

+ Product Manufacturer

FIGURE: Approving Product Record

The product goes to the **APPROVED** state as shown in the figure:

Product

Product02
PC02 | Approved

Product Name01
pc01 | Approved

pt02
pc01 | Correction

PN01
pc01 | Correction

Product01
Allergens | Completed

PNPN
Albumins | Completed

1 2 3 4 ... 10 1 - 10 of 102

Product02
APPROVED

Product Category: PC02
User Role: Study Director
Contact User: Carl Dolman
EDQM Product Official Name: BCG vaccine
Charge Band: A
Product Version: -

Manufacturer Approval History

Carl Dolman 2344

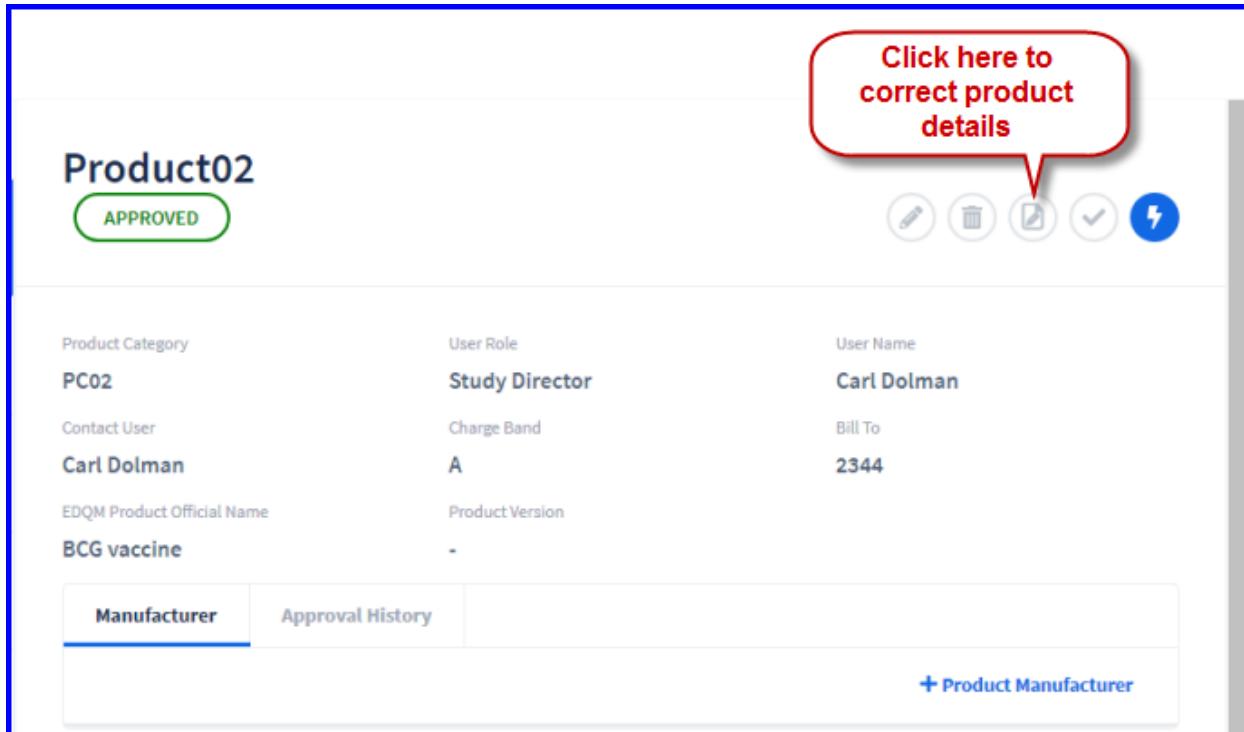
+ Product Manufacturer

FIGURE: Product in the APPROVED State

3.7.2.5 Correcting Product Details

Once you approve a product, you cannot edit product details. Instead, you can correct product details. To do so, follow these steps: 

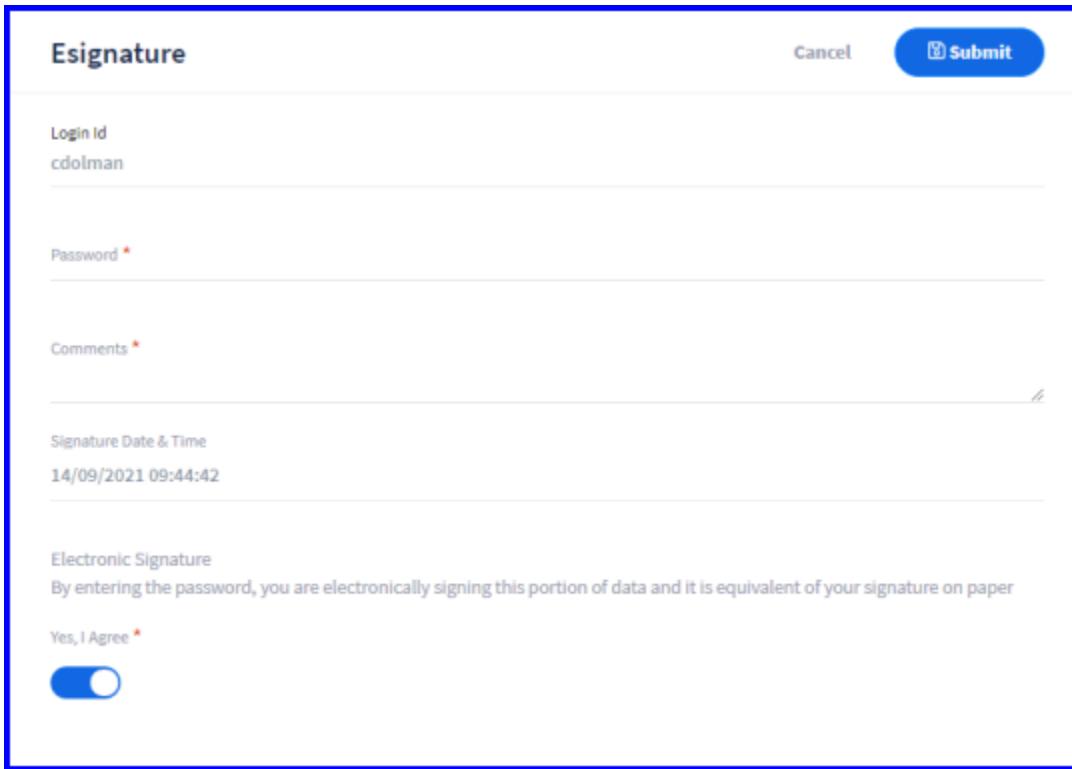
1. In the Product master screen, select the product you want to correct details and then click  as shown in the figure:



Manufacturer	Approval History
+ Product Manufacturer	

FIGURE: Correcting Product Details

The **Esignature** dialog appears for authentication as shown in the figure:



Esignature

Cancel 

Login Id
cdolman

Password *

Comments *

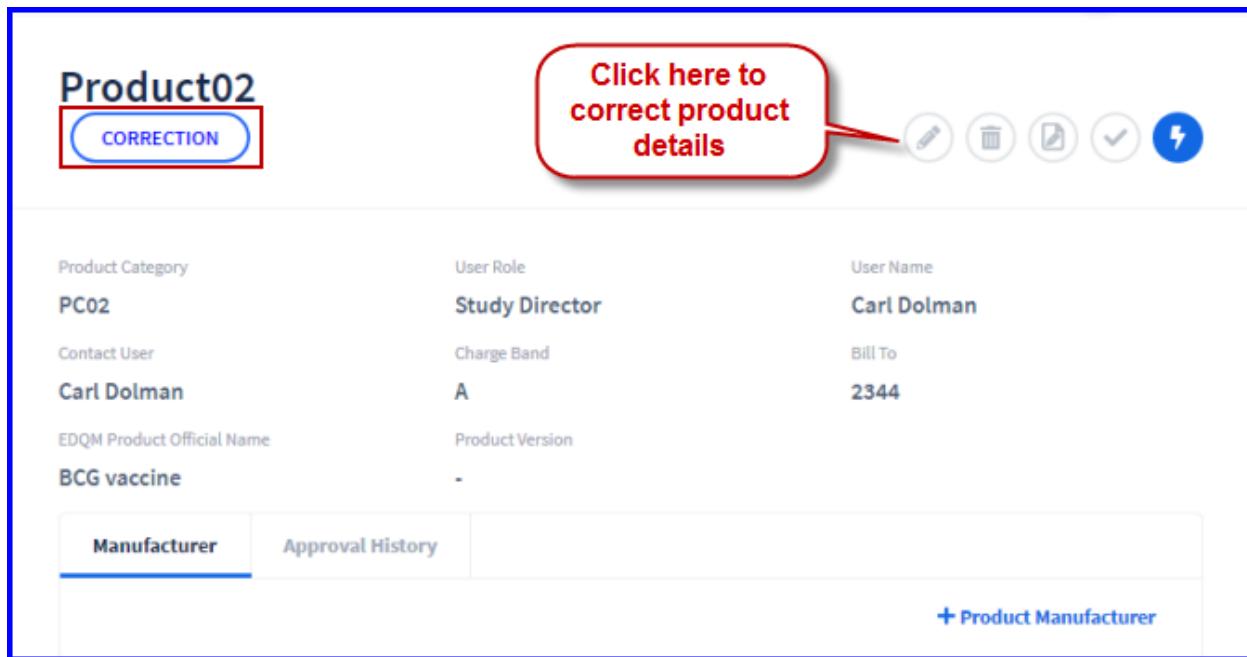
Signature Date & Time
14/09/2021 09:44:42

Electronic Signature
By entering the password, you are electronically signing this portion of data and it is equivalent of your signature on paper

Yes, I Agree *

FIGURE: Esignature Dialog

2. In the **Login Id** field, your user name will appear.
3. In the **Password** field type valid password.
4. In the **Comments** field, type your comments for correction and then click **Submit**.
5. Now the product record goes to the **CORRECTION** state as shown in the figure:



Product Category PC02	User Role Study Director	User Name Carl Dolman
Contact User Carl Dolman	Charge Band A	Bill To 2344
EDQM Product Official Name BCG vaccine	Product Version -	

Manufacturer **Approval History**

[+ Product Manufacturer](#)

FIGURE: Product Record in the CORRECTION State

In the **CORRECTION** state, you can edit product details.

6. Click  as shown in the above figure to edit product details. The **Edit Product** screen appears as shown in the figure:

Edit Product

Cancel  Save

Product Category *	PC02		
Product Name *	Product02		
User Role *	Study Director	User Name *	Carl Dolman
Contact User *	Carl Dolman		
Charge Band *	A		
Bill To	2344		
EDQM Product Official Name *	BCG vaccine		

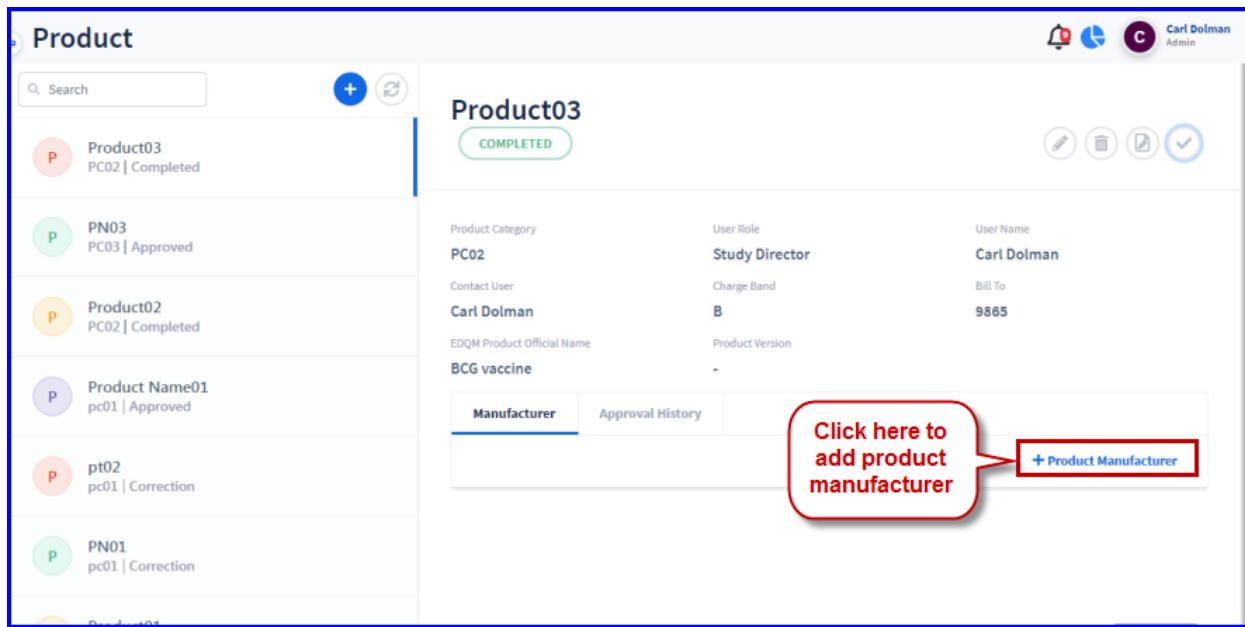
FIGURE: Edit Product Dialog

7. Do required changes and then click **Save**.
8. Once you correct product details, you need to change the status of the record to **COMPLETED**. And then you can approve the product.

3.7.2.6 Adding Manufacturer to the Product

Once you add a new product, you can add product manufacturer(s) to the product. To do so, follow these steps:

1. In the Product master screen, select a product you want to add manufacturer and then click **+ Product Manufacturer** as shown in the figure:



The screenshot shows the product management interface. On the left, a list of products is displayed with their status (e.g., Completed, Approved, Pending). On the right, a detailed view of a specific product (Product03) is shown, including its category (PC02), contact user (Carl Dolman), and product name (BCG vaccine). A callout box highlights the '+ Product Manufacturer' button, which is used to add a manufacturer to the product.

FIGURE: Adding Product Manufacturer to the Product

The **Add Manufacturer** dialog appears as shown in the figure:



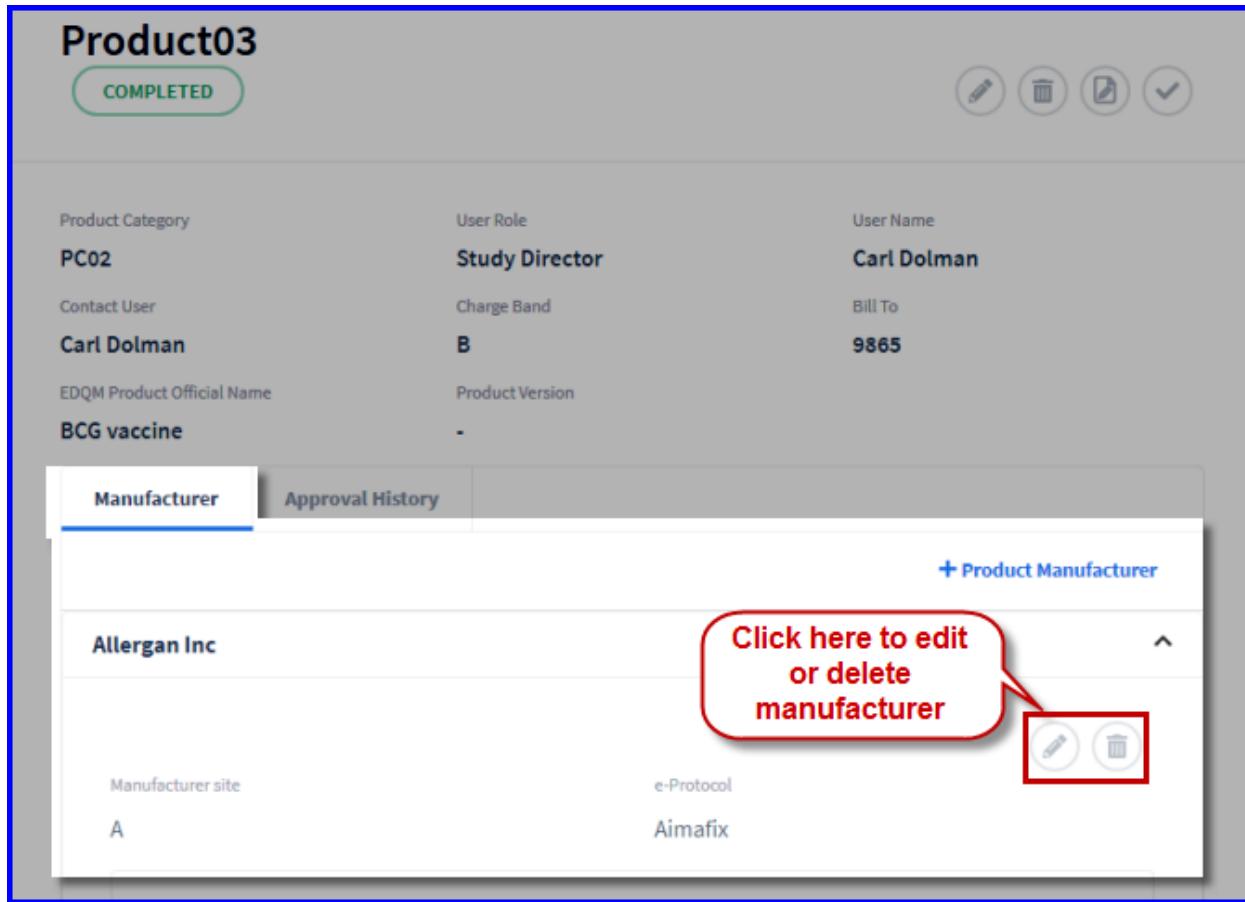
The dialog box is titled 'Add Product Manufacturer'. It contains three input fields: 'Manufacturer Name' (with a dropdown arrow), 'Manufacturer Site Name' (with a dropdown arrow), and 'e-Protocol' (with a dropdown arrow). The 'Manufacturer Name' field has 'Allergan Inc' selected. The 'Save' button is located at the top right of the dialog.

FIGURE: Add Product Manufacturer Dialog

2. In the **Manufacturer Name** field, select the manufacturer name. Manufacturer names added in the Manufacturer master appears here.

3. In the **Manufacturer Site Name** field, select the site name of the manufacturer for the product.
4. In the **e-Protocol** field, select e-Protocol for the product.
5. Click **Save**.

You can see the product manufacturer you just added listed under Manufacturer as shown in the figure:



The screenshot shows the 'Product03' detail page. At the top, there is a 'COMPLETED' status indicator and four circular icons for edit, delete, print, and checkmark. Below this, product details are listed in a grid:

Product Category	User Role	User Name
PC02	Study Director	Carl Dolman
Contact User	Charge Band	Bill To
Carl Dolman	B	9865
EDQM Product Official Name	Product Version	
BCG vaccine	-	

Below the grid, there are two tabs: 'Manufacturer' (selected) and 'Approval History'. A 'Product Manufacturer' button is located above a list of manufacturers. The list contains one item: 'Allergan Inc'. To the right of this list is a red callout bubble with the text 'Click here to edit or delete manufacturer' and a red box around the edit and delete icons. The edit icon is a pencil inside a circle, and the delete icon is a trash can inside a circle.

FIGURE: Added Manufacturer to the Selected Product

Same way, you can add more manufacturers to the product. For each manufacturer added you can see edit and delete options. You can edit or delete manufacture(s) as required until the product is approved.

3.7.2.7 Viewing Approval History of the Product

In the Product master, select a product and then click Approval History tab as shown in the figure:

Product03

APPROVED

Product Category	User Role	User Name
PC02	Study Director	Carl Dolman
Contact User	Charge Band	Bill To
Carl Dolman	B	9865
EDQM Product Official Name	Product ID	
BCG vaccine	-	

Manufacturer
Approval History

Approval Status	User Name	User Role	Approval Date & ..	Comments
Approved	Carl Dolman	Study Director	14/09/2021 13:...	approve
Completed	Carl Dolman	Admin	14/09/2021 00:...	complete

1
5
▼
1 - 2 of 2

Click this tab to view approval history of the product

FIGURE: Viewing Approval History of the Product

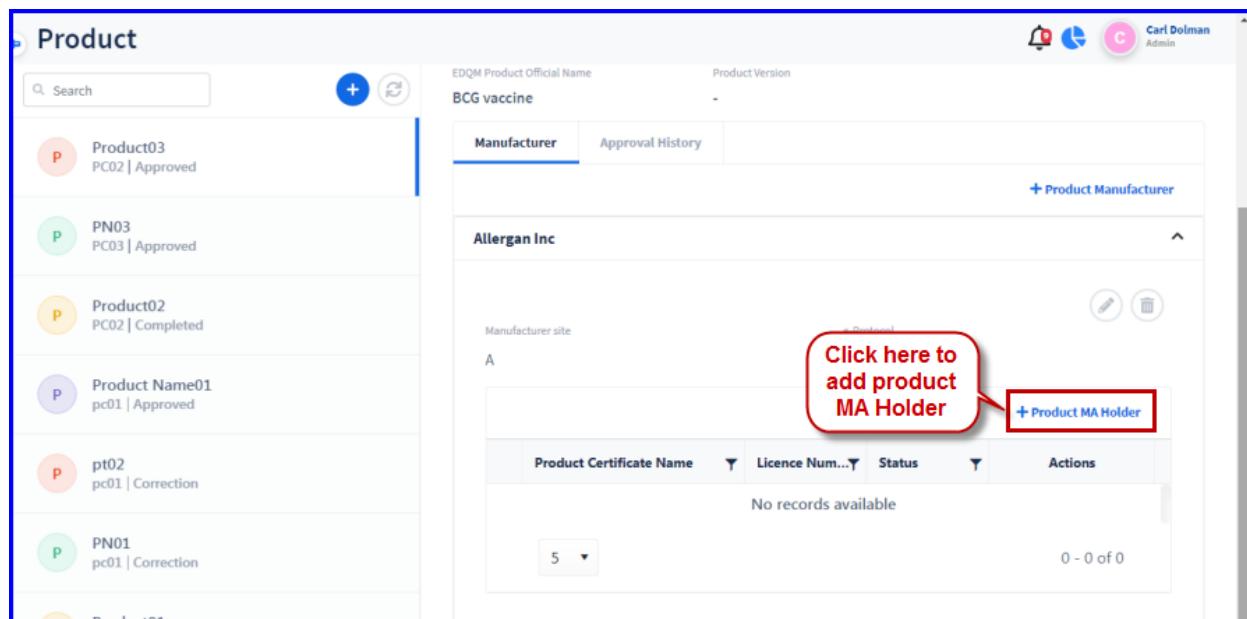
You can see the approval history of the product like approval status, user approved, user role date and time of approval and comments as shown in the above figure.

3.7.2.8 Adding MA Holder to the Product Manufacturer

Once you add product manufacturer to the product, you can add product Marketing Authorization (MA) Holders to the manufacturer. To do so, follow these steps:

1. In the Product master screen, select a product and select the manufacturer you want to add MA Holder and then click **+Product MA Holder** as shown in the figure:

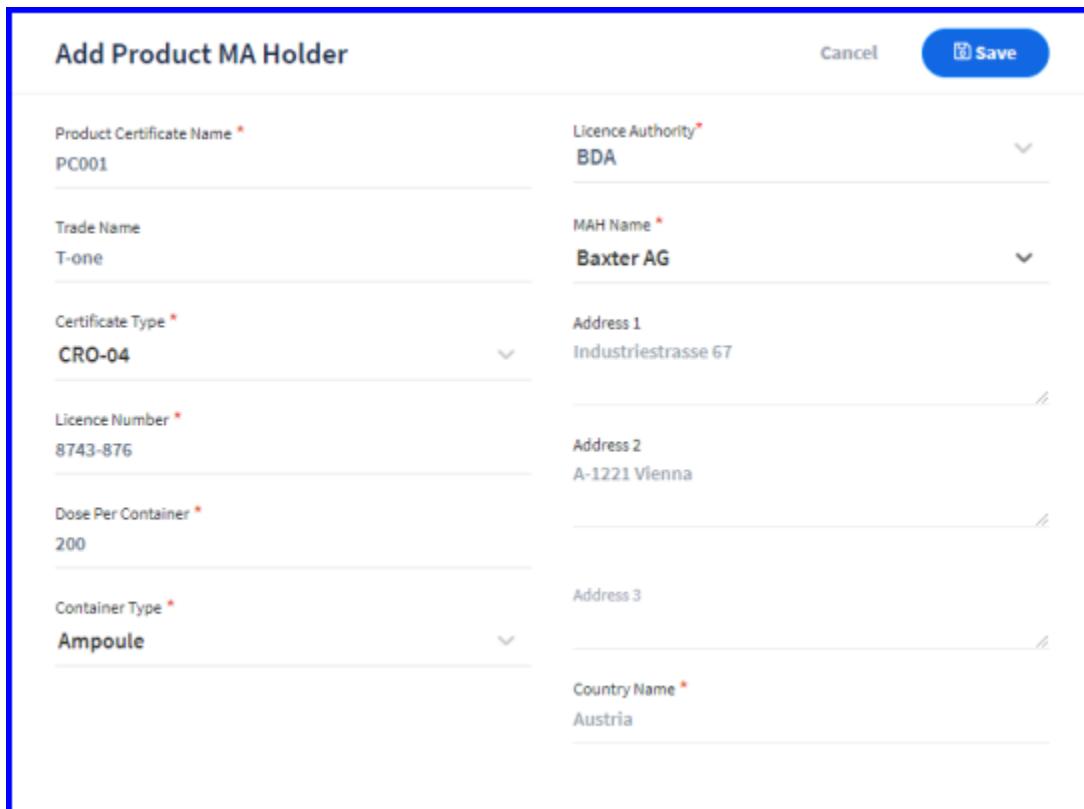
168



The screenshot shows the 'Product' management screen. On the left, a list of products is displayed with columns for status and action. On the right, a detailed view for 'BCG vaccine' is shown, including the manufacturer 'Allergan Inc' and a table for 'Product Certificate Name', 'Licence Num...', 'Status', and 'Actions'. A callout box highlights the '+ Product MA Holder' button.

FIGURE: Adding Product MA Holder

The **Add Product MA Holder** dialog appears as shown in the figure:



The dialog box contains the following fields:

- Product Certificate Name *: PC001
- Licence Authority *: BDA
- Trade Name: T-one
- MAH Name *: Baxter AG
- Certificate Type *: CRO-04
- Address 1: Industriestrasse 67
- Licence Number *: 8743-876
- Address 2: A-1221 Vienna
- Dose Per Container *: 200
- Address 3
- Container Type *: Ampoule
- Country Name *: Austria

FIGURE: Add Product MA Holder Dialog

2. In the **Product Certificate Name** field, type the MA holder name. MA Holder names added in the MA Holder master appears here.
3. In the **Trade Name** field, type the trade name.
4. In the **Certificate Type** field, select the certificate type for the product. Certificate types added in the Certificate Type master appears here.
5. In the **License Number** field, type the licence number of the MA Holder.
6. In the **Dose Per Container** field, type number of doses per container.
7. In the **Container Type** field, select the container type. Types added in the Container Type master appears here
8. In the **Licence Authority** field, select the licence authority.
9. In the **MAH Name** field, select the MA Holder name.
10. Based on the selected **MAH Name, Address 1, Address 2, Address 3** and **Country Name** appears.
11. Click **Save**.

You can see the product MA holder you just added listed under Manufacturer as shown in the figure:

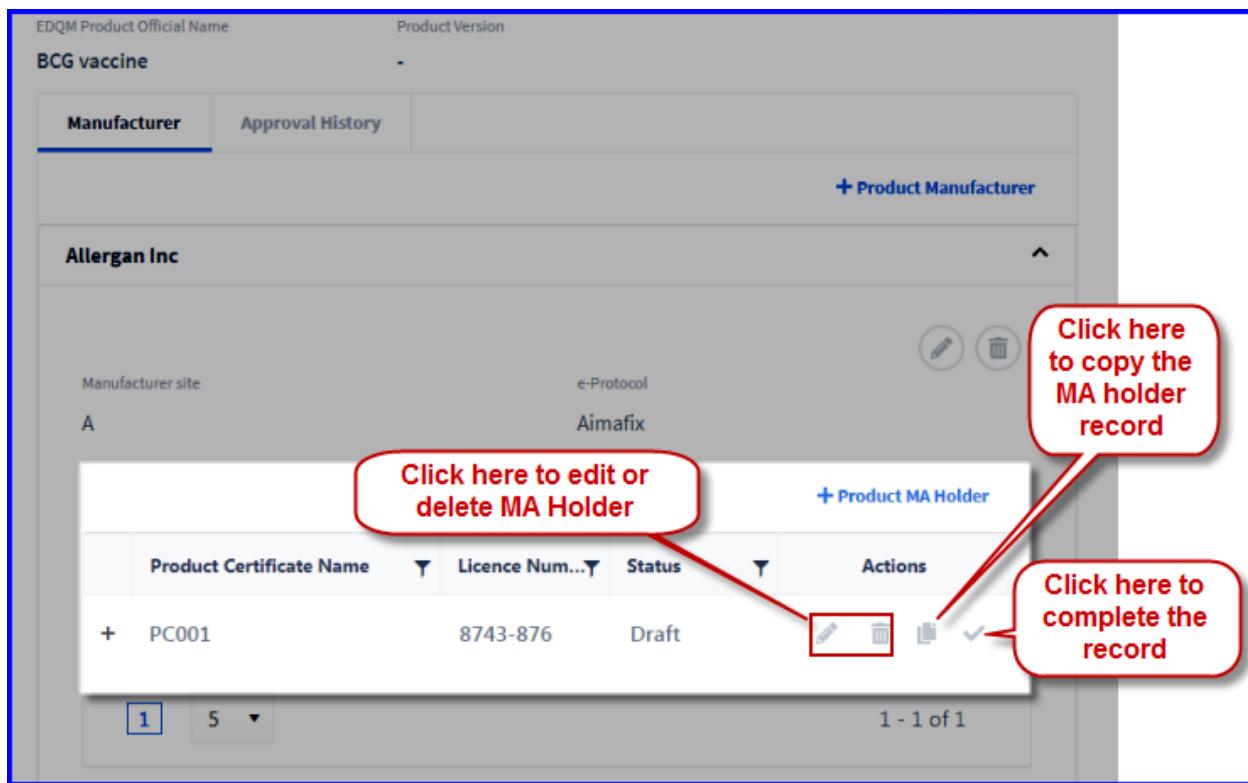


FIGURE: Added MA Holder for the Product

Same way, you can add more MA Holders to the product manufacturer. For each MA Holder added you can see edit and delete options. You can edit or delete MA Holder(s) as required until the product is approved.

Click  to expand to view more information of the record.

Click  to collapse more information view of the record.

Click  to copy the MA Holder record.

Click  to complete the MA Holder record.

3.7.3 Product MA Holder Master

Product MA Holder master is used to add and manage product MA holders to Qualis LIMS. When you add a product MA holder it will be in the Draft state. You can edit, delete, complete, copy or approve the product MA holders. Once approved, you cannot edit or delete the product MA holder.

3.7.3.1 Adding a New Product MA Holder

To add a new product MA holder, follow these steps:

1. On the main menu, click  **Product** and then click **Product MA Holder**. The **Product MA Holder** master screen appears as shown in the figure:

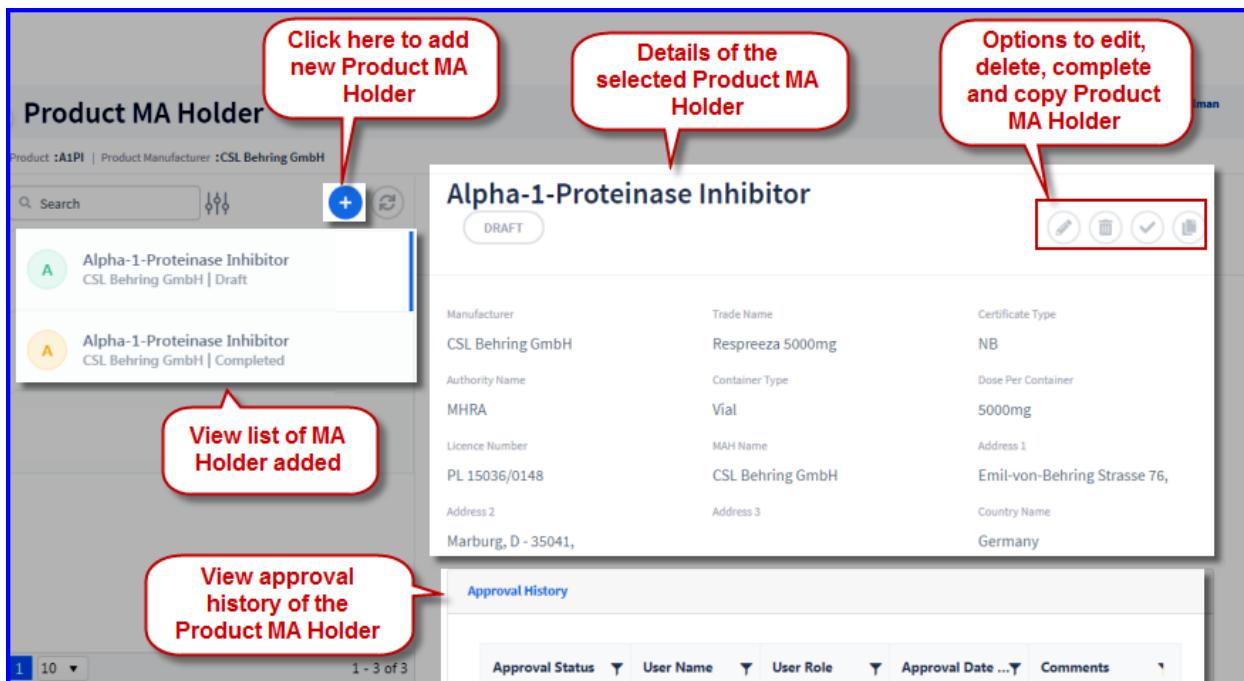
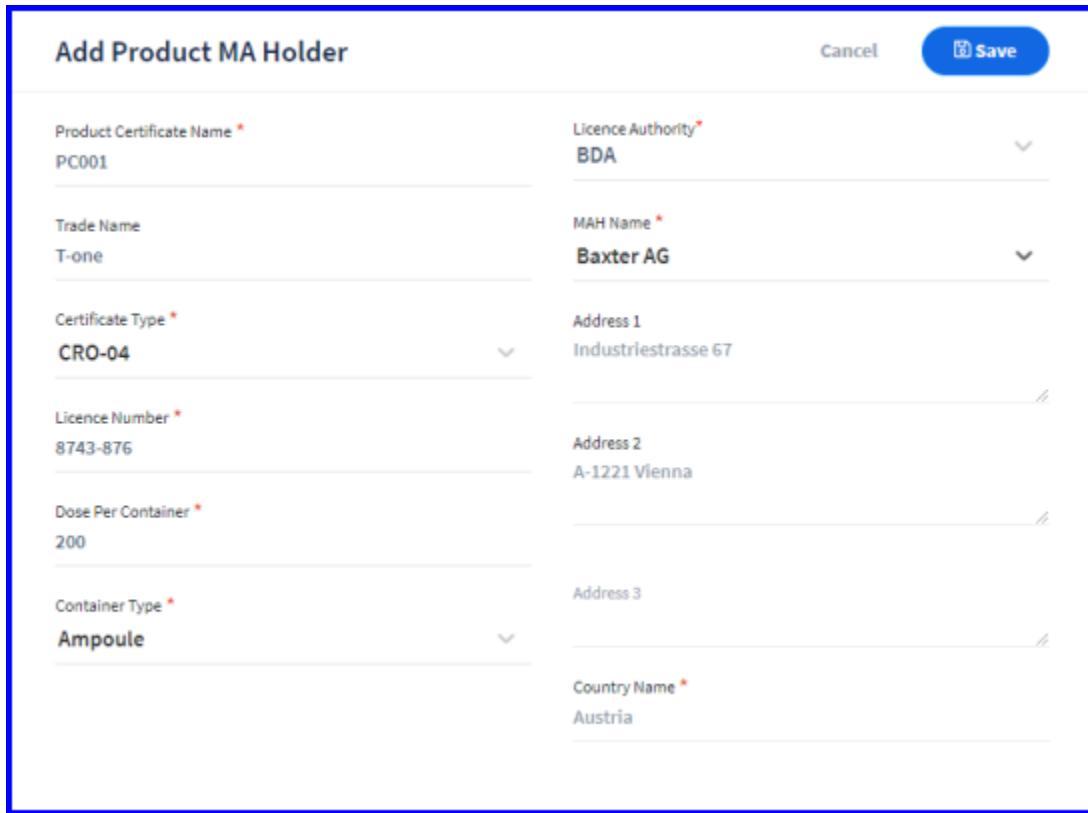


FIGURE: Product MA Holder Master Screen

In the Product MA Holder master screen, you can see the list of MA holder added. Options to edit, delete, complete and copy product MA holder appear in the each record.

2. Click  . The **Add Product MA Holder** screen appears as shown in the figure:



Add Product MA Holder

Product Certificate Name * PC001

Trade Name T-one

Certificate Type * CRO-04

Licence Number * 8743-876

Dose Per Container * 200

Container Type * Ampoule

Address 1 Industriestrasse 67

Address 2 A-1221 Vienna

Address 3

Country Name * Austria

Cancel Save

FIGURE: Add Product MA Holder Dialog

3. In the **Product Certificate Name** field, type the MA holder name.
4. In the **Trade Name** field, type the trade name.
5. In the **Certificate Type** field, select the certificate type for the product. Certificate types added in the Certificate Type master appears here.
6. In the **License Number** field, type the licence number of the MA Holder.
7. In the **Dose Per Container** field, type number of doses per container.
8. In the **Container Type** field, select the container type. Types added in the Container Type master appears here
9. In the **Licence Authority** field, select the licence authority.
10. In the **MAH Name** field, select the MA Holder name.
11. Based on the selected **MAH Name**, **Address 1**, **Address 2**, **Address 3** and **Country Name** appears.

12. Click **Save**.

You can see the product MA holder you just added listed.

3.7.3.2 Editing and Deleting Product MA Holder Records

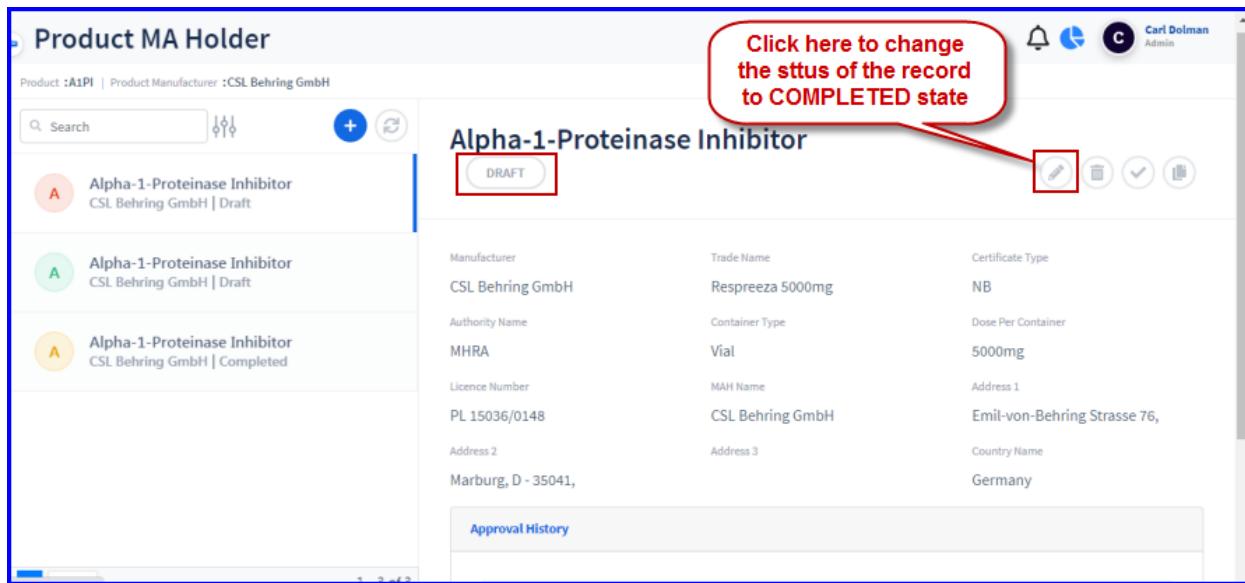
You can edit or delete a product MA holder in the Draft state. You cannot edit or delete a record in Completed state.

1. To edit product MA holder details, in the Product MA Holder master screen, select the product MA holder and then click . In the **Edit Product MA Holder** screen, do required changes and then click **Save**.
2. To delete a product MA holder, in the Product MA Holder master screen, select the product MA holder you want to delete and then click .

3.7.3.3 Change Product MA Holder Record Status to COMPLETED

Records in the DRAFT state should be COMPLETED. Only records in the COMPLETED state shall be approved. To complete a record, follow these steps:

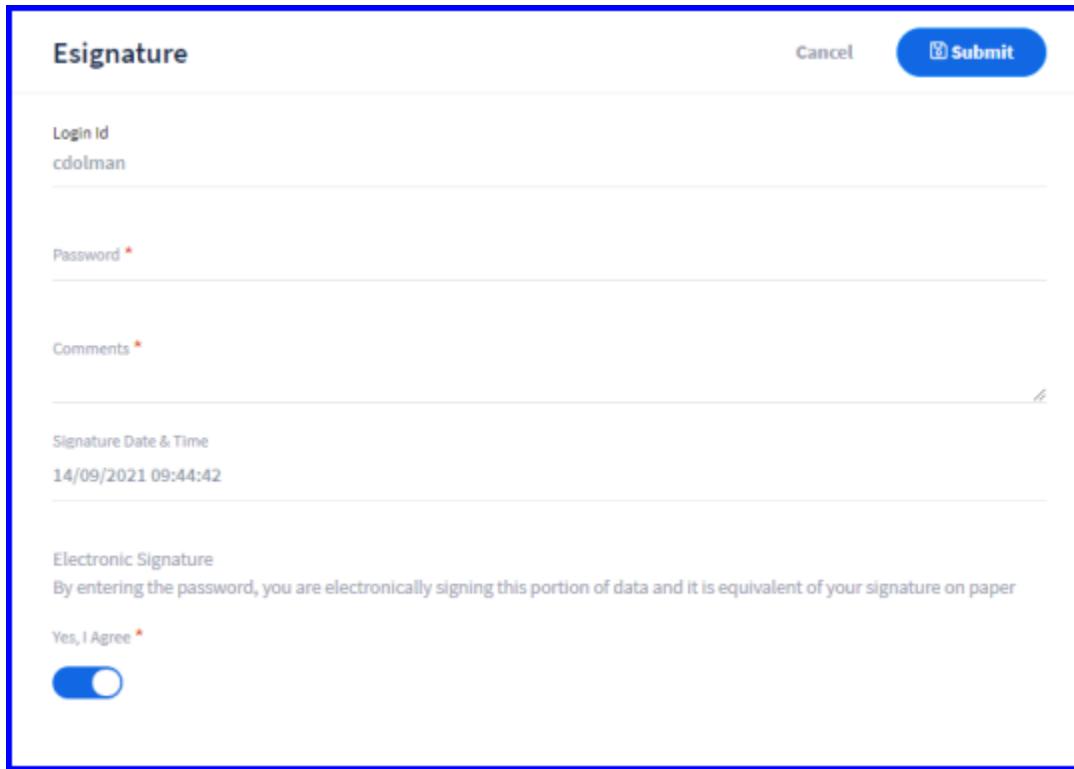
1. In the Product MA Holder master screen, select the product MA holder you want to complete and then click  as shown in the figure:



The screenshot shows the Product MA Holder master screen for product A1PI. The left sidebar lists three entries for 'Alpha-1-Proteinase Inhibitor' from CSL Behring GmbH: one in Draft status (labeled A) and two in Completed status (labeled B and C). The main panel shows a detailed view of the first entry, which is currently in Draft status. A red box highlights the 'DRAFT' button. A red callout bubble with the text 'Click here to change the status of the record to COMPLETED state' points to the 'DRAFT' button. The right side of the screen shows the user profile of Carl Dolman, Admin.

FIGURE: Changing the Status of the Product MA Holder Record to COMPLETED State

The **Esignature** dialog appears for authentication as shown in the figure:



Esignature

Cancel Submit

Login Id
cdolman

Password *

Comments *

Signature Date & Time
14/09/2021 09:44:42

Electronic Signature
By entering the password, you are electronically signing this portion of data and it is equivalent of your signature on paper

Yes, I Agree *

FIGURE: Esignature Dialog

2. In the **Login Id** field, your user name will appear.
3. In the **Password** field type valid password.
4. In the **Comments** field, type your comments and then click **Submit**.

Now the record goes to the **COMPLETED** state.

3.7.3.4 Approving Product MA Holder Record

You can approve a product MA holder record that is in the COMPLETED state.

Note: Once you approve a product MA holder, you cannot edit product details.

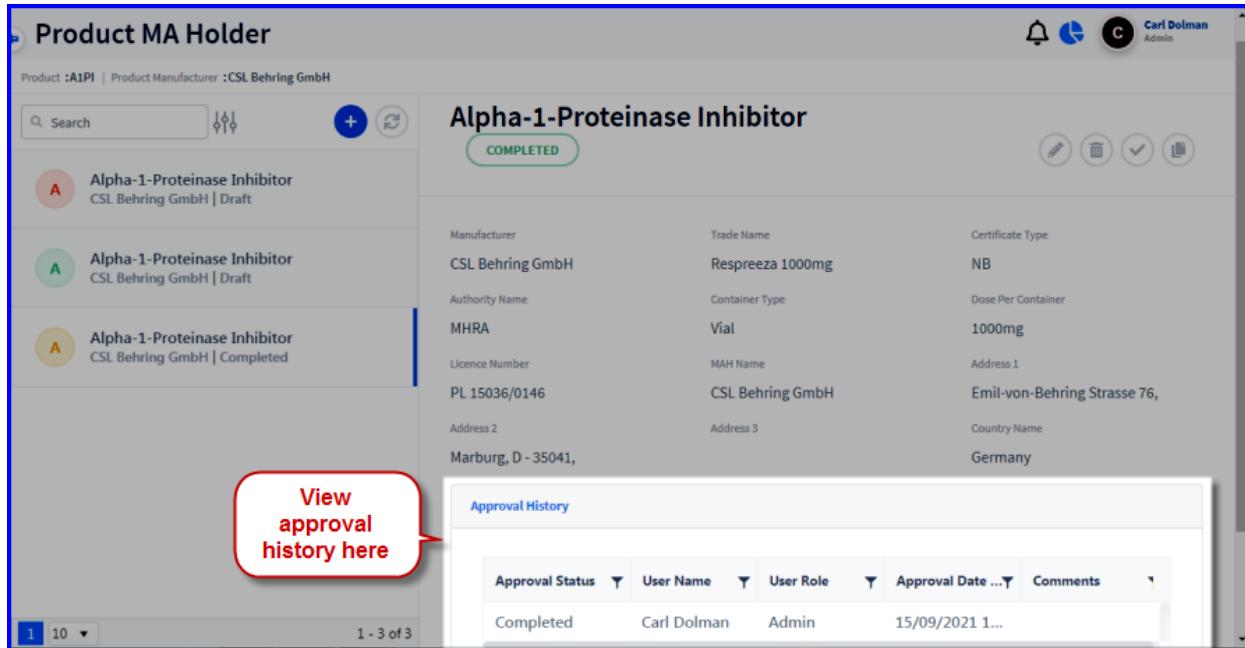
To approve a product MA holder record, follow these steps:

1. In the Product MA Holder master screen, select the product MA holder record you want to approve, click  and then click .

The product MA holder record goes to the **APPROVED** state.

3.7.3.5 Viewing Approval History of the Product MA Holder

In the Product MA Holder master, select a record. Under **Approval History** you can see approval history of the record as shown in the figure:



The screenshot shows the Product MA Holder master screen for the product 'Alpha-1-Proteinase Inhibitor'. The product details are as follows:

Manufacturer	Trade Name	Certificate Type
CSL Behring GmbH	Respreeza 1000mg	NB
Authority Name	Container Type	Dose Per Container
MHRA	Vial	1000mg
Licence Number	MAH Name	Address 1
PL 15036/0146	CSL Behring GmbH	Emil-von-Behring Strasse 76,
Address 2	Address 3	Country Name
Marburg, D - 35041,		Germany

A red callout box with the text 'View approval history here' points to the 'Approval History' section, which displays the following table:

Approval Status	User Name	User Role	Approval Date	Comments
Completed	Carl Dolman	Admin	15/09/2021 1...	

FIGURE: Viewing Approval History of the Product MA Holder Record

You can see the approval history of the record like approval status, user approved, user role date and time of approval and comments as shown in the above figure.

Click  to copy the MA Holder record.

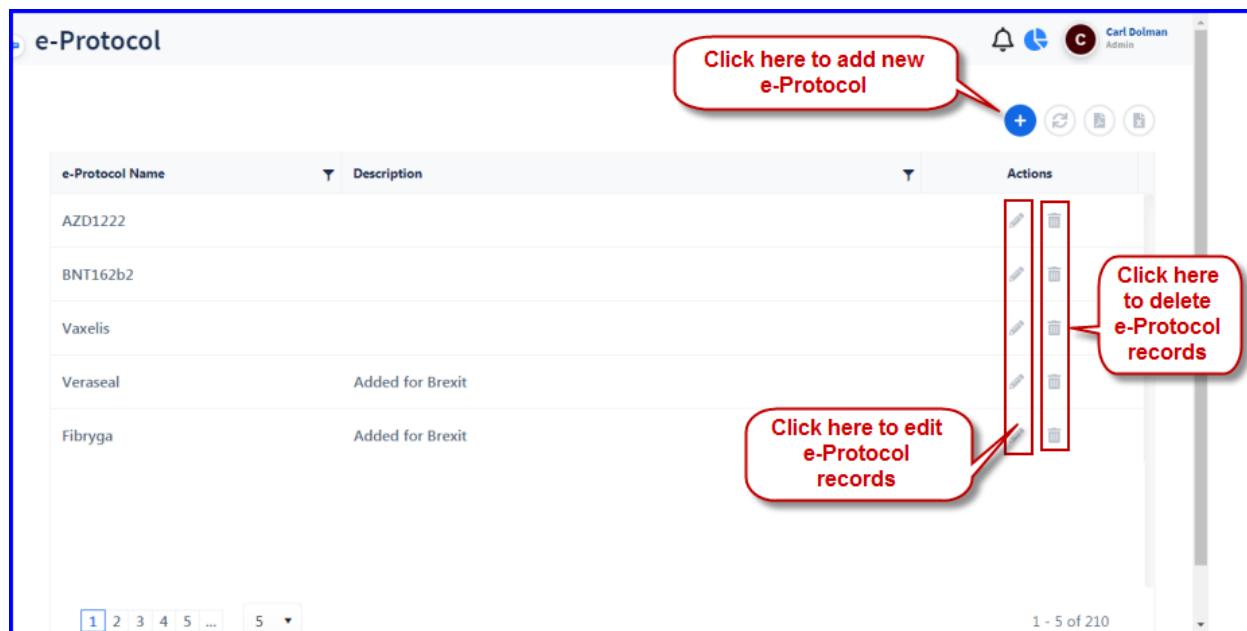
3.7.4 e-Protocol Master

e-Protocol master is used to add and manage e-protocols that are used in Add Product Manufacturer screen.

3.7.4.1 Adding a New e-Protocol

To create a new e-Protocol, follow these steps:

1. On the main menu, click , **Product** and then click **e-Protocol**. The **e-Protocol** master screen appears as shown in the figure:



The screenshot shows the 'e-Protocol' master screen. At the top, there is a header with a bell icon, a blue circle with a white dot, a user profile for 'Carl Dolman Admin', and a red callout box that says 'Click here to add new e-Protocol' with a red arrow pointing to a blue '+' button. Below the header is a table with columns: 'e-Protocol Name', 'Description', and 'Actions'. The table contains five rows of data:

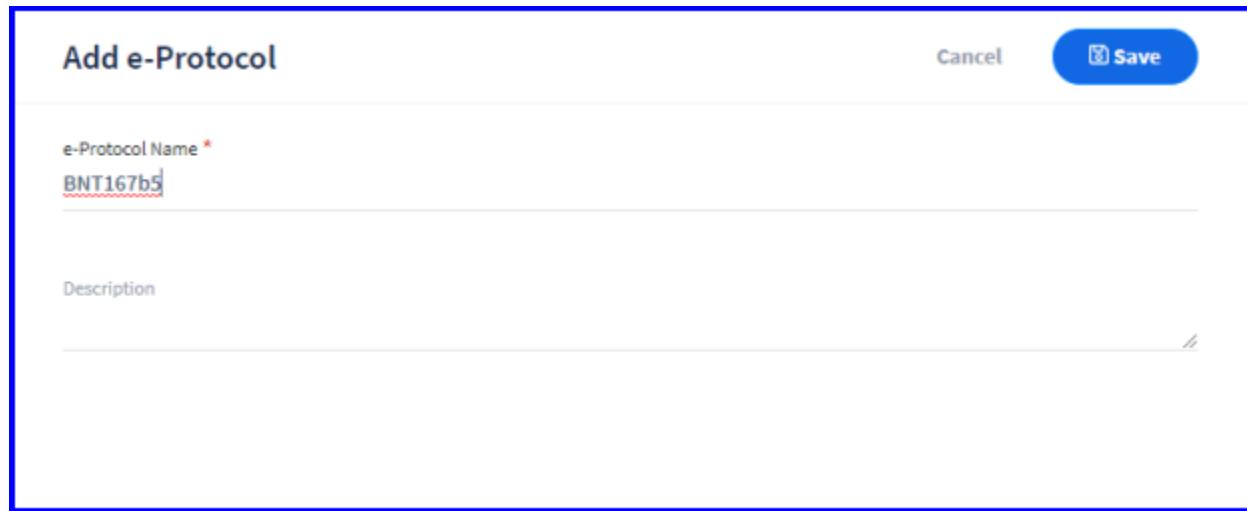
e-Protocol Name	Description	Actions
AZD1222		
BNT162b2		
Vaxelis		
Veraseal	Added for Brexit	
Fibryga	Added for Brexit	

At the bottom of the table, there is a page navigation bar with buttons for 1, 2, 3, 4, 5, ..., 5 and a dropdown menu. To the right of the table, there is a vertical scrollbar. Three red callout boxes are overlaid on the 'Actions' column: one pointing to the first row with the text 'Click here to delete e-Protocol records', one pointing to the second row with the text 'Click here to edit e-Protocol records', and one pointing to the third row with the text 'Click here to add new e-Protocol'.

FIGURE: e-Protocol Master Screen

In the e-Protocol master screen you can see the list of e-Protocols created. Options to edit and delete e-Protocols appear in each record.

2. Click . The **Add e-Protocol** screen appears as shown in the figure:



The screenshot shows the 'Add e-Protocol' dialog box. At the top, there is a title 'Add e-Protocol' and a 'Cancel' button to the right. To the far right, there is a blue rounded rectangle button with a white checkmark icon and the word 'Save'. Below the title, there is a field labeled 'e-Protocol Name *' with a red asterisk. The text 'BNT167b5' is typed into the field. Below this is a 'Description' field with a long, empty text area.

FIGURE: Add e-Protocol Dialog

3. In the **e-Protocol Name** field, type the category name.
4. In the **Description** field, type the description.

-
5. Click **Save**.

You can see the e-Protocol you just created listed in the e-Protocol master.

3.7.4.2 Editing and Deleting e-Protocol

Options to edit and delete e-Protocol appear in each record in the e-Protocol master.

1. To edit e-Protocol details, in the e-Protocol master screen, click  to edit the e-Protocol record. In the **Edit e-Protocol** screen, do required changes and then click **Save**.
2. To delete an e-Protocol, in the e-Protocol master screen, click  to delete the e-Protocol record.

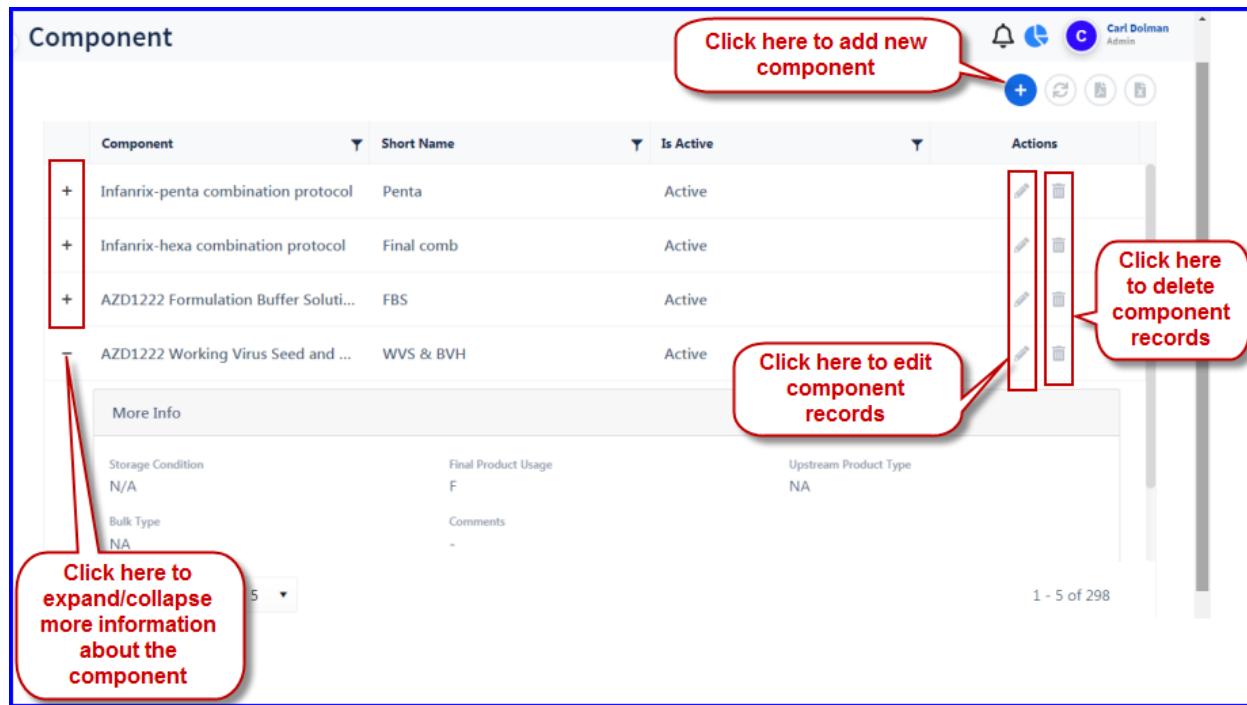
3.7.5 Component Master

Component master is used to add and manage components that are used in Study Plan Template.

3.7.5.1 Adding a New component

To create/add a new component, follow these steps:

1. On the main menu, click , **Product** and then click **Component**. The **Component** master screen appears as shown in the figure:



The screenshot shows a table of components with the following data:

Component	Short Name	Is Active	Actions
Infanrix-penta combination protocol	Penta	Active	 
Infanrix-hexa combination protocol	Final comb	Active	 
AZD1222 Formulation Buffer Soluti...	FBS	Active	 
AZD1222 Working Virus Seed and ...	WVS & BVH	Active	 

Below the table, there is a "More Info" section with the following details:

- Storage Condition: N/A
- Final Product Usage: F
- Upstream Product Type: NA
- Comments: -

On the left side of the table, there is a red callout pointing to the first row with the text: "Click here to expand/collapse more information about the component".

At the top right, there is a red callout pointing to the "Actions" column with the text: "Click here to add new component".

On the right side of the table, there are three red callouts pointing to the "Actions" column of the last two rows with the text: "Click here to edit component records", "Click here to edit component records", and "Click here to delete component records".

FIGURE: Component Master Screen

In the Component master screen you can see the list of components added. Options to edit and delete components appear in each record.

2. Click . The **Add Component** screen appears as shown in the figure:

Add Component

Cancel Save

Component *

AZD1222 Master Virus Seed and Bulk Virus Harvest

Short Name *

MVS & BVH

Comments

Is Active

Storage Condition *

N/A

Final Product Usage *

F

Upstream Product Type

Select Record...

Bulk Type

NA

FIGURE: Add Component Dialog

3. In the **Component** field, type the component name.
 4. In the **Short Name** field, type short name for the component.
 5. In the **Comments** field, type your comments.
 6. Click to turn on the **Is Active** option to make the component active.
 7. In the **Storage Condition** field, select storage condition for the component if applicable. Else, select **N/A**.
 8. In the **Final Product Usage** field, select appropriate code.
 9. In the **Upstream Product Type** field, select product type for the component.

10. In the **Bulk Type** field, select bulk type for the component.

11. Click **Save**.

You can see the component you just created listed in the Component master.

3.7.5.2 Editing and Deleting Component

Options to edit and delete component appear in each record in the Component master.

1. To edit component details, in the Component master screen, click  to edit the component record. In the **Edit Component** screen, do required changes and then click **Save**.
2. To delete a component, in the Component master screen, click  to delete the component record.

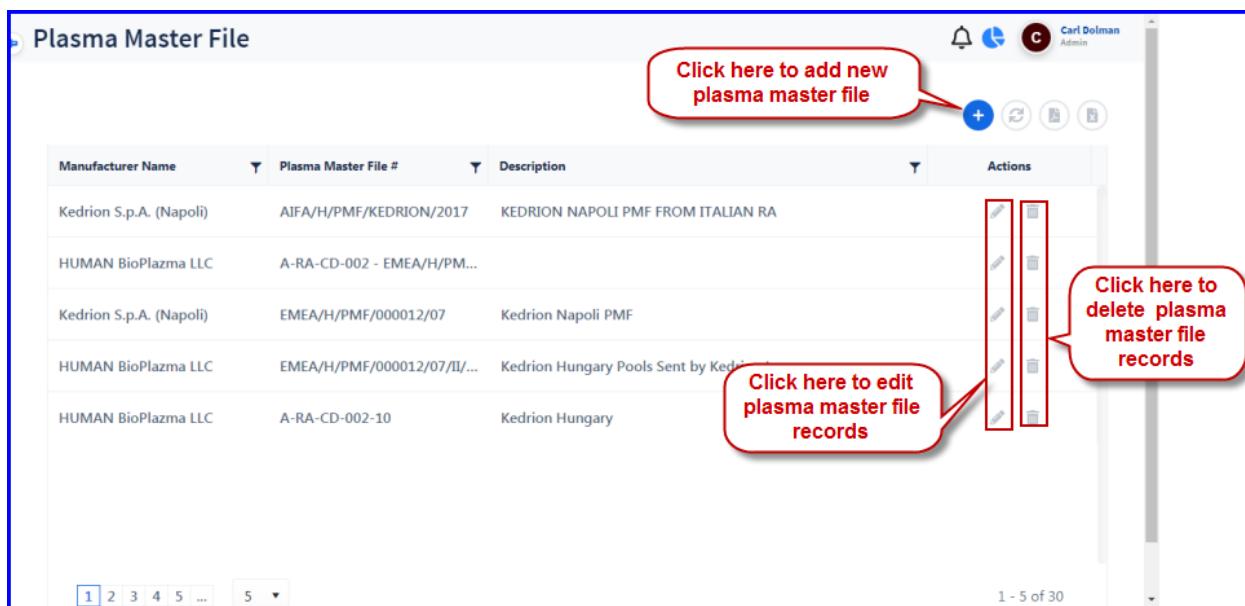
3.7.6 Plasma Master File Master

Plasma Master File master is used to add and manage plasma master file.

3.7.6.1 Adding a New Plasma Master File

To add a new plasma master file, follow these steps:

1. On the main menu, click , **Product** and then click **Plasma Master File**. The **Plasma Master File** master screen appears as shown in the figure:



Manufacturer Name	Plasma Master File #	Description	Actions
Kedrion S.p.A. (Napoli)	AIFA/H/PMF/KEDRION/2017	KEDRION NAPOLI PMF FROM ITALIAN RA	 
HUMAN BioPlazma LLC	A-RA-CD-002 - EMEA/H/PM...		 
Kedrion S.p.A. (Napoli)	EMEA/H/PMF/000012/07	Kedrion Napoli PMF	 
HUMAN BioPlazma LLC	EMEA/H/PMF/000012/07/II/...	Kedrion Hungary Pools Sent by Kedrion	 
HUMAN BioPlazma LLC	A-RA-CD-002-10	Kedrion Hungary	 

1 - 5 of 30

FIGURE: Plasma Master File Master Screen

In the Plasma Master File master screen you can see the list of master files added. Options to edit and delete plasma master files appear in each record.

2. Click . The **Add Plasma Master File** screen appears as shown in the figure:



Add Plasma Master File

Manufacturer Name *

HUMAN BioPlazma LLC

Plasma Master File # *

A-RA-CD-002-10

Description

Kedrion Hungary

Save

FIGURE: Add Plasma Master File Dialog

3. In the **Manufacturer Name** file, select manufacturer of the plasma master file.
4. In the **Plasma Master File #** field, type name of the plasma master file you want to add.
5. In the **Comments** field, type your comments.
6. Click **Save**.

You can see the plasma master file you just created listed in the Plasma Master File master.

3.7.6.2 Editing and Deleting Plasma Master File

Options to edit and delete plasma master file appear in each record in the Plasma Master File master.

1. To edit plasma master file details, in the Plasma Master File master screen, click  to edit the plasma master file record. In the **Edit Plasma Master File** screen, do required changes and then click **Save**.
2. To delete a plasma master file, in the Plasma Master File master screen, click  to delete the plasma master file record.

3.8 Test Management

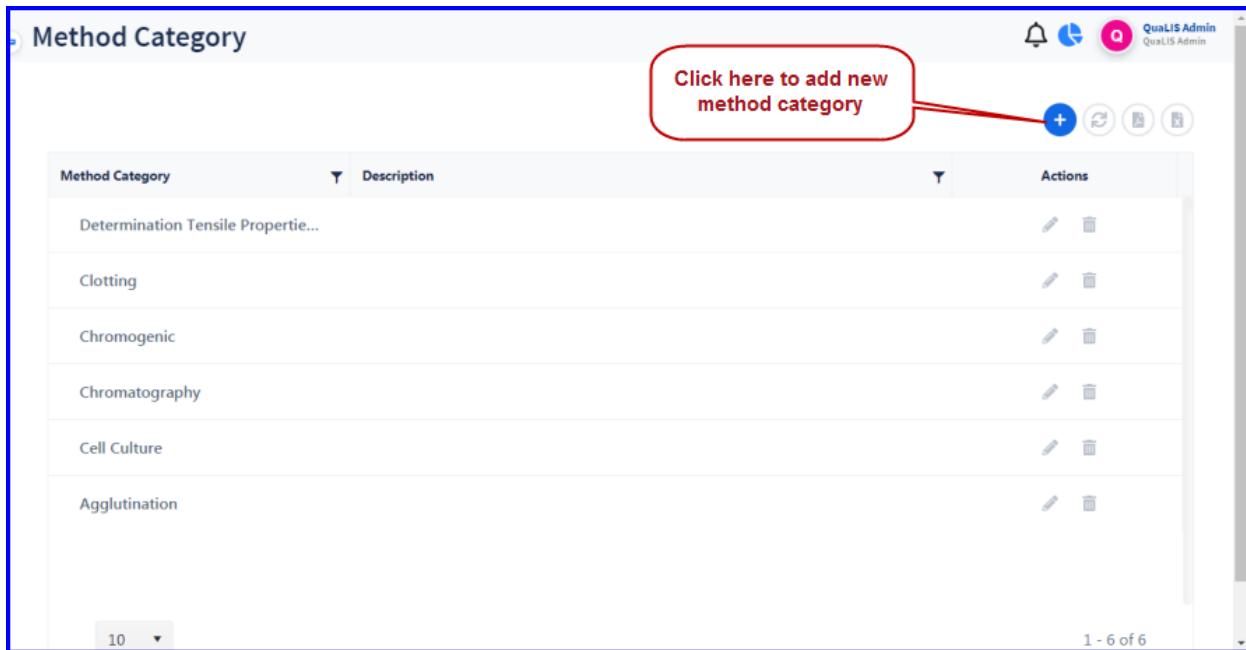
3.8.1 Method Category Master

Method category master is used to create and manage method categories that are used to group methods.

3.8.1.1 Adding a New Method Category

To create a new method category, follow these steps:

1. On the main menu, click  **Test Management** and then click **Method Category**. The **Method Category** master screen appears as shown in the figure:



Method Category	Description	Actions
Determination Tensile Propertie...		 
Clotting		 
Chromogenic		 
Chromatography		 
Cell Culture		 
Agglutination		 

FIGURE: Method Category Master Screen

In the Method Category master screen, you can see the list of categories created. Options to edit and delete categories appear in each record.

2. Click  **Add Method Category**. The **Add Method Category** dialog appears as shown in the figure:



FIGURE: Add Method Category Dialog

3. In the **Method Category** field, type the method category name you want to add.
4. In the **Description** field, type the description.
5. Click **Save**.

You can see the method category you just created listed in the Method Category master.

3.8.1.2 Editing and Deleting Method Category

Options to edit and delete method category appear in each record in the method category master.

1. To edit method category details, in the method category master screen, click  to edit the method category record. In the **Edit Method Category** screen, do required changes and then click **Save**.
2. To delete a method category, in the method category master screen, click  to delete the method category record.

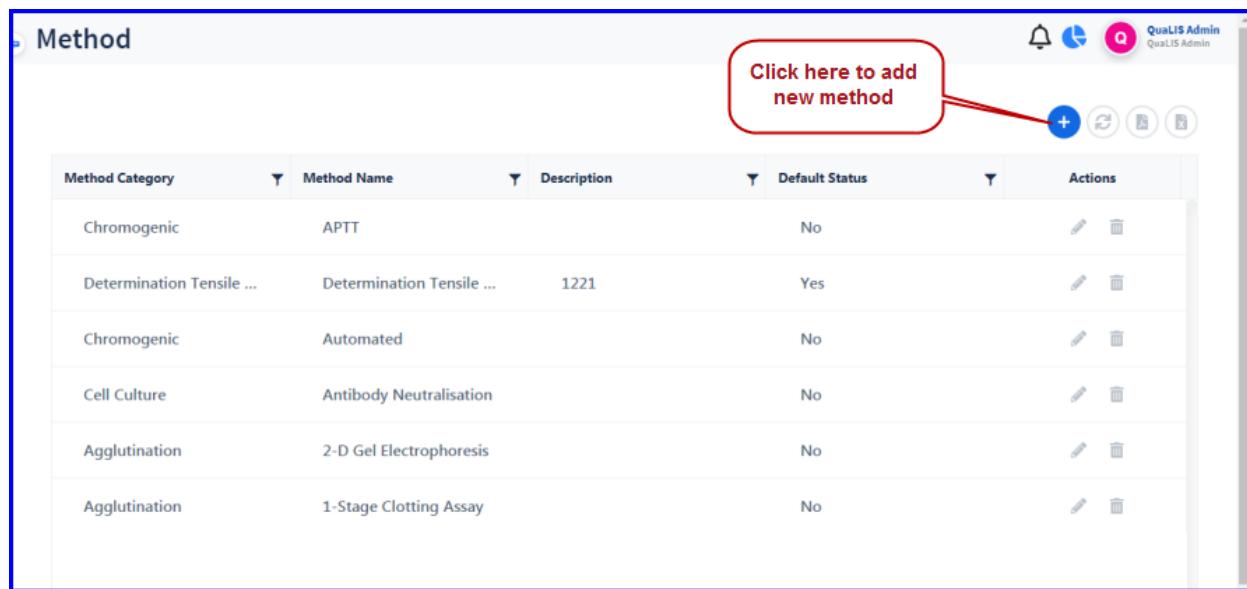
3.8.2 Method Master

Method master is used to create and manage methods that are used in test master. Methods are grouped under method category and are associated with tests.

3.8.2.1 Adding a New Method

To create a new method, follow these steps:

1. On the Explorer, click , **Test Management** and then click **Method**. The **Method** master screen appears as shown in the figure:



The screenshot shows a table titled 'Method' with columns: Method Category, Method Name, Description, Default Status, and Actions. The table contains six rows of data. A red callout box with the text 'Click here to add new method' points to a blue '+' button in the top right corner of the table header.

Method Category	Method Name	Description	Default Status	Actions
Chromogenic	APTT		No	 
Determination Tensile ...	Determination Tensile ...	1221	Yes	 
Chromogenic	Automated		No	 
Cell Culture	Antibody Neutralisation		No	 
Agglutination	2-D Gel Electrophoresis		No	 
Agglutination	1-Stage Clotting Assay		No	 

FIGURE: Method Master Screen

In the Method master screen you can see the list of methods added. Options to edit and delete methods appear in each record.

2. Click . The **Add Method** dialog appears as shown in the figure:



The dialog has a title 'Add Method' and a 'Save' button. It contains the following fields:

- Method Category **Chromogenic**
- Method Name **APTT**
- Description (empty)
- Default Status (switch is off)

FIGURE: Add Method Dialog

3. In the **Method Category** field, select category to group the method you want to create.

4. In the **Method Name** field, type the method name you want to create.
5. In the **Descriptions** field, type descriptions if any.
6. Click to turn on the **Default Status** option to make the method active.
7. Click **Save**.

You can see the method you just added listed in the Method master.

3.8.2.2 Editing and Deleting Method

Options to edit and delete methods appear in each record in the method master.

1. To edit method details, in the method master screen, click  to edit the method record. In the **Edit Method** screen, do required changes and then click **Save**.
2. To delete a method, in the method master screen, click  to delete the method record.

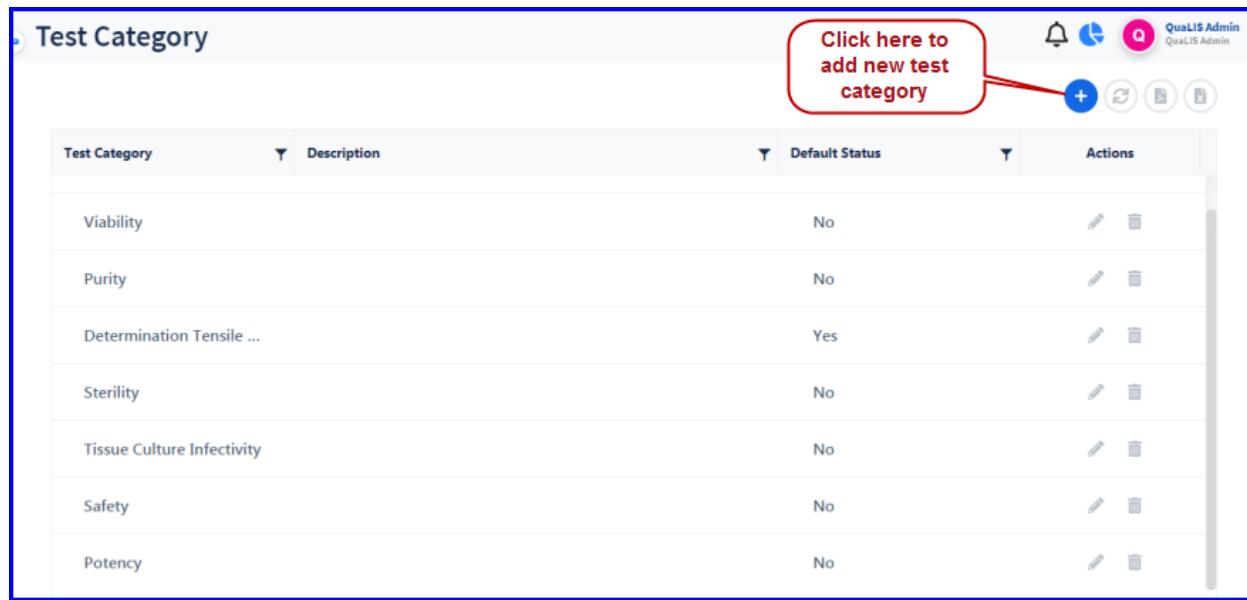
3.8.3 Test Category Master

Test category master is used to create and manage test categories that are used to group tests.

3.8.3.1 Adding a New Test Category

To create a new test category, follow these steps:

1. On the main menu, click , **Test Management** and then click **Test Category**. The **Test Category** master screen appears as shown in the figure:



Test Category	Description	Default Status	Actions
Viability		No	 
Purity		No	 
Determination Tensile ...		Yes	 
Sterility		No	 
Tissue Culture Infectivity		No	 
Safety		No	 
Potency		No	 

FIGURE: Test Category Master Screen

In the Test Category master screen you can see the list of categories created. Options to edit and delete test categories appear in each record.

2. Click  . The Add Test Category dialog appears as shown in the figure:



The dialog has the following fields:

- Test Category ***: Detection
- Description**: (empty text area)
- Default Status**: (checkbox is off)

FIGURE: Add Test Category Dialog

3. In the **Test Category** field, type the test category name.
4. In the **Description** field, type the description.
5. Click to turn on the **Default Status** option to make the test category active.

6. Click **Save**.

You can see the test category you just created listed in the Test Category master.

3.8.3.2 Editing and Deleting Test Category

Options to edit and delete test category appear in each record in the test category master.

1. To edit test category details, in the test category master screen, click  to edit the test category record. In the **Edit Test Category** screen, do required changes and then click **Save**.
2. To delete a test category, in the test category master screen, click  to delete the test category record.

3.8.4 Test Master

Test master is used to create and manage tests. Tests are grouped under test categories.

Test master enables to do the following:

- Create new test
- Edit or delete tests
- Create new test by copying a test
- Add lab, method, file and instrument to the test
- Add parameter, formula and specification to the test

3.8.4.1 Adding a New Test

To create a new test, follow these steps:

1. On the Explorer, click  **Test Management** and then click **Test Master**. The Test master screen appears as shown in the figure:

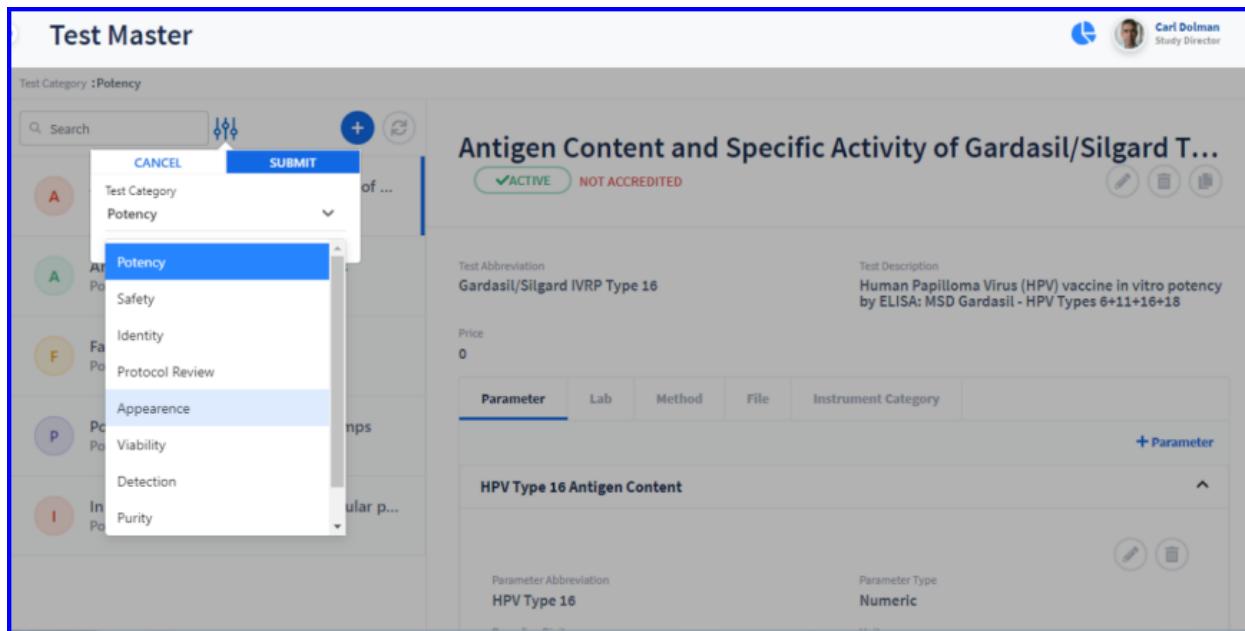


FIGURE: Test Master Screen

2. In the filter , select the **Test Category** and then click **Submit**. Tests that are added to the selected test category will appear as shown in the figure:

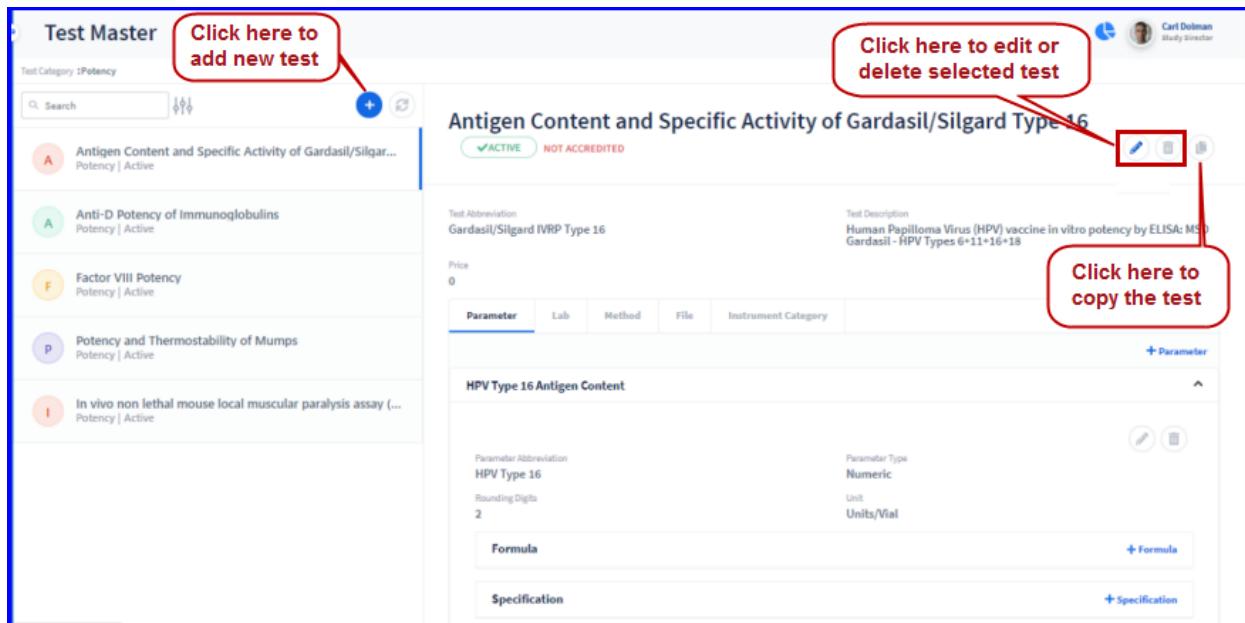
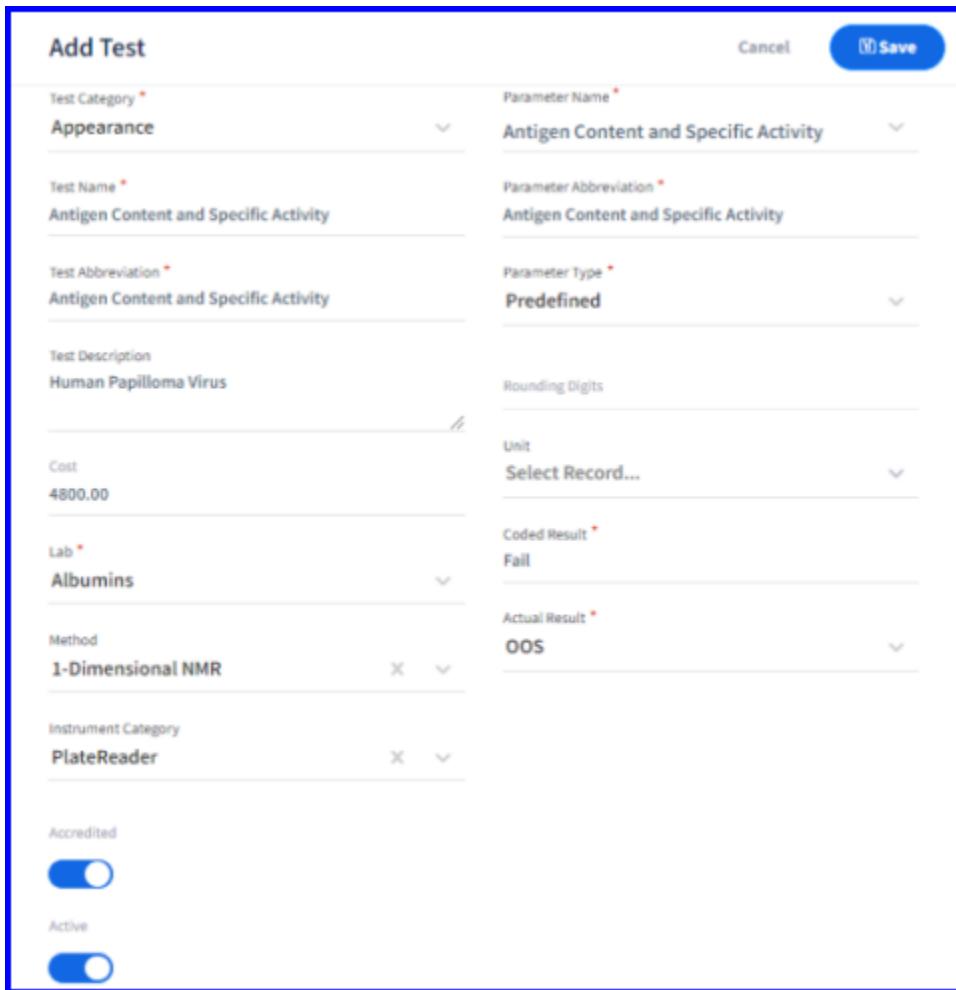


FIGURE: Test Master Showing Tests in the Selected Test Category

Options to edit, delete and copy test appear as shown in the above figure.

3. Click . The **Add Test** dialog appears as shown in the figure:



The screenshot shows the 'Add Test' dialog box. The fields and their current values are:

- Test Category:** Appearance
- Test Name:** Antigen Content and Specific Activity
- Test Abbreviation:** Antigen Content and Specific Activity
- Test Description:** Human Papilloma Virus
- Cost:** 4800.00
- Lab:** Albumins
- Method:** 1-Dimensional NMR
- Instrument Category:** PlateReader
- Accredited:** (checkbox is checked)
- Active:** (checkbox is checked)
- Parameter Name:** Antigen Content and Specific Activity
- Parameter Abbreviation:** Antigen Content and Specific Activity
- Parameter Type:** Predefined
- Rounding Digits:** (empty)
- Unit:** Select Record...
- Coded Result:** Fail
- Actual Result:** OOS

FIGURE: Add Test Dialog

4. In the **Test Category** field, select category to group the test you want to create.
5. In the **Test Name** field, type the test name you want to create.
6. In the **Test Abbreviation** field, type abbreviation for the test.
7. In the **Test Description** field, type description or comments for the test if any.
8. In the **Cost** field, type test price.
9. From the **Lab** field, select the lab name to map to the test.
10. In the **Method** field, select the method to be used while testing.

11. In the **Instrument Category** field, select the instrument category to be used for testing.
12. In the **Parameter Name** field, type a parameter to add to the test.
13. In the **Parameter Abbreviation** field, type an abbreviation for the parameter.
14. From the **Parameter Type** field, select parameter type. i.e. Numeric / Character /Predefined.
 - For Numeric parameter type: **Unit** field becomes mandatory.
 - For Character parameter type: **Coded Result** and **Actual Result** fields are mandatory.
15. In the **Rounding Digits** field, mention the number of digits allowed for rounding.
16. From the **Unit** field, select the unit for measurement of the sample/test.
17. In the **Coded Result** field, type the code for result: Example: Pass / Fail.
18. In the **Actual Result** field, select the code from the list.
19. Fill in other fields as required.
20. Turn on the **Accredited** option to enable certification.
21. Turn on then **Active** option to make the test active.
22. Click **Save**.

You can see the Test you just added listed in the Test master in the selected test category.

3.8.4.2 Editing and Deleting Test

Options to edit and delete test appear in each record in the test master.

1. To edit test details, in the test master screen, click  to edit the test record. In the **Edit Test** screen, do required changes and then click **Save**.
2. To delete a test, in the test master screen, click  to delete the test record.

3.8.4.3 Adding Parameters to the Test

1. In the **Test Master** screen, select the test you want to add parameter.
2. Go to the **Parameter** tab. The **Parameter** tab appears as shown in the figure:

Antigen Content and Specific Activity of Gardasil/Silgard Type 16

ACTIVE NOT ACCREDITED

Test Abbreviation: Gardasil/Silgard IVRP Type 16

Test Description: Human Papilloma Virus (HPV) vaccine in vitro potency by ELISA: MSD Gardasil - HPV Types 6+11+16+18

Price: 0

Parameter	Lab	Method	File	Instrument Category
-----------	-----	--------	------	---------------------

HPV Type 16 Antigen Content

Parameter Abbreviation: HPV Type 16

Parameter Type: Numeric

Rounding Digits: 2

Unit: Units/Vial

Formula: [+ Formula](#)

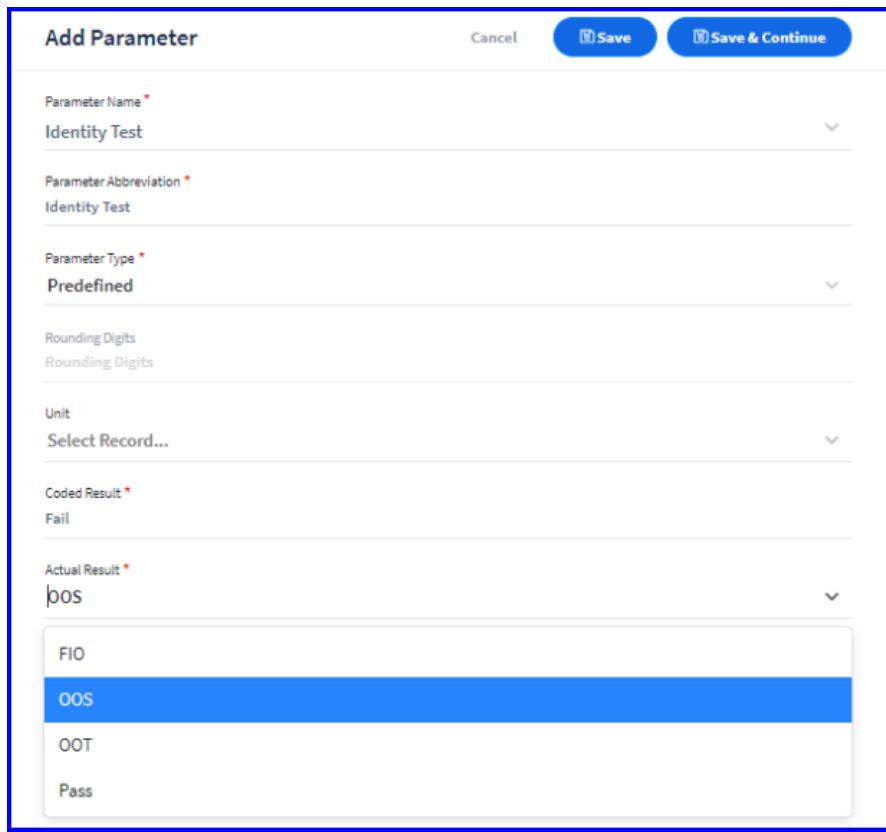
Specification: [+ Specification](#)

Click here to add new parameter

[+ Parameter](#)

FIGURE: Parameter Tab

3. Click **+ Parameter**. The **Add Parameter** dialog appears as shown in the figure:



The screenshot shows the 'Add Parameter' dialog box. At the top, there are buttons for 'Cancel', 'Save', and 'Save & Continue'. The 'Parameter Name' field contains 'Identity Test'. The 'Parameter Abbreviation' field also contains 'Identity Test'. Under 'Parameter Type', 'Predefined' is selected. In the 'Rounding Digits' field, 'Rounding Digits' is typed. The 'Unit' field has 'Select Record...' and is currently empty. The 'Coded Result' field contains 'Fail'. In the 'Actual Result' field, 'DOS' is typed. Below this, a dropdown menu is open with options: FIO, DOS (which is highlighted in blue), OOT, and Pass.

FIGURE: Add Parameter Dialog

4. In the **Parameter Name** field, type a parameter to add to the test.
5. In the **Parameter Abbreviation** field, type an abbreviation for the parameter.
6. From the **Parameter Type** field, select parameter type. i.e. Numeric / Character /Predefined. Based on the selected parameter type, fill in the following mandatory fields:
 - In the **Rounding Digits** field, mention the number of digits allowed for rounding (For numeric parameters).
 - From the **Unit** field, select the unit for measurement of the sample/test.
 - In the **Coded Result** field, type the code for result: Example: Pass / Fail.
 - In the **Actual Result** field, select the code from the list.
7. Fill in other fields as required.
8. Click **Save** to save the parameter.

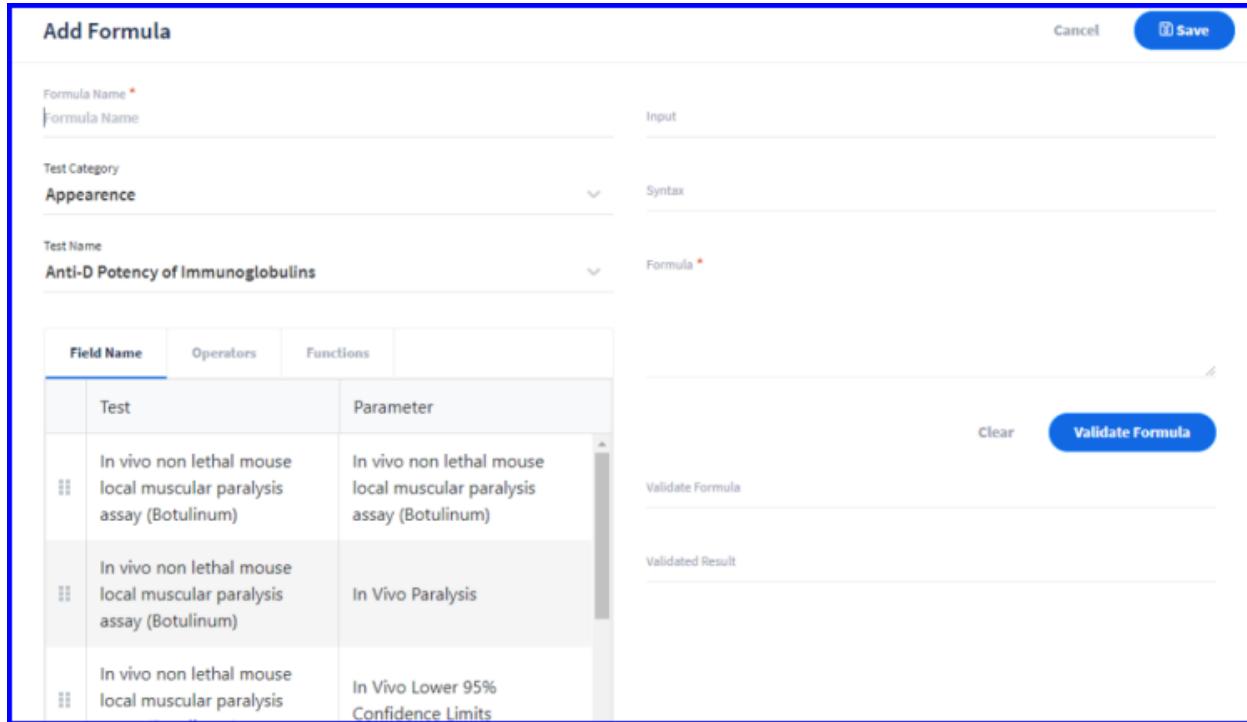
9. Click **Save and Continue** to add another parameter to the test.

You can see the parameter you just added listed in the Parameter tab.

3.8.4.4 Add Formula

Once you add parameters to the test, you can add formula to the selected parameter. To do so, follow these steps:

1. In the **Parameter** tab, select numeric parameter and then click **+ Formula**. The **Add Formula** screen appears as shown in the figure:



The screenshot shows the 'Add Formula' interface. At the top, there are fields for 'Formula Name' (with a red asterisk), 'Test Category' (set to 'Appearance'), and 'Test Name' (set to 'Anti-D Potency of immunoglobulins'). Below these are four tabs: 'Input', 'Syntax', 'Formula' (with a red asterisk), and 'Validate Formula'. A 'Validate Result' section is also present. On the left, there is a table with columns 'Field Name', 'Operators', 'Functions', and 'Input'. The table contains three rows of data:

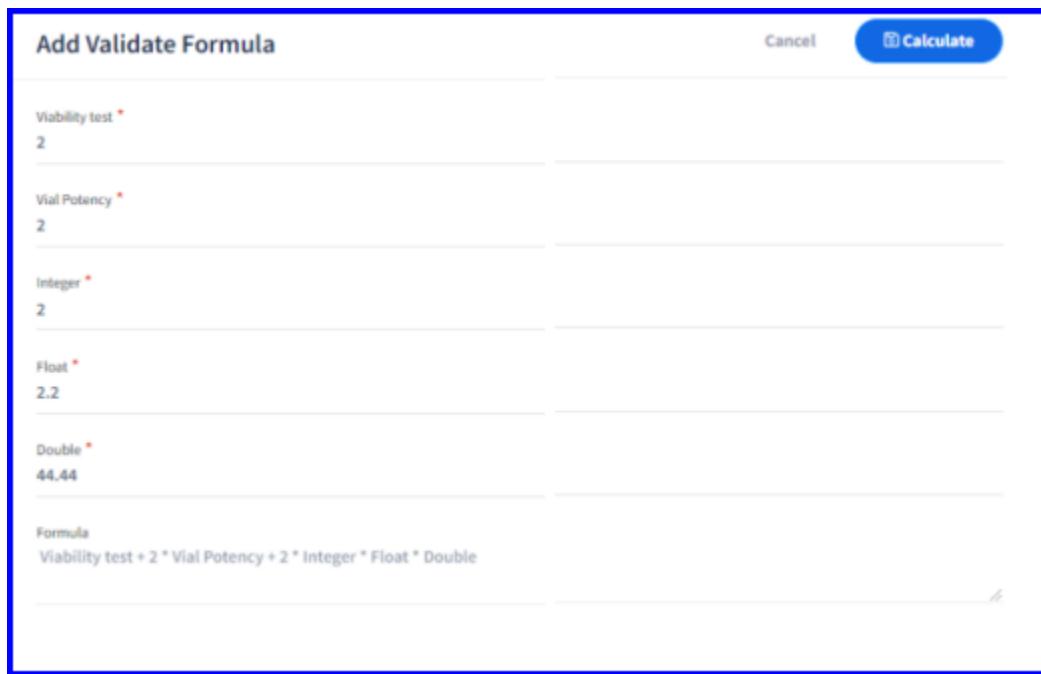
Field Name	Operators	Functions	Input
In vivo non lethal mouse local muscular paralysis assay (Botulinum)			In vivo non lethal mouse local muscular paralysis assay (Botulinum)
In vivo non lethal mouse local muscular paralysis assay (Botulinum)			In Vivo Paralysis
In vivo non lethal mouse local muscular paralysis			In Vivo Lower 95% Confidence Limits

FIGURE: Add Formula Screen

You can create and test formula using the fields, operators and functions available in the formula screen.

2. In the **Formula Name** field, type name for the formula you create.
3. In the **Test Category** field, select the test category you want to create formula.
4. In the **Test Name** field, select the test you want to create formula.
5. Use the **Field Name**, **Operators**, **Functions** and **Input** fields to create a formula.

6. You can click  that appears near the fields, operators and functions to drag **Field Name**, **Operators** and **Functions** and drop in the **Formula** field.
7. In the **Input** field, type a numeric value and then press ENTER to add to the formula.
8. The **Syntax** field gives you suggestions when you type a formula.
9. Click **Clear** to clear formula if required. When you click **Clear**, the entire formula is cleared and you need to build the formula from the scratch.
10. Click **Validate Formula** to validate the formula. The **Add Validate Formula** dialog appears as shown in the figure:



The screenshot shows the 'Add Validate Formula' dialog box. It has a title bar with 'Add Validate Formula', a 'Cancel' button, and a 'Calculate' button. Below the title bar are five input fields with validation requirements (indicated by a red asterisk):

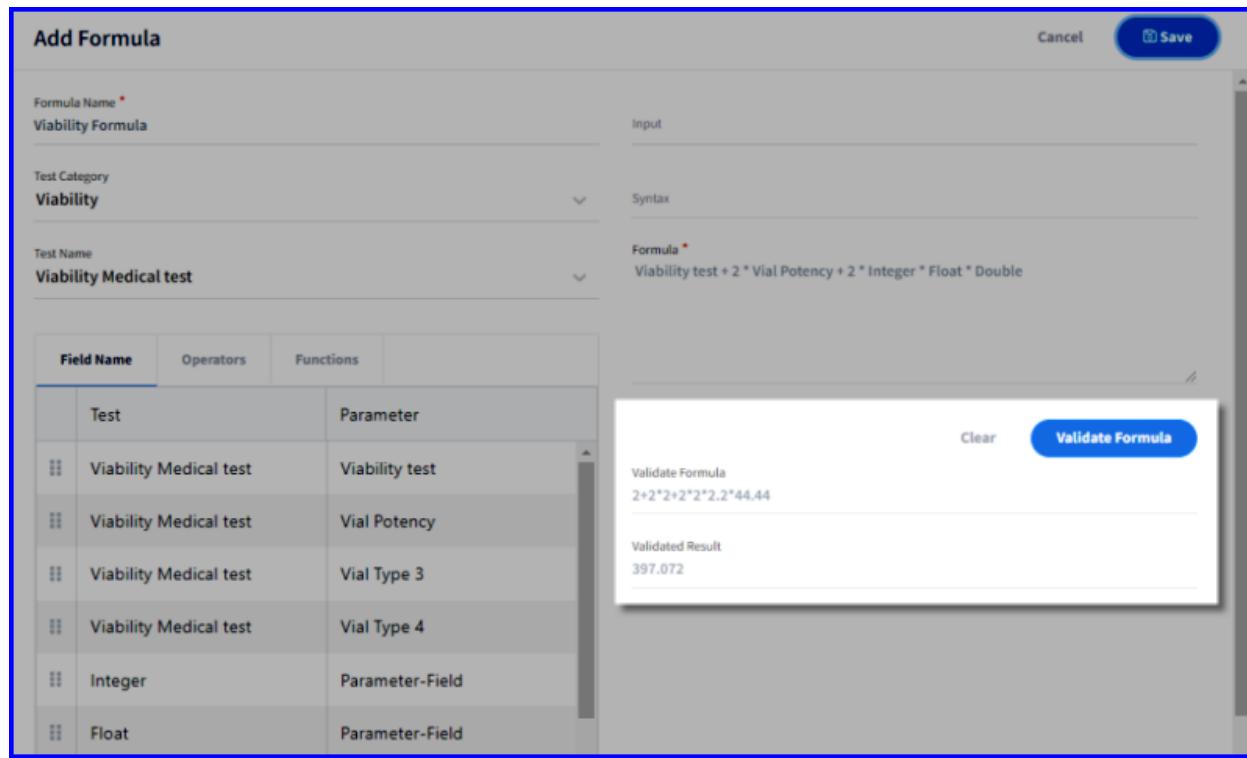
- Viability test *
- Vial Potency *
- Integer *
- Float *
- Double *

Each input field contains a numerical value: 2, 2, 2, 2.2, and 44.44 respectively. Below these fields is a 'Formula' field containing the expression: `Viability test + 2 * Vial Potency + 2 * Integer * Float * Double`.

FIGURE: Validate Formula

11. Fields in the formula appears. Type value for the fields and then click **Calculate**.

You can see the validated result as shown in the figure:



The screenshot shows the 'Add Formula' dialog box. At the top, there are fields for 'Formula Name' (Viability Formula), 'Test Category' (Viability), and 'Test Name' (Viability Medical test). Below these, a table lists fields and their types:

Field Name	Operators	Functions
Test		Parameter
Viability Medical test		Viability test
Viability Medical test		Vial Potency
Viability Medical test		Vial Type 3
Viability Medical test		Vial Type 4
Integer		Parameter-Field
Float		Parameter-Field

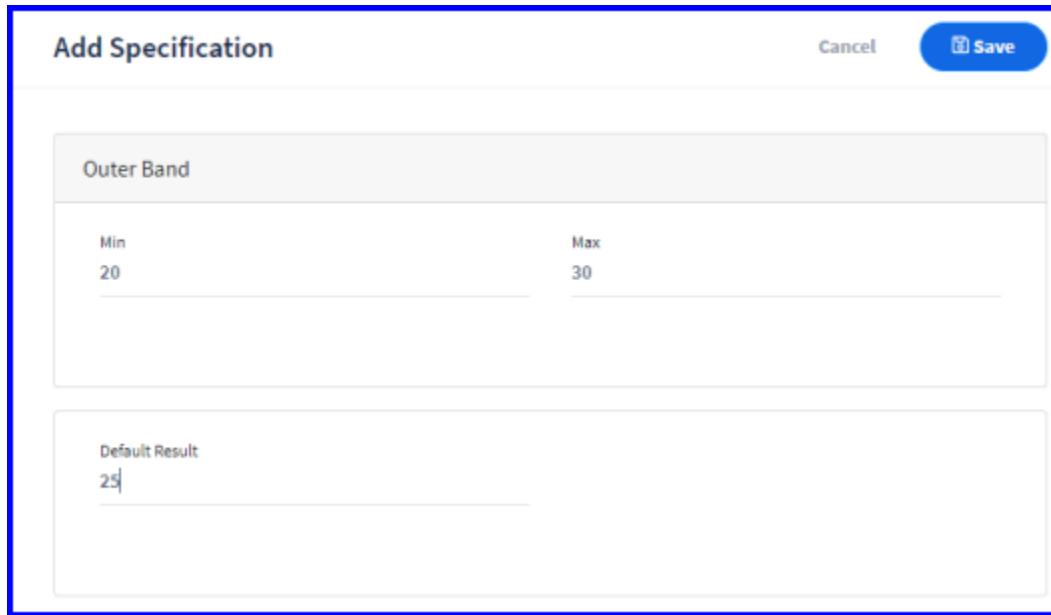
On the right, there is a validation result window with a 'Validate Formula' button. The window shows the formula $2+2*2+2*2*2.2*44.44$ and the validated result 397.072.

FIGURE: Result Calculated

3.8.4.5 Add Specifications to the Parameter

Once you add formula to the test, you can add specifications to the parameter. To do so, follow these steps:

1. Click **+ Specification**. The **Add Specification** dialog appears as shown in the figure:



Outer Band

Min
20

Max
30

Default Result
25

Save

FIGURE: Add Specification Dialog

You need to set minimum and maximum values for the outer band here.

2. In the **Min** field, type minimum value for the outer band.
3. In the **Max** field, type maximum value for the outer band.
4. In the **Default Result** field, type default value for the test.
5. Click **Save**.

You can add only one specification for the test.

3.8.4.6 Map Labs to Test

1. In the **Test Master** screen, select the test you want to add lab/s.
2. Go to the **Lab** tab. The **Lab** tab appears as shown in the figure:

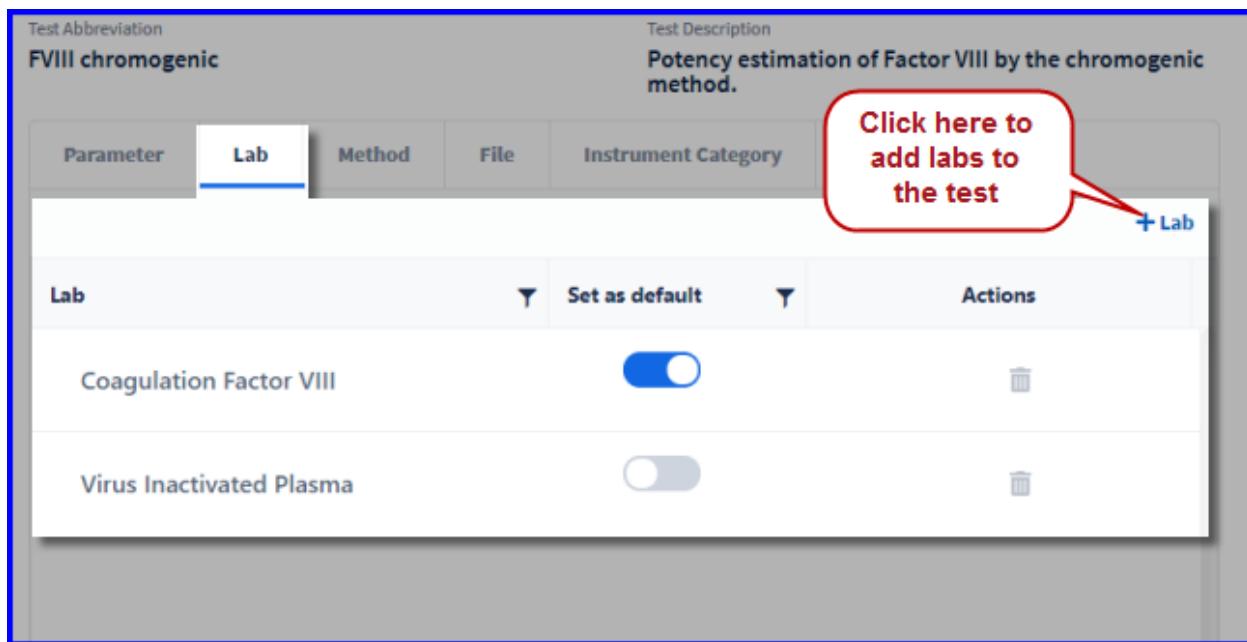


FIGURE: Test master – Lab Tab

3. Click **+ Lab**. The **Add Lab** screen appears as shown in the figure:

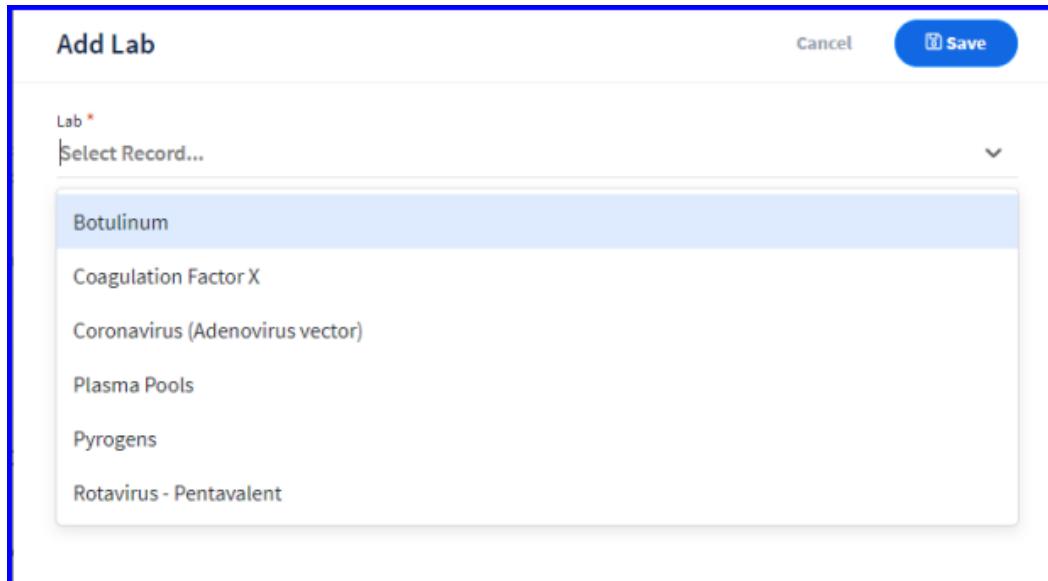


FIGURE: Test master – Add Lab Dialog

4. In the **Lab** field, click to select the lab/s to map to the selected test.
5. Click **Save**. You can see the lab you just added to the test listed in the **Lab** tab as shown in the figure:

Parameter	Lab	Method	File	Instrument Category	
					+ Lab
Lab					
Cholera				<input type="checkbox"/>	
Albumins				<input checked="" type="checkbox"/>	

FIGURE: Labs Added to the Selected Test

Each lab added appears in a row with **Set as default** and **Actions** fields.

6. You can turn on **Set as default** option to make the lab default lab.
7. Click  to delete the lab.

3.8.4.7 Add Methods to Test

1. In the **Test Master** screen, select the test you want to add method/s.
2. Go to the **Method** tab.
3. Click . The **Add Method** screen appears as shown in the figure:

Add Method
[Cancel](#)
 Save

Method *

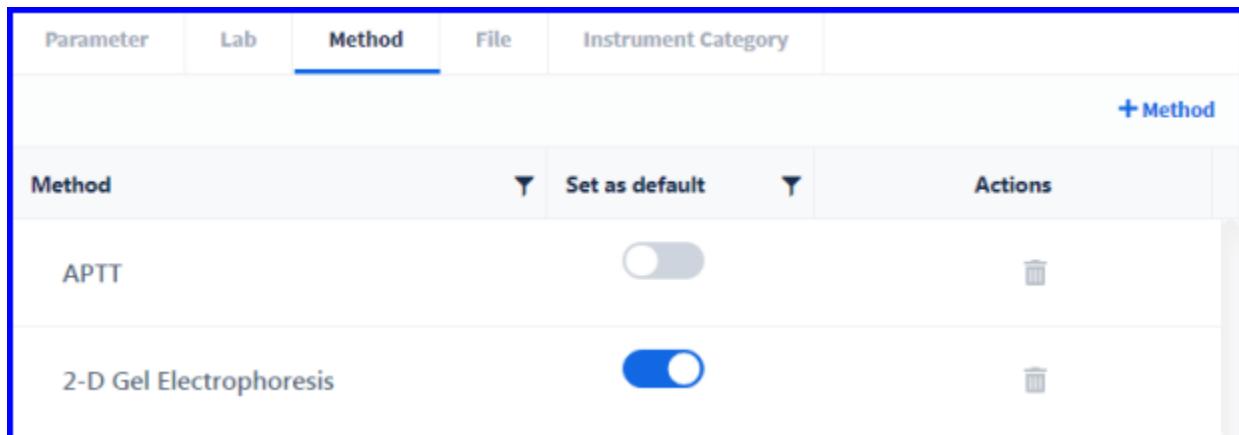
2-D Gel Electrophoresis 
APTT 



1-Stage Clotting Assay
Antibody Neutralisation
Automated
Determination Tensile Properties Method

FIGURE: Test master – Add Method Screen

4. You can see the list of methods available here. Click to select the method/s to map to the selected test.
5. Click **Save**. You can see the method you just added to the test listed in the **Method** tab as shown in the figure:



Parameter	Lab	Method	File	Instrument Category
+ Method				
Method		Set as default		Actions
APTT		<input type="checkbox"/>		
2-D Gel Electrophoresis		<input checked="" type="checkbox"/>		

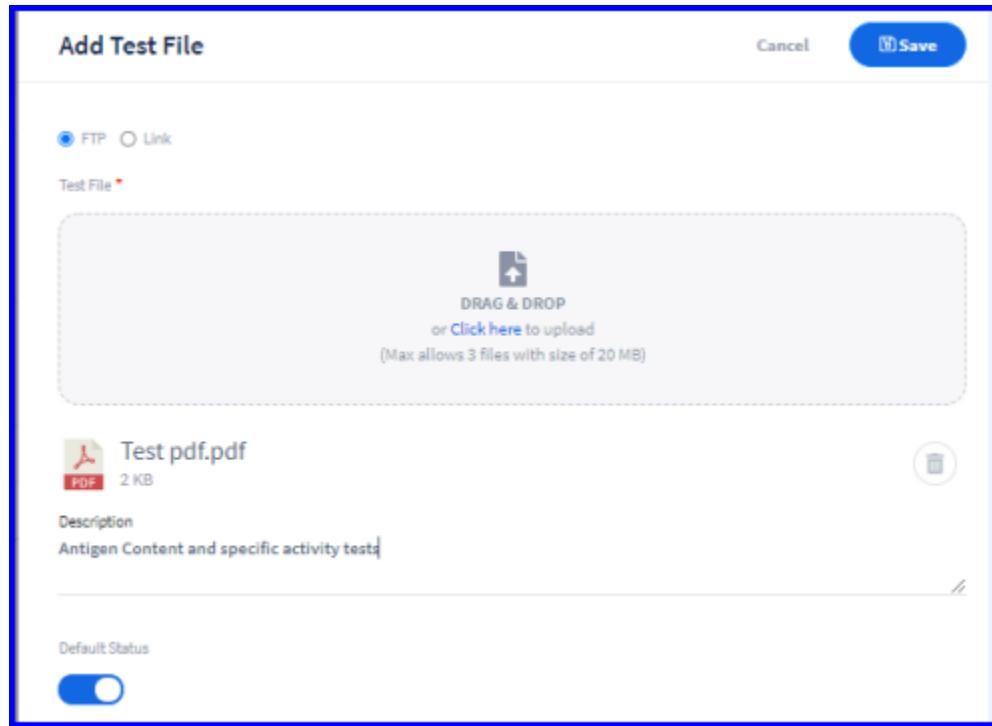
FIGURE: Test master – List of Add Methods Added to the Test

Each method added appears in a row with **Set as default** and **Actions** fields.

6. You can turn on **Set as default** option to make the method default method.
7. Click  to delete the method.

3.8.4.8 Attach Files to Test

1. In the **Test Master** screen, select the test you want to attach file/s.
2. Go to the **File** tab. The **File** tab appears.
3. Click **+ File**. The **Add Test File** screen appears as shown in the figure:



Add Test File

FTP Link

Test File *

DRAG & DROP
or [Click here](#) to upload
(Max allows 3 files with size of 20 MB)

 Test pdf.pdf 2 KB 

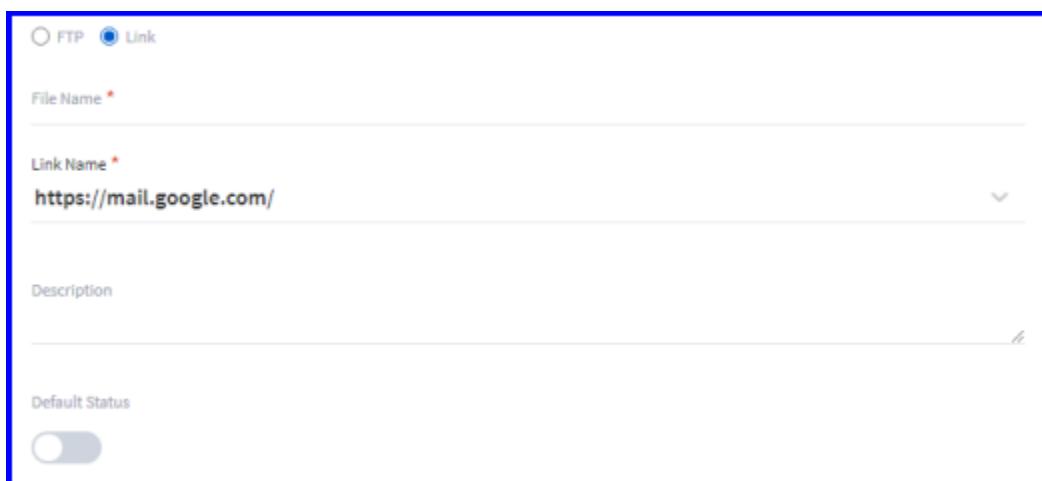
Description
Antigen Content and specific activity tests

Default Status 

Save

FIGURE: Test master – Add Test File Screen

4. Click **FTP** to upload file from the local drive.
 - In the **Test File** field, drag and drop the file or click **Click here** and locate the file from the local drive.
5. Click **Link** to upload a link. The screen appears as shown in the figure:



FTP Link

File Name *

Link Name *

<https://mail.google.com/>

Description

Default Status 

FIGURE: Test master – Add Test File – Link Option

- In the **File Name** field, type the file name.

- In the **Link Name** field, paste the link.
6. In the **Description** field, type description for the test file if any.
 7. Click to turn on the **Default Status** option to make the test file category active.
 8. Click **Save**. You can see the file you just added to the test listed in the **File** tab

3.8.4.9 Attach Instruments to Test

1. In the **Test Master** screen, select the test you want to map instrument categories.
2. Go to the **Instrument Categories** tab. The **Instrument Category** tab appears as shown in the figure:

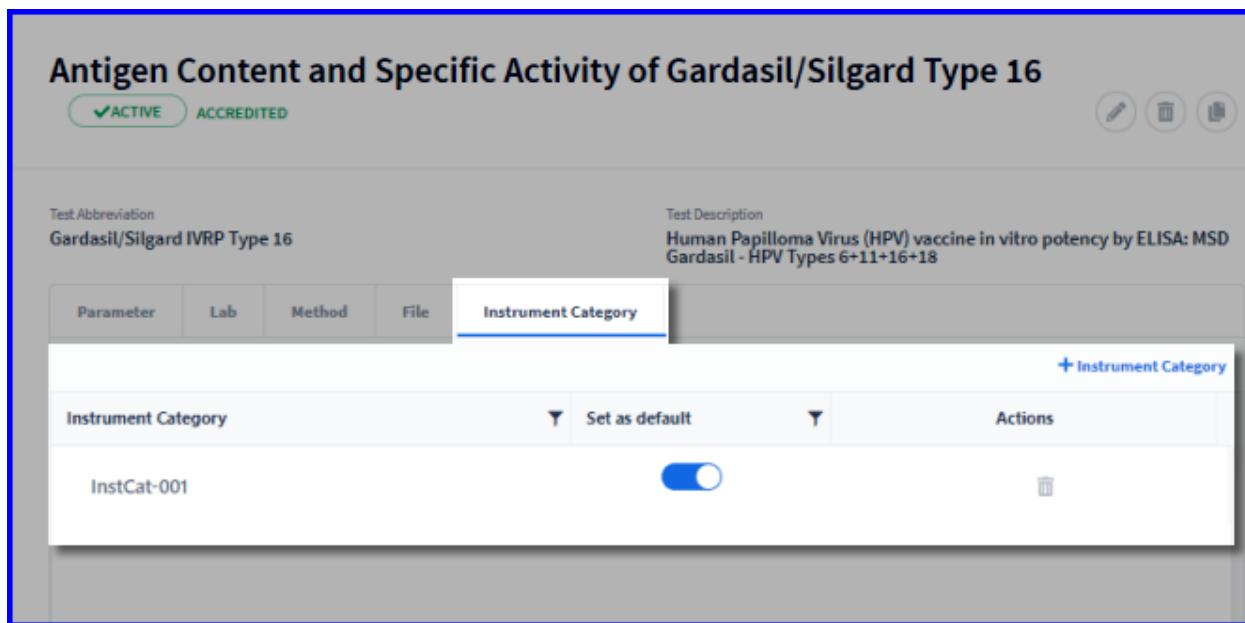


FIGURE: Test Master – Instrument Category Tab

3. Click **+ Instrument Category**. The **Add Instrument Category** dialog appears as shown in the figure:

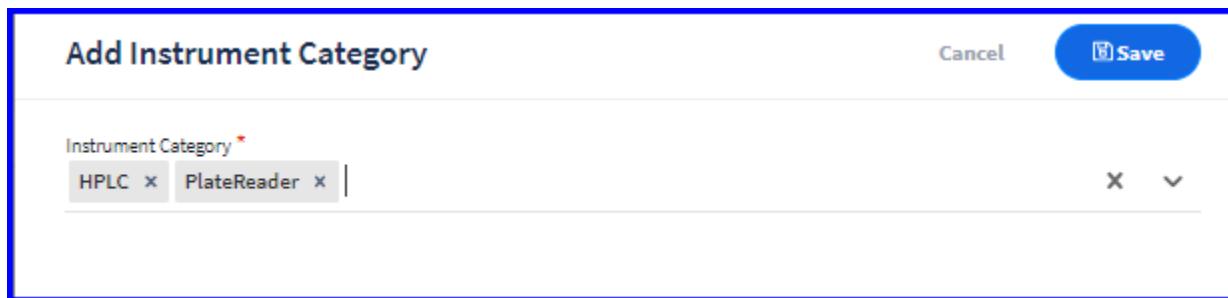


FIGURE: Add Instrument Category Dialog

4. In the **Instrument Category** field, click to select the instrument categories to map to the selected test.
5. Click **Save**. You can see the instrument categories you just added to the test listed in the **Instrument Categories** tab.

Each instrument category added appears in a row with **Set as default** and **Actions** fields.

6. You can turn on **Set as default** option to make the instrument category default instrument category.
7. Click  to delete the instrument category.

3.9 Instrument Management

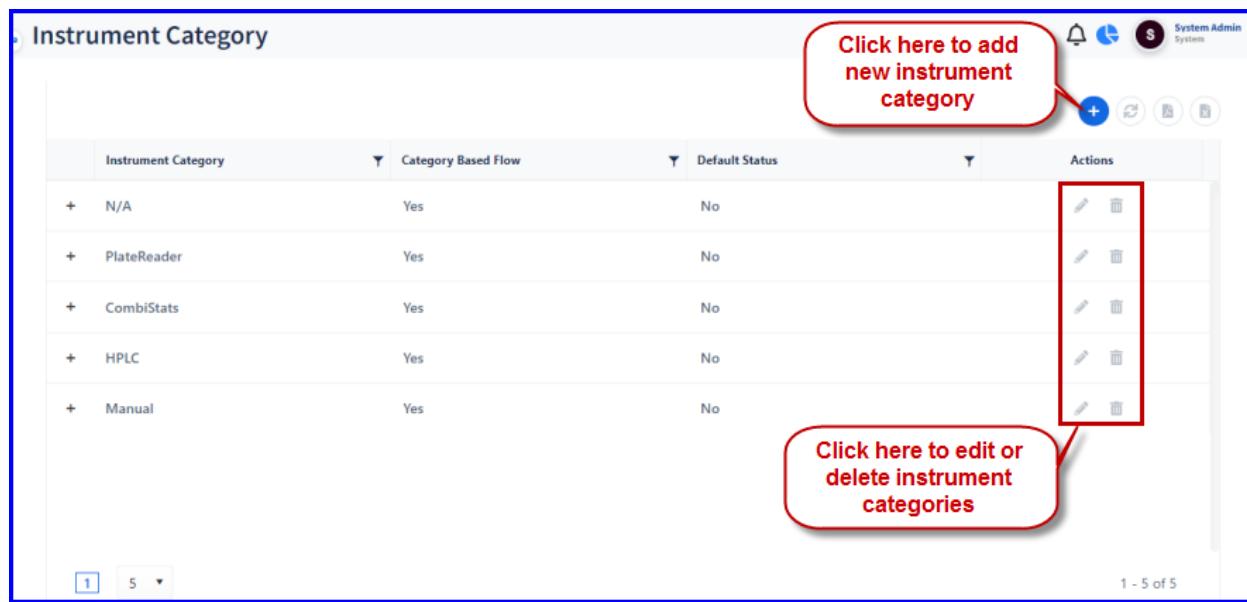
3.9.1 Instrument Category

Instrument category master is used to create and manage instrument categories that are used to group instruments.

3.9.1.1 Creating a New Instrument Category

To create a new instrument category, follow these steps:

1. On the main menu, click , **Instrument Management** and then click **Instrument Category**. The **Instrument Category** master screen appears as shown in the figure:



The screenshot shows a table titled 'Instrument Category' with columns: 'Instrument Category', 'Category Based Flow', 'Default Status', and 'Actions'. The table contains five rows with data: N/A (Yes, No), PlateReader (Yes, No), CombiStats (Yes, No), HPLC (Yes, No), and Manual (Yes, No). A red callout box points to the top right of the table area with the text 'Click here to add new instrument category'. Another red callout box points to the 'Actions' column of the first row with the text 'Click here to edit or delete instrument categories'.

Instrument Category	Category Based Flow	Default Status	Actions
+	N/A	Yes	No
+	PlateReader	Yes	No
+	CombiStats	Yes	No
+	HPLC	Yes	No
+	Manual	Yes	No

FIGURE: Instrument Category Master Screen

In the Instrument Category master screen you can see the list of instrument categories created. Options to edit and delete instrument category appears in each record.

2. Click . The **Add Instrument Category** dialog appears as shown in the figure:

Instrument Category *

Interfacer

Description

Interfacer Inst Category

Technique *

ELISA

Interface type *

LogiLab

Category Based Flow

Default Status

FIGURE: Add Instrument Category Dialog

3. In the **Instrument Category** field, type the instrument category name you want to create.
4. In the **Description** field, type the description.
5. In the **Technique** field, select the technique name to map instrument.
6. In the **Interface Type** field, select Logilab / Interfacer. Here you group the instrument if it is Interfacer instrument or LogiLab instrument.
7. Click to check **Category Based Flow** field if applicable.
8. Click to turn on the **Default Status** option to make the instrument category active.
9. Click **Save**.

You can see the instrument category you just created listed in the Instrument Category master.

3.9.1.2 Editing and Deleting Instrument Category

Options to edit and delete instrument category appear in each record in the instrument category master.

1. To edit instrument category details, in the instrument category master screen, click  to edit the instrument category record. In the **Edit Instrument Category** screen, do required changes and then click **Save**.
2. To delete a instrument category, in the instrument category master screen, click  to delete the instrument category record.

3.9.2 Instrument Master

Instrument master is used to add and manage instruments in Qualis LIMS. Instruments are grouped under Instrument Categories.

3.9.2.1 Adding a New Instrument

To create a new instrument, follow these steps:

1. On the main menu, click , **Instrument Management** and then click **Instrument**. The **Instrument** master screen appears as shown in the figure:

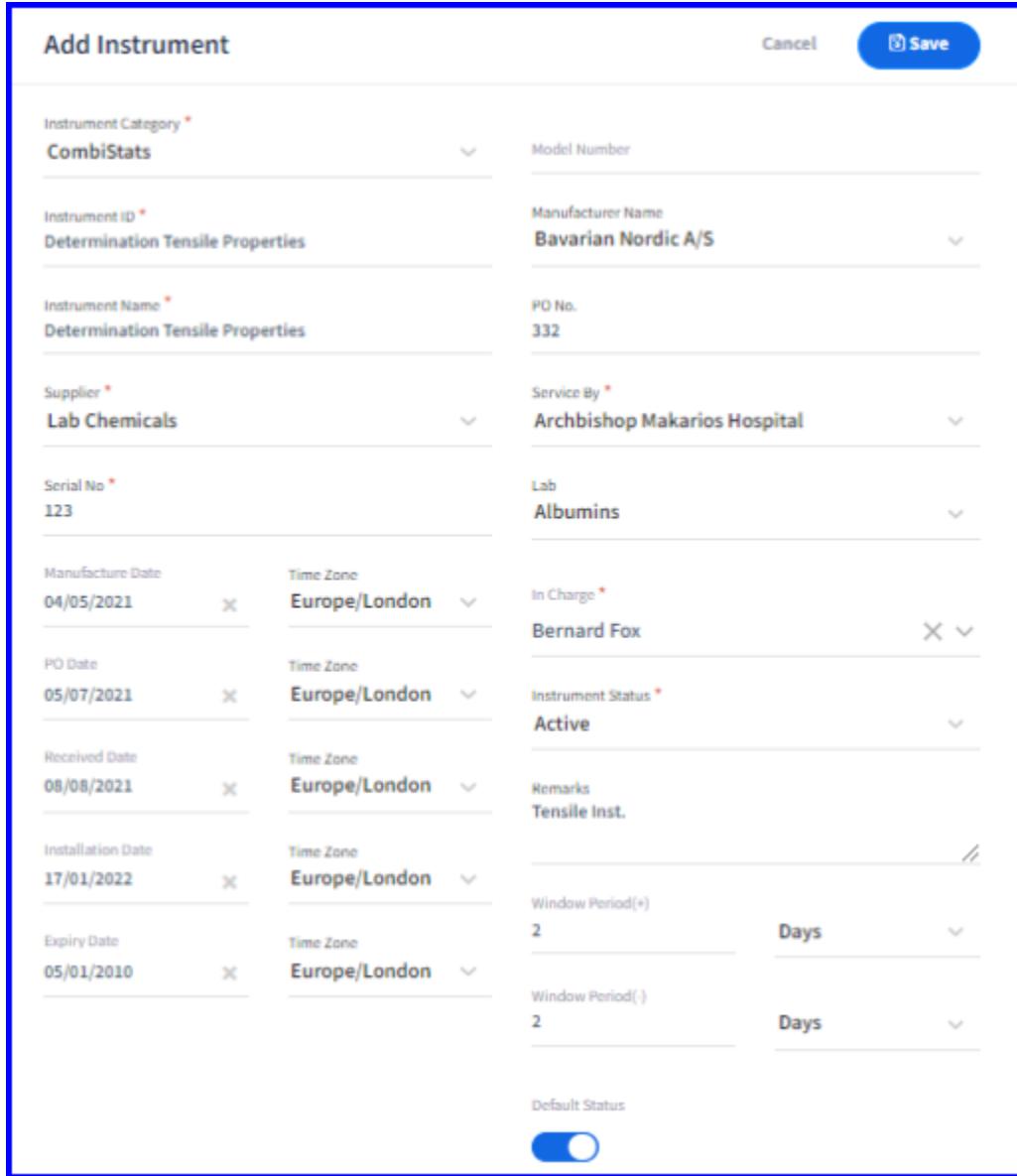


FIGURE: Instrument Master Screen

2. In the filter , select the **Instrument Category** and then click **Submit**. Instruments that are added to the selected instrument category will appear.

Options to edit and delete instruments appear in each record.

3. Click . The **Add Instrument** dialog appears as shown in the figure:



Add Instrument

Instrument Category *: CombiStats

Instrument ID *: Determination Tensile Properties

Instrument Name *: Determination Tensile Properties

Supplier *: Lab Chemicals

Serial No *: 123

Manufacture Date: 04/05/2021

PO Date: 05/07/2021

Received Date: 08/08/2021

Installation Date: 17/01/2022

Expiry Date: 05/01/2010

Time Zone: Europe/London

Time Zone: Europe/London

Time Zone: Europe/London

Time Zone: Europe/London

Model Number:

Manufacturer Name: Bavarian Nordic A/S

PO No.: 332

Service By *: Archbishop Makarios Hospital

Lab: Albumins

In Charge *: Bernard Fox

Instrument Status *: Active

Remarks: Tensile Inst.

Window Period(+): 2 Days

Window Period(-): 2 Days

Default Status:

Cancel  Save

FIGURE: Add Instrument Dialog

4. In the **Instrument Category** field, select the instrument category to which you create the instrument.
5. In the **Instrument ID** field, type a unique identification number for the instrument.
6. In the **Instrument Name** field, type the name of the instrument.

7. In the **Supplier** field, select the instrument supplier name.
8. In the **Service By** field, select the vendor who will service the instrument.
9. In the **Serial No** field, type the serial number of the instrument.
10. In the **In Charge** field, select the person in charge for the instrument.
11. In the **Window +** and **Window-** fields, mention the window period for the test.

Note: The window period for a test designed to detect a specific disease (particularly infectious disease) is the time between first infection and when the test can reliably detect that infection.

12. Fill in other fields appropriately
13. In the **Instrument Status** field, select **Active** to make the instrument active.
14. Click to turn on the **Default Status** option to keep the instrument active by default.
15. Click **Save**.

You can see the instrument you just created listed in the Instrument master.

3.9.2.2 Editing and Deleting Instrument

Options to edit and delete instrument appear in each record in the Instrument master.

1. To edit instrument details, in the Instrument master screen, click  to edit the instrument record. In the **Edit Instrument** screen, do required changes and then click **Save**.
2. To delete an instrument, in the Instrument master screen, click  to delete the instrument record.

3.10 Material Management

3.10.1 Material Category Master

Material Category master is used to add and manage material categories. Material category is used in various forms and master to group materials.

3.10.1.1 Adding a New Material Category

To create a new material category, follow these steps:

1. On the main menu, click  Material and then click Material Category. The Material Category master screen appears as shown in the figure:



The screenshot shows the 'Material Category' master screen. At the top, there is a header with the title 'Material Category' and a user profile for 'Carl Dolman Admin'. Below the header is a toolbar with four icons: a blue circle with a plus sign, a blue circle with a copy symbol, a blue circle with a document symbol, and a blue circle with a delete symbol. The main area is a table with the following columns: 'Material Type', 'Material Category', 'Description', 'Category Based Flow', 'Default Status', and 'Actions'. There is one record in the table:

Material Type	Material Category	Description	Category Based Flow	Default Status	Actions
Standard Type	IPV		Yes	No	 

FIGURE: Material Category Master Screen

In the Material Category master screen you can see the list of categories created. Options to edit and delete categories appear in each record.

2. Click  . The Add Material Category screen appears as shown in the figure:

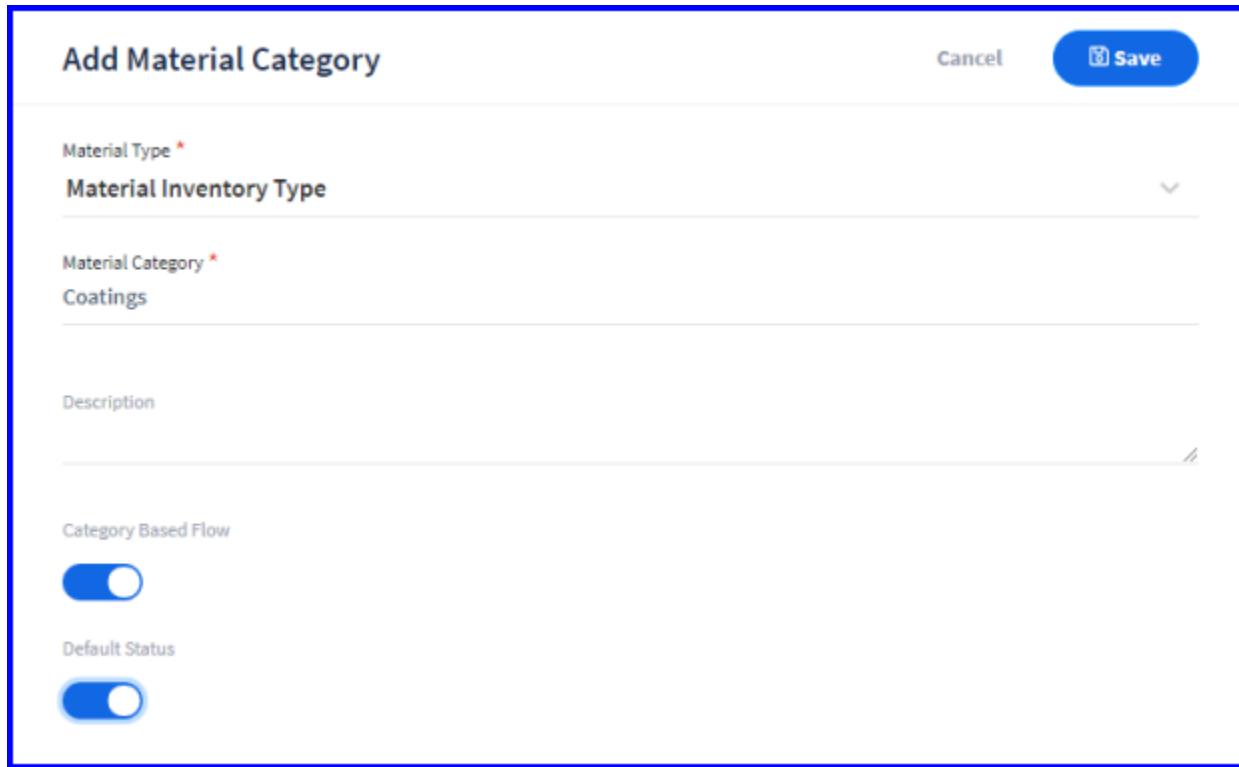


FIGURE: Add Material Category Screen

3. In the **Material Type** field, select the material type.
4. In the **Material Category** field, type the material category name you want to create.
5. In the **Description** field, type description if any.
6. Turn on the **Category Based Flow** option if required.
7. Click to turn on the **Default Status** option to make the material category active.
8. Click **Save**.

You can see the material category you just created listed in the Material Category master.

3.10.1.2 Editing and Deleting Material Category

Options to edit and delete material category appear in each record in the material category master.

1. To edit material category details, in the material category master screen, click  to edit the material category record. In the **Edit Material Category** screen, do required changes and then click **Save**.

2. To delete a material category, in the material category master screen, click  to delete the material category record.

3.11 Checklist

3.11.1 QB Category

QB (Question Bank) Category master is used to create and manage QB categories. QB Categories are used to group questions. Using question bank you can create checklists.

3.11.1.1 Adding a New QB Category

To create a new QB Category, follow these steps:

1. On the main menu, click  Checklist and then click QB Category. The QB Category master screen appears as shown in the figure:

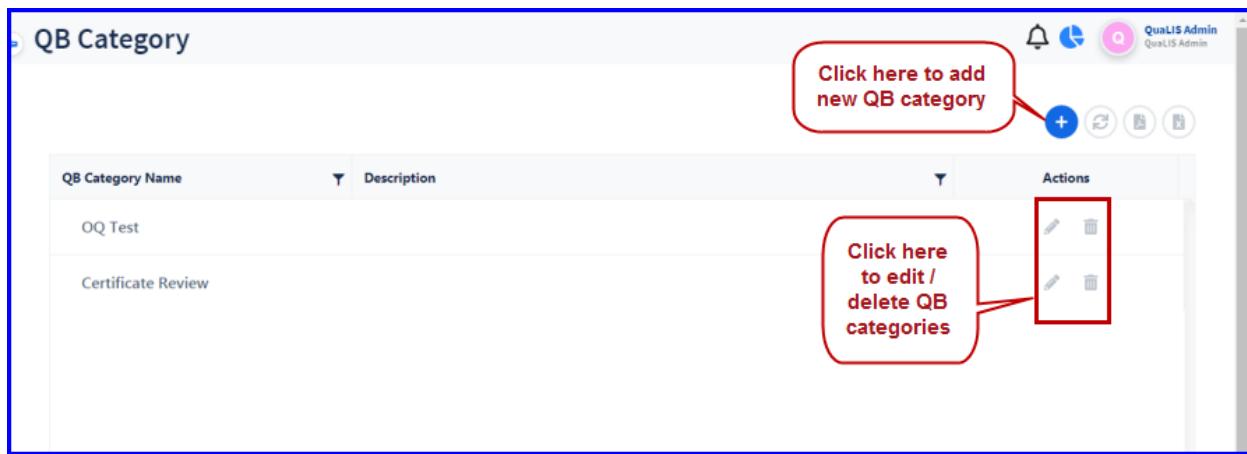


FIGURE: QB Category Master Screen

In the QB Category master screen you can see the list of QB categories created. Options to edit and delete categories appear in each record.

2. Click . The Add QB Category dialog appears as shown in the figure:



QB Category Name *

Sampling

Description

For Sampling

Save

FIGURE: Add QB Category Screen

3. In the **QB Category Name** field, type the QB category name.
4. In the **Description** field, type the description.
5. Click **Save**.

You can see the QB Category you just created listed in the QB Category master.

3.11.1.2 Editing and Deleting QB Category

Options to edit and delete QB category appear in each record in the QB category master.

1. To edit QB category details, in the QB category master screen, click  to edit the QB category record. In the **Edit QB Category** screen, do required changes and then click **Save**.
2. To delete a QB category, in the QB category master screen, click  to delete the QB category record.

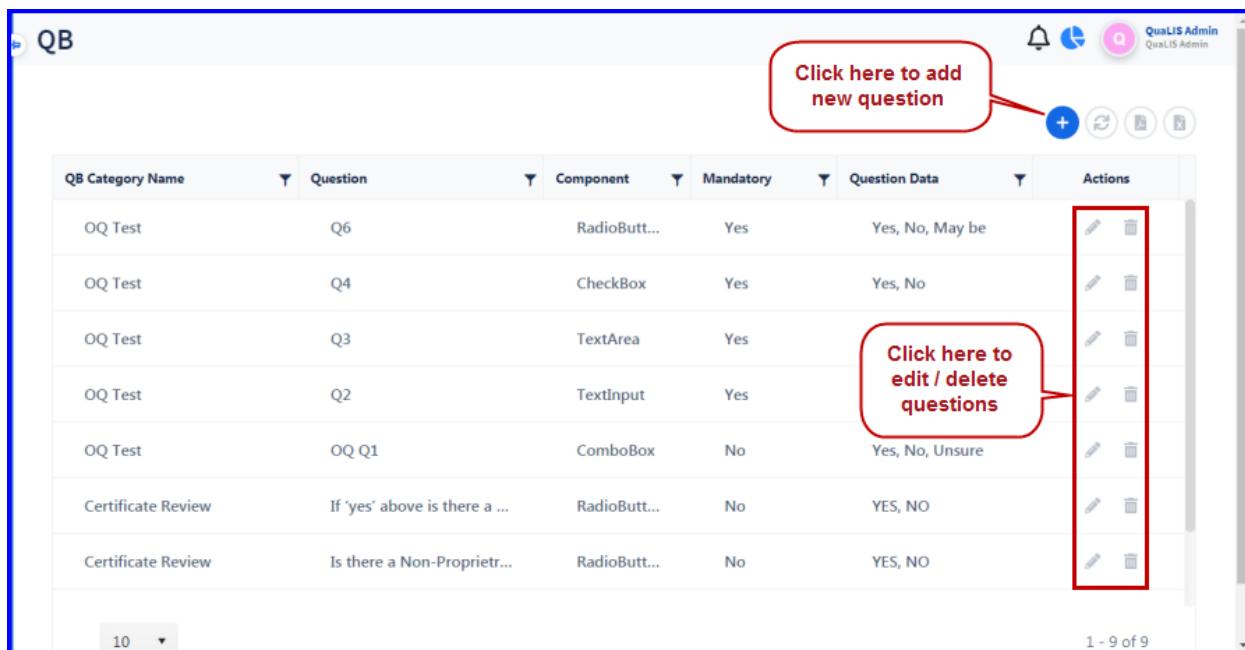
3.11.2 QB Master

QB master is used to add and manage questions.

3.11.2.1 Adding a New Question to QB

To create a new question, follow these steps:

1. On the main menu, click **Masters, Checklist** and then click **QB**. The **QB** master screen appears as shown in the figure:



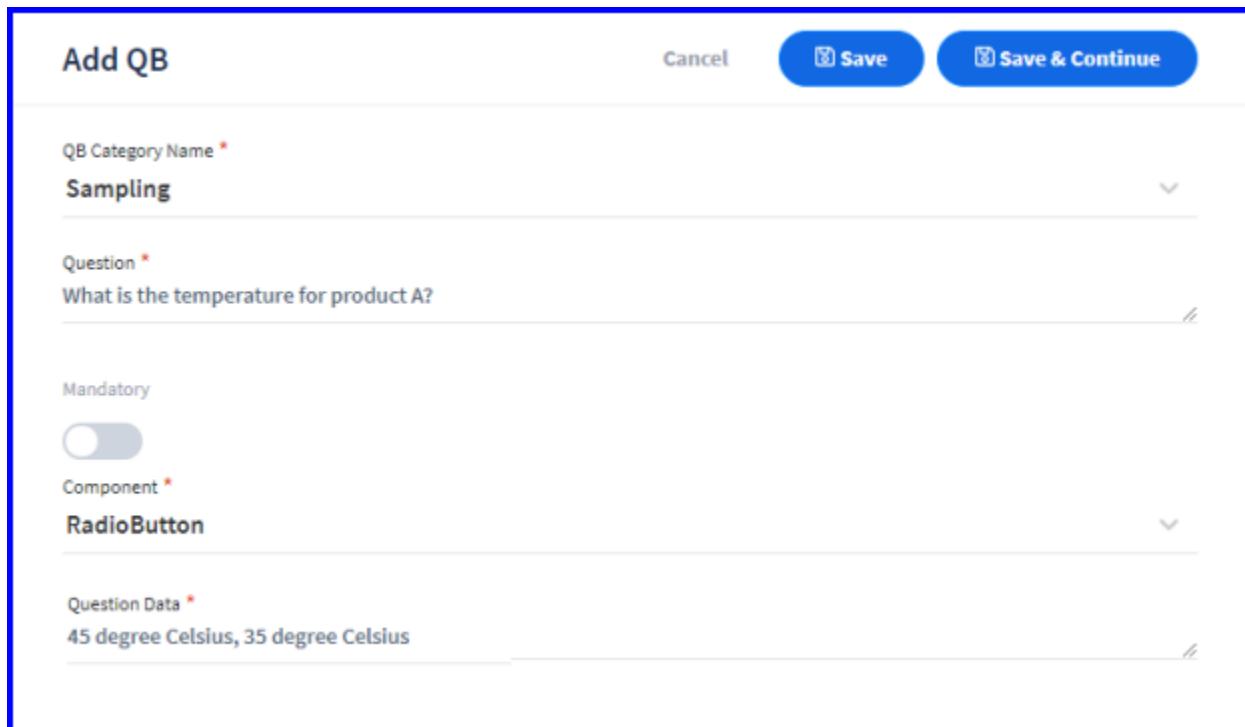
The screenshot shows a table titled 'QB' with the following columns: QB Category Name, Question, Component, Mandatory, Question Data, and Actions. The 'Actions' column contains icons for edit and delete. Two red callout boxes highlight these icons. The first box points to the 'edit' icon with the text 'Click here to add new question'. The second box points to the 'edit' and 'delete' icons with the text 'Click here to edit / delete questions'.

QB Category Name	Question	Component	Mandatory	Question Data	Actions
QQ Test	Q6	RadioButt...	Yes	Yes, No, May be	 
QQ Test	Q4	CheckBox	Yes	Yes, No	 
QQ Test	Q3	TextArea	Yes		 
QQ Test	Q2	TextInput	Yes		 
QQ Test	QQ Q1	ComboBox	No	Yes, No, Unsure	 
Certificate Review	If 'yes' above is there a ...	RadioButt...	No	YES, NO	 
Certificate Review	Is there a Non-Proprietr...	RadioButt...	No	YES, NO	 

FIGURE: QB Master Screen

In the QB master screen you can see the list of questions added. Options to edit and delete questions appear in each record.

2. Click . The Add QB screen appears as shown in the figure:



The screenshot shows the 'Add QB' form with the following fields:

- QB Category Name ***: Sampling
- Question ***: What is the temperature for product A?
- Mandatory**: A toggle switch is turned off.
- Component ***: RadioButton
- Question Data ***: 45 degree Celsius, 35 degree Celsius

At the top right are 'Cancel', 'Save', and 'Save & Continue' buttons.

FIGURE: Add Question Screen

3. In the **QB Category Name** field, select the category.
4. In the **Question** field, type the question you want to add to the QB.
5. Check to select the **Mandatory** field to make the question mandatory in the QB.
6. In the **Component** field, select the type of question. i.e Combo field, radio button, Text Area etc.
7. In the **Question Data** field, type the text/value for component selected. For example, for component: Radio button, you can type Yes/No.
8. Click **Save**.

You can see the question you just added listed in the QB master.

3.11.2.2 Editing and Deleting Questions in QB

Options to edit and delete questions appear in each record in the QB master.

1. To edit question details, in the QB master screen, click  to edit the question record. In the **Edit QB** screen, do required changes and then click **Save**.
2. To delete a question, in the QB master screen, click  to delete the question record.

3.11.3 Checklist

Checklist master is used to create and manage checklists.

3.11.3.1 Creating a New Checklist

To create a new checklist, follow these steps:

1. On the main menu, click , **Checklist** and then click **Checklist**. The **Checklist** master screen appears as shown in the figure:

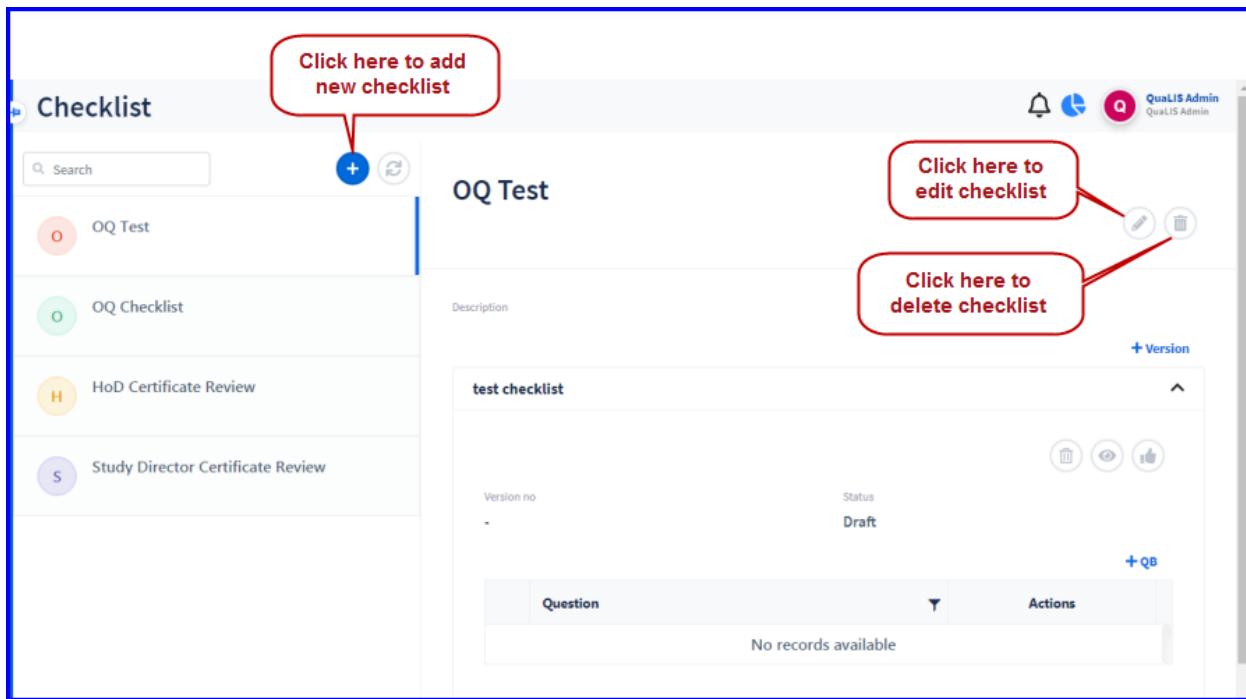


FIGURE: Checklist Master Screen

In the checklist master screen you can see the list of checklists created. Options to edit and delete appear in each record as shown in the above figure.

Creating a checklist consists of the following steps:

- Add a draft version of the checklist.
 - Add questions to the check list draft.
 - Approve checklist draft.
2. In the Checklist master screen, click . The **Add Checklist** screen appears as shown in the figure:



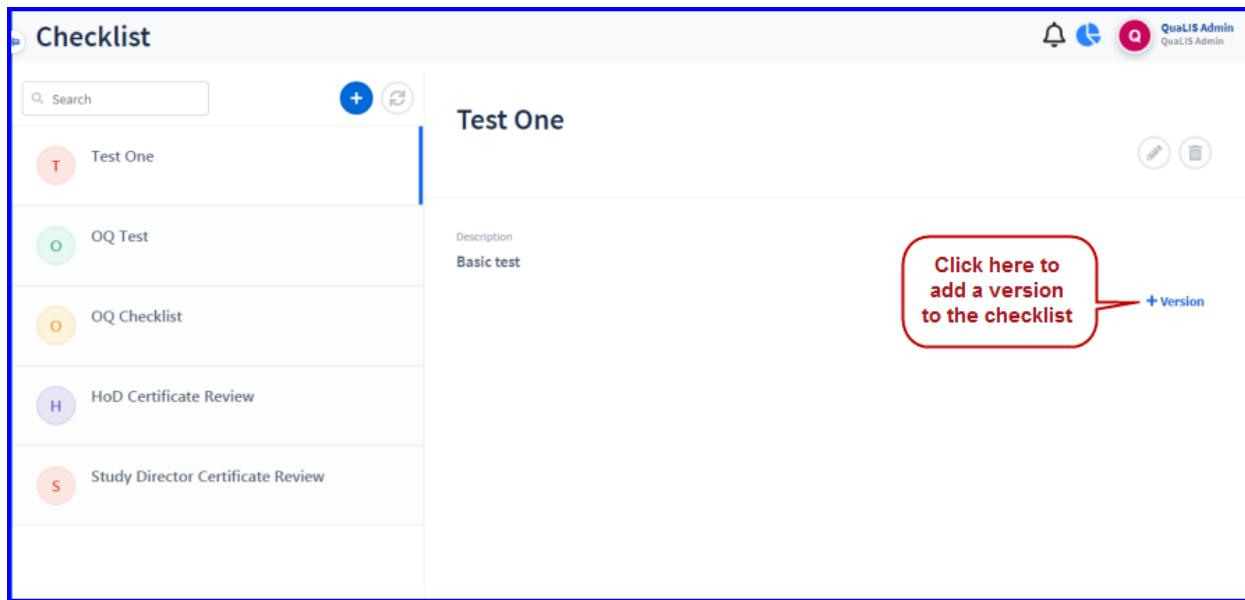
The screenshot shows the 'Add Checklist' dialog box. At the top left is the title 'Add Checklist'. At the top right are two buttons: 'Cancel' and a blue 'Save' button with a checkmark icon. The dialog contains two text input fields. The first field is labeled 'Checklist Name *' and contains the text 'Test One'. The second field is labeled 'Description' and contains the text 'Basic test'. There is also a large, empty text area below these fields.

FIGURE: Add Checklist Dialog

3. In the **Checklist Name** field, type a name for the checklist you create.
4. In the **Description** field, type the description.
5. Click **Save**.

You can see the checklist you just created listed in the Checklist master.

6. Select the checklist, click **+ Version** as shown in the figure:



The screenshot shows the 'Checklist' master page. At the top left is the title 'Checklist'. At the top right are three icons: a bell, a person, and a gear, followed by the text 'Qualis Admin'. The main area is a table with a list of checklists. The first row, 'Test One', is selected and highlighted in blue. To the right of the table, there is a detailed view of 'Test One'. This view includes the 'Description' field with the value 'Basic test'. At the bottom right of this view, there is a red callout bubble with the text 'Click here to add a version to the checklist' pointing to a blue '+ Version' button. The table has columns for 'Icon', 'Name', and 'Actions'.

FIGURE: Adding Version to the Checklist

7. The **Add Checklist Version** dialog appears as shown in the figure:

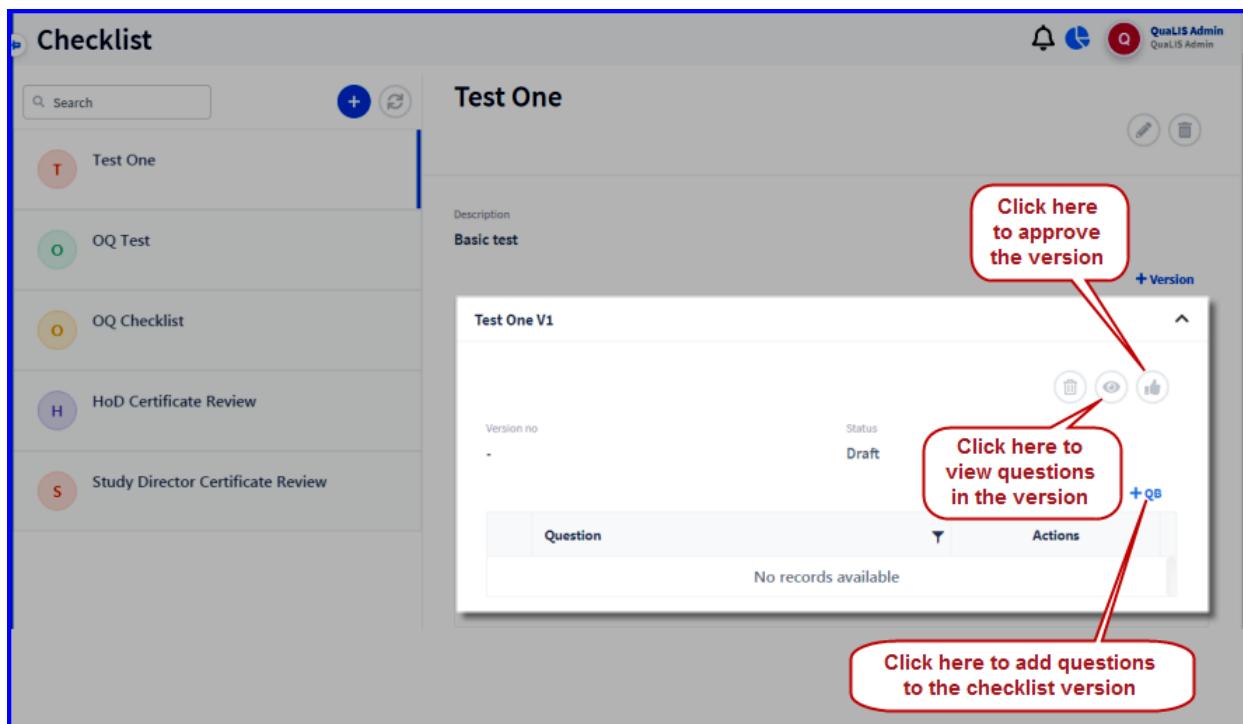


The screenshot shows a dialog box titled "Add Checklist Version". It has a "Checklist Version Name" field containing "Test One V1" with a red asterisk indicating it is required. There are "Cancel" and "Save" buttons at the top right. The entire dialog is enclosed in a blue border.

FIGURE: Add Checklist Version Dialog

8. In the **Checklist Version Name** field, type the name for the version.
9. Click **Save**.

The check list version is created and appears as shown in the figure:



The screenshot shows the "Checklist" module. On the left, a sidebar lists items: "Test One" (selected, highlighted in orange), "OQ Test", "OQ Checklist", "Hod Certificate Review", and "Study Director Certificate Review". The main area shows "Test One" details: "Description: Basic test". Below is a list for "Test One V1": "Version no: -", "Status: Draft". A callout box points to the "Status" button with the text "Click here to approve the version". Another callout box points to the "Actions" column with the text "Click here to view questions in the version". A third callout box points to the "Actions" column with the text "Click here to add questions to the checklist version". The entire screenshot is enclosed in a blue border.

FIGURE: Checklist version in Draft State

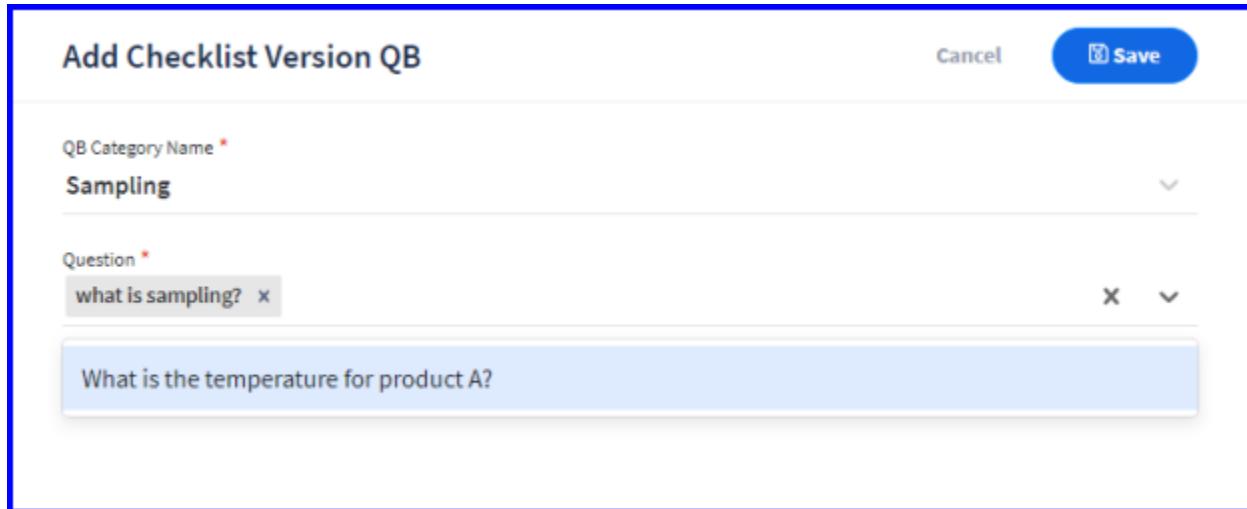
Approve checklist draft: Select a checklist version in draft state and then click .

View Checklist Items: Once the checklist is approved, click  to view list of questions in the checklist.

You can add multiple drafts to a checklist.

10. Select the draft checklist to add questions and click **+QB** as shown in the figure:

11. The **Add Checklist Version QB** dialog appears as shown in the figure:



QB Category Name *

Sampling

Question *

what is sampling? X

What is the temperature for product A?

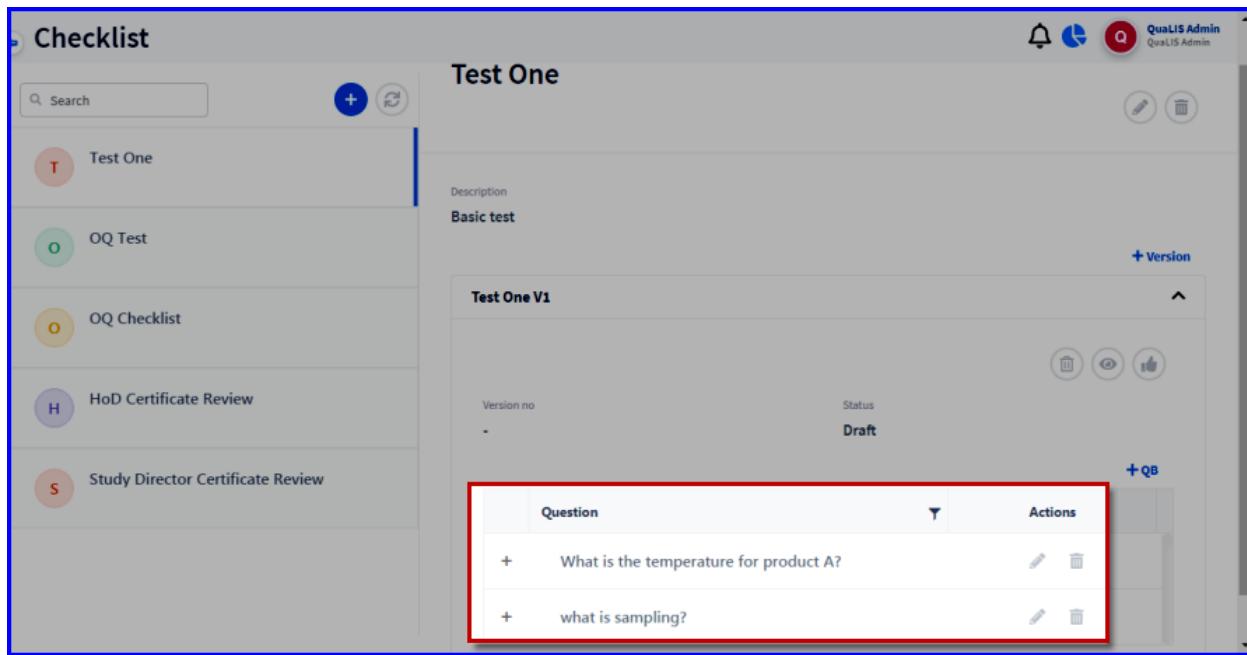
FIGURE: Add Question to Checklist Screen

Here you can add questions to the checklist.

12. Select the **QB Category Name**. Questions from the selected category appear.

13. In the Question field, select the questions to add to the checklist. You can add multiple questions.

14. Click **Save**. The questions added appears as shown in the figure:



The screenshot shows the Qualis LIMS Checklist module. On the left, a sidebar lists several checklist items: 'Test One' (selected), 'OQ Test', 'OQ Checklist', 'HoD Certificate Review', and 'Study Director Certificate Review'. The main area is titled 'Test One' and shows a 'Basic test' description. A 'Test One V1' section is displayed, showing a table with two questions: 'What is the temperature for product A?' and 'what is sampling?'. The 'Actions' column for each question includes edit and delete icons. The entire 'Test One V1' section is highlighted with a red box.

FIGURE: Questions Added to the Checklist Version

Until the draft is approved, you can edit or delete questions from the checklist.

3.11.3.2 Editing and Deleting Checklist

Options to edit and delete checklist appear in each record in the Checklist master.

1. To edit checklist details, in the Checklist master screen, click  to edit the Checklist record. In the **Edit Checklist** screen, do required changes and then click **Save**.
2. To delete a checklist, in the Checklist master screen, click  to delete the checklist record.

3.11.3.3 Approving Checklist Draft

1. Select a checklist version in draft state and then click .

3.11.3.4 Viewing Checklist Items

1. Once the checklist is approved, click  . List of questions added to the checklist appears as shown in the figure:

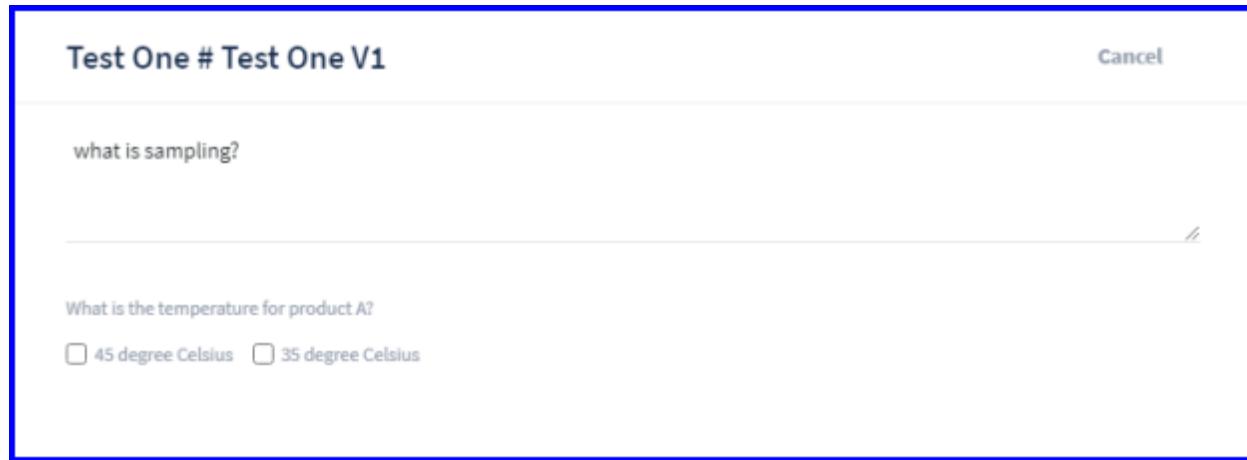


FIGURE: View Checklist Items

3.12 Competence Management

3.12.1 Technique

Technique master is used to create and manage techniques. Technique is used to map instrument categories in the Instrument Category master. To create a new technique, follow these steps:

1. On the main menu, click , **Competence Management** and then click **Technique**. The **Technique** master screen appears as shown in the figure:



FIGURE: Technique Master Screen

In the Technique master screen you can see the list of techniques created. Options to edit and delete techniques appear in the action menu.

2. In the **Technique** screen, click . The **Add Technique** screen appears as shown in the figure:



The screenshot shows the 'Add Technique' dialog box. At the top, there is a title bar with the text 'Add Technique' on the left and 'Cancel' and 'Save' buttons on the right. The 'Save' button is highlighted with a blue background and white text. Below the title bar, there are two input fields. The first field is labeled 'Technique *' and contains the text 'QC Technique'. The second field is labeled 'Description' and contains the text 'QC'. There is also a small text area at the bottom of the dialog box.

FIGURE: Add Technique Dialog

3. In the **Technique** field, type the name of the technique you want to add.
4. In the **Description** field, type descriptions if any.
5. Click **Save**.

The new technique is added and listed in the Technique master screen.

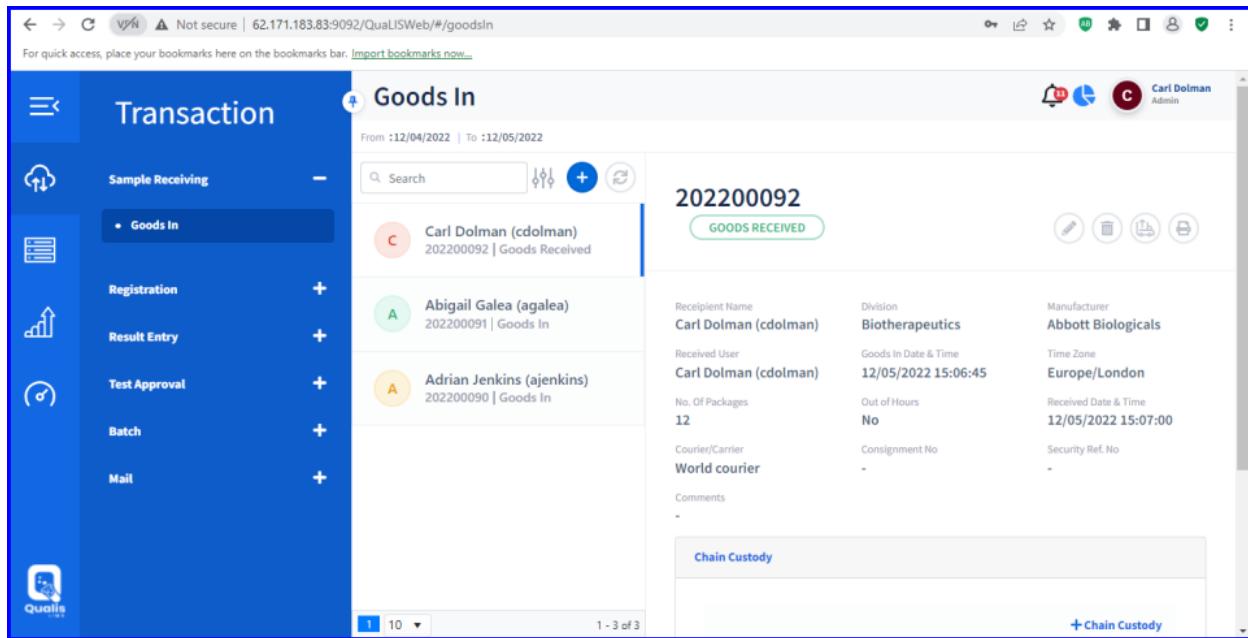
4 Transactions

4.1.1 Goods In

Goods In screen helps the user to capture details of goods that are coming in to the company through courier or any other mode.

To receive goods in storage, follow these steps:

1. On the main menu, click **Transaction**, **Sample Receiving** and then click **Goods In**. The **Goods In** screen appears as shown in the figure:



The screenshot shows the Qualis LIMS web interface. On the left, a sidebar menu titled 'Transaction' is open, showing 'Sample Receiving' as the active section. Under 'Sample Receiving', 'Goods In' is selected and highlighted with a blue box. Other options in the sidebar include 'Registration', 'Result Entry', 'Test Approval', 'Batch', and 'Mail'. The main content area is titled 'Goods In' and shows a list of received goods. The first item is '202200092' (202200092 | Goods Received) for 'Carl Dolman (cdolman)'. Below it are 'Abigail Galea (agalea)' and 'Adrian Jenkins (ajenkins)'. To the right of the list, detailed information is provided for the first item: Recipient Name (Carl Dolman (cdolman)), Division (Biotherapeutics), Manufacturer (Abbott Biologicals), and Time Zone (Europe/London). Other details include Goods In Date & Time (12/05/2022 15:06:45), Received Date & Time (12/05/2022 15:07:00), and a 'Comments' section.

Goods In Screen

To add goods details, follow these steps:

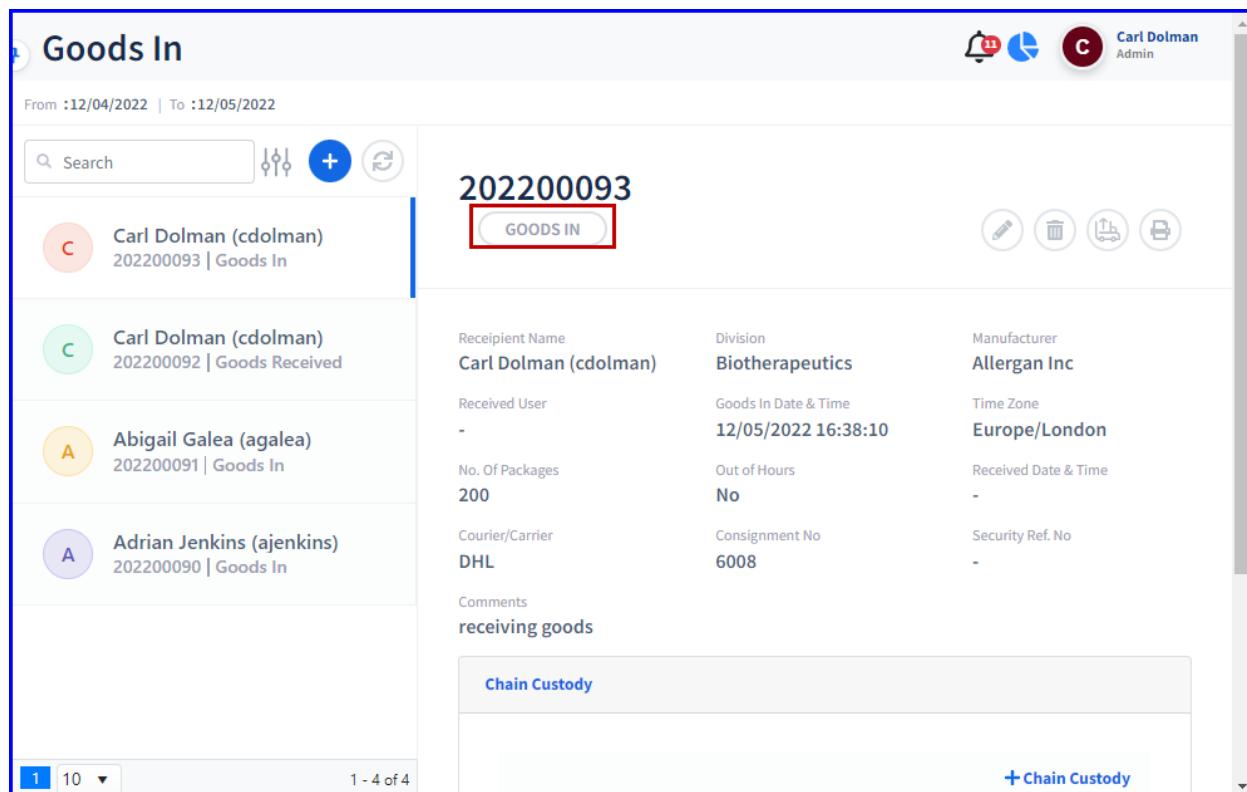
2. In the **Goods In** screen, click . The **Add Goods In** screen appears as shown in the figure:

Add Goods In
Cancel
 Save
 Save & Continue

Manufacturer * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="Allergan Inc"/>	Goods In Date & Time * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="12/05/2022 16:38:10"/>
Recipient Name * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="Carl Dolman (cdolman)"/>	Time Zone * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="Europe/London"/>
Division * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="Biotherapeutics"/>	Out of Hours <input style="width: 20px; height: 20px;" type="checkbox"/>
No. Of Packages * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="200"/>	Security Ref. No <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text"/>
Courier/Carrier <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="DHL"/>	Comments <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="receiving goods"/>
Consignment No <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="6008"/>	<input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text"/>

Add Goods In Screen

3. In the **Manufacturer Name** field, type the manufacturer of the goods.
4. In the **Recipient Name** field, select the user who receives the goods. Based on the selected recipient, the Division appears.
5. In the **No. Of Packages** field, type number of packages receiving.
6. In the **Courier/Carrier** field, select the courier or carrier name that delivers the goods to the company.
7. In the **Consignment No** field, type the consignment number.
8. If the time of receiving the goods is out of office hours, then click to turn on the **Out of Hours** option. If the **Out of Hours** option is turned on, then the **Security Ref. No** field becomes mandatory. Type the security reference number.
9. In the **Comments** field, type your comments if any.
10. Click **Save**. The goods are added and appear in the **Goods In** screen with status showing as **GOODS IN** as shown in the figure:



From :12/04/2022 | To :12/05/2022

Search Filter Add Reset

202200093 GOODS IN

Carl Dolman (cdolman)
202200093 | Goods In

Carl Dolman (cdolman)
202200092 | Goods Received

Abigail Galea (agalea)
202200091 | Goods In

Adrian Jenkins (ajenkins)
202200090 | Goods In

Recipient Name: **Carl Dolman (cdolman)**
Division: **Biotherapeutics**
Manufacturer: **Allergan Inc**

Received User: -
Goods In Date & Time: **12/05/2022 16:38:10**
Time Zone: **Europe/London**

No. Of Packages: **200**
Out of Hours: **No**
Received Date & Time: -

Courier/Carrier: **DHL**
Consignment No: **6008**
Security Ref. No: -

Comments:
receiving goods

Chain Custody

+ Chain Custody

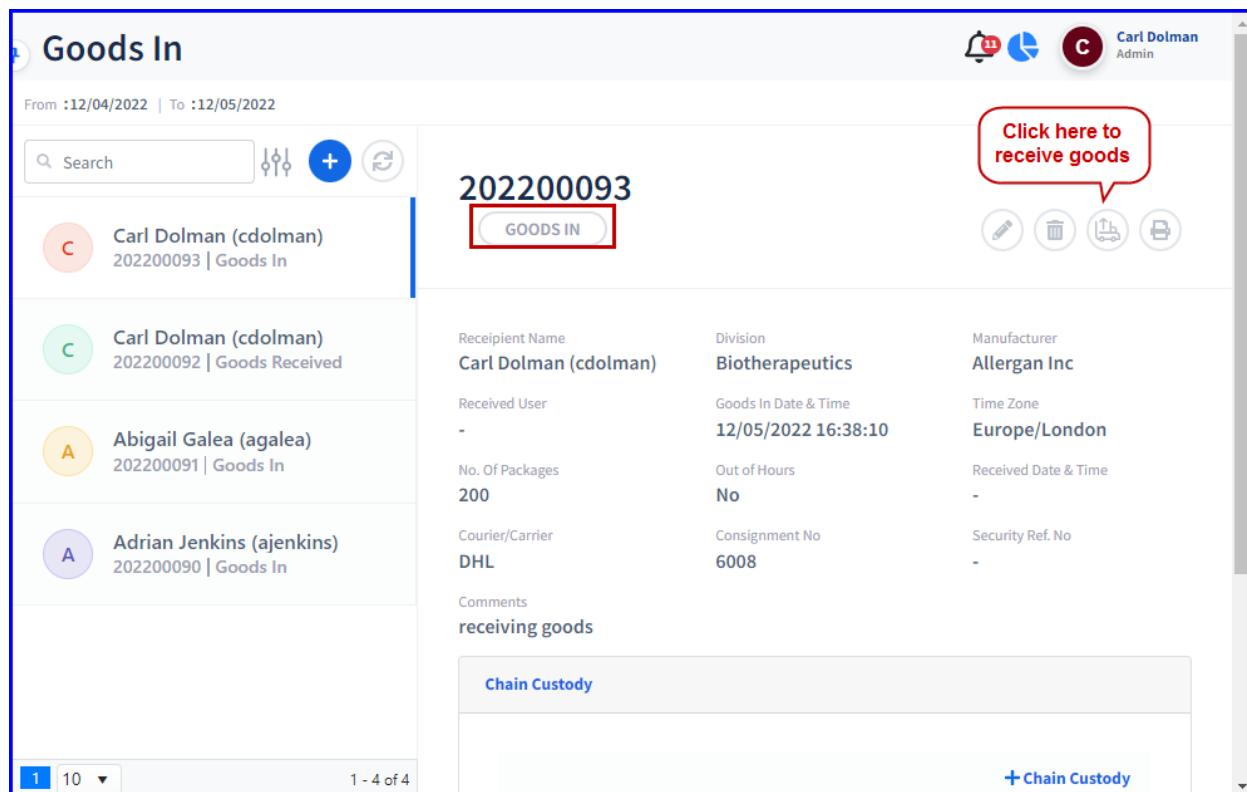
1 10 ▾ 1 - 4 of 4

Goods Showing Status as Goods In

4.1.2 Receiving Goods

The recipient user should log in to their log in to receive goods. To receive goods, follow these steps:

In the Goods In screen, select a record to receive goods and then click  as shown in the figure:



From :12/04/2022 | To :12/05/2022

Search Filter Add Print

202200093 GOODS IN

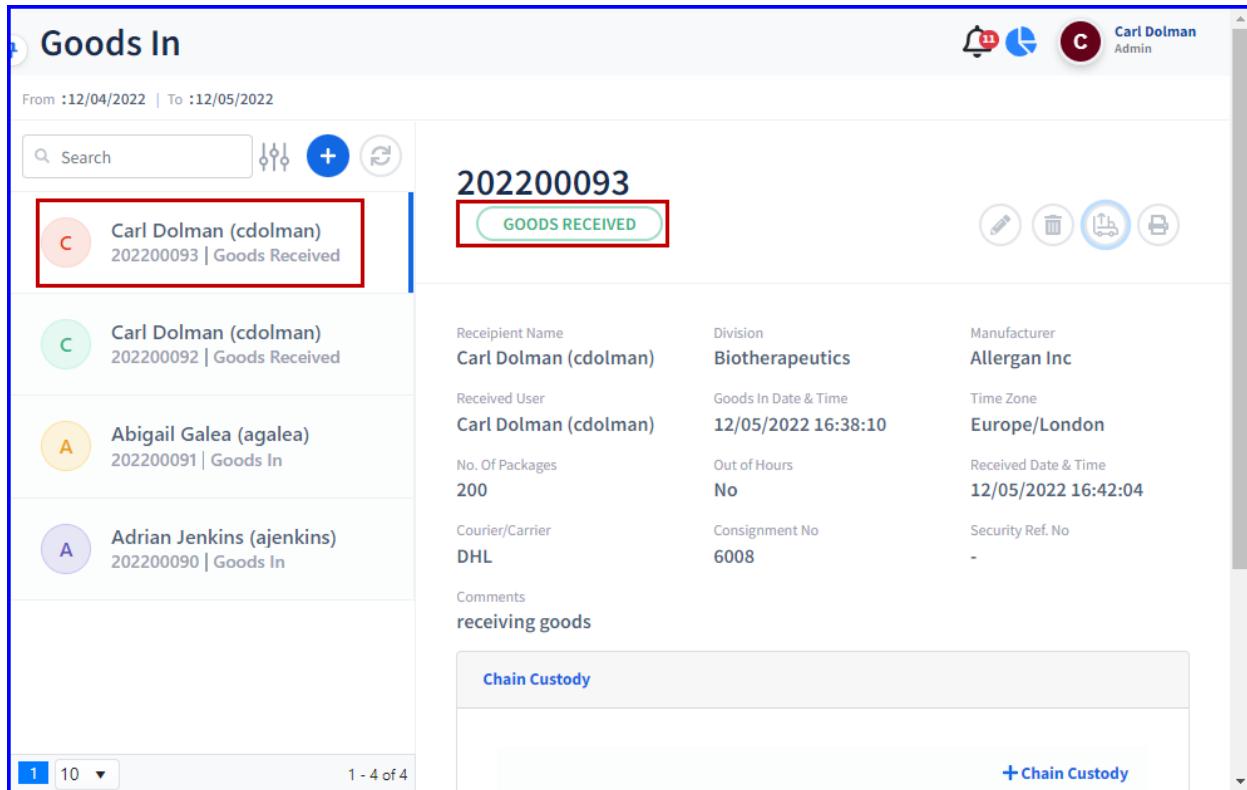
Click here to receive goods

Recipient Name	Division	Manufacturer
Carl Dolman (cdolman)	Biotherapeutics	Allergan Inc
Received User	Goods In Date & Time	Time Zone
-	12/05/2022 16:38:10	Europe/London
No. Of Packages	Out of Hours	Received Date & Time
200	No	-
Courier/Carrier	Consignment No	Security Ref. No
DHL	6008	-
Comments		
receiving goods		
Chain Custody		
+ Chain Custody		

1 10 ▾ 1 - 4 of 4

FIGURE: Receiving Goods

The status will turn to **GOODS RECEIVED** as shown in the figure:



The screenshot shows the 'Goods In' screen with a list of records on the left and a detailed view of a selected record on the right. The selected record is '202200093' with the status 'GOODS RECEIVED' highlighted with a red box. The detailed view includes fields for Recipient Name (Carl Dolman (cdolman)), Division (Biotherapeutics), Manufacturer (Allergan Inc), Received User (Carl Dolman (cdolman)), Goods In Date & Time (12/05/2022 16:38:10), Time Zone (Europe/London), No. Of Packages (200), Out of Hours (No), Received Date & Time (12/05/2022 16:42:04), Courier/Carrier (DHL), Consignment No (6008), and Comments (receiving goods). A 'Chain Custody' section is also visible. The top right corner shows the user profile of 'Carl Dolman Admin'.

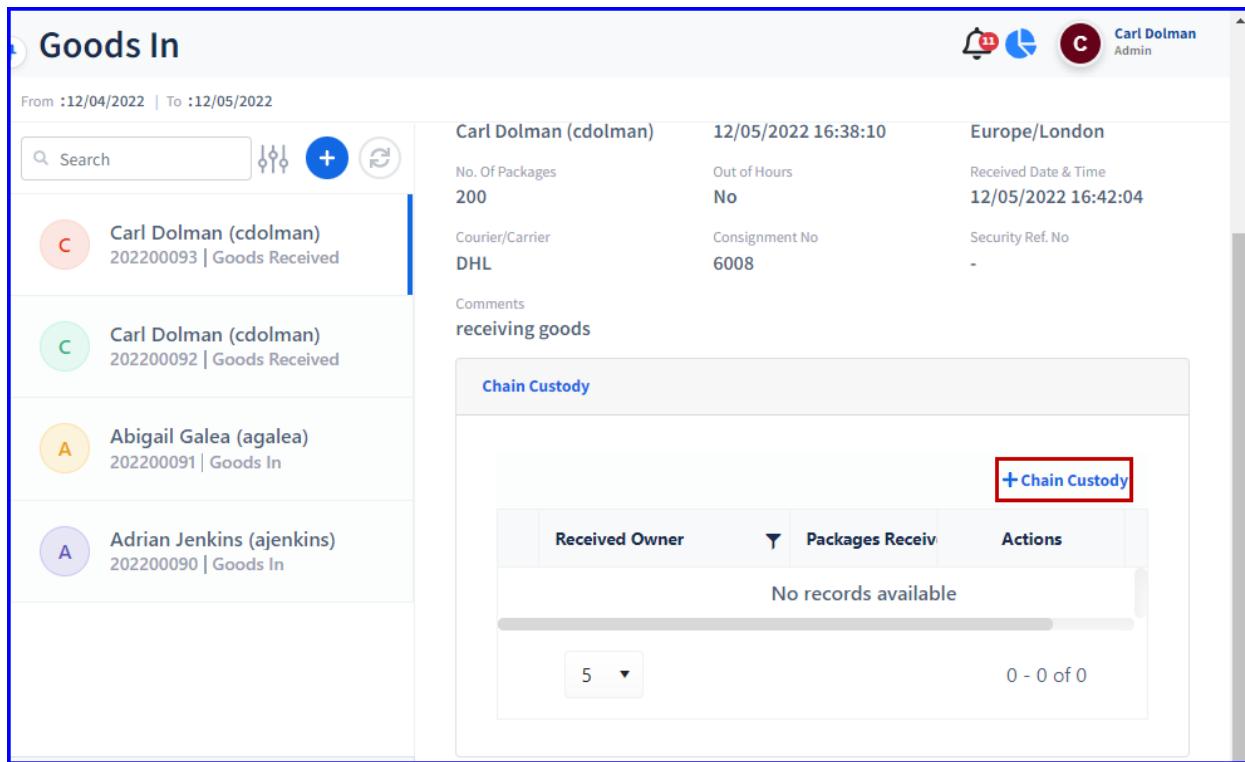
FIGURE: Record in GOODS RECEIVED State

4.1.3 **Chain Custody**

The Chain Custody option in the Goods In screen enables the user to split and receive goods in storage.

To receive goods in storage, follow these steps:

1. In the **Goods In** screen, open the record to split and receive goods in storage.
2. Click **+ Chain Custody** as shown in the figure:



The screenshot shows the Qualis LIMS Goods In module. On the left, a sidebar lists received items with icons and labels: 'Carl Dolman (cdolman) 202200093 | Goods Received' (red 'C'), 'Carl Dolman (cdolman) 202200092 | Goods Received' (green 'C'), 'Abigail Galea (agalea) 202200091 | Goods In' (orange 'A'), and 'Adrian Jenkins (ajenkins) 202200090 | Goods In' (purple 'A'). The main area displays a summary for Carl Dolman (cdolman):

Carl Dolman (cdolman)	12/05/2022 16:38:10	Europe/London
No. Of Packages 200	Out of Hours No	Received Date & Time 12/05/2022 16:42:04
Courier/Carrier DHL	Consignment No 6008	Security Ref. No -

Comments: receiving goods

Chain Custody

+ Chain Custody (button highlighted with a red box)

Received Owner	Packages Receiv.	Actions
No records available		

5 ▾ 0 - 0 of 0

Chain custody Option

The **Add Chain Custody** dialog appears as shown in the figure:

Add Chain Custody

[Cancel](#) [Save](#)

Goods In Details		
RMS No	Manufacturer	Recipient Name
202200093	Allergan Inc	Carl Dolman (cdolman)
Division	Received User	
Biotherapeutics	Carl Dolman (cdolman)	

Packages Received *
50

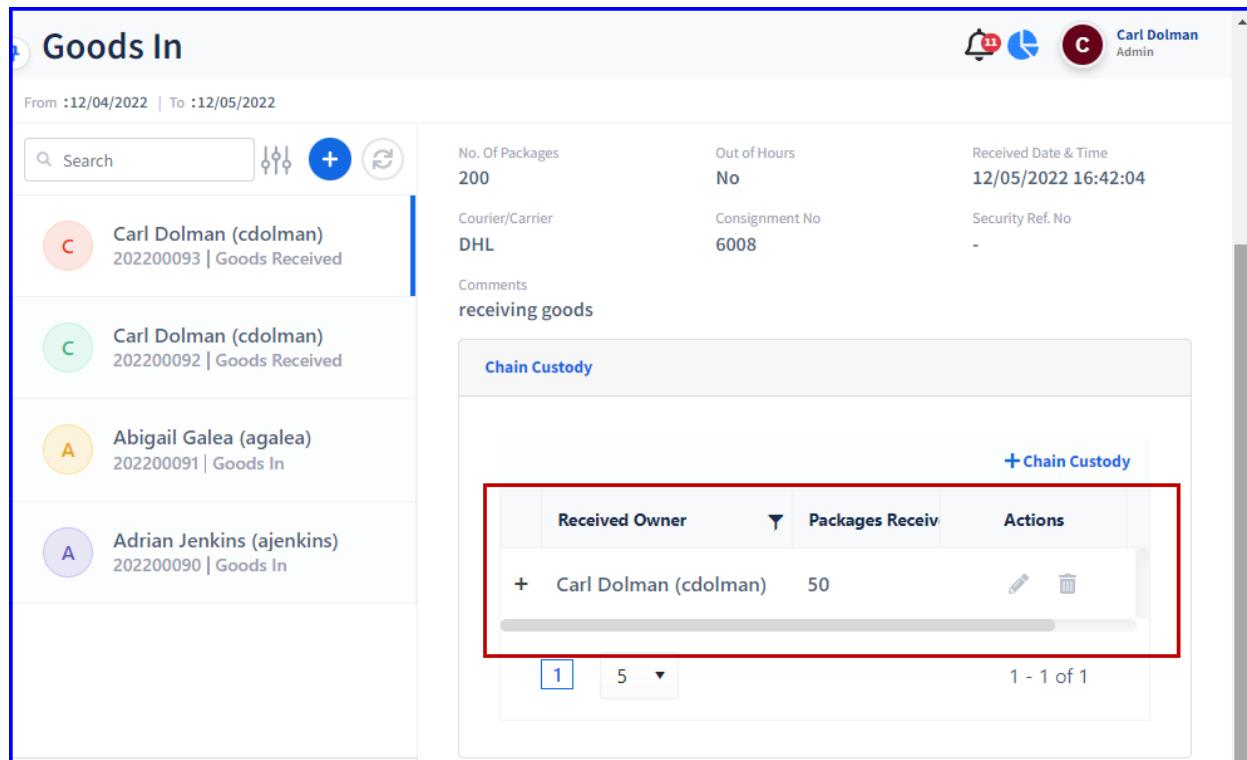
Received Date *
12/05/2022

Time Zone *
Europe/London

Comments
receiving 50 packages

Chain Custody Dialog

3. In the **Packages Received** field, type number of packages receiving in custody.
4. In the **Comments** field, type your comments if any.
5. Click **Save**. Goods received in custody is saved and appears as shown in the figure:



From :12/04/2022 | To :12/05/2022

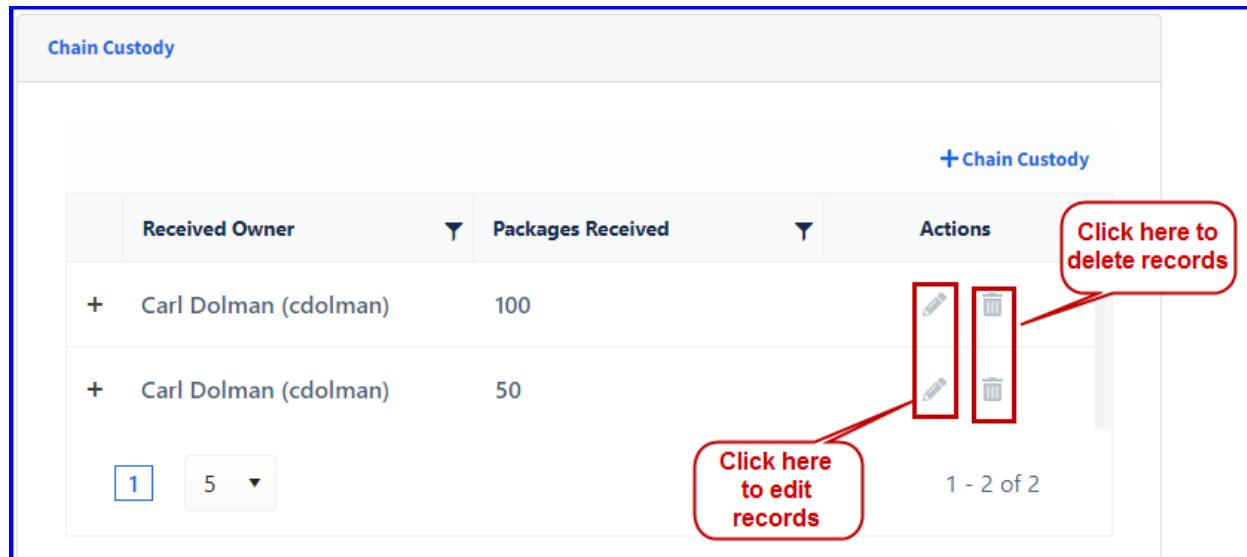
Search Filter Add Print

Received Owner	Packages Received	Actions
Carl Dolman (cdolman)	50	Edit Delete

1 - 1 of 1

Goods in Chain Custody

Same way, you can add more goods to chain custody. You can edit or delete chain custody record using edit and delete options that appear in each record as shown in the figure:



Received Owner	Packages Received	Actions
Carl Dolman (cdolman)	100	Edit Delete
Carl Dolman (cdolman)	50	Edit Delete

1 - 2 of 2

FIGURE: Edit and Delete Options for Chain Custody Records

4.1.4 Registration

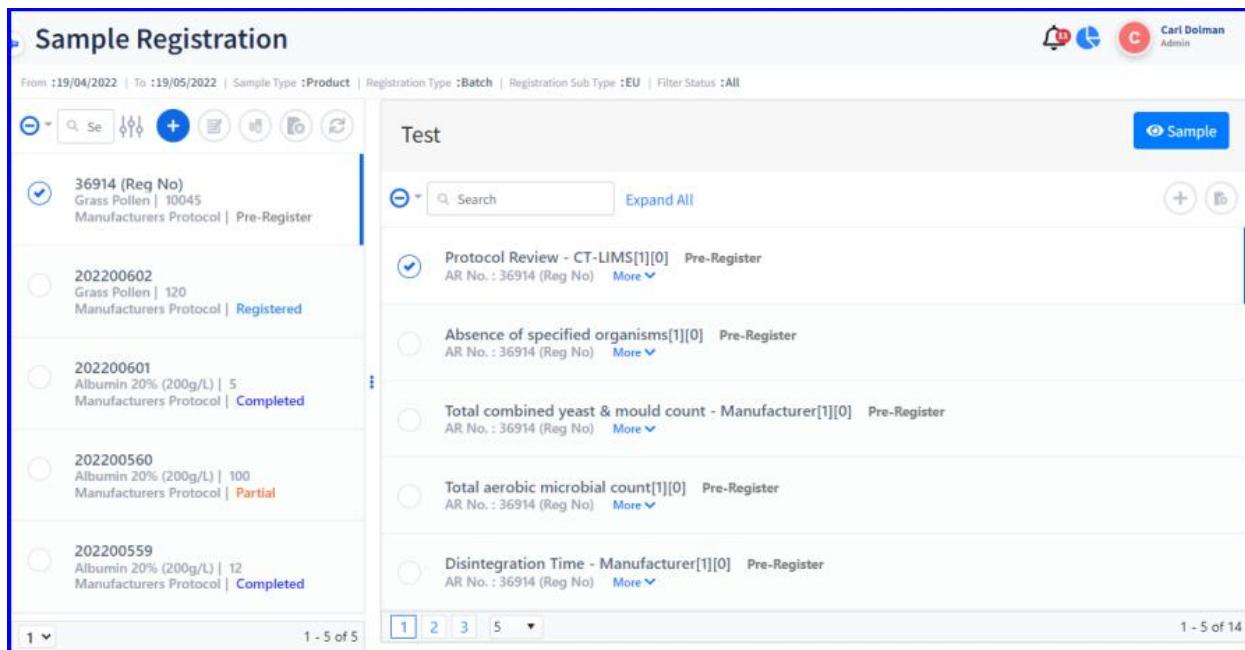
Sample Registration screen is where you add and register sample details. Once you pre-register samples, you can register, add tests and attach files to the samples and then accept the sample to register it. If required, you can cancel the sample registration or quarantine the sample for some reason.

Following is the list of color codes for the sample records in each status:

- Pre-register - Grey
- Registered - Blue
- Completed - Dark blue
- Partial - Red
- Quarantined - Orange
- Cancelled / Rejected - Red

To register a sample, follow these steps:

1. On the main menu, click  **Registration** and then click **Sample Registration**. The **Sample Registration** screen appears as shown in the figure:



Sample Details	Test Details
36914 (Reg No) Grass Pollen 10045 Manufacturers Protocol Pre-Register	Protocol Review - Pre-Register AR No.: 36914 (Reg No) More
202200602 Grass Pollen 120 Manufacturers Protocol Registered	Absence of specified organisms - Pre-Register AR No.: 36914 (Reg No) More
202200601 Albumin 20% (200g/L) 5 Manufacturers Protocol Completed	Total combined yeast & mould count - Pre-Register AR No.: 36914 (Reg No) More
202200560 Albumin 20% (200g/L) 100 Manufacturers Protocol Partial	Total aerobic microbial count - Pre-Register AR No.: 36914 (Reg No) More
202200559 Albumin 20% (200g/L) 12 Manufacturers Protocol Completed	Disintegration Time - Pre-Register AR No.: 36914 (Reg No) More

FIGURE: Sample Registration Screen

Click  in the Filter dialog, select **From** and **To** date, **Sample Type**: Product, **Registration Type**: Batch / Non Batch / Plasma Pool, **Registration Sub Type** and **Filter Status**. And then click **SUBMIT** as shown in the figure:

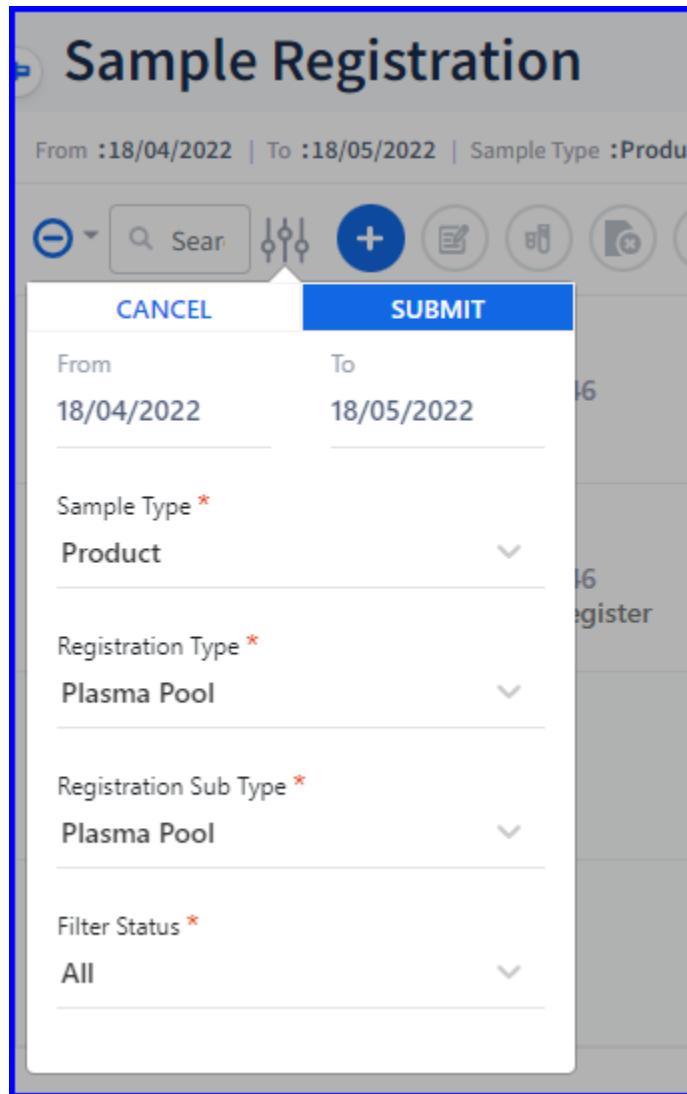


FIGURE: Using Filter in Registration Screen

List of samples registered for the selected criteria appears. You can register sample for the selected Registration Type and Registration Sub Type.

2. Click  to register a sample. The screen appears as shown in the figure:

Add Plasma Pool(Plasma Pool)

Study plan for the selected product appears here

Click here to get components from the study plan

Click here to add Manufacturer Lot No in Edit dialog

View list of tests in the selected component

Add tests to the component if required

Click here to add source of the sample

Registration Add Screen

Component Name	Manuf Lot No	No Of Container	Pool/Bulk Volume	Plasma Master File #	Actions
Final Lot Protocol Revi...	10046	1	1		 
OCABR Certificate	10046	1	1		 

Test	Source	Actions
Protocol signed and d...	NIBSC	
Protocol review - WB ...	NIBSC	

Source	Actions
No records available	

3. In the **RMS No** field, select the RMS number for which the sample is registered.

Note: RMS number is generated in the Goods In screen.

4. In the **Product Category** field, select the product category.
5. In the **Product** field, select the product to register. Based on the selected product, the study plan created in the Study Plan screen for the selected product along with the **Study Plan** name will appear on the right side as shown in the above figure.
6. In the **Manufacturer Name** field, select the product manufacturer. Based on the selected manufacturer, the **Manufacturer Site** appears.
7. In the **e-Protocol** field, select **e-Protocol** for the sample.
8. Click  to get components from the study plan. All components from the study plan will appear under **Components** as shown in the above figure.
9. The **All Test** option will be turned on by default and all the tests in the component will be available for registration. If required, you can turn off this option and remove tests from the selected component.
10. Note: **Manuf Lot No.** field in the component record is mandatory. Hence, click  to edit the component. The **Edit Component** dialog appears as shown in the figure:

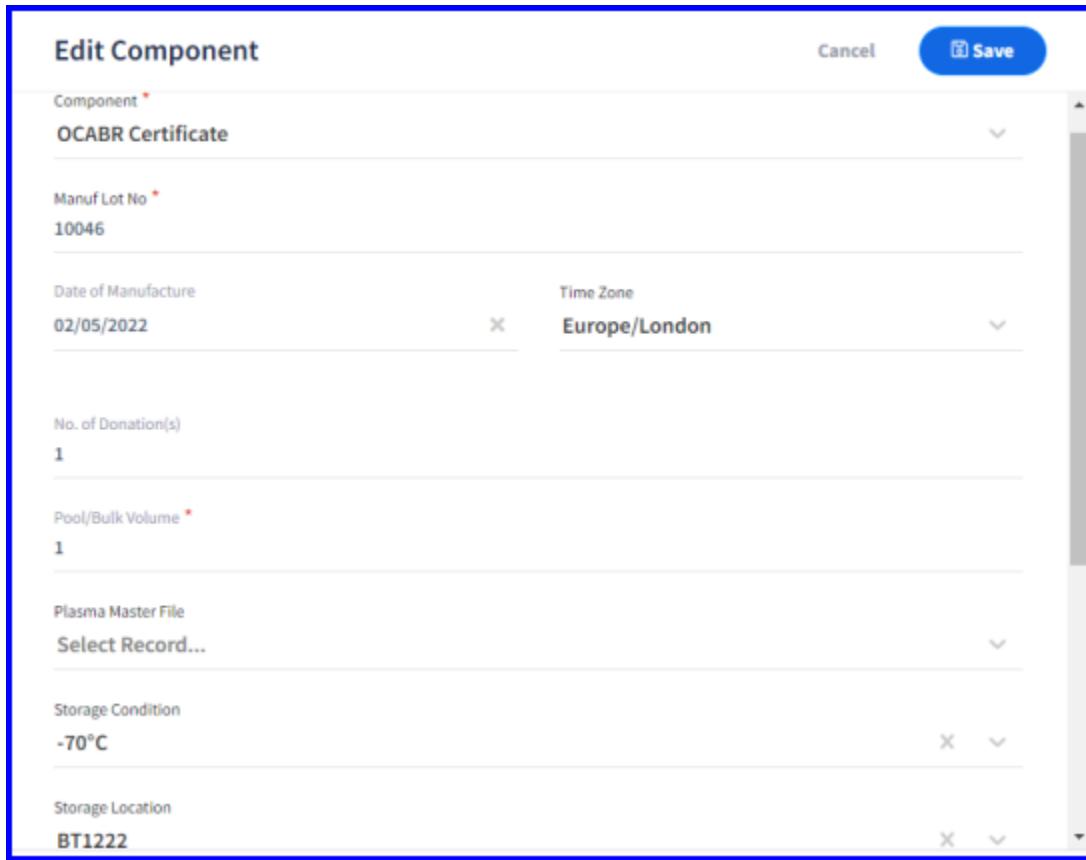


FIGURE: Edit Component Dialog

11. In the **Manuf Lot No.** field, type the lot number.
12. In the **Storage Condition** field, select storage condition for the selected product.
13. In the **Storage Location** field, select storage location for the selected product.
14. Click **Save**. Same way, you can add **Manuf Lot No.** to other components.
15. Under **Tests**, you can see list of tests in the selected component. If required, you can delete tests from the list or add tests to the list. Click **+ Test** to add more tests to the component.
16. Click **+ Source** and add source of sample.
17. Click **Save**. The sample is registered for each component in the registration screen, you can see samples registered as shown in the figure:

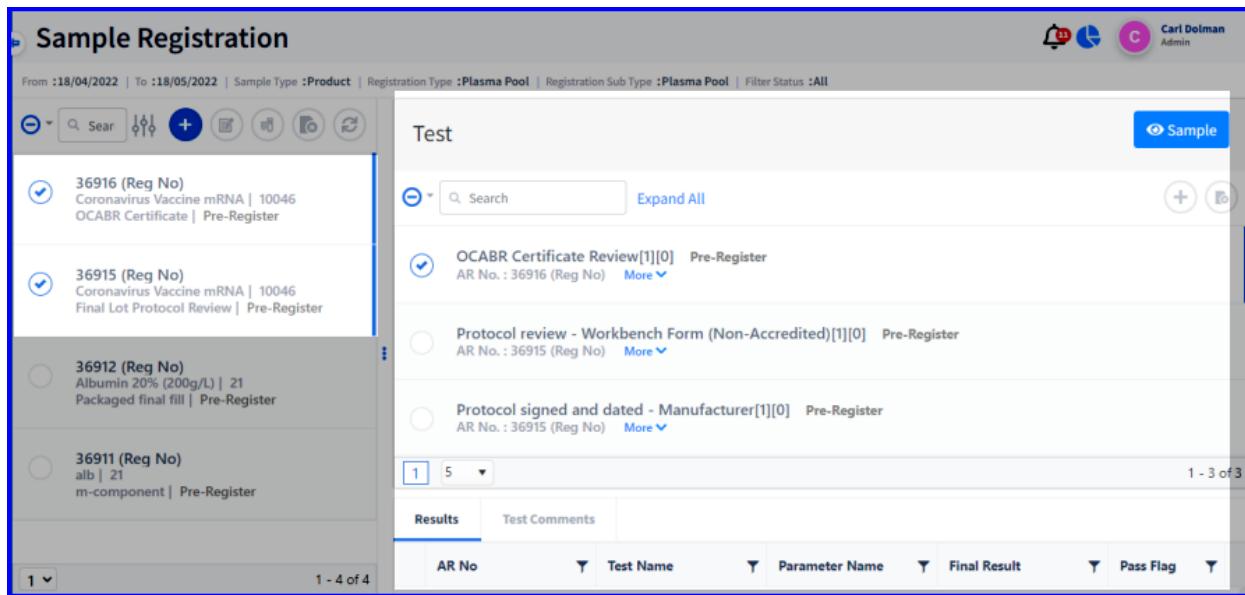


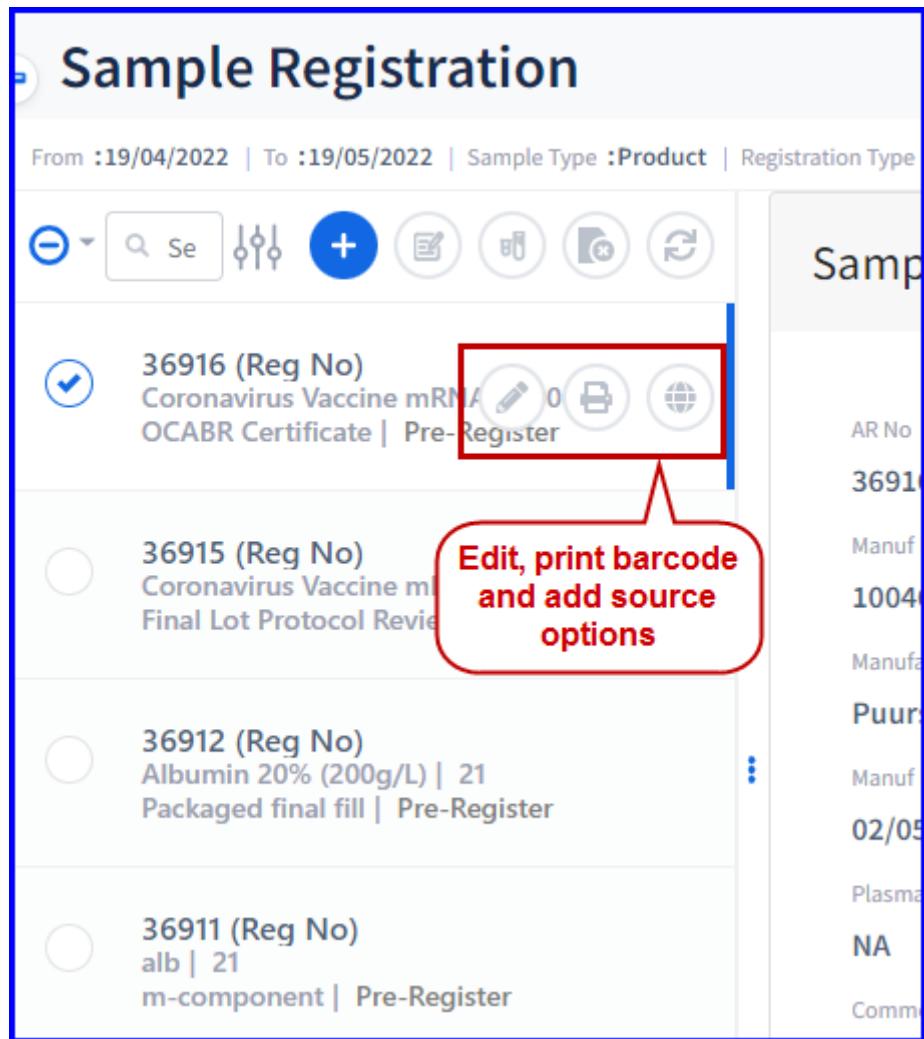
FIGURE: Registered Sample

You can see the samples registered. In this example, there are two components, hence two records are generated for the sample as shown in the above figure.

The samples appear in **Pre-Register** state. In this state, you can accept the sample to register the sample. Or you can cancel / reject the sample.

4.1.4.1 Edit, Print Barcode and Add Source options

Mouse over a record. You can see options to edit the record details, print barcode and add source options as shown in the figure:



From :19/04/2022 | To :19/05/2022 | Sample Type :Product | Registration Type

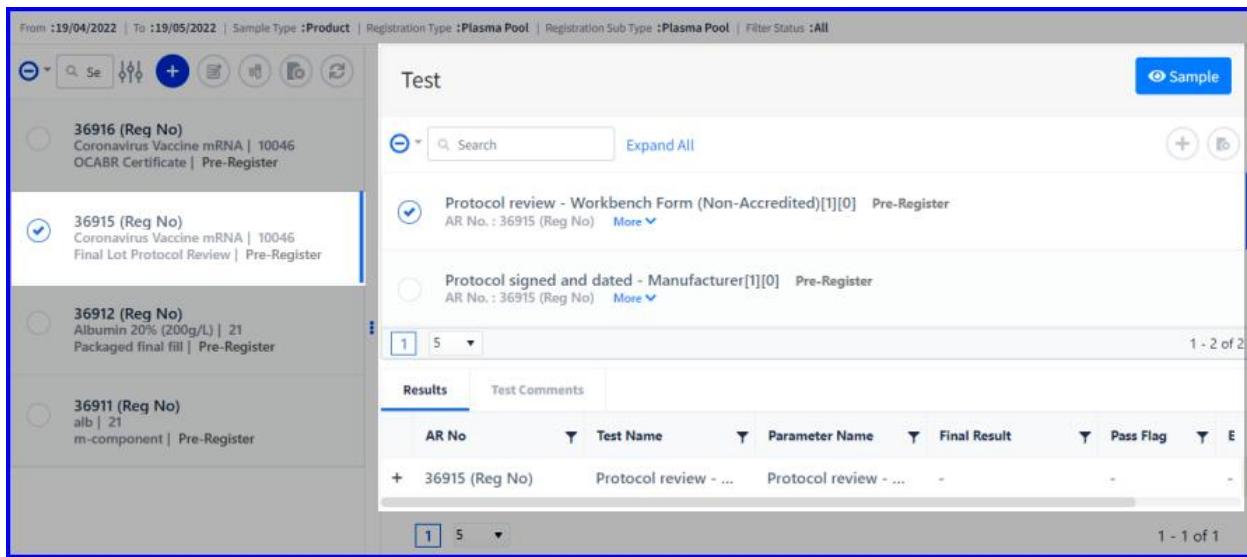
Sample Registration

Sample ID	Reg No	Description	Actions
<input checked="" type="radio"/>	36916	Coronavirus Vaccine mRNA OCABR Certificate Pre-Register	  
<input type="radio"/>	36915	Coronavirus Vaccine mRNA Final Lot Protocol Review	
<input type="radio"/>	36912	Albumin 20% (200g/L) 21 Packaged final fill Pre-Register	
<input type="radio"/>	36911	alb 21 m-component Pre-Register	

FIGURE: Registered Sample Showing Edit, Print Barcode and Add Source Options

4.1.4.2 Viewing Tests added to sample

Select a record; you can see the tests added for the sample listed on the right side as shown in the figure:



The screenshot shows the 'Test' screen of the LIMS Qualis software. At the top, there are search and filter buttons, and a 'Sample' button. The main area displays a list of tests with their details. One test is selected, showing a detailed view of its protocol and results. A table at the bottom shows the results for the selected test.

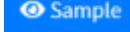
AR No	Test Name	Parameter Name	Final Result	Pass Flag	E
36915 (Reg No)	Protocol review - ...	Protocol review - ...	-	-	-

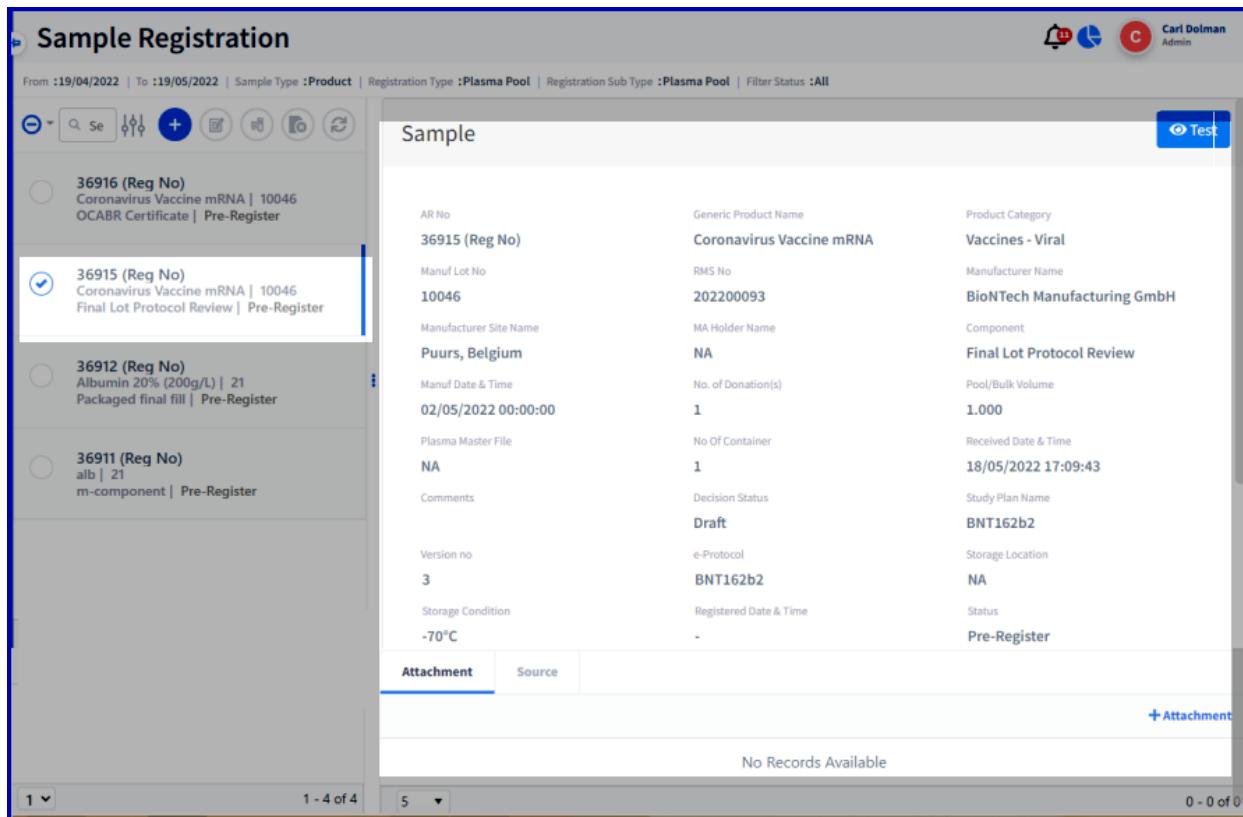
FIGURE: Viewing Tests Added to the Sample

Click  to add more test(s) to the selected sample registered.

Select a test and then click  to cancel / Reject test.

4.1.4.3 Viewing Sample Details

Click  to view sample details. The sample details appear as shown in the figure:



The screenshot shows the 'Sample Registration' screen. On the left, a list of samples is displayed, including:

- 36916 (Reg No) - Coronavirus Vaccine mRNA | 10046 OCABR Certificate | Pre-Register
- 36915 (Reg No) - **Selected** Coronavirus Vaccine mRNA | 10046 Final Lot Protocol Review | Pre-Register
- 36912 (Reg No) - Albumin 20% (200g/L) | 21 Packaged final fill | Pre-Register
- 36911 (Reg No) - alb | 21 m-component | Pre-Register

The right panel shows the detailed view for the selected sample (36915):

AR No	36915 (Reg No)	Generic Product Name	Coronavirus Vaccine mRNA	Product Category	Vaccines - Viral
Manuf Lot No	10046	RMS No	202200093	Manufacturer Name	BioNTech Manufacturing GmbH
Manufacturer Site Name	Puurs, Belgium	MA Holder Name	NA	Component	Final Lot Protocol Review
Manuf Date & Time	02/05/2022 00:00:00	No. of Donation(s)	1	Pool/Bulk Volume	1.000
Plasma Master File	NA	No Of Container	1	Received Date & Time	18/05/2022 17:09:43
Comments		Decision Status	Draft	Study Plan Name	BNT162b2
Version no	3	e-Protocol	BNT162b2	Storage Location	NA
Storage Condition	-70°C	Registered Date & Time	-	Status	Pre-Register
Attachment		Source			
+ Attachment					
No Records Available					

Navigation controls at the bottom include: 1 - 4 of 4, 5, 0 - 0 of 0.

FIGURE: Viewing Sample Details

Click **+ Attachment** to add attachments to the sample.

4.1.4.4 Register Sample

In the Pre-Register state, you can accept the sample.

1. In the Sample Registration screen, select a sample that is in the **Pre Register** state and then click  to accept the sample as shown in the figure:

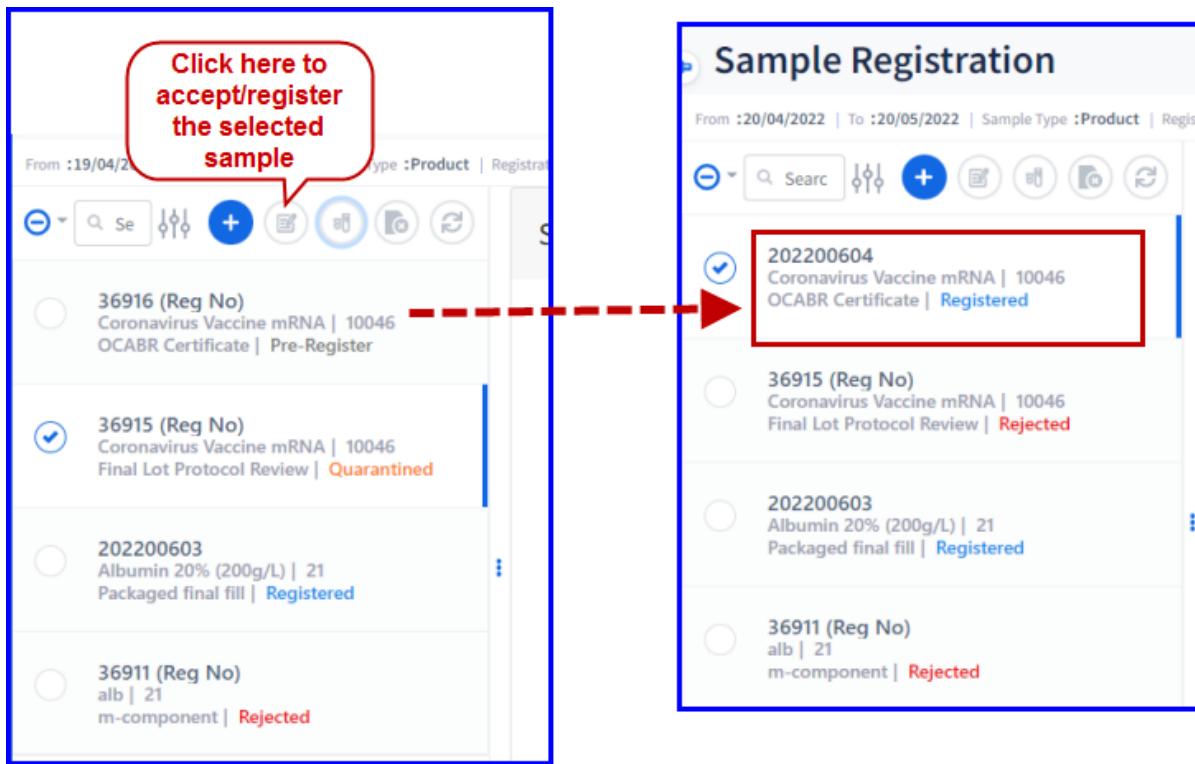


FIGURE: Accepting Sample

2. In the **Confirmation** dialog, click **Ok**.

The accepted sample appears as **Registered** and the AR No is generated as shown in the above figure.

4.1.4.5 Cancel/Reject

You can cancel/reject the sample before or after registration.

1. To cancel/reject the sample, in the **Sample Registration** screen, select the sample and then click  as shown in the figure:

Sample Registration

From :19/04/2022 | To :19/05/2022 | Sample Type :Product | Registration Type :Plasma Pool

		Fluenz UK - Me		
<input type="radio"/>	36916 (Reg No) Coronavirus Vaccine mRNA 10046 OCABR Certificate Pre-Register	Manuf Date & Time 022 00:		
<input type="radio"/>	36915 (Reg No) Coronavirus Vaccine mRNA 10046 Final Lot Protocol Review Pre-Register	Comments		
<input type="radio"/>	36912 (Reg No) Albumin 20% (200g/L) 21 Packaged final fill Pre-Reg	Version no 1		
<input checked="" type="radio"/>	36911 (Reg No) alb 21 m-component Rejected	Storage Condition IA		
		Attachment		

Click here to
Cancel/Reject the
sample

The pre-registered
sample is rejected

FIGURE: Cancel / Reject Sample

2. If you cancel/reject sample in the preregister stage then the sample is rejected.
3. If you cancel/reject sample in the registered stage then the sample is cancelled

4.1.4.6 Quarantine

You can quarantine the sample that is in the Pre-register state.

1. To quarantine the sample, in the **Sample Registration** screen, select the sample and then click  as shown in the figure:

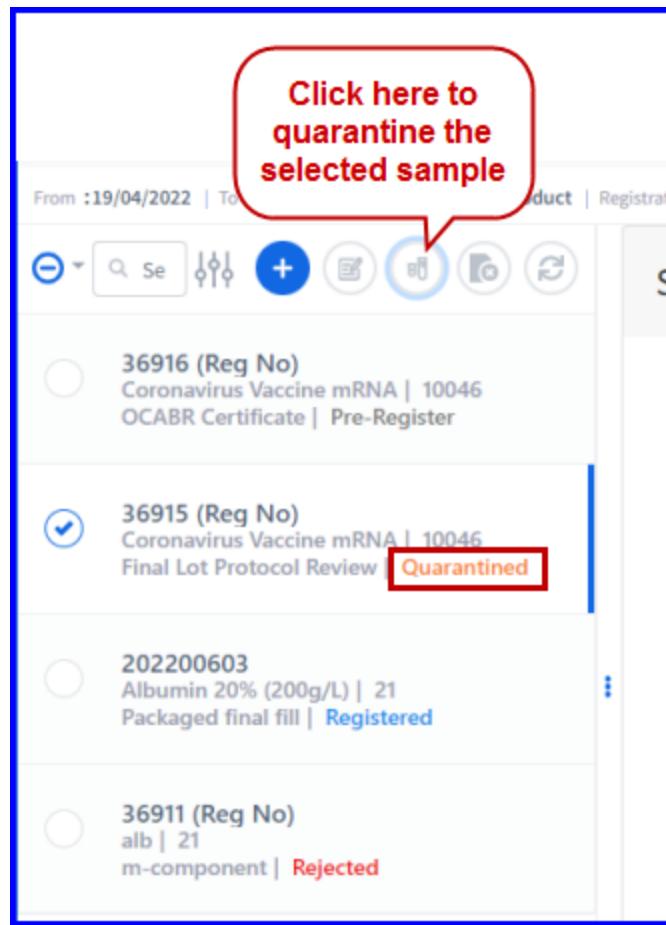
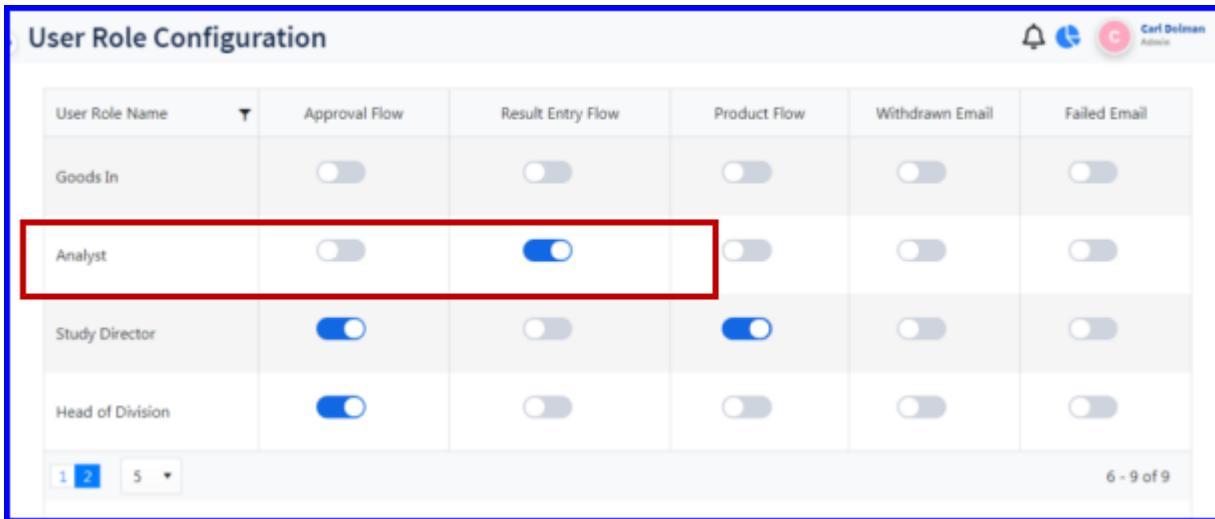


FIGURE: Quarantine Sample

The status of the sample appears as **Quarantined**. You can accept a quarantined sample to register it or cancel/reject it.

4.2 Result Entry

The result entry flow will be available for the users enabled in the User Role Configuration screen as shown in the figure:



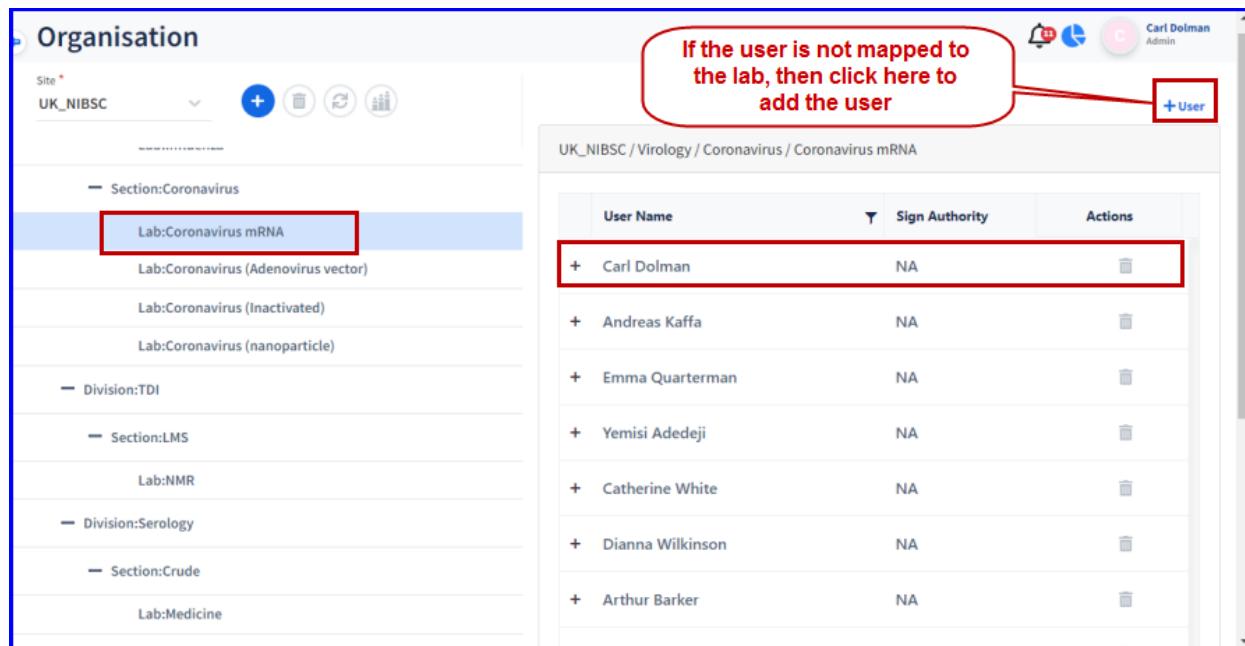
The screenshot shows a 'User Role Configuration' table with the following data:

User Role Name	Approval Flow	Result Entry Flow	Product Flow	Withdrawn Email	Failed Email
Goods In	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Analyst	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study Director	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Head of Division	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Page navigation: 1 2 5 ... 6 - 9 of 9

FIGURE: User Role Configuration Screen Showing Result Entry Flow

Also ensure that the user is mapped to the lab the test is mapped to as shown in the Organisation screen:



The screenshot shows the 'Organisation' screen with the following details:

- Site:** UK_NIBSC
- Section:Coronavirus** (highlighted with a red box)
 - Lab:Coronavirus mRNA** (highlighted with a red box)
 - Lab:Coronavirus (Adenovirus vector)
 - Lab:Coronavirus (Inactivated)
 - Lab:Coronavirus (nanoparticle)
- Division:TDI**
 - Section:LMS**
 - Lab:NMR
 - Section:Serology**
 - Section:Crude**
 - Lab:Medicine

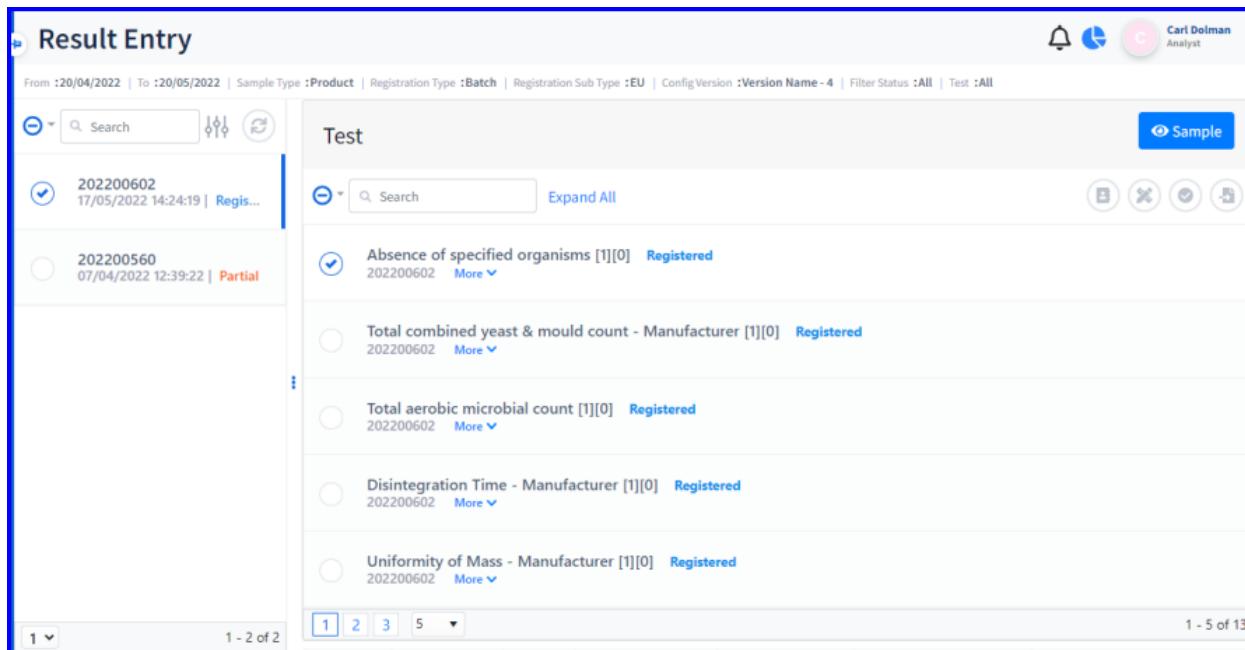
A callout bubble with the text 'If the user is not mapped to the lab, then click here to add the user' points to the '+User' button in the top right corner of the user list table.

User Name	Sign Authority	Actions
Carl Dolman	NA	
Andreas Kaffa	NA	
Emma Quarterman	NA	
Yemisi Adedeji	NA	
Catherine White	NA	
Dianna Wilkinson	NA	
Arthur Barker	NA	

FIGURE: Organisation Screen Showing User Mapped to the Test Lab

For registered samples, you can enter results. To do so, follow these steps:

1. On the main menu, click **Result Entry** and then click **Result Entry**. The **Result Entry** screen appears as shown in the figure:



Result Entry

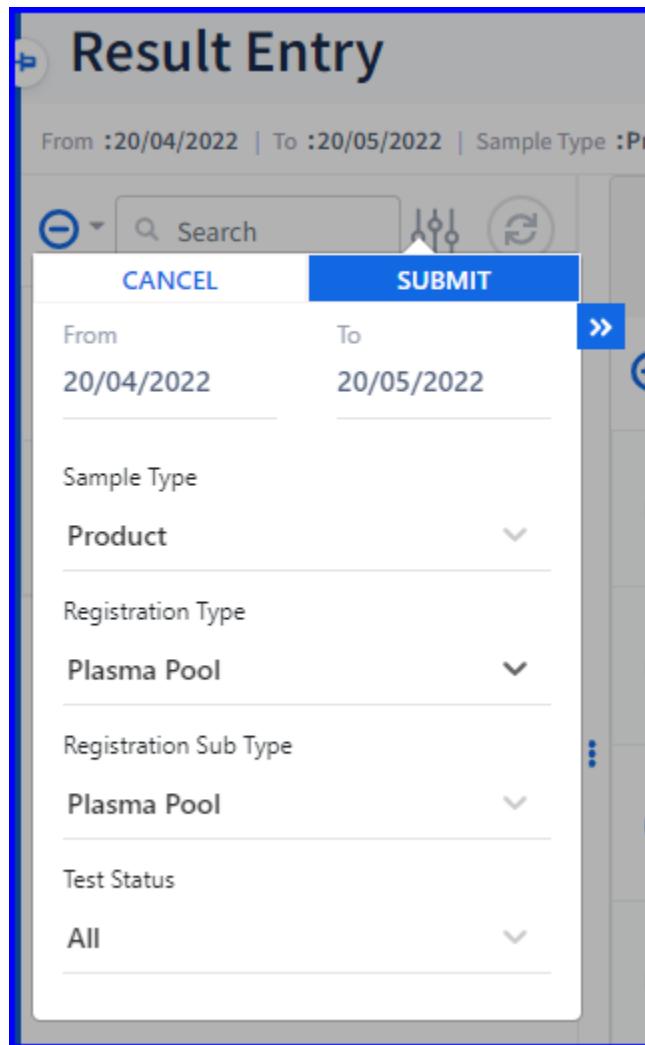
From :20/04/2022 | To :20/05/2022 | Sample Type :Product | Registration Type :Batch | Registration Sub Type :EU | Config Version :Version Name - 4 | Filter Status :All | Test :All

Test

<input checked="" type="checkbox"/>	202200602 17/05/2022 14:24:19 Regis...	<input type="button" value="Sample"/>		
<input type="checkbox"/>	202200560 07/04/2022 12:39:22 Partial			
<input type="button" value="Search"/> <input type="button" value="Print"/> <input type="button" value="Print All"/> <input type="button" value="Print All Selected"/> <input type="button" value="Print All Filtered"/> <input type="button" value="Print All Filtered Selected"/>				
<input type="button" value="Expand All"/>				
<input checked="" type="checkbox"/>	Absence of specified organisms [1][0] Registered 202200602 More			
<input type="checkbox"/>	Total combined yeast & mould count - Manufacturer [1][0] Registered 202200602 More			
<input type="checkbox"/>	Total aerobic microbial count [1][0] Registered 202200602 More			
<input type="checkbox"/>	Disintegration Time - Manufacturer [1][0] Registered 202200602 More			
<input type="checkbox"/>	Uniformity of Mass - Manufacturer [1][0] Registered 202200602 More			
<input type="button" value="1"/> <input type="button" value="2"/> <input type="button" value="3"/> <input type="button" value="4"/> <input type="button" value="5"/> <input type="button" value="Next"/>				
1 - 5 of 13				

FIGURE: Result Entry Screen

Click , in the Filter dialog, select **From** and **To** date, **Sample Type**: Product, **Registration Type**: Batch / Non Batch / Plasma Pool, **Registration Sub Type** and **Filter Status**. And then click **SUBMIT** as shown in the figure:



Result Entry

From :20/04/2022 | To :20/05/2022 | Sample Type :Pr

Search

CANCEL SUBMIT

From: 20/04/2022 To: 20/05/2022

Sample Type: Product

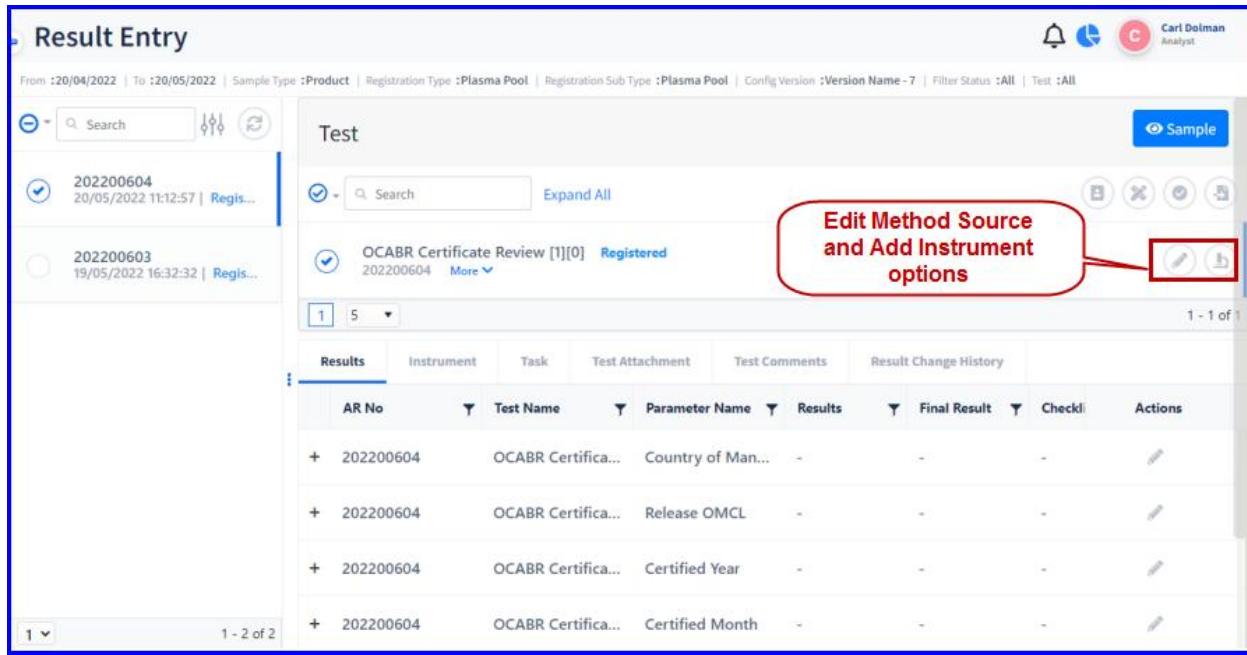
Registration Type: Plasma Pool

Registration Sub Type: Plasma Pool

Test Status: All

FIGURE: Using Filter in Result Entry Screen

Registered samples in the Sample Registration screen appears on the left panel and list of tests added to the selected sample appears on the right side as shown in the figure:



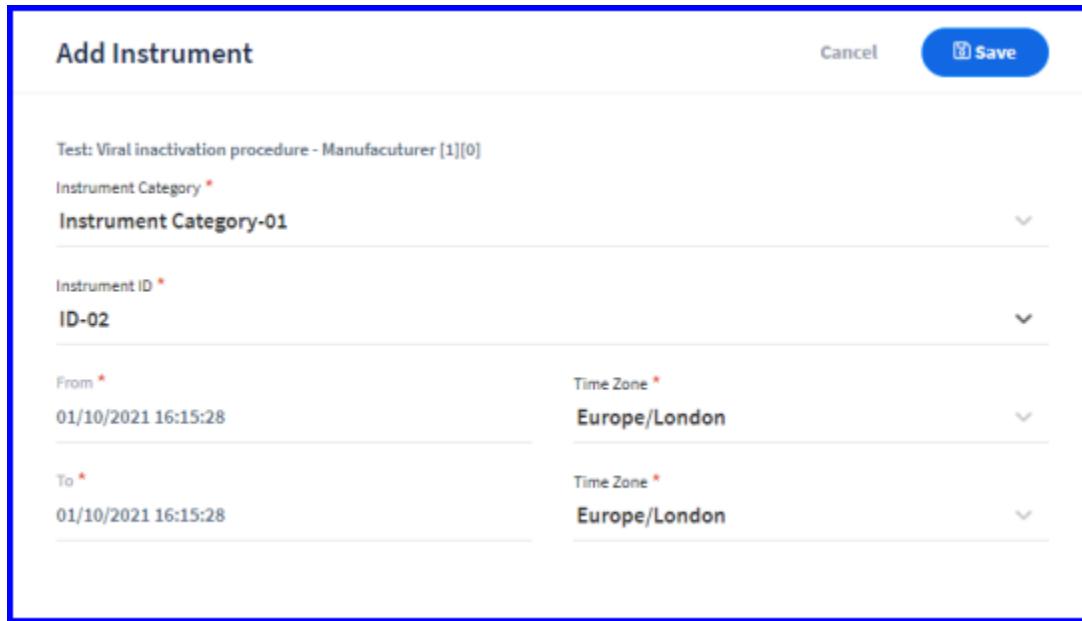
The screenshot shows the 'Result Entry' screen in Qualis LIMS. At the top, there are search and filter options, and a user profile for 'Carl Dolman Analyst'. The main area is divided into two sections: 'Sample' (left) and 'Test' (right). The 'Sample' section shows a list of registered samples with details like AR Number, Date, and Registration Status. The 'Test' section shows a list of tests for a specific sample, with columns for AR No, Test Name, Parameter Name, Results, Final Result, Checklist, and Actions. A red callout box highlights the 'Edit Method Source and Add Instrument options' button in the 'Actions' column of the test table.

FIGURE: Result Entry Screen Showing Registered Sample and the List of Tests

Edit Method Source

4.2.1 Adding Instruments

1. When you mouse over a test in the list you can see option for adding instrument to the test.
2. Mouse over a test and click . The Add Instrument dialog appears as shown in the figure:



Add Instrument

Test: Viral inactivation procedure - Manufacuturer [1][0]

Instrument Category *

Instrument Category-01

Instrument ID *

ID-02

From *

01/10/2021 16:15:28

Time Zone *

Europe/London

To *

01/10/2021 16:15:28

Time Zone *

Europe/London

Cancel  Save

FIGURE: Add Instrument Dialog

3. In the **Instrument Category** field, select instrument category.
4. In the **Instrument** field, select the instrument to add to the selected test.
5. In the **From** and **To** date and time fields select date and time range to block the instrument for the test.
6. Click **Save**. The instrument will be added to the test and blocked for the given date and time range.

4.2.2 Result Entry

You can enter results for each test individually or select multiple tests from the list for result entry.

1. Select test(s) and then click . To select all the tests click  that appears near search box and then select **All** to select all the test in the page as shown in the figure:

Result Entry

From : 20/04/2022 | To : 20/05/2022 | Sample Type : Product | R

Test

202200604 20/05/2022 11:12:57 | Regis...

202200603 19/05/2022 16:32:32 | Regis...

Test

202200603 More

Albumin [1][0] Registered

Prekallikrein Activator of Albumin [1][0] Registered

1 5 1 - 3 of 3

Results	Instrument	Task	Test Attachment	Test Comments	Result Change History	
AR No	Test Name	Parameter Name	Results	Final Result	Checklist	Actions
202200603	Prekallikrein Act...	PKA (IU/mL)	-	-	-	<input type="button" value="Edit"/>

1 1 - 2 of 2

2. Click . The **Result Entry** dialog appears prompting for result entry for all the selected tests as shown in the figure:

Result Entry

202200603

Appearance [1][0]

Appearance

Complies

PASS

202200603

Molecular size distribution of Albumin [1][0]

P&A (%)

.2

PASS

202200603

Prekallikrein Activator of Albumin [1][0]

PKA (IU/mL)

20

PASS

Cancel

FIGURE: Result Entry for Multiple Tests

3. Enter results for all the test in the dialog and then click **Save**. Same way, you can go to the next page and then select tests for result entry.

Note: If you have selected one test, the Result Entry dialog will prompt for the selected single test.

4.2.3 Result Entry Screen Tabs

Following tabs are available in the Result Entry screen:

Results: View results entered for selected tests as shown in the figure:

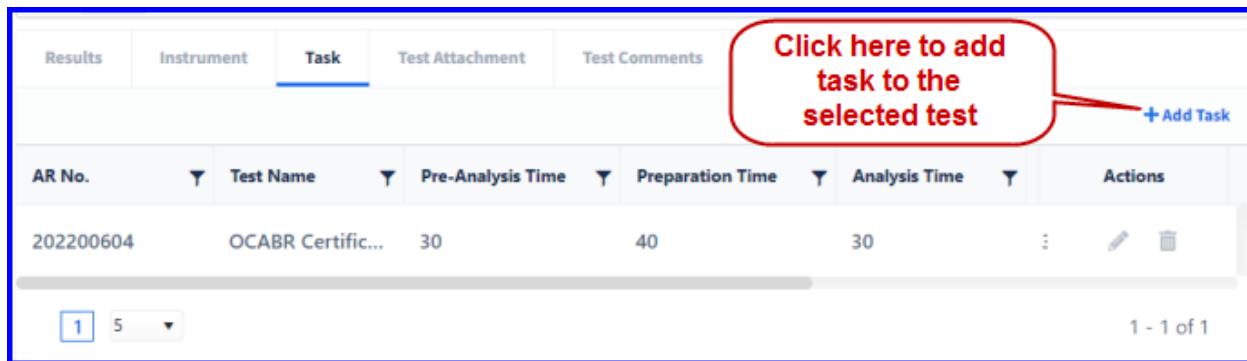
Results	Instrument	Task	Test Attachment	Test Comments	Result Change History	
AR No	Test Name	Parameter Name	Results	Final Result	Checklist	Actions
+ 202200604	OCABR Certifica...	Country of Man...	Belgium	Belgium	-	
+ 202200604	OCABR Certifica...	Release OMCL	AT_BASG_B	AT_BASG_B	-	
+ 202200604	OCABR Certifica...	Certified Year	2022	2022	-	
+ 202200604	OCABR Certifica...	Certified Month	April	April	-	
+ 202200604	OCABR Certifica...	Certified Day	02	02	-	

4.2.3.1 Instruments

View instruments added to the selected tests.

Results	Instrument	Task	Test Attachment	Test Comments	Result Change History	
AR No	Test Name	Instrument Category	Instrument Name		Actions	
202200604	OCABR Certificate Review [1]...	Manual	fdsafds		 	
1	5					1 - 1 of 1

Add Task: Add efforts/time taken to complete the test(s)



The screenshot shows a table with the following data:

AR No.	Test Name	Pre-Analysis Time	Preparation Time	Analysis Time	Actions
202200604	OCABR Certific...	30	40	30	⋮ edit trash

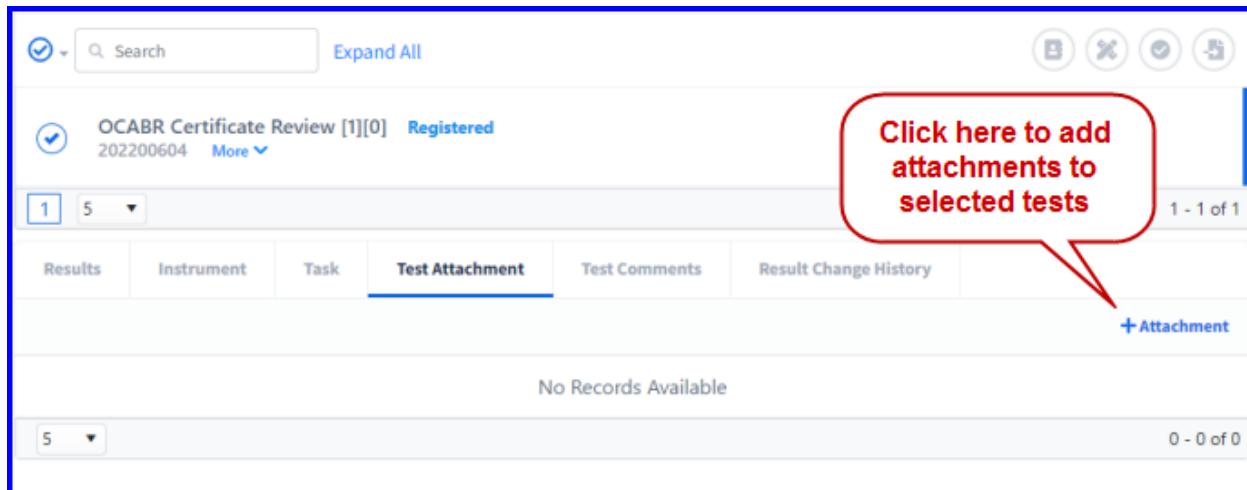
Below the table, there is a page navigation section with '1' and '5' and a status message '1 - 1 of 1'.

A red callout box with the text 'Click here to add task to the selected test' points to the '+ Add Task' button in the top right corner of the table header.

4.2.3.2 Test Attachment

To attach files to tests, follow these steps:

1. Select test(s) you want to add attachments.
2. And then click **+ Attachment** as shown in the figure:



The screenshot shows a table with the following data:

Results	Instrument	Task	Test Attachment	Test Comments	Result Change History
OCABR Certificate Review [1][0] Registered	202200604 More				

Below the table, there is a page navigation section with '1' and '5' and a status message '1 - 1 of 1'.

A red callout box with the text 'Click here to add attachments to selected tests' points to the '+ Attachment' button in the bottom right corner of the table header.

FIGURE: Attaching files to tests

The **Add Test Attachment** dialog appears as shown in the figure:

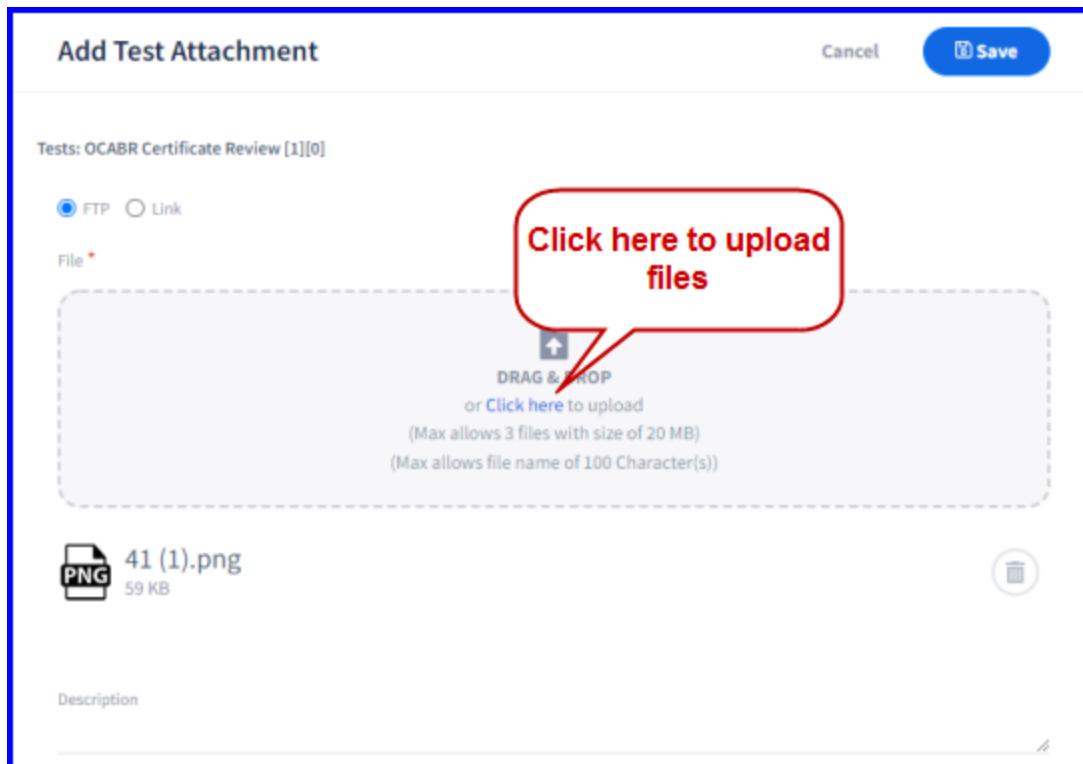


FIGURE: Add Test Attachment Dialog

Do any one of the following:

Select **FTP**. Then drag and drop a file to attach. Or Click [Click here](#) to locate and attach the file and then click **Save**.

Or

Select **Link**. Type the **File Name** and paste the link in the **Link Name** field and then click **Save**.

The file is attached to the test(s) as shown in the figure:

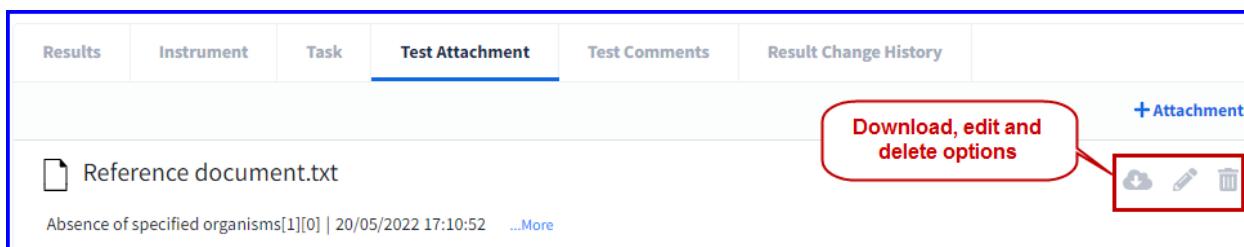
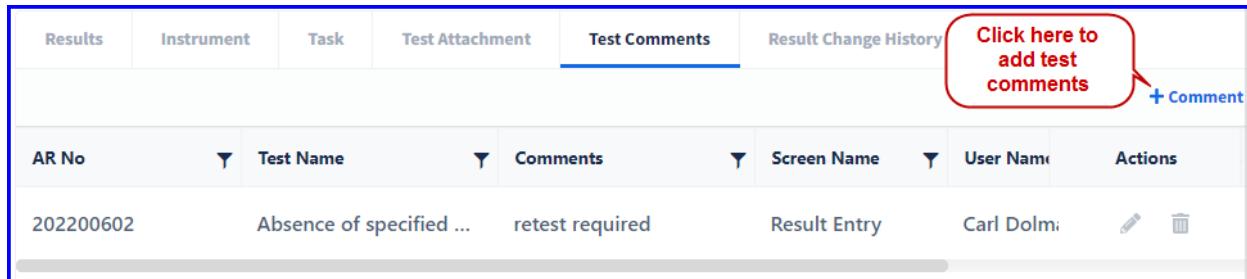


FIGURE: Attachment Added to the selected Test(s)

4.2.3.3 Test Comments

Test Comments tab enables you to add test comments to the selected test(s).

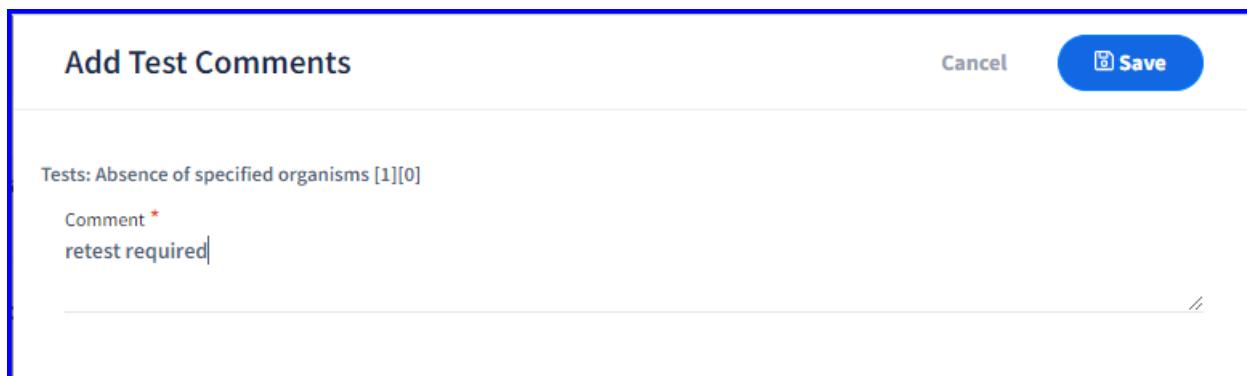
1. Select test(s) to add comments and then click **+ Comment** as shown in the figure:



Results	Instrument	Task	Test Attachment	Test Comments	Result Change History		
AR No	Test Name	Comments	Screen Name	User Name	Actions		
202200602	Absence of specified ...	retest required	Result Entry	Carl Dolm...			

FIGURE: Adding Test Comments

The **Add Test Comments** dialog appears as shown in the figure:



Add Test Comments

Cancel 

Tests: Absence of specified organisms [1][0]

Comment *

retest required

FIGURE: Add Test Comments Dialog

2. In the **Comment** field, type your comments. This comment will be added to all the tests selected.

4.2.3.4 Result Change History:

Result Change History tab helps you to view history of changes done to the selected test results.

Results	Instrument	Task	Test Attachment	Test Comments	Result Change History			
	AR No	Test Name	Parameter Name	Form Name	Results	Final Result	Remark	
+	202200604	OCABR Certifica...	Release OMCL	Result Entry by ...	N/A	N/A		
+	202200604	OCABR Certifica...	Certified Year	Result Entry by ...	N/A	N/A		
+	202200604	OCABR Certifica...	Certified Month	Result Entry by ...	N/A	N/A		
+	202200604	OCABR Certifica...	Certified Day	Result Entry by ...	N/A	N/A		
+	202200604	OCABR Certifica...	OCABR Certifica...	Result Entry by ...	N/A (NIBSC...	N/A (NIBSC...		

FIGURE: Result Change History Tab

4.2.3.5 Fill Default Results

Select test(s) and then click  to fill default results as shown in the figure:



Test								
<input checked="" type="checkbox"/> <input type="checkbox"/> Search Expand All								
<input checked="" type="checkbox"/> OCABR Certificate Review [1][0] Registered 202200604 More								
1 5 ▼								
Results	Instrument	Task	Test Attachment	Test Comments	Result Change History			
	AR No	Test Name	Parameter Name	Form Name	Results	Final Result	Remark	
+	202200604	OCABR Certifica...	Release OMCL	Result Entry by ...	N/A	N/A		

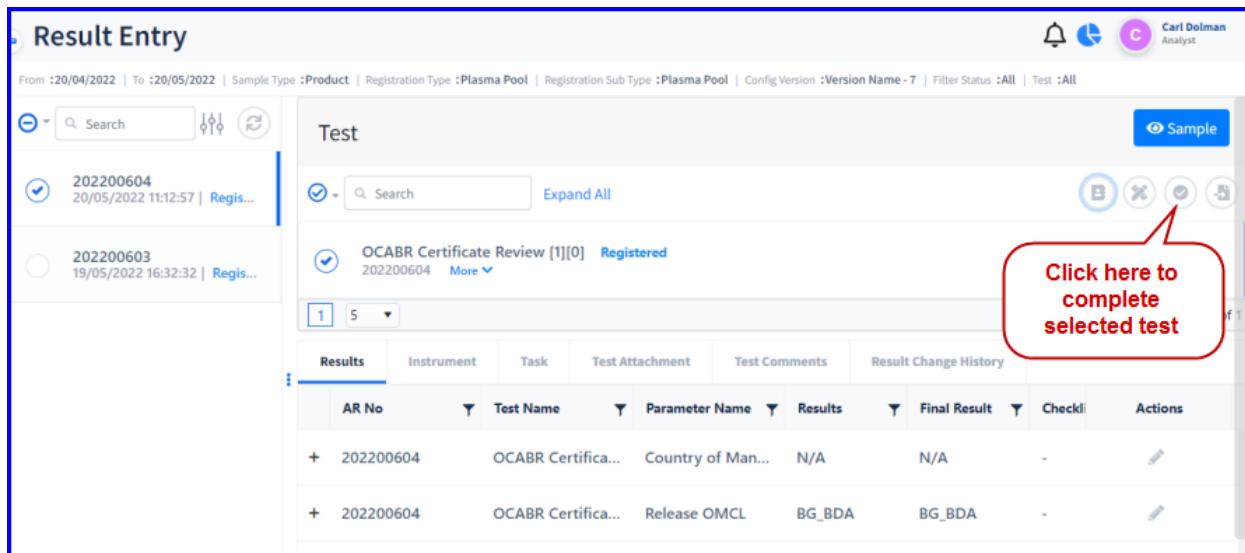
FIGURE: Filling Default Results to Selected Test(s)

Default result that is given in the test master will be filled as result.

4.2.3.6 Complete Test

Once you add test result, task, attachment and comments to the test/tests you can complete the test.

1. To complete the test, select the test or tests from the list and then click as shown in the figure:



The screenshot shows the 'Result Entry' page with a list of tests for sample 202200604. The 'Test' section displays a table with columns: AR No, Test Name, Parameter Name, Results, Final Result, Checklist, and Actions. Two rows are visible: one for OCABR Certificate Review and one for OCABR Certification. A red callout box with the text 'Click here to complete selected test' points to the 'Complete Test' button in the Actions column of the first row.

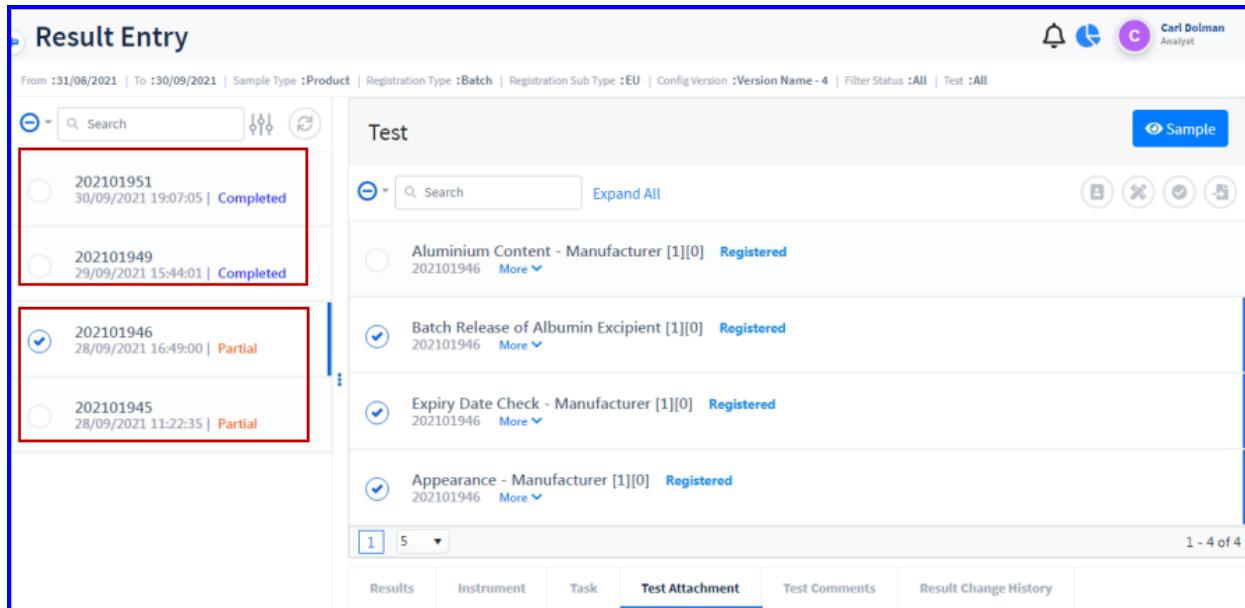
FIGURE: Completing Tests

Completed tests will disappear from the list

4.2.3.7 Sample Status

Once all tests are completed, then the status of the sample appears as **Completed**.

If few tests are completed and other tests are yet to be completed, then the status of the sample appears as **Partial** as shown in the figure:



The screenshot shows the 'Result Entry' page with a list of tests for sample 202101946. The 'Test' section displays a table with columns: AR No, Test Name, Parameter Name, Results, Final Result, Checklist, and Actions. Four rows are visible: two 'Completed' rows and two 'Partial' rows. The first two rows are highlighted with red boxes, and the last two rows are also highlighted with red boxes.

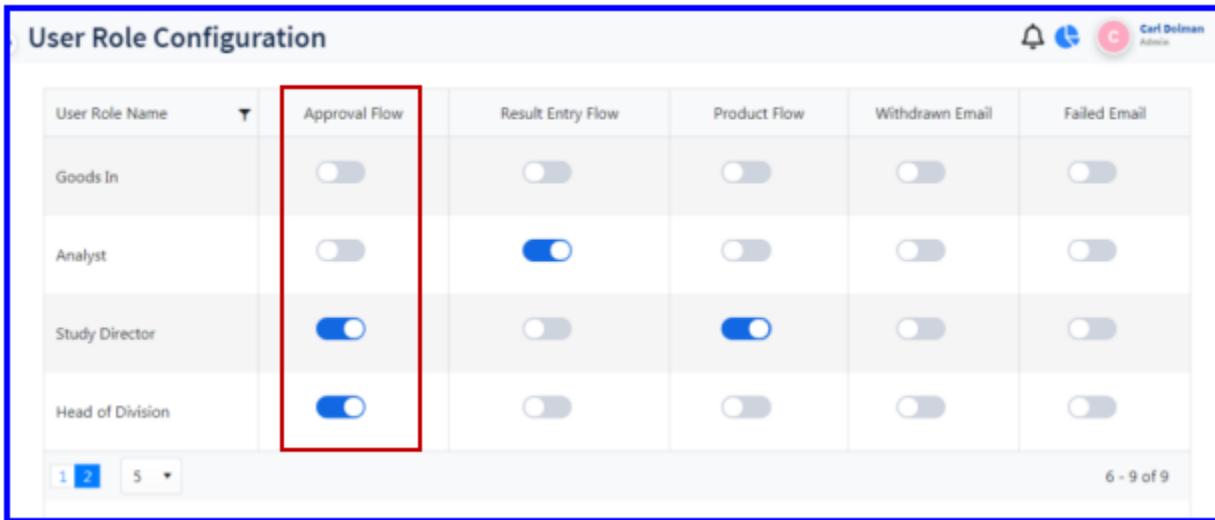
FIGURE: Sample with Completed and Partial Status

4.3 Test approval

To receive completed samples from the result entry screen, ensure that the following configurations are done appropriately:

4.3.1 User Role Configuration

The test approval flow will be available for the users enabled in the User Role Configuration screen as shown in the figure:

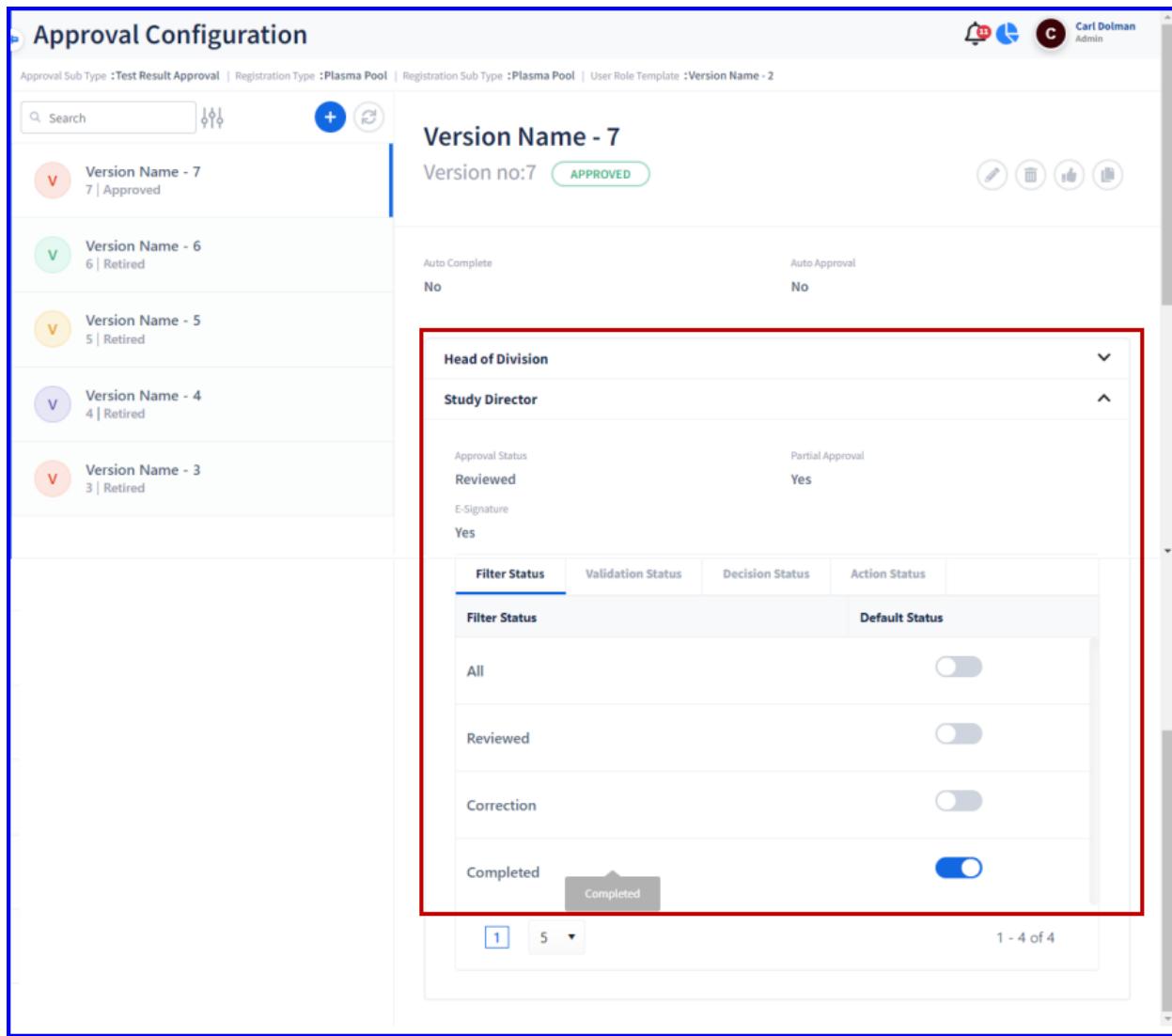


User Role Name	Approval Flow	Result Entry Flow	Product Flow	Withdrawn Email	Failed Email
Goods In	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Analyst	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study Director	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Head of Division	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FIGURE: User Role Configuration Screen Showing Approval Flow

4.3.2 Approval Configuration

Once result entry is done, the completed samples will appear in the next user in the approval flow as configured in the Approval Configuration screen as shown in the figure:



The screenshot shows the 'Approval Configuration' screen in Qualis LIMS. On the left, a list of versions is displayed:

- Version Name - 7 | Approved
- Version Name - 6 | Retired
- Version Name - 5 | Retired
- Version Name - 4 | Retired
- Version Name - 3 | Retired

On the right, the details for 'Version Name - 7' are shown. The status is 'APPROVED'. The 'Head of Division' and 'Study Director' sections are expanded. A red box highlights the 'Filter Status' table under 'Head of Division'.

Filter Status	Validation Status	Decision Status	Action Status
All	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Correction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Completed	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

At the bottom, there is a navigation bar with page numbers 1, 5, and a dropdown, and a message '1 - 4 of 4'.

FIGURE: Approval Configuration Screen Showing User in the Approval Flow

4.3.3 User Mapping

In the User Mapping screen, you can map user for the approval flow in the user level. Samples completed in the result entry screen by a selected user will go to the user selected in the next level in the approval configuration as shown in the figure:

User Mapping

Filter
Head of Division

UK_NIBSC

User Name	Login Id	Division	Actions
Carl Dolman	cdolman	Biotherapeutics	
Sjoerd Rijpkema	srijpkem	Bacteriology	
Barbara Bolgiano	BBolgian	Bacteriology	
Mei Mei Ho	mho	Bacteriology	
Kevin Markey	kmarkey	Bacteriology	
Fatme Mawas	fmawas	Bacteriology	
Paul Stickings	pstickin	Bacteriology	
Nicola Rose	nrose	Virology	
Gill Cooper	GCooper	Virology	
Dianna Wilkinson	dwilkins	Virology	

1 2 10 ▾ 1 - 10 of 16

Study Director

User Name	Login Id	Division	Actions
Paul Stickings	pstickin	Bacteriology	

1 5 ▾ 1 - 1 of 1

Analyst

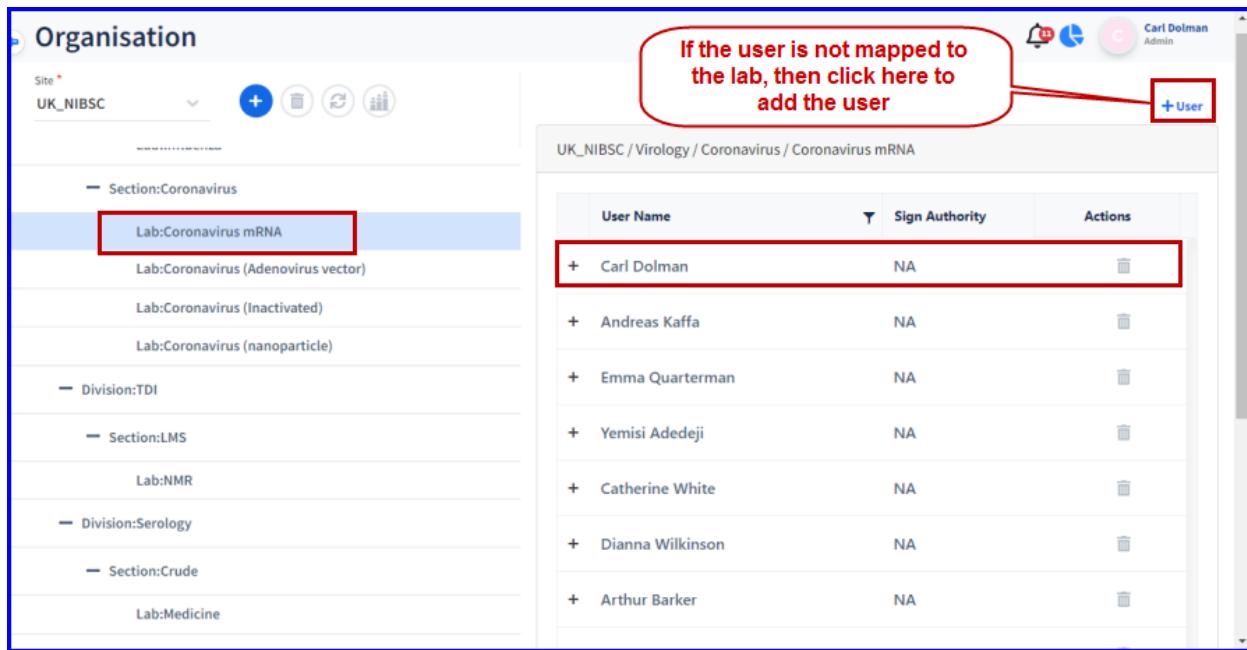
User Name	Login Id	Division	Actions
Sunil Maharjan	smaharja	Bacteriology	
Shalini Rajagopal	srajagop	Bacteriology	
Robert Tierney	rtierney	Bacteriology	
Yvonne Liu	yliu	Bacteriology	

1 5 ▾ 1 - 4 of 4

FIGURE: User Mapping Screen Showing User Level Mapping in the Approval Flow

4.3.4 Organization Mapping

Tests are mapped to labs in the test master. Users have to be mapped to that particular lab to receive tests/samples in the result entry and test approval screen as shown in the figure:



The screenshot shows two main windows. The left window is titled 'Organisation' and displays a tree structure of sites and sections. A specific section 'Lab:Coronavirus mRNA' is highlighted with a red box. The right window shows a list of users mapped to this lab, with a red box around the first user 'Carl Dolman'. A red callout bubble with the text 'If the user is not mapped to the lab, then click here to add the user' points to the '+ User' button in the top right corner of the user list window.

User Name	Sign Authority	Actions
Carl Dolman	NA	
Andreas Kaffa	NA	
Emma Quarterman	NA	
Yemisi Adedeji	NA	
Catherine White	NA	
Dianna Wilkinson	NA	
Arthur Barker	NA	

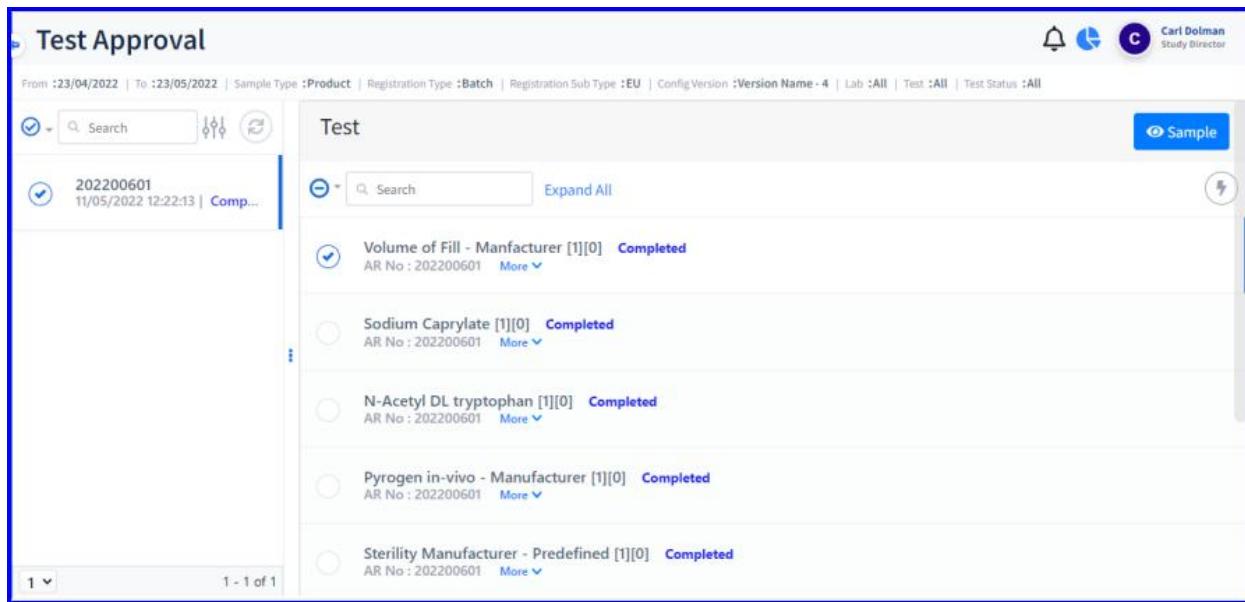
FIGURE: Organisation Screen Showing User Mapped to a Selected Lab

Once result entry is done, the completed samples will appear in the next user queue in the approval flow as configured in the Approval Configuration screen as shown in the figure:

4.4 Reviewing Test Results

To review the result entry, follow these steps:

1. On the main menu, click , **Test approval** and then click **Test Approval**. The **Test Approval** screen appears as shown in the figure:



From :23/04/2022 | To :23/05/2022 | Sample Type :Product | Registration Type :Batch | Registration Sub Type :EU | Config Version :Version Name - 4 | Lab :All | Test :All | Test Status :All

Test

202200601
11/05/2022 12:22:13 | Comp...

Volume of Fill - Manufacturer [1][0] **Completed**
AR No : 202200601 More

Sodium Caprylate [1][0] **Completed**
AR No : 202200601 More

N-Acetyl DL tryptophan [1][0] **Completed**
AR No : 202200601 More

Pyrogen in-vivo - Manufacturer [1][0] **Completed**
AR No : 202200601 More

Sterility Manufacturer - Predefined [1][0] **Completed**
AR No : 202200601 More

1 1 - 1 of 1

Test Approval Screen

Click , in the Filter dialog, select **From** and **To** date, **Sample Type**: Product, **Registration Type**: Batch / Non Batch / Plasma Pool, **Registration Sub Type** and **Test Status**. Click the  to view more fields in the filter. In the **Config Version** field select the latest template. Select **Lab** and **Test**. Select **All** to select all the test in the sample/component. And then click **SUBMIT** as shown in the figure:

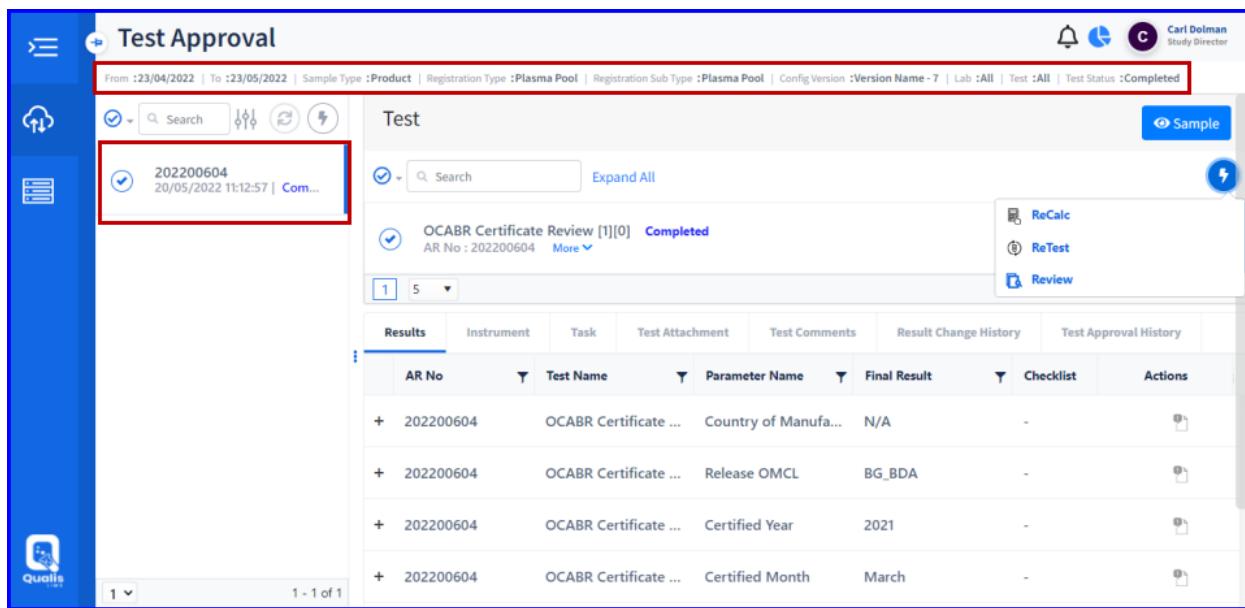
Test Approval

From :23/04/2022 | To :23/05/2022 | Sample Type :Product | Registration Type :Plas

CANCEL	SUBMIT
From 23/04/2022	To 23/05/2022
Sample Type Product	Config Version Version Name - 7
Registration Type Plasma Pool	Lab All
Registration Sub Type Plasma Pool	Test All
Test Status Completed	All OCABR Certificate Review

FIGURE: Using Filter

Samples for the given search criteria appears as shown in the figure:



AR No	Test Name	Parameter Name	Final Result	Actions
202200604	OCABR Certificate ...	Country of Manufa...	N/A	
202200604	OCABR Certificate ...	Release OMCL	BG_BDA	
202200604	OCABR Certificate ...	Certified Year	2021	
202200604	OCABR Certificate ...	Certified Month	March	

FIGURE: Test Approval Screen Showing Filtered Records

You can review the tests and then do any one of the following:

- Recommend recalculation: The tests go to the previous user(Analyst) and appear in **ReCalc** state.
- Recommend retest: The tests go to the previous user and appear in ReTest **ReTest** state.
- Complete review: Tests appear as **Reviewed** state.

4.4.1 **Changing Decision Status**

Before you recommend Recalc, Retest or finish review, you must change decision status of the sample. To do so follow these steps:

In the Test Approval screen, select a sample, click  and then click **Pass / Fail / Withdraw** as shown in the figure:

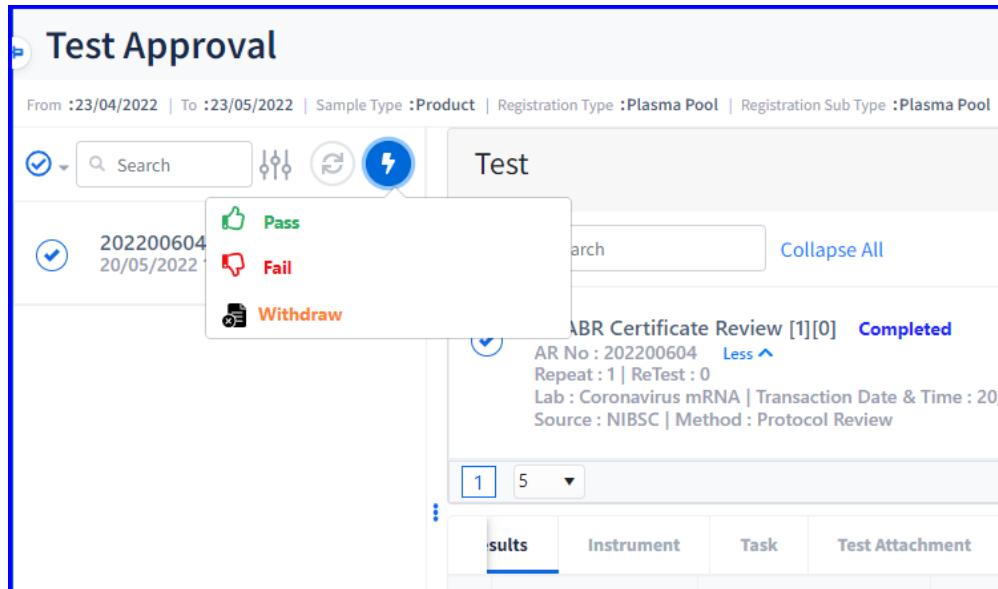
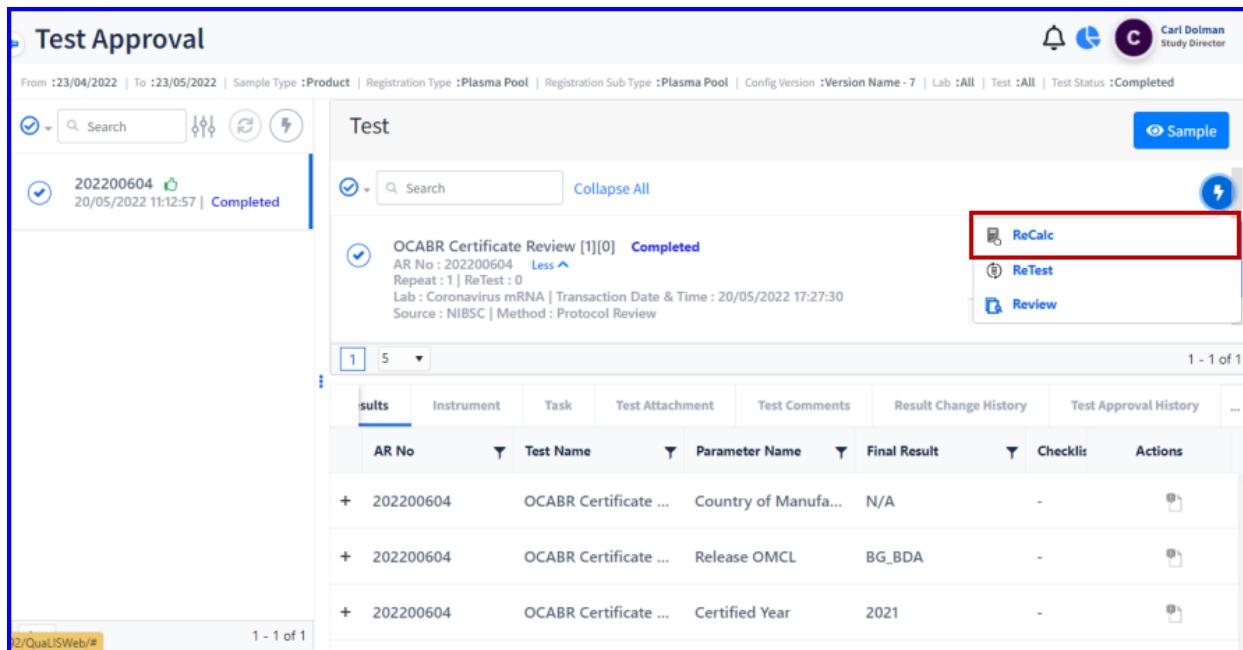


FIGURE: Changing Decision Status

4.4.2 Recommend Recalculation

Reviewer can recommend recalculation if required. To recommend recalculation, follow these steps:

1. In the Test Approval screen, select the sample, click  and then click **ReCalc** as shown in the figure:

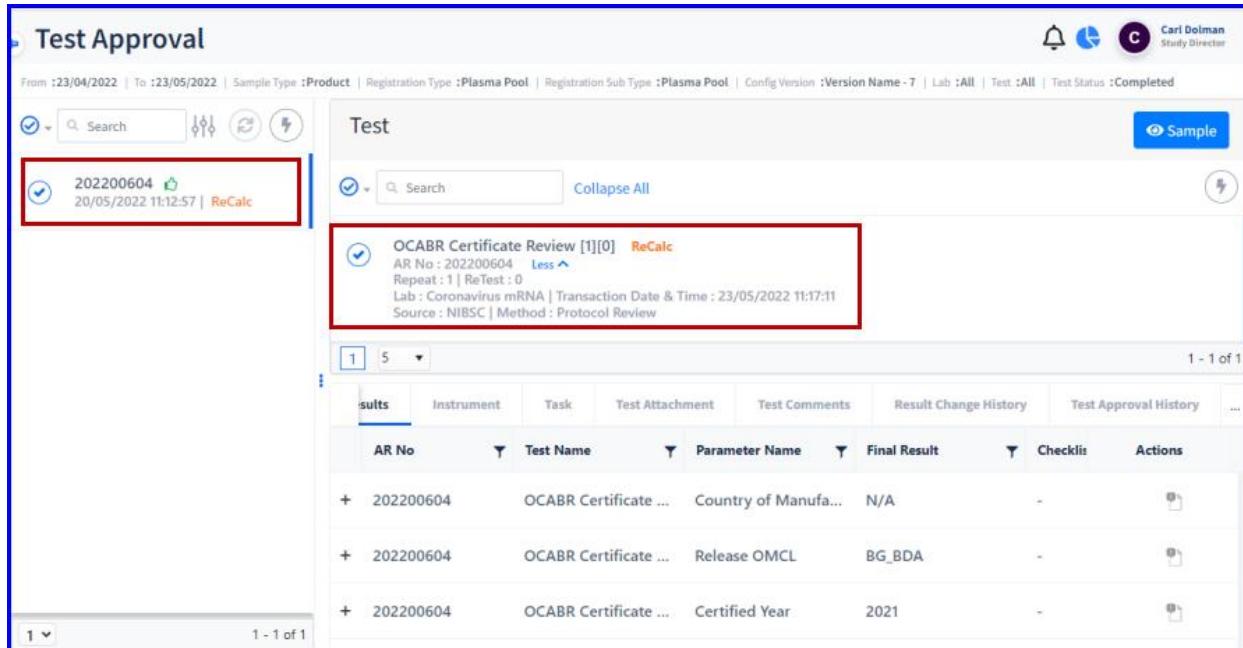


The screenshot shows the 'Test Approval' page with a blue border. At the top, there are search and filter options, and a user profile for 'Carl Dolman, Study Director'. The main area is titled 'Test' and shows a list of tests. A specific test entry for 'OCABR Certificate Review [1][0]' is highlighted with a red box. The status of this test is 'Completed', but it is also labeled 'ReCalc' in the status column. Below this, there are buttons for 'ReTest' and 'Review'. The table below lists test details such as AR No, Test Name, Parameter Name, Final Result, and Actions. The table has columns for AR No, Test Name, Parameter Name, Final Result, Checklist, and Actions.

AR No	Test Name	Parameter Name	Final Result	Checklist	Actions
202200604	OCABR Certificate ...	Country of Manufa...	N/A	-	View
202200604	OCABR Certificate ...	Release OMCL	BG_BDA	-	View
202200604	OCABR Certificate ...	Certified Year	2021	-	View

FIGURE: Recommend Recalculation

The sample goes to the **ReCalc** state as shown in the figure:



This screenshot is identical to the one above, showing the 'Test Approval' page with a blue border. The 'OCABR Certificate Review [1][0]' test entry is highlighted with a red box. The status is now explicitly labeled 'ReCalc' in the status column, indicating that the sample has been moved to a recalibration state. The rest of the interface, including the table below, is the same.

AR No	Test Name	Parameter Name	Final Result	Checklist	Actions
202200604	OCABR Certificate ...	Country of Manufa...	N/A	-	View
202200604	OCABR Certificate ...	Release OMCL	BG_BDA	-	View
202200604	OCABR Certificate ...	Certified Year	2021	-	View

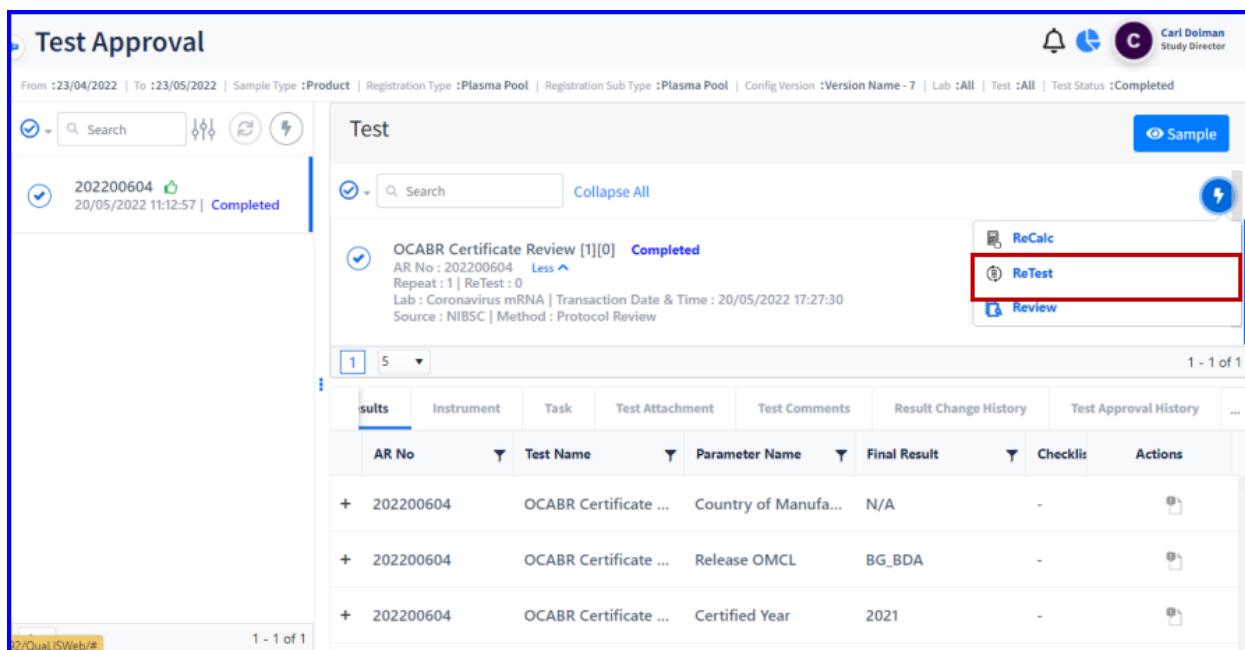
FIGURE: Sample in the ReCalc State

At this state, the sample goes to the previous(Analyst) user for recalculation in the Result Entry screen. The User can recalculate and then enter recalculated results in the result entry screen and complete. The completed test comes to review again.

4.4.3 Recommend ReTest

Reviewer can recommend retest and should specify number of times the test has to be carried.

1. In the Test Approval screen, select the sample, click  and then click **ReTest** as shown in the figure:

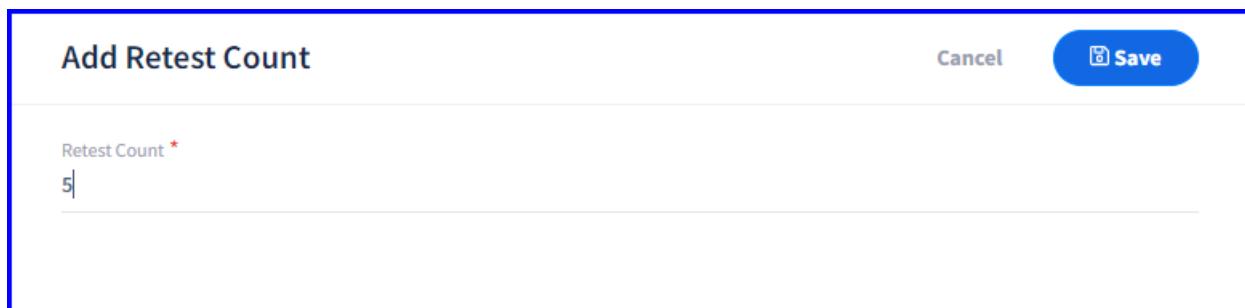


The screenshot shows the 'Test Approval' screen. On the left, a sidebar shows a sample list with '202200604' selected. The main area is titled 'Test' and shows a table of test results. A modal dialog is open over the table, with the 'ReTest' button highlighted by a red box. The dialog contains buttons for 'ReCalc', 'ReTest' (highlighted), and 'Review'.

AR No	Test Name	Parameter Name	Final Result	Actions
202200604	OCABR Certificate ...	Country of Manufa...	N/A	
202200604	OCABR Certificate ...	Release OMCL	BG_BDA	
202200604	OCABR Certificate ...	Certified Year	2021	

FIGURE: Recommend ReTest

The **Add Retest Count** dialog appears as shown in the figure:

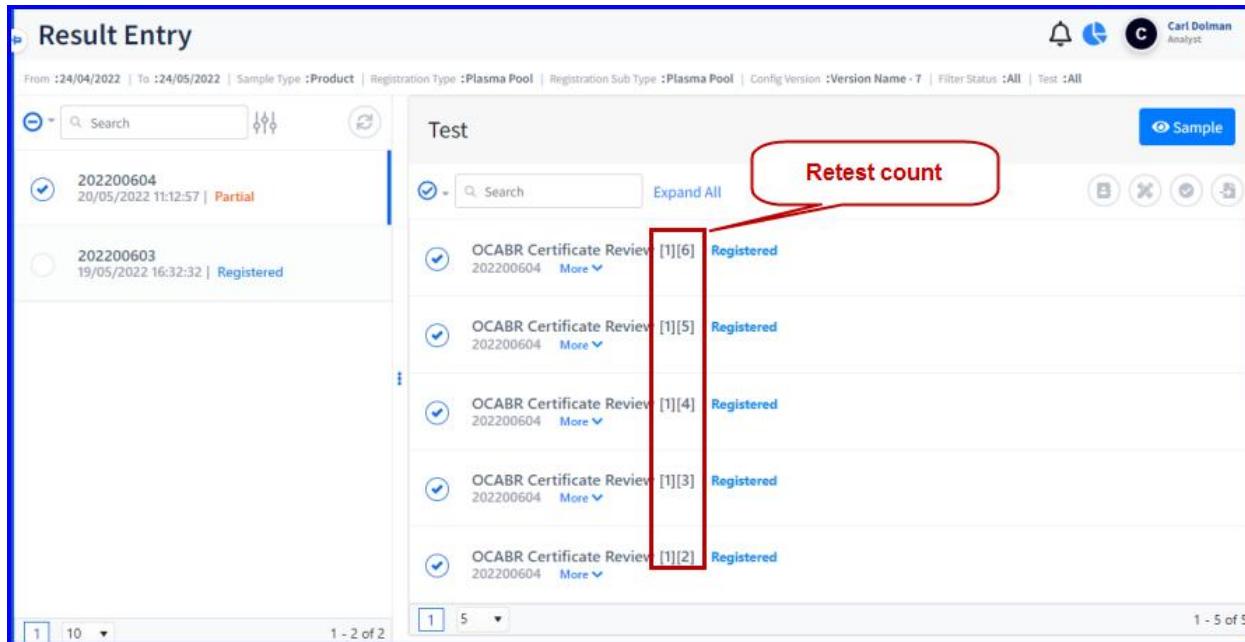


The dialog box is titled 'Add Retest Count'. It has a text input field labeled 'Retest Count *' with the value '5' entered. There are 'Cancel' and 'Save' buttons at the top right.

FIGURE: Add Retest Count Dialog

2. In the **Retest Count** field, type number of times the test has to be carried again and then click **Save**. The sample goes to the **ReTest** state.

At this state, the sample goes to the previous(Analyst) user for retest in the Result Entry screen and appears as shown in the figure:



The screenshot shows the 'Result Entry' screen. At the top, there is a search bar and a 'Sample' button. Below the search bar, there is a list of samples. The first sample is '202200604' with a status of 'Partial'. The second sample is '202200603' with a status of 'Registered'. The main area shows a list of tests for the sample '202200604'. Each test entry has a red border around the 'Retest count' field. The test details are as follows:

Test	Retest count	Status
OCABR Certificate Review 202200604	[1][6]	Registered
OCABR Certificate Review 202200604	[1][5]	Registered
OCABR Certificate Review 202200604	[1][4]	Registered
OCABR Certificate Review 202200604	[1][3]	Registered
OCABR Certificate Review 202200604	[1][2]	Registered

FIGURE: Result Entry Screen Showing Sample Registered for Retest

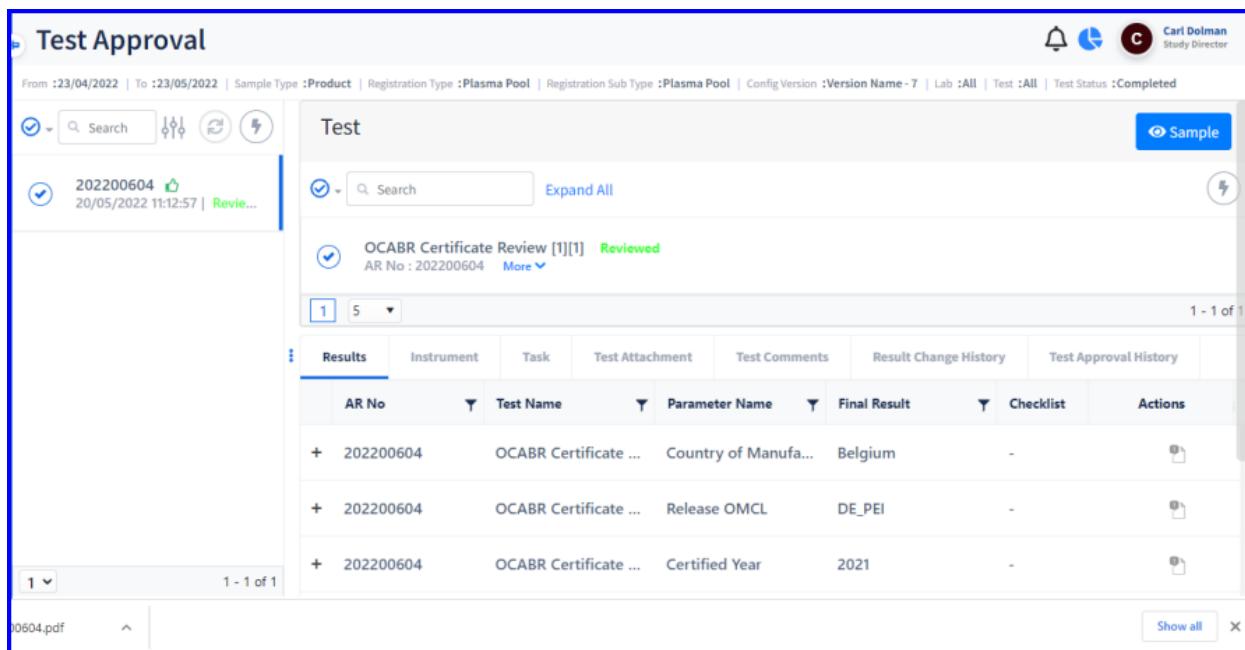
The sample is registered multiple times as per the retest count mentioned by the reviewer. The user can retest, enter results for each test in the result entry screen and then complete the tests. The completed tests comes to review again.

4.4.4 Review

The reviewer can review the test and complete review. Reviewed tests go to the next user in the approval configuration for approval.

To review test, follow these steps:

1. In the Test Approval screen, select the sample to be reviewed.
2. Select test(s) from the list to review.
3. Click  and then click **Review**. The selected tests status appears as **Reviewed** as shown in the figure:



The screenshot shows the 'Test Approval' screen in Qualis LIMS. The top navigation bar includes filters for 'From: 23/04/2022' to '23/05/2022', 'Sample Type: Product', 'Registration Type: Plasma Pool', 'Registration Sub Type: Plasma Pool', 'Config Version: Version Name - 7', 'Lab: All', 'Test: All', and 'Test Status: Completed'. The main area is titled 'Test' and shows a list of tests for sample '202200604' reviewed on '20/05/2022 11:12:57'. The list includes columns for AR No, Test Name, Parameter Name, Final Result, Checklist, and Actions. The data shows three entries for OCABR Certificate Review, with results for Country of Manufacture (Belgium), Release OMCL (DE_PEI), and Certified Year (2021). A 'Sample' button is visible in the top right corner.

FIGURE: Tests in Reviewed State

Once all tests are reviewed, the sample goes to the next user in the approval configuration for approval.

4.5 Approving Tests

Once the tests are reviewed, the tests comes to the next user as configured in the Approval Configuration screen.

To approve result entry, follow these steps:

1. On the main menu, click , **Test approval** and then click **Test Approval**. The **Test Approval** screen appear.
2. In the Test Approval screen, click , in the Filter dialog, select **From** and **To** date, **Sample Type: Product**, **Registration Type: Batch / Non Batch / Plasma Pool**, **Registration Sub Type** and **Test Status**. Click the  to view more fields in the filter. In the **Config Version** field select the latest template. Select **Lab** and **Test**. Select **All** to select all the test in the sample/component. And then click **SUBMIT** as shown in the figure:

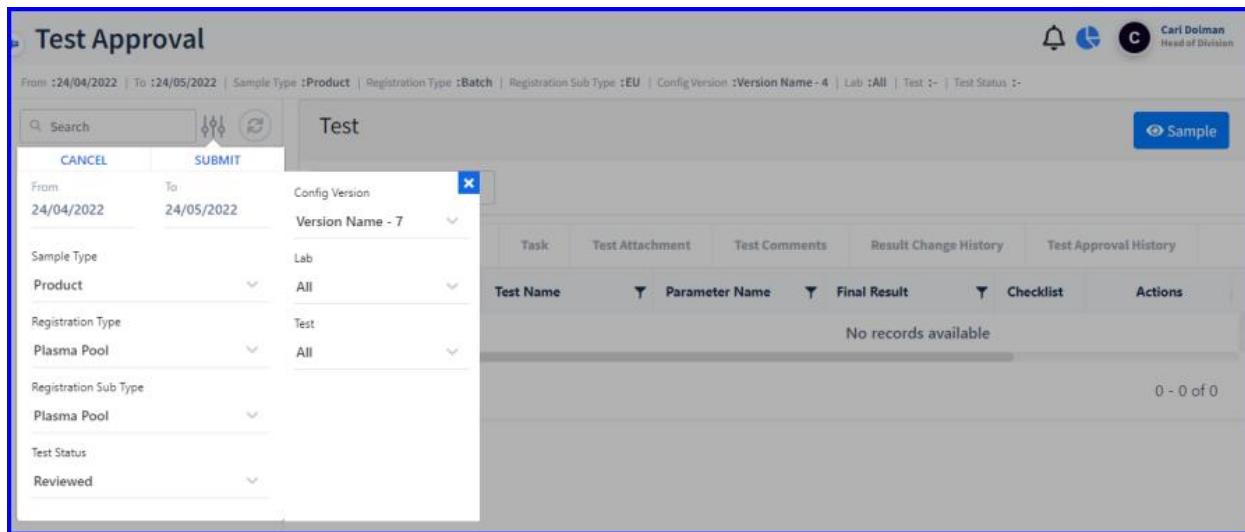


FIGURE: Using Filter

Samples for the given search criteria appears as shown in the figure:

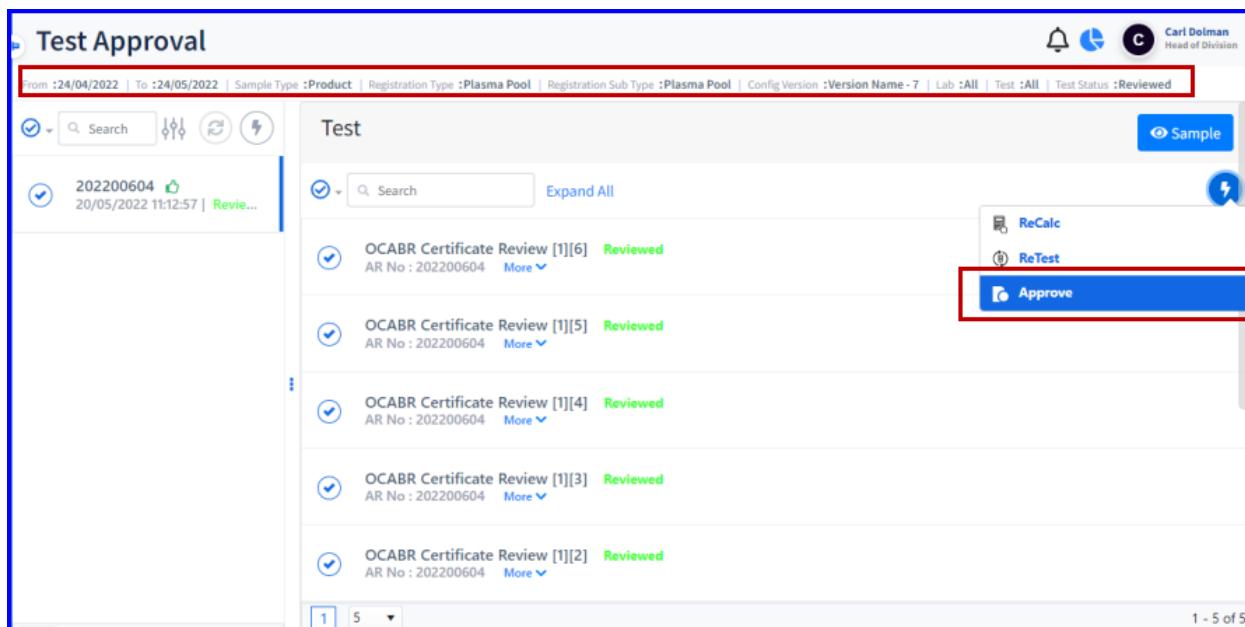


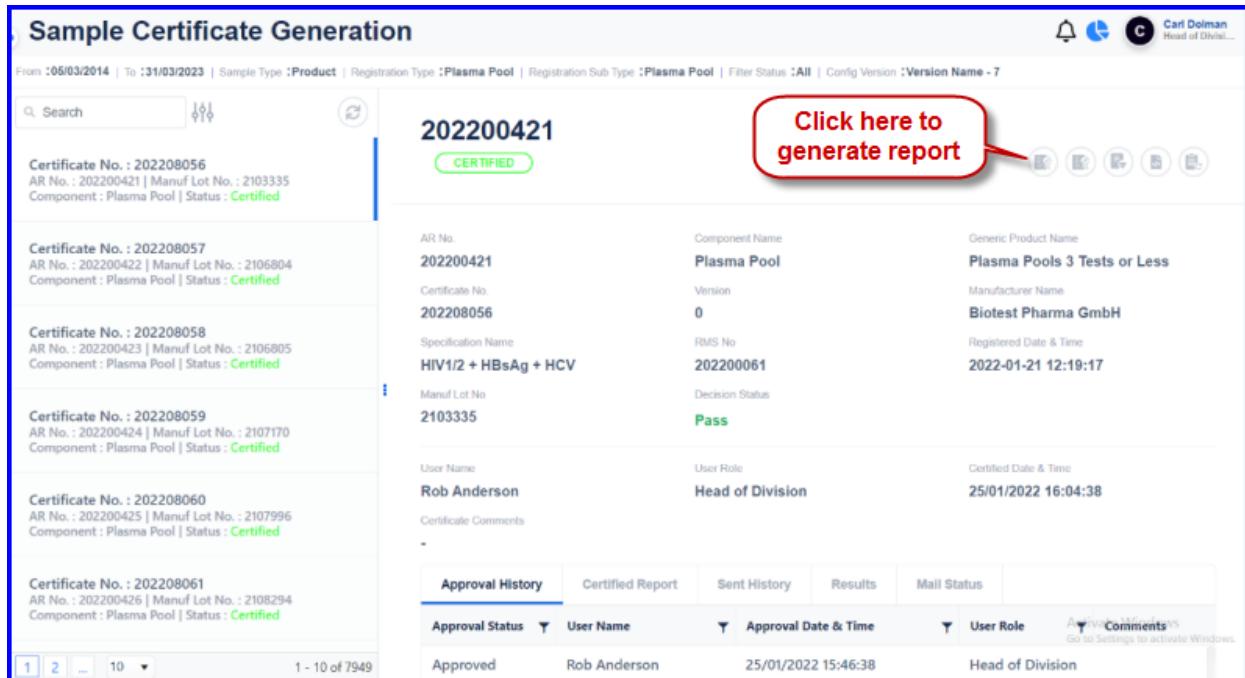
FIGURE: Test Approval Screen Showing Filtered Records

You can review the tests and then do any one of the following:

- Recommend recalculation: The tests go to the Analyst and appear in **ReCalc** state.
- Recommend retest: The tests go to the analyst and appear in **ReTest** state.
- Approve: Tests appear as **Approved** state.

3. Select tests to approve, click  and then click **Approve** as shown in the above figure. The test goes to the **Approved** state.

4. Click  to generate report as shown in the figure:



Sample Certificate Generation

From :05/03/2014 | To :31/03/2023 | Sample Type :Product | Registration Type :Plasma Pool | Registration Sub Type :Plasma Pool | Filter Status :All | Config Version :Version Name - 7

202200421 

Click here to generate report

AR No.	Component Name	Generic Product Name															
202200421	Plasma Pool	Plasma Pools 3 Tests or Less															
202208056	0	Manufacturer Name															
	RMS No	Biotest Pharma GmbH															
HIV1/2 + HBsAg + HCV	202200061	Registered Date & Time															
Manuf Lot No	Decision Status	2022-01-21 12:19:17															
2103335	Pass																
User Name	User Role	Certified Date & Time															
Rob Anderson	Head of Division	25/01/2022 16:04:38															
Certificate Comments																	
<table border="1"> <thead> <tr> <th>Approval History</th> <th>Certified Report</th> <th>Sent History</th> <th>Results</th> <th>Mail Status</th> </tr> </thead> <tbody> <tr> <td>Approval Status</td> <td>User Name</td> <td>Approval Date & Time</td> <td>User Role</td> <td>Comments</td> </tr> <tr> <td>Approved</td> <td>Rob Anderson</td> <td>25/01/2022 15:46:38</td> <td>Head of Division</td> <td>Go to Settings to activate Windows.</td> </tr> </tbody> </table>			Approval History	Certified Report	Sent History	Results	Mail Status	Approval Status	User Name	Approval Date & Time	User Role	Comments	Approved	Rob Anderson	25/01/2022 15:46:38	Head of Division	Go to Settings to activate Windows.
Approval History	Certified Report	Sent History	Results	Mail Status													
Approval Status	User Name	Approval Date & Time	User Role	Comments													
Approved	Rob Anderson	25/01/2022 15:46:38	Head of Division	Go to Settings to activate Windows.													

1 | 2 | 10 | 1 - 10 of 7949

FIGURE: Generating Report

The report is generated and appears as shown in the figure:

 Medicines & Healthcare products Regulatory Agency	 NIBSC																								
NATIONAL CONTROL AUTHORITY RELEASE CERTIFICATE FOR IMMUNOLOGICAL PRODUCTS																									
Finished Product																									
Finished Product																									
Examined in accordance with regulations 60A and 60B of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020																									
<table border="1"> <tr> <td>NIBSC Release Certificate Number:</td> <td>202200095</td> </tr> <tr> <td>Trade name:</td> <td>Grazax 75,000 SQ-T Oral Lyophilisate</td> </tr> <tr> <td>International non-proprietary name / Pharmacopoeia Name / Common Name:</td> <td>Timothy Grass Pollen Extract</td> </tr> <tr> <td>Batch number appearing on package and other identification numbers associated with this batch:</td> <td>340</td> </tr> <tr> <td>Type of container:</td> <td>Blister Pack</td> </tr> <tr> <td>Total number of containers in this batch:</td> <td>2</td> </tr> <tr> <td>Nominal dose per container:</td> <td>1</td> </tr> <tr> <td>Date of start of period of validity:</td> <td>27th May 2022</td> </tr> <tr> <td>Date of expiry:</td> <td>26th May 2026</td> </tr> <tr> <td>Marketing Authorisation Number (member state / EU): Issued by:</td> <td>PL 10085/0039 MHRA, United Kingdom</td> </tr> <tr> <td>Name and address of Manufacturer:</td> <td>ALK-Abello A/S Bøge Allé 6-8, P O Box 408, DK - 2970 Hørsholm, Denmark</td> </tr> <tr> <td>Name and address of Marketing Authorisation Holder if different</td> <td></td> </tr> </table>		NIBSC Release Certificate Number:	202200095	Trade name:	Grazax 75,000 SQ-T Oral Lyophilisate	International non-proprietary name / Pharmacopoeia Name / Common Name:	Timothy Grass Pollen Extract	Batch number appearing on package and other identification numbers associated with this batch:	340	Type of container:	Blister Pack	Total number of containers in this batch:	2	Nominal dose per container:	1	Date of start of period of validity:	27 th May 2022	Date of expiry:	26 th May 2026	Marketing Authorisation Number (member state / EU): Issued by:	PL 10085/0039 MHRA, United Kingdom	Name and address of Manufacturer:	ALK-Abello A/S Bøge Allé 6-8, P O Box 408, DK - 2970 Hørsholm, Denmark	Name and address of Marketing Authorisation Holder if different	
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Name and address of Marketing Authorisation Holder if different																									
This batch has been examined using documented procedures forming part of a quality system accredited to ISO/IEC 17025. NIBSC is a UKAS accredited testing laboratory No. 1470. All tests may not be accredited. Tests may include those for which accreditation is claimed under the bounds of our flexible scope of accreditation.																									
This examination is based on either: <ul style="list-style-type: none"> - the relevant control testing guideline for this product, or, in the absence of this, - the appropriate control laboratory tests as indicated in the marketing authorisation application and/or the review of the manufacturer's protocol. 																									
This batch is compliant with the approved specifications laid down in the above marketing authorisation.																									
Name: Carl Dolman Function of Signatory: Head of Division Date of Issue: 30 th May 2022 Signed: 																									
(Form: NI Version: 1) <small>National Institute for Biological Standards and Control, Potton Way, Hertfordshire, EN6 3QG, United Kingdom T +44(0)1707 641000, nibsc.org WHO International Laboratory for Biological Standards, UK Official Medicines Control Laboratory</small>																									
Page 1 of 1																									
																									

FIGURE: Report Generated