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.

Click here

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:

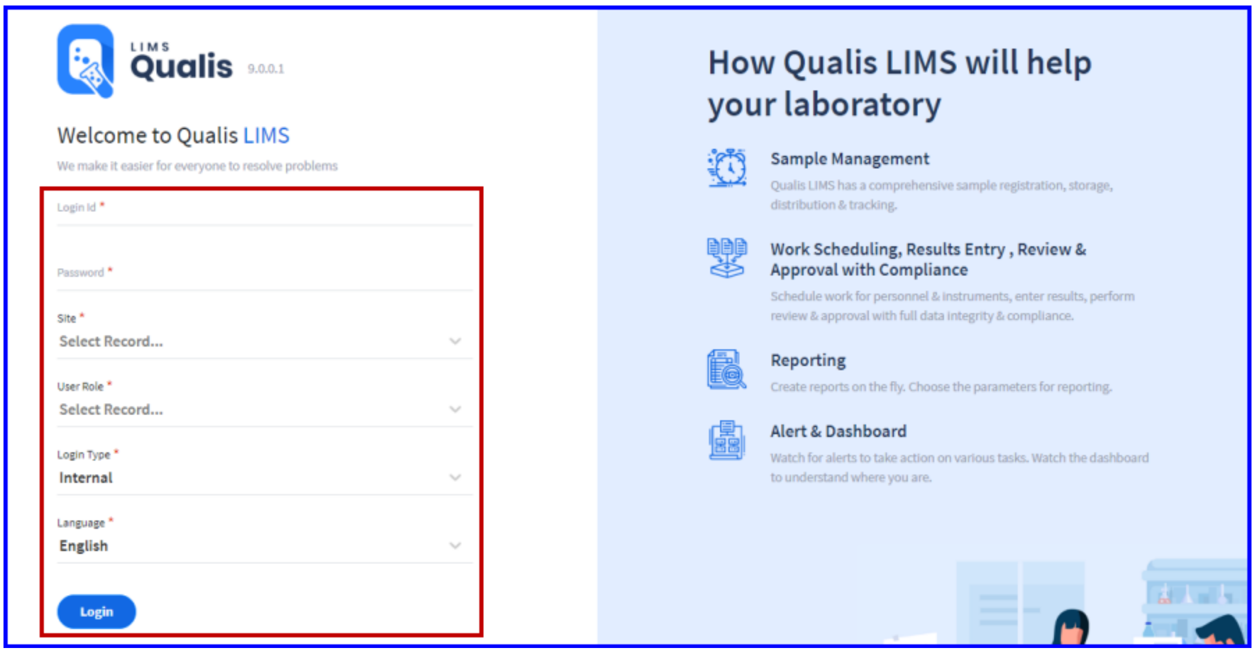


FIGURE: Qualis LIMS – Log in Screen

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:

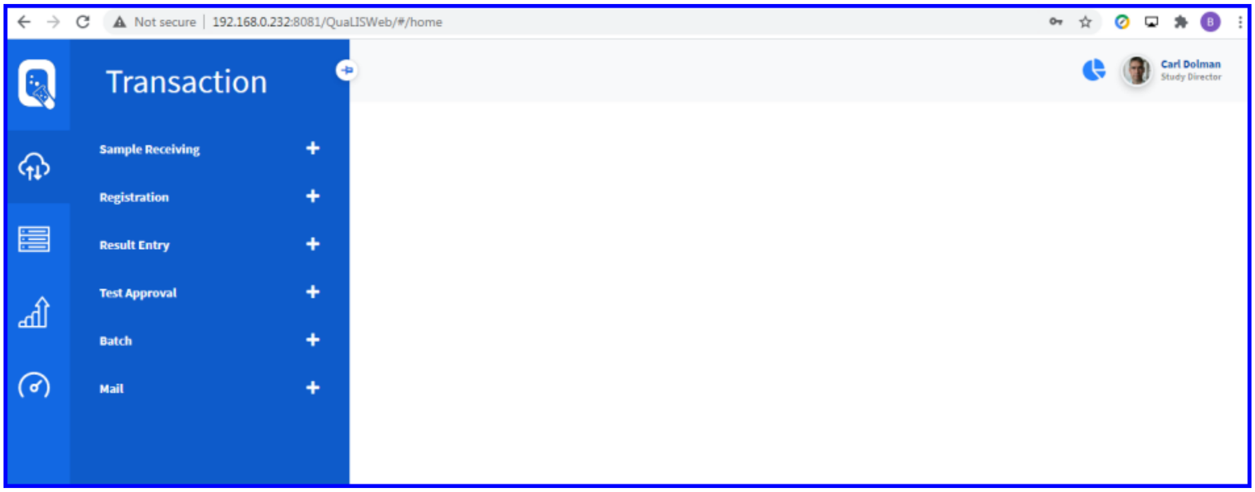


FIGURE: Qualis LIMS Home Page

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:

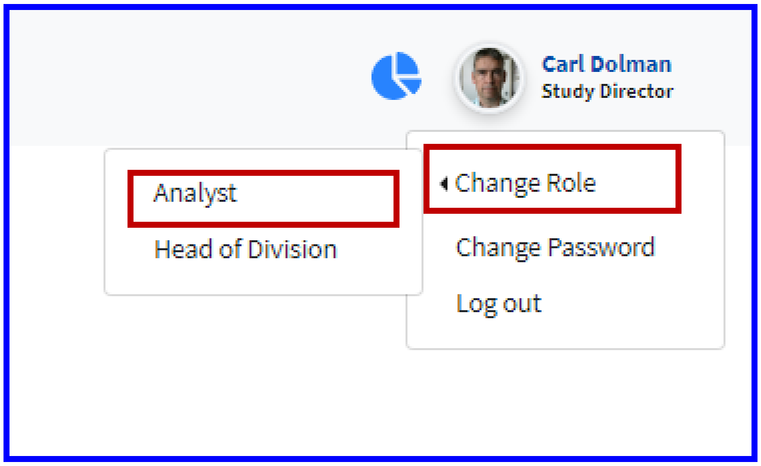


FIGURE: Profile Menu-Change Role Option

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:

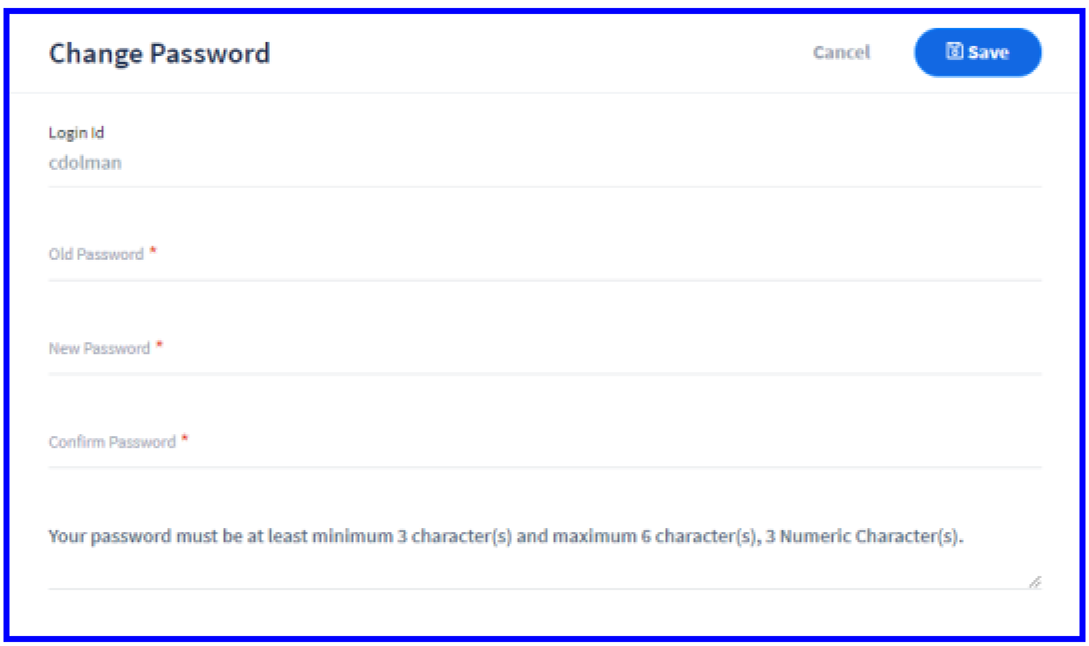


FIGURE: Profile Menu-Change Password Screen

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.

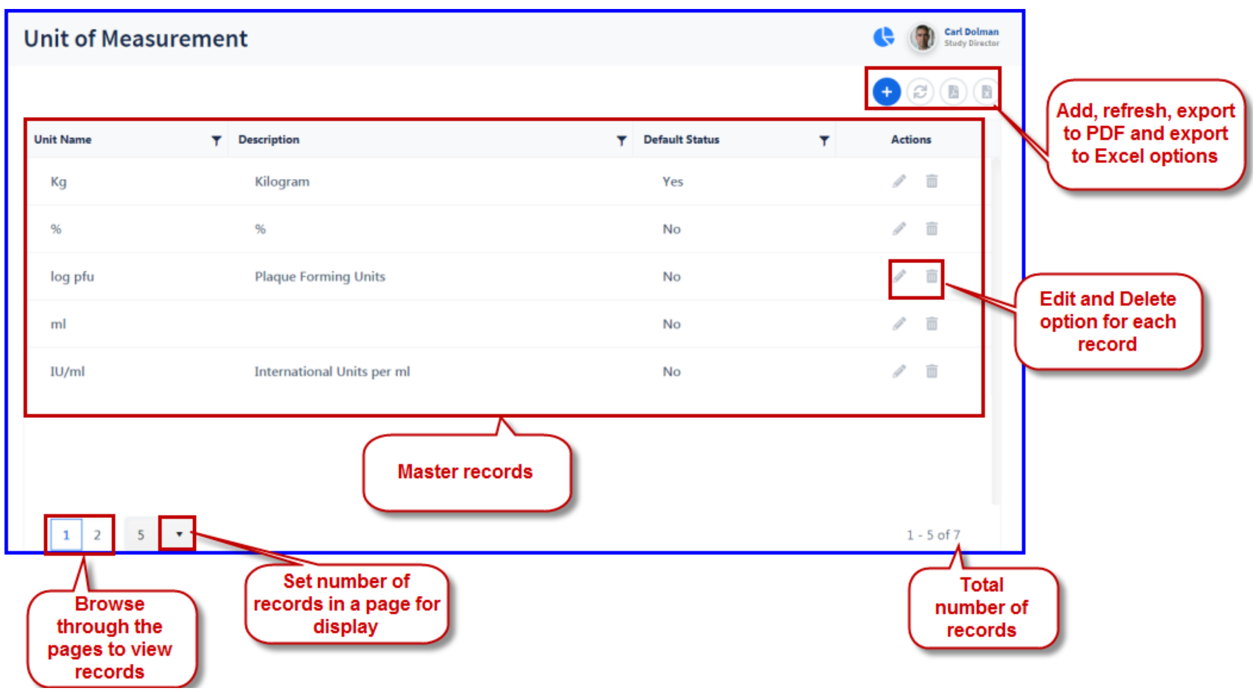
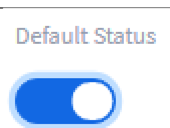
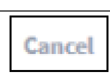


FIGURE: Masters – Screen Layout

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		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:

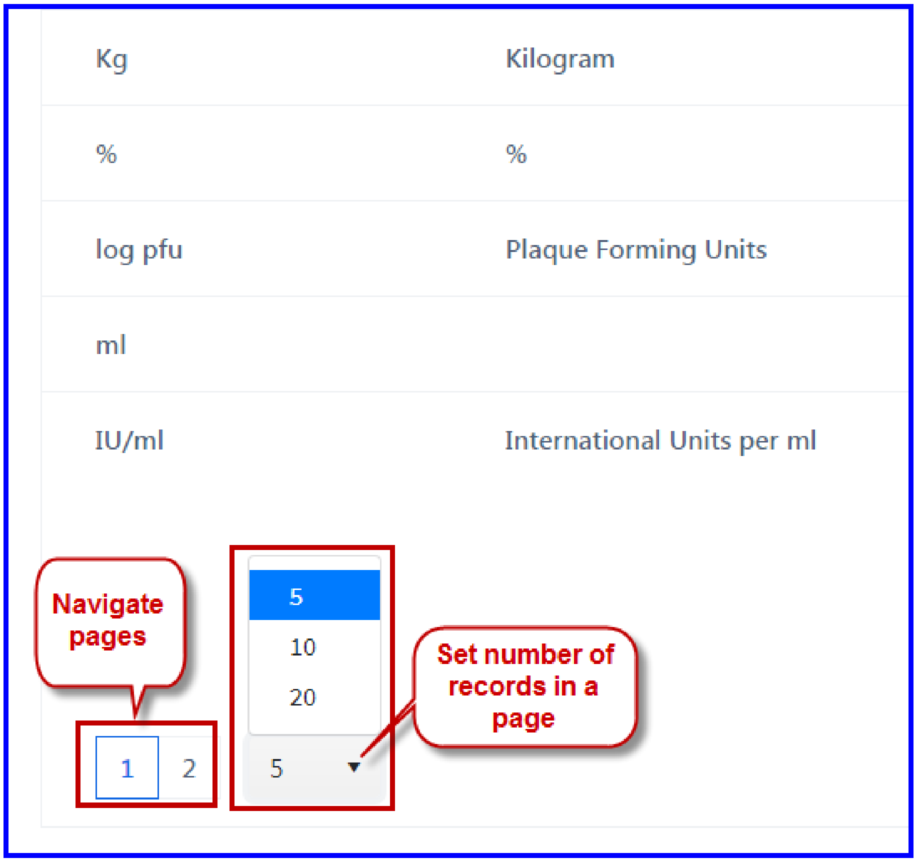


FIGURE: Set Number of Records for View

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:

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:

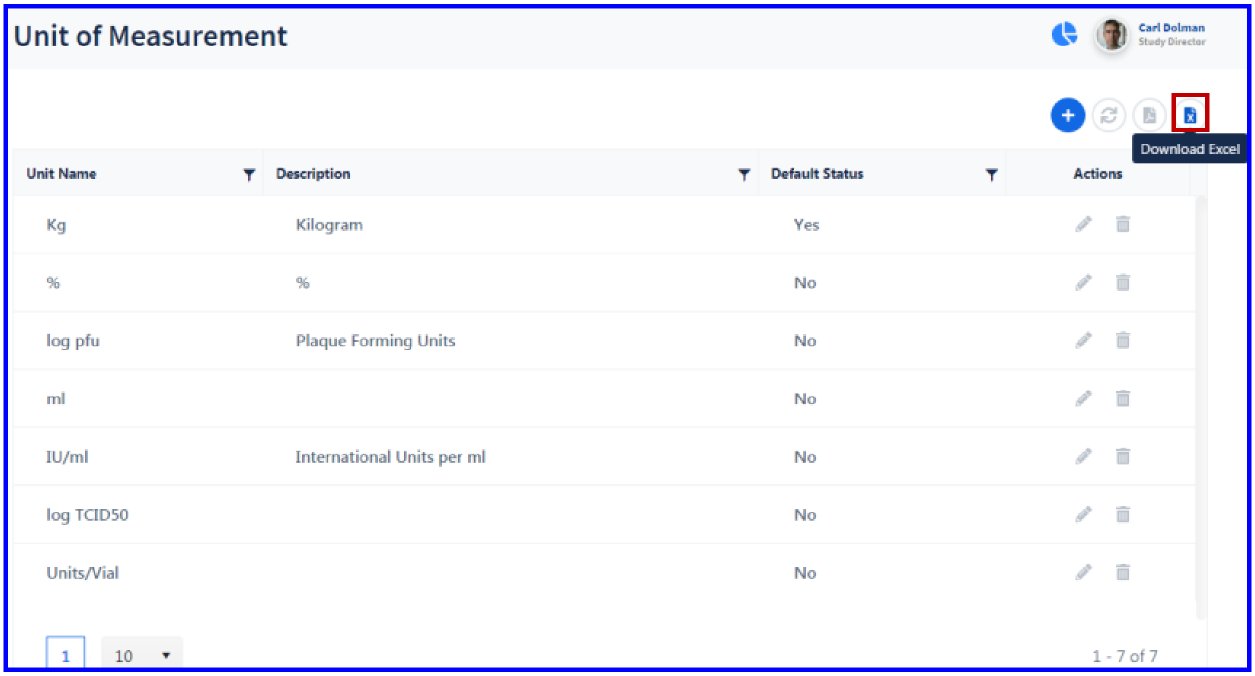
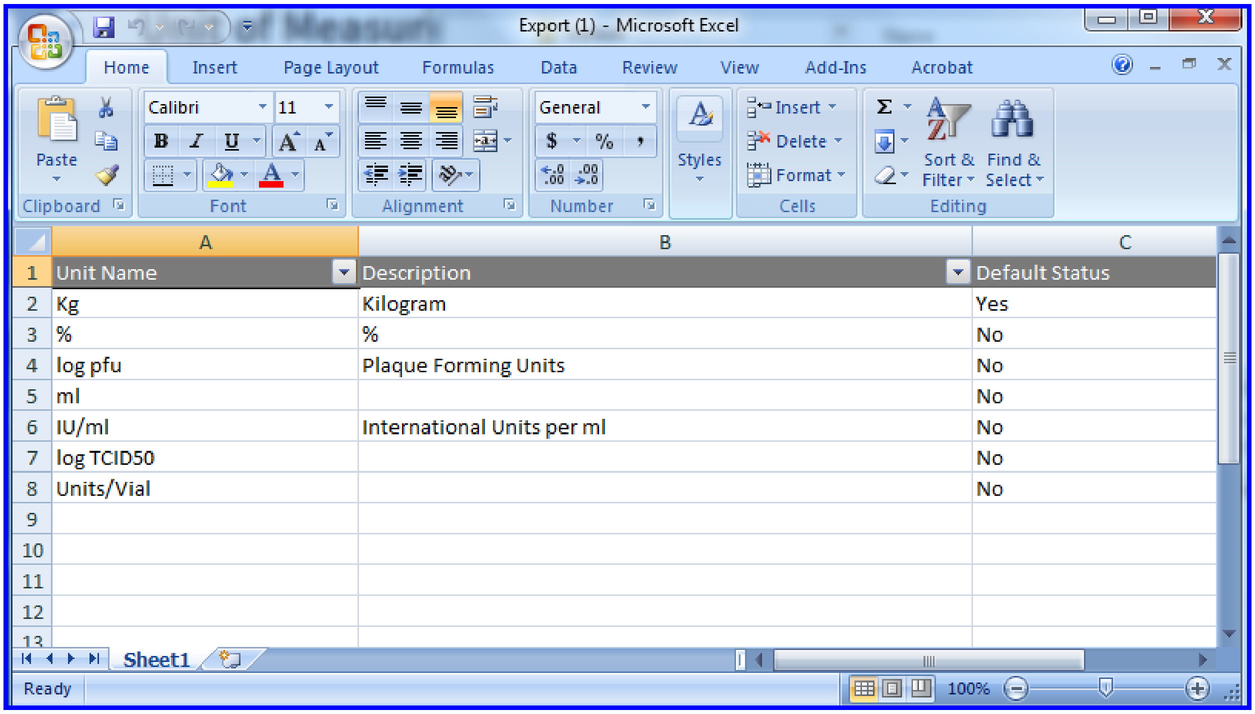


FIGURE: Downloading UOM Master Records to Excel

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:



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 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:

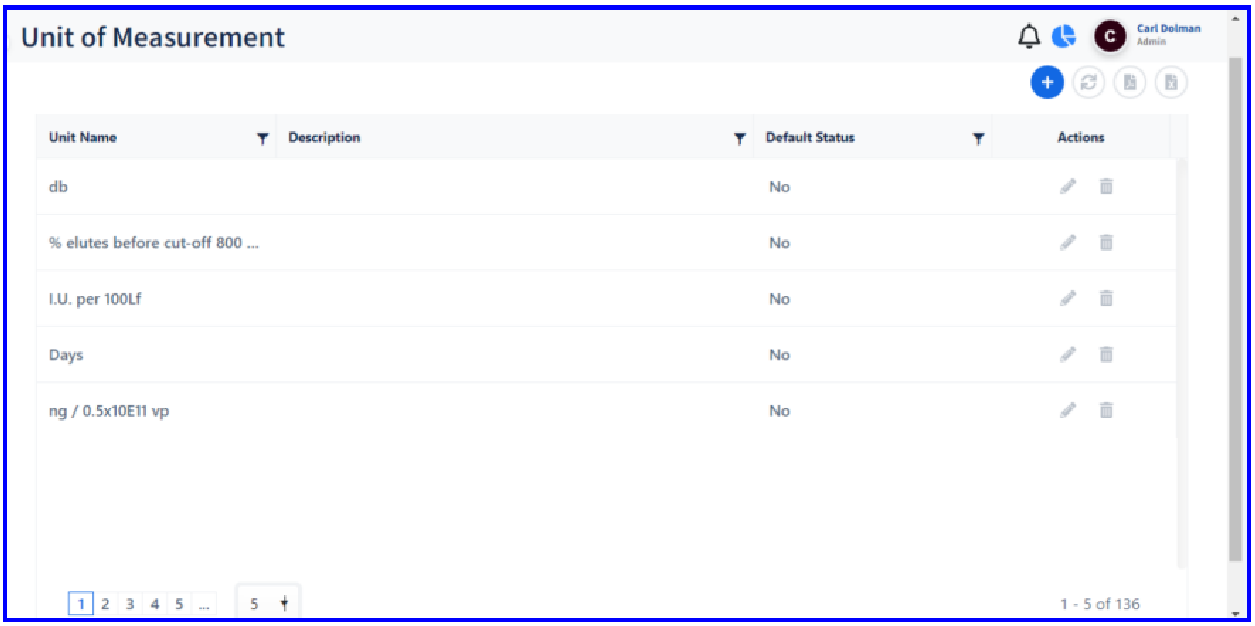


FIGURE: Unit of Measurement Master Screen

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:

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:

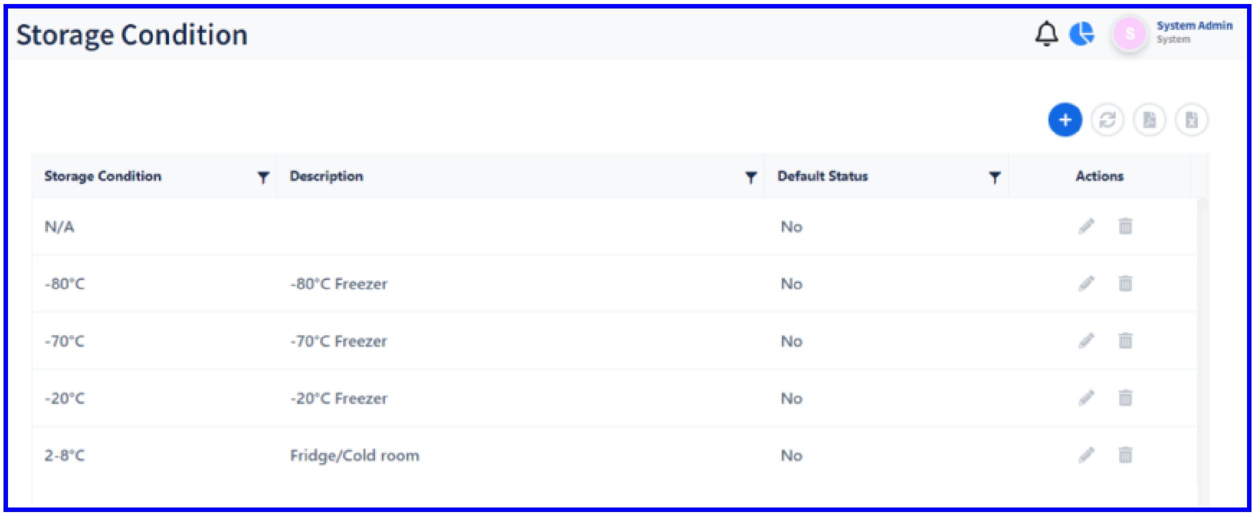


FIGURE: Storage Condition Master Screen

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:

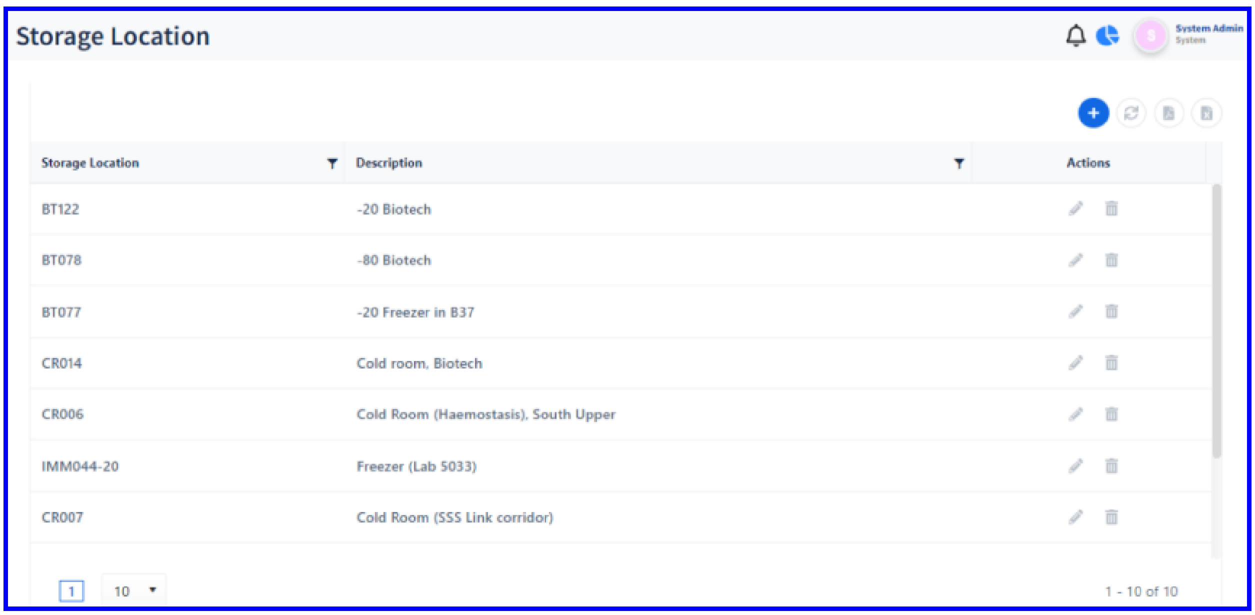


FIGURE: Storage Location Master Screen

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:

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:

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:

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:

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:

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:

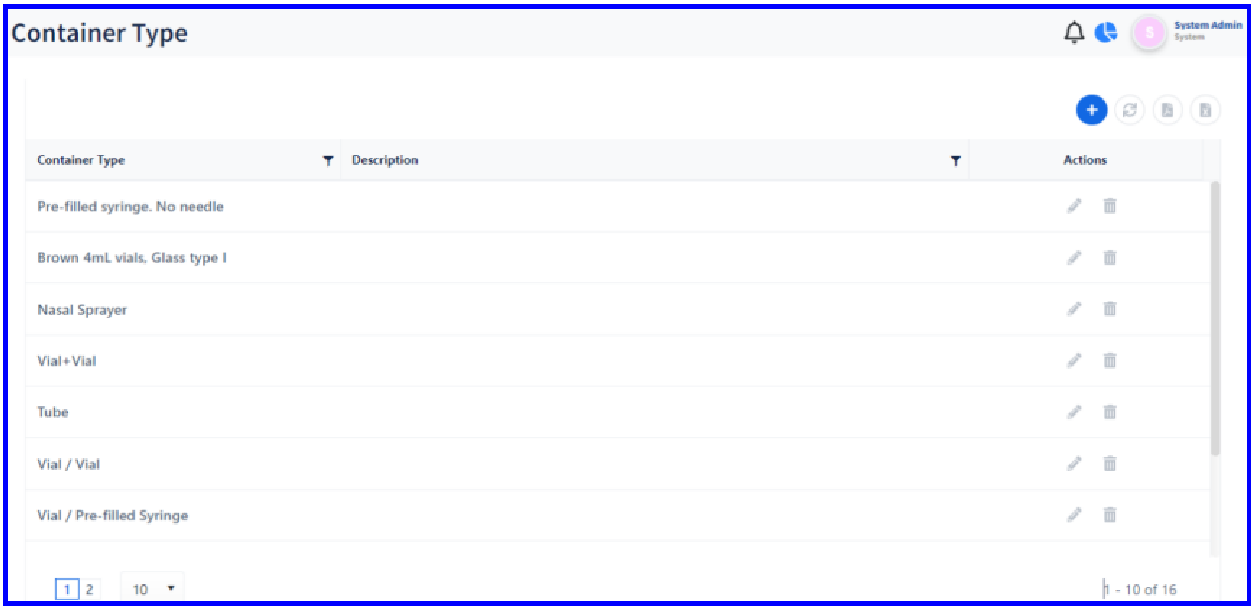


FIGURE: Container Type Master Screen

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:

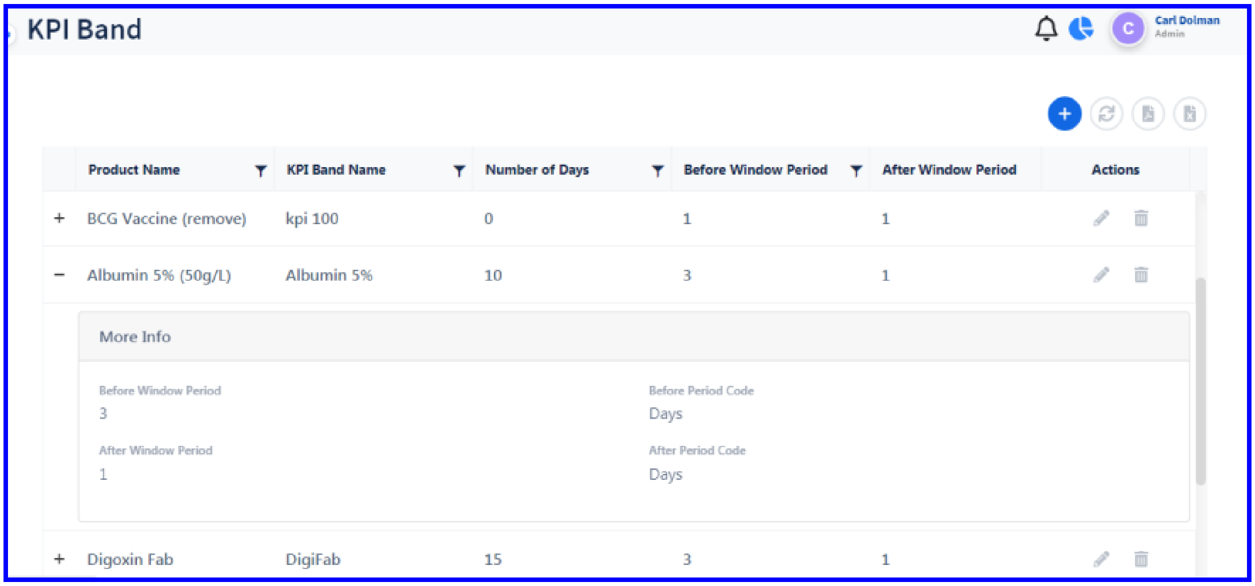


FIGURE: KPI Band Master Screen

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

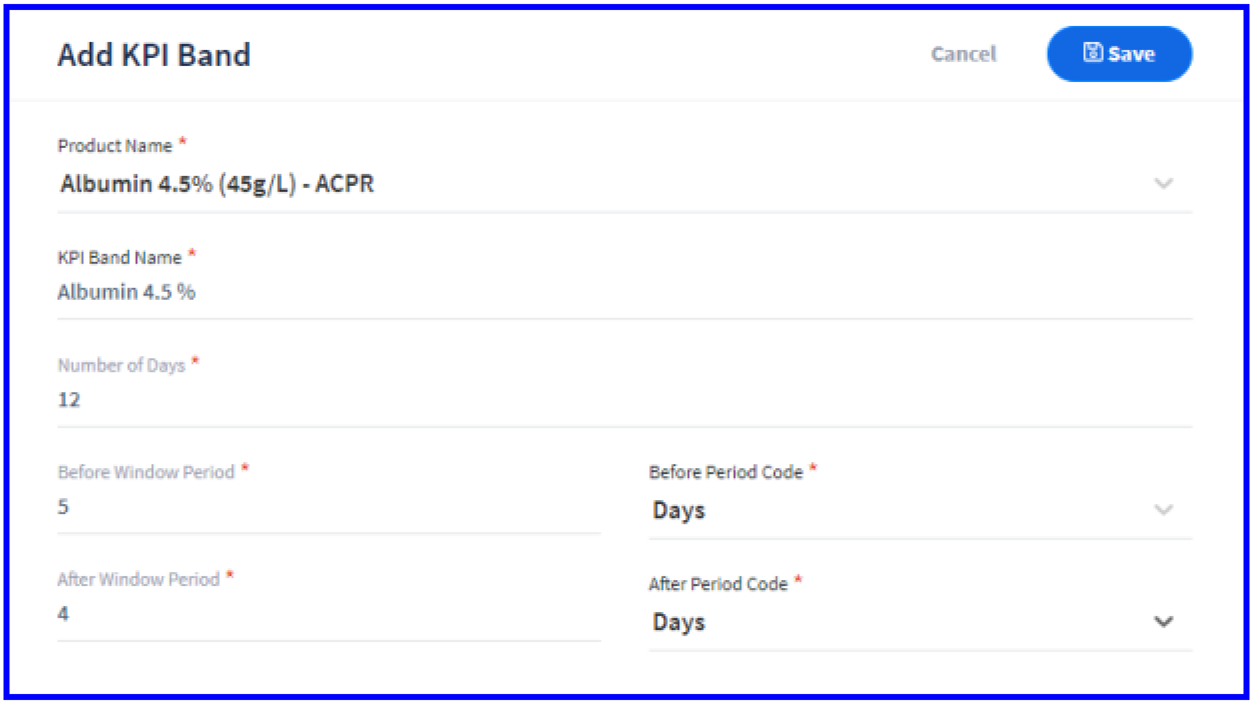


FIGURE: Add KPI Band screen

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:

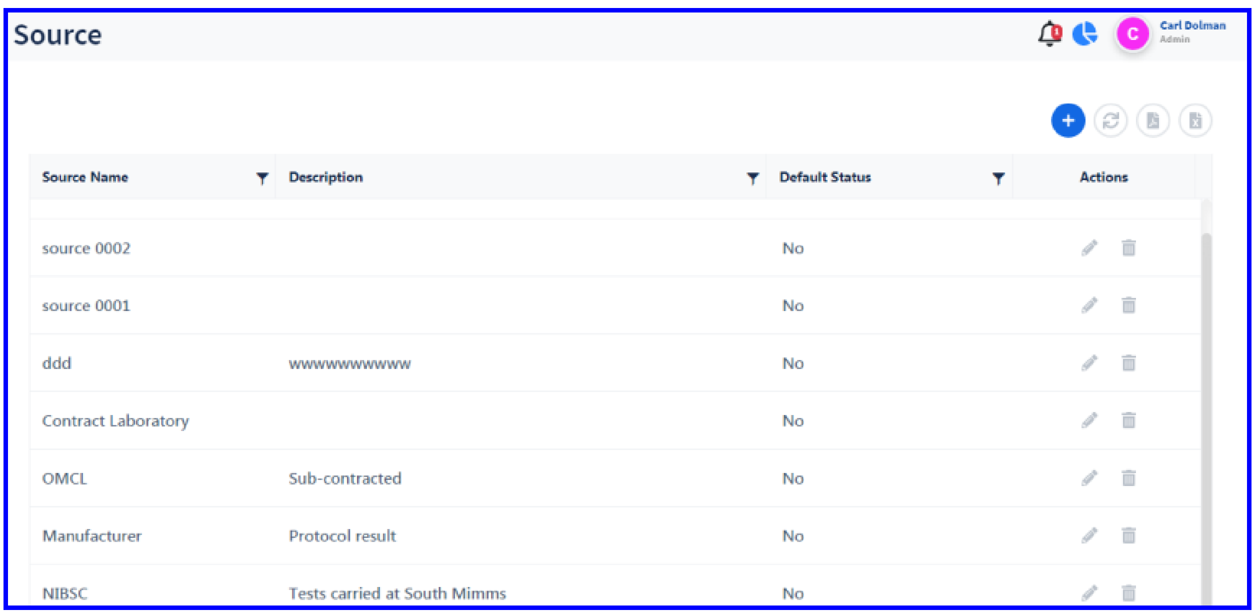


FIGURE: Source Master Screen

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:

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:

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:

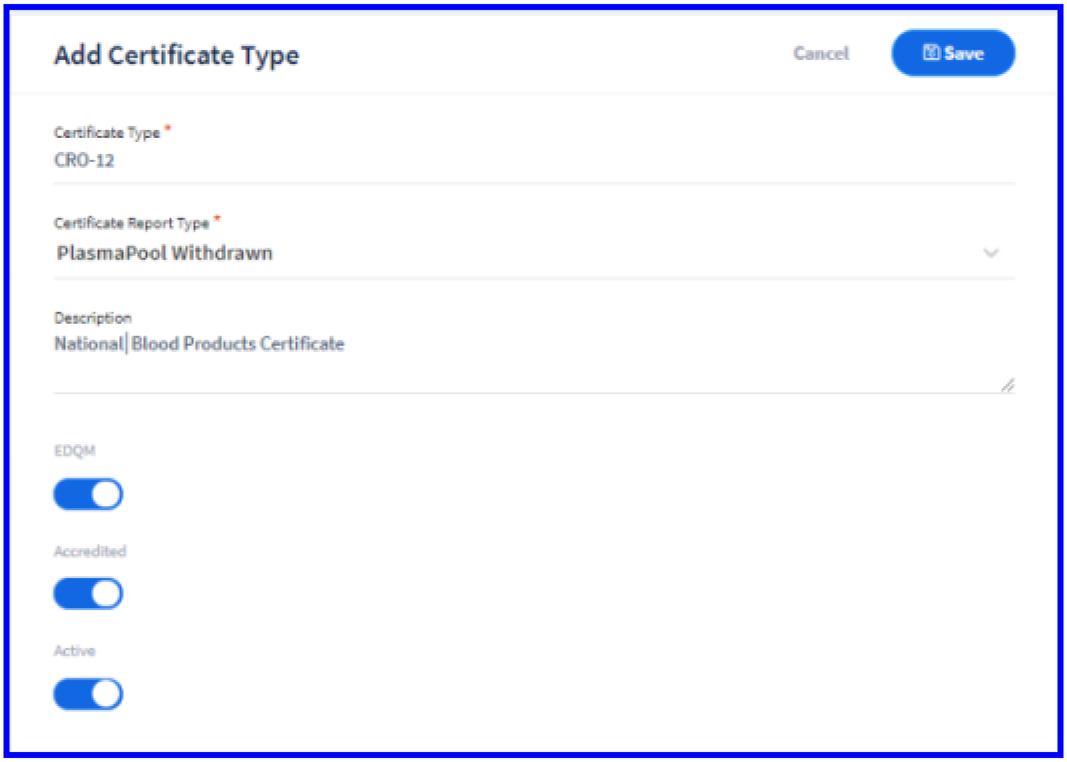


FIGURE: Add Certificate Type Screen

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:

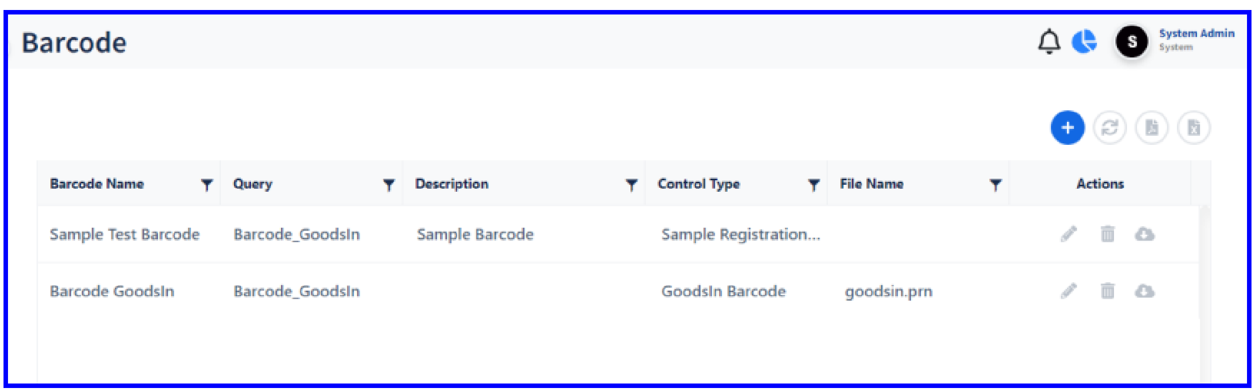


FIGURE: Barcode Master Screen

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:

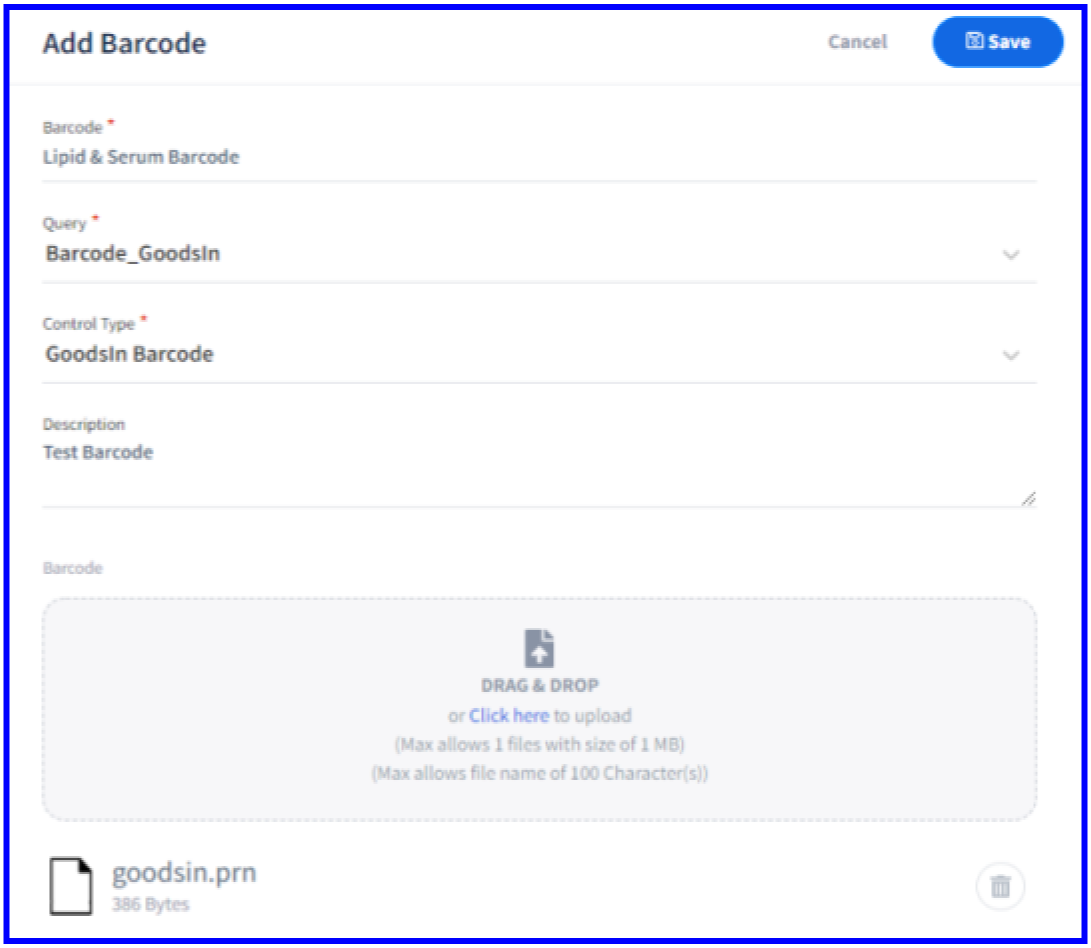


FIGURE: Add Barcode Screen

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:

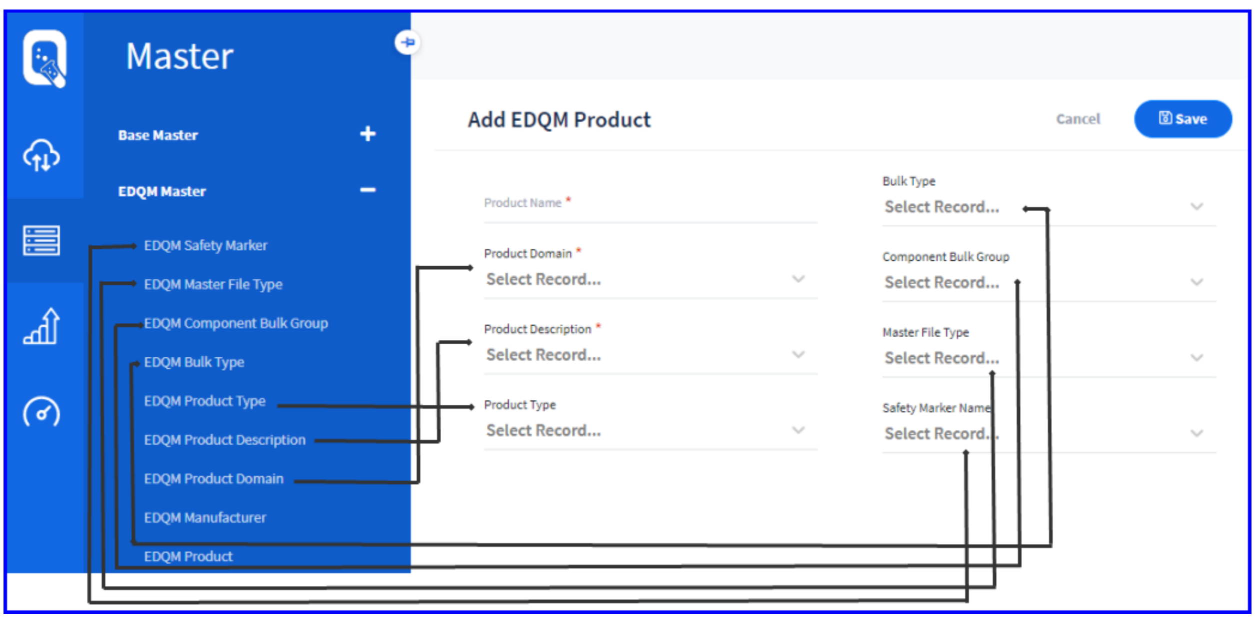


FIGURE: EDQM Master

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:

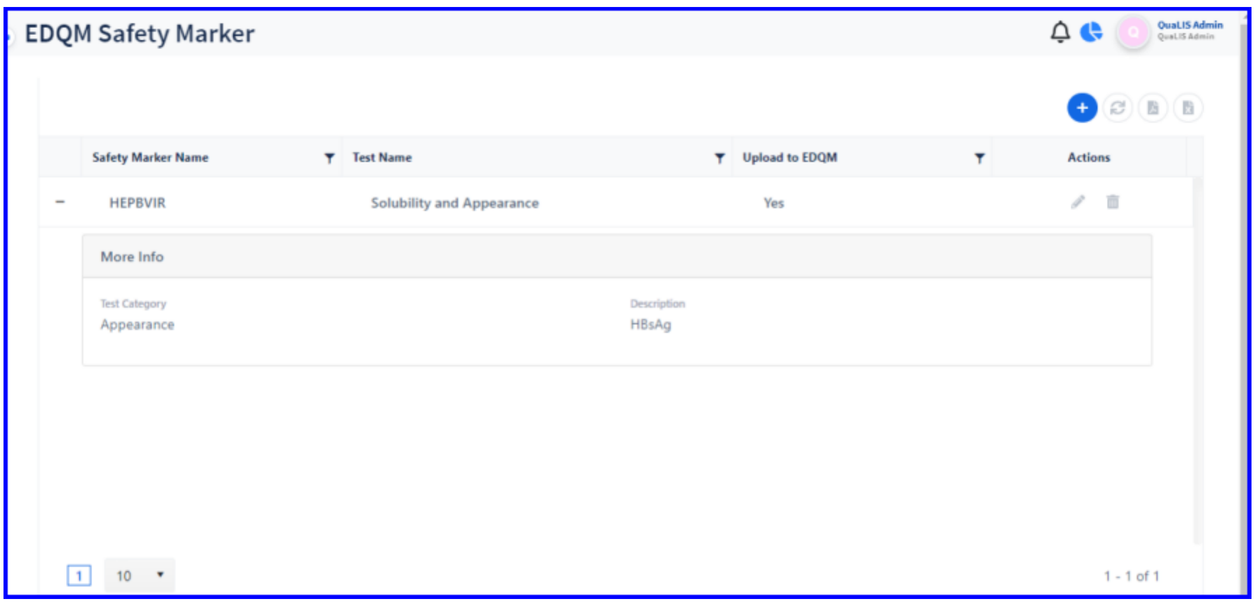


FIGURE: EDQM Safety Marker Master Screen

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:

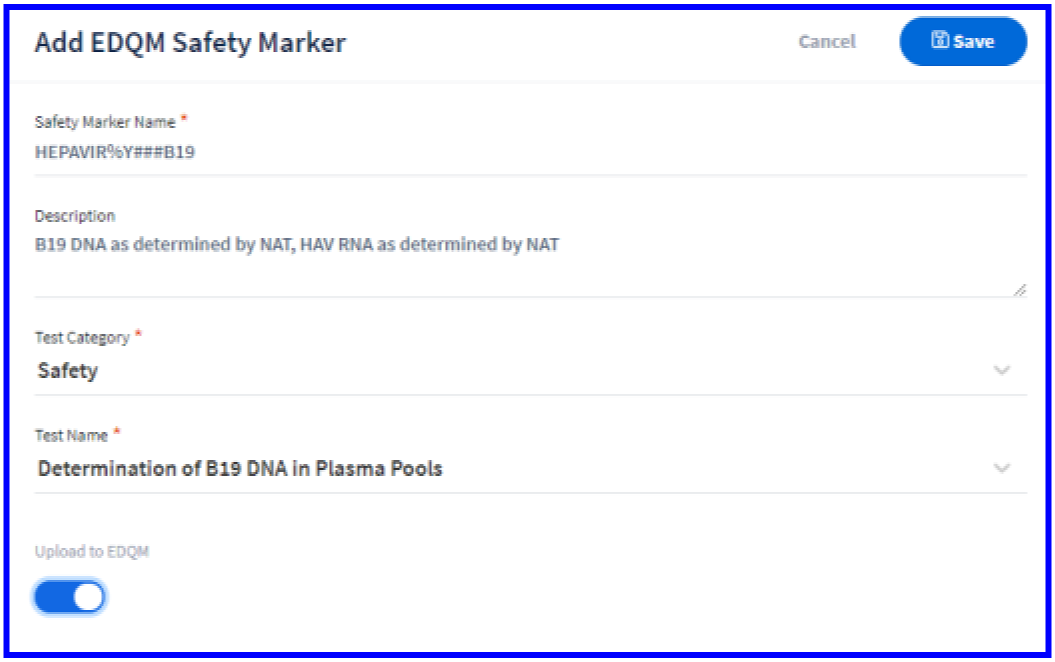


FIGURE: Add EDQM Safety Marker Screen

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:

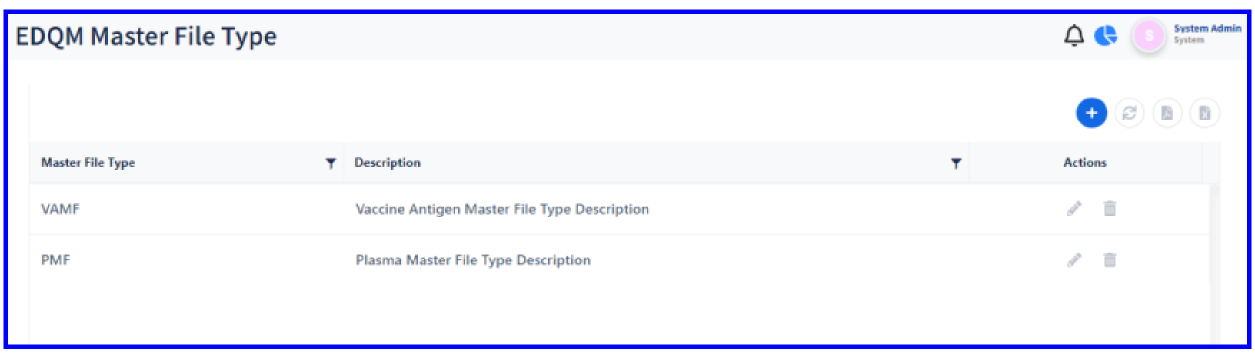


FIGURE: EDQM Master File Type Master Screen

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:

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:

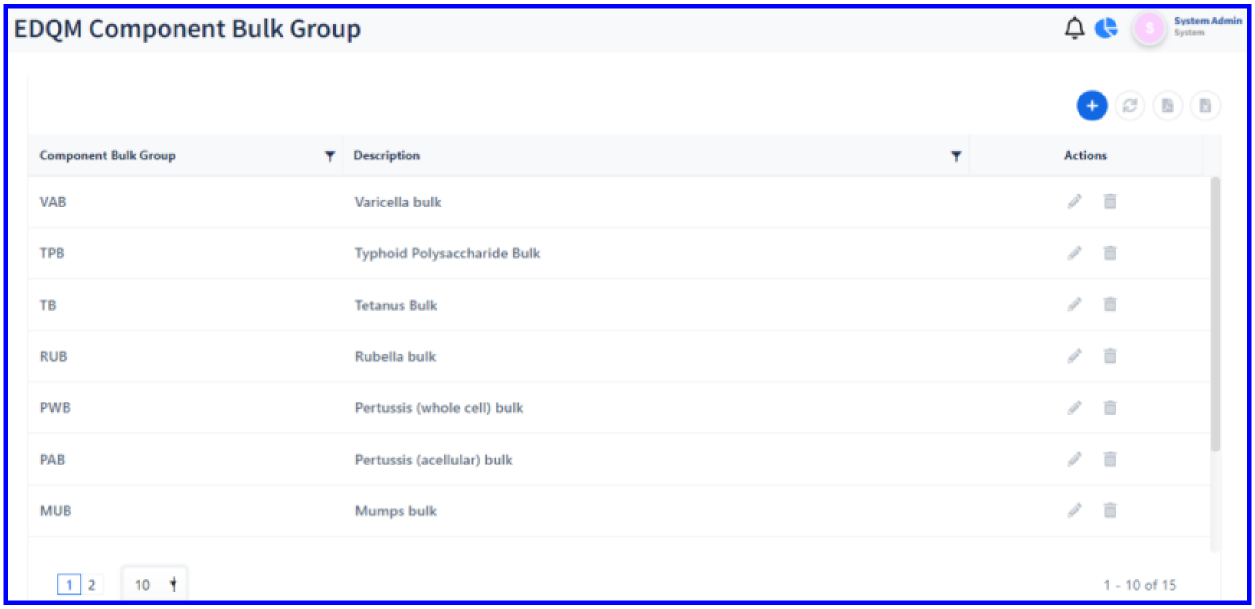


FIGURE: EDQM Component Bulk Group Master Screen

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:

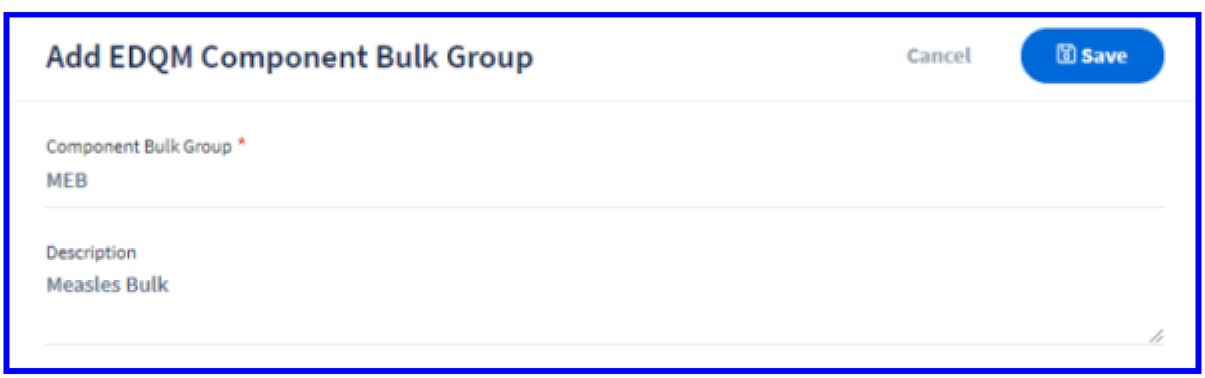


FIGURE: Add EDQM Component Bulk Group Screen

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:

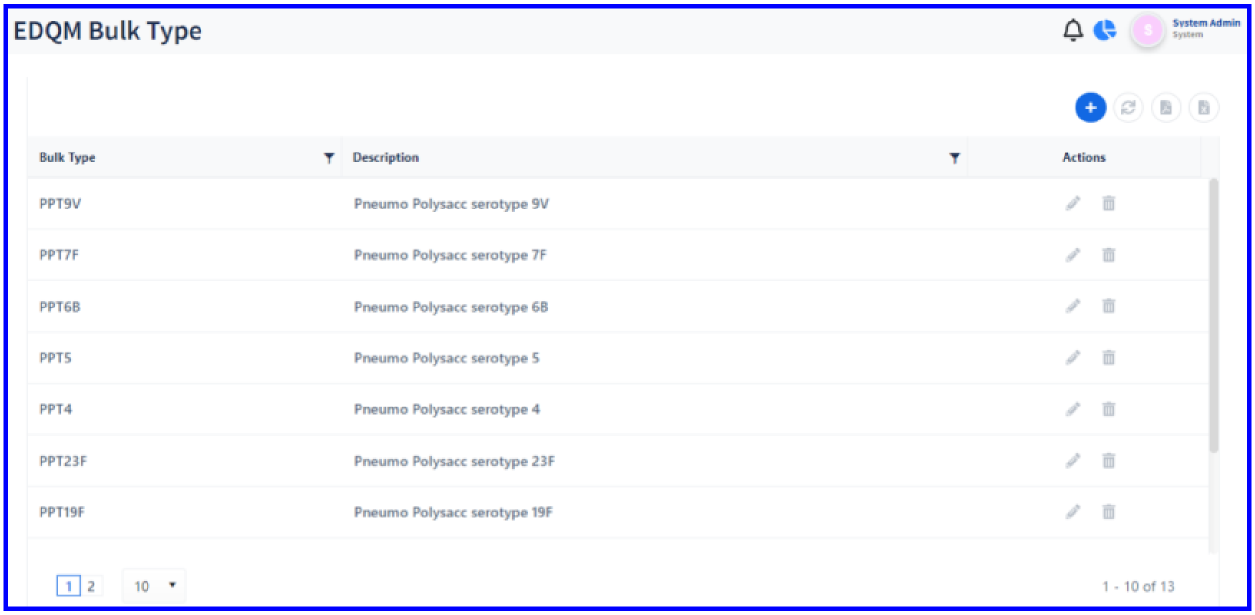


FIGURE: EDQM Bulk Type Master Screen

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:

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:

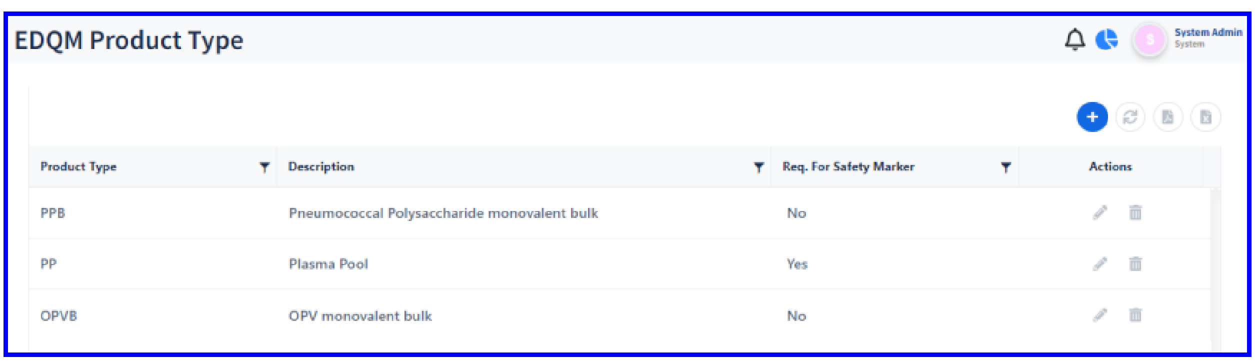


FIGURE: EDQM Product Type Master Screen

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:

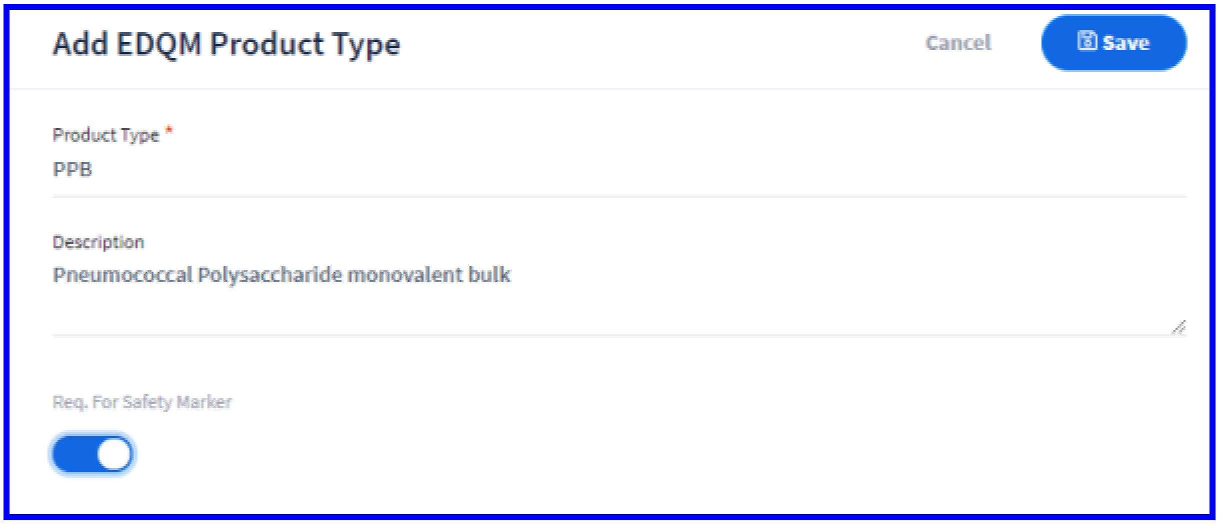


FIGURE: Add EDQM Product Type Dialog

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:

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:

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:

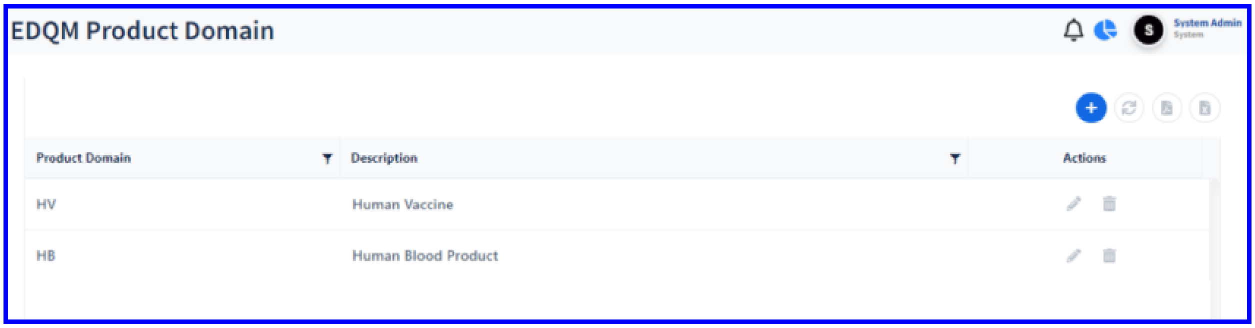


FIGURE: EDQM Product Domain Master Screen

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:

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:

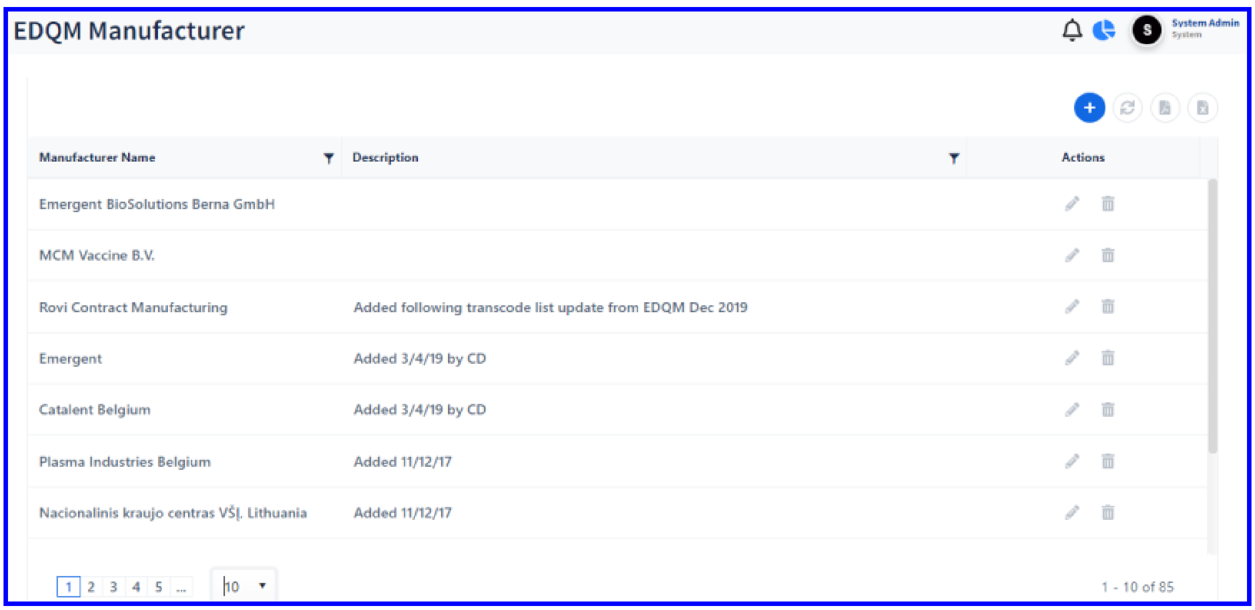


FIGURE: EDQM Manufacturer Master Screen

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:

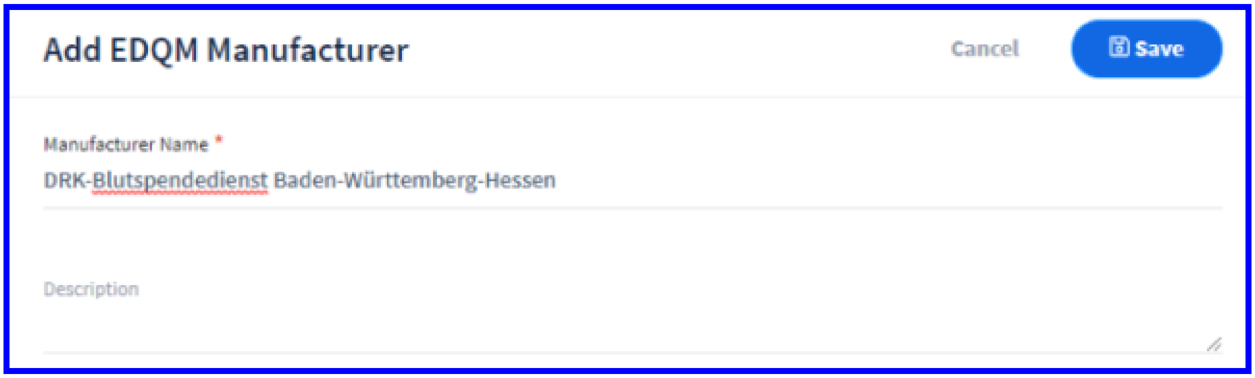


FIGURE: Add EDQM Manufacturer Dialog

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:

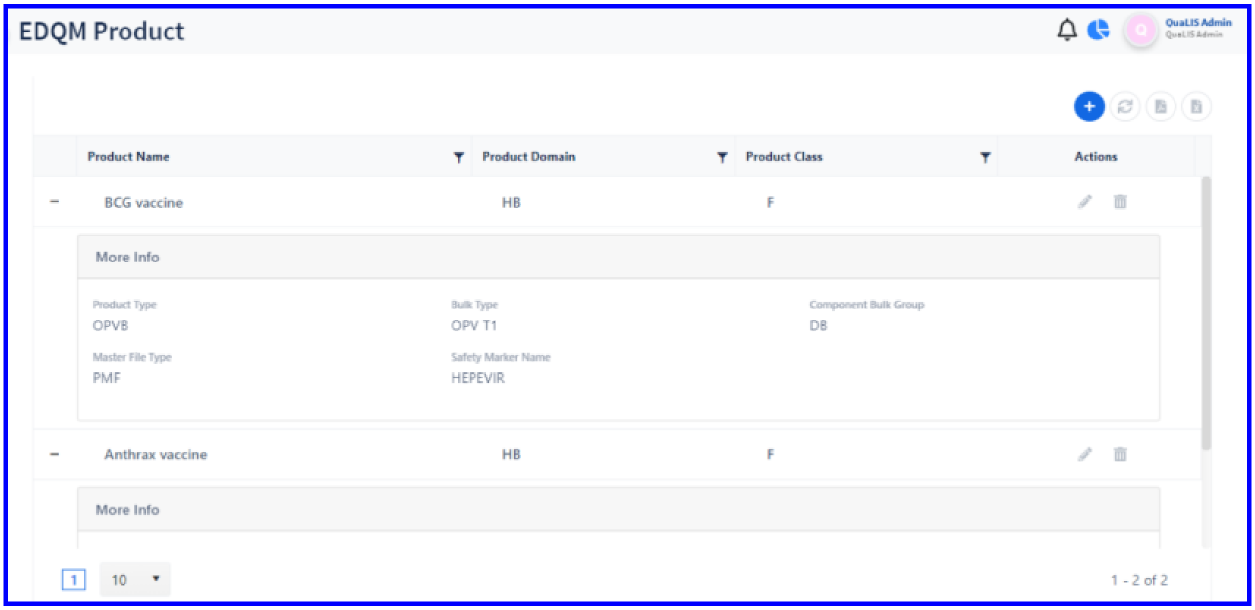


FIGURE: EDQM Product Master Screen

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:

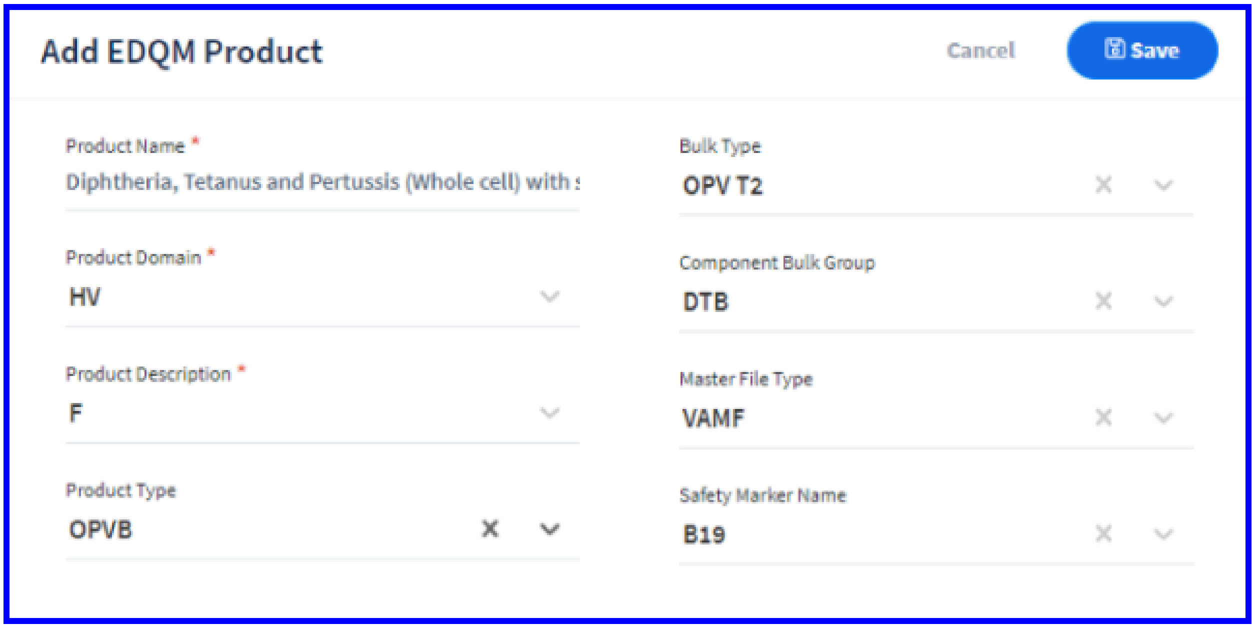


FIGURE: Add EDQM Product Dialog

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:

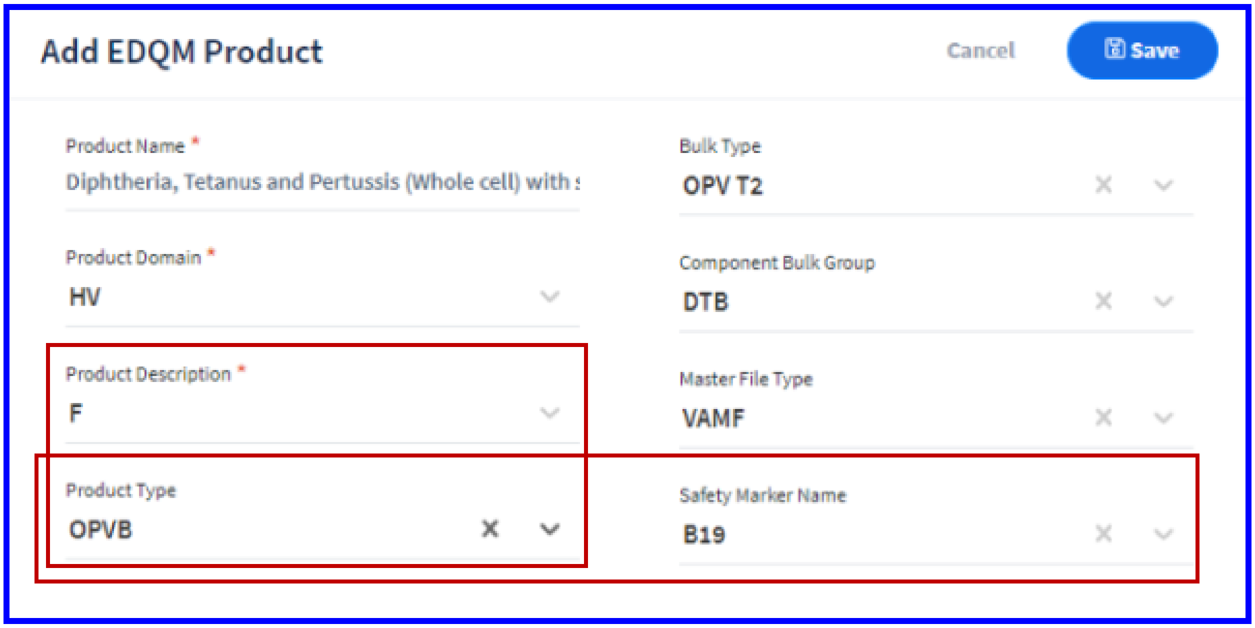


FIGURE: Add EDQM Product Dialog – With Product Type and Safety Marker Name Fields as Mandatory Fields

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:

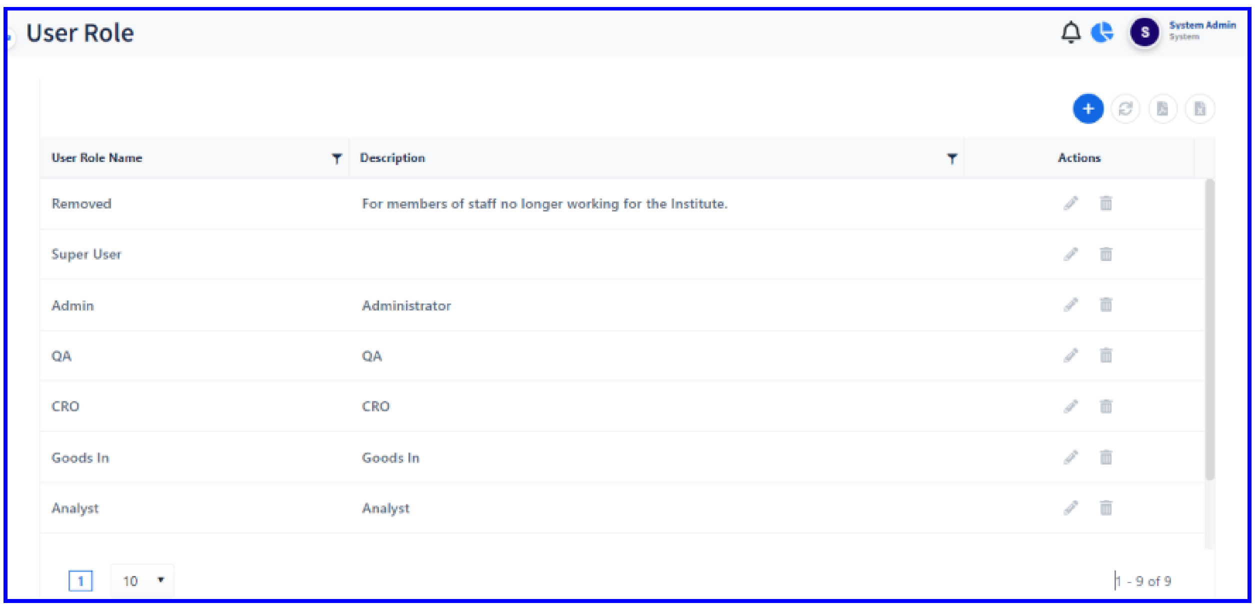


FIGURE: User role Master Screen

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:

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:

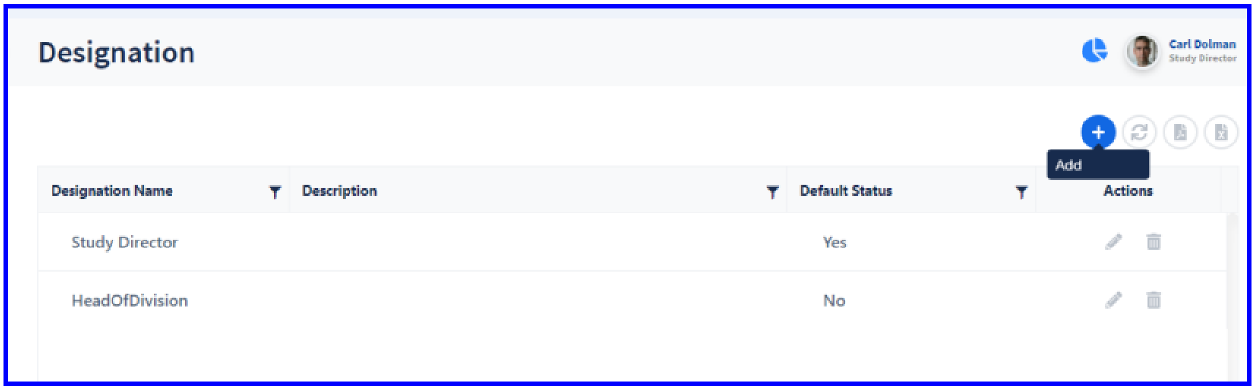


FIGURE: Designation Master Screen

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:

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:

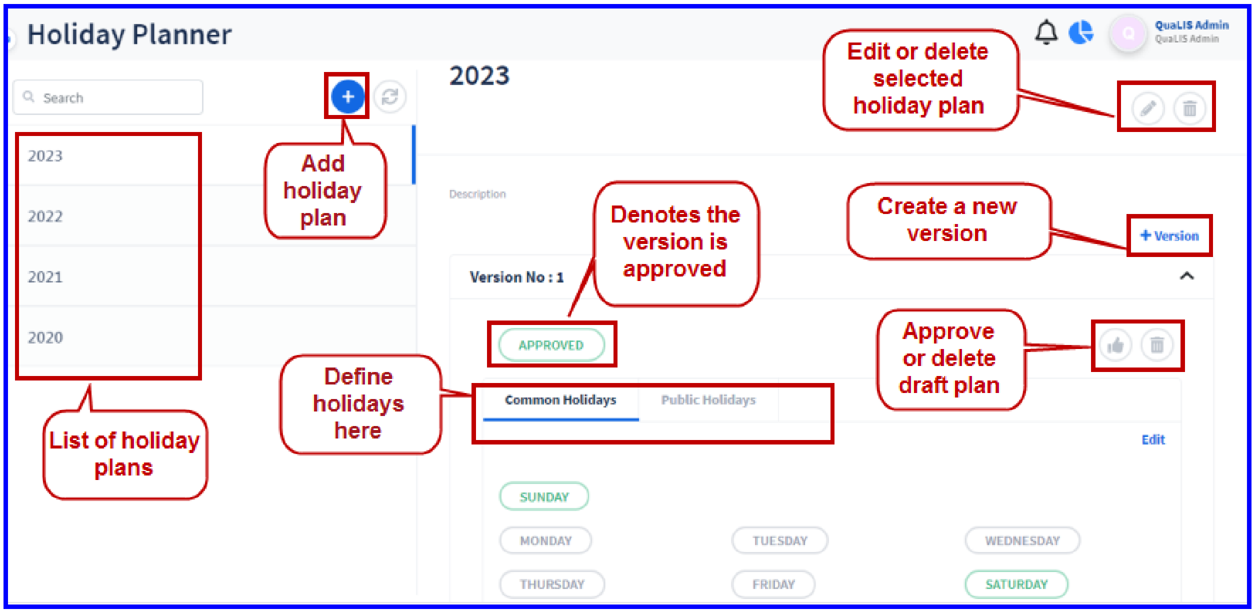


FIGURE: Holiday Planner Screen

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:

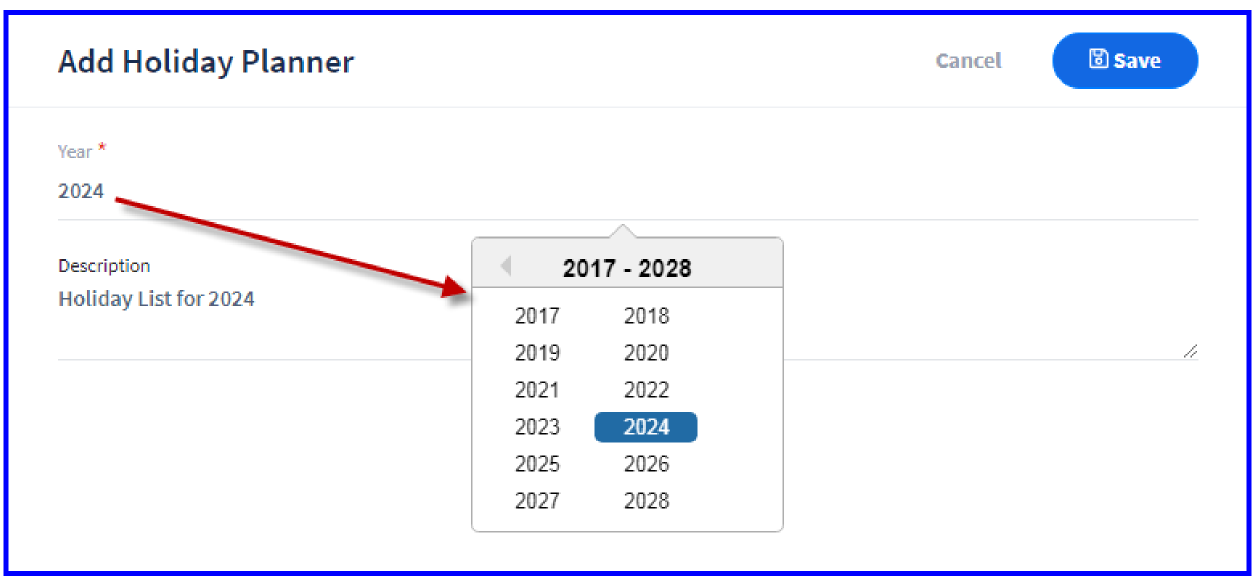


FIGURE: Add Holiday Planner Screen

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:

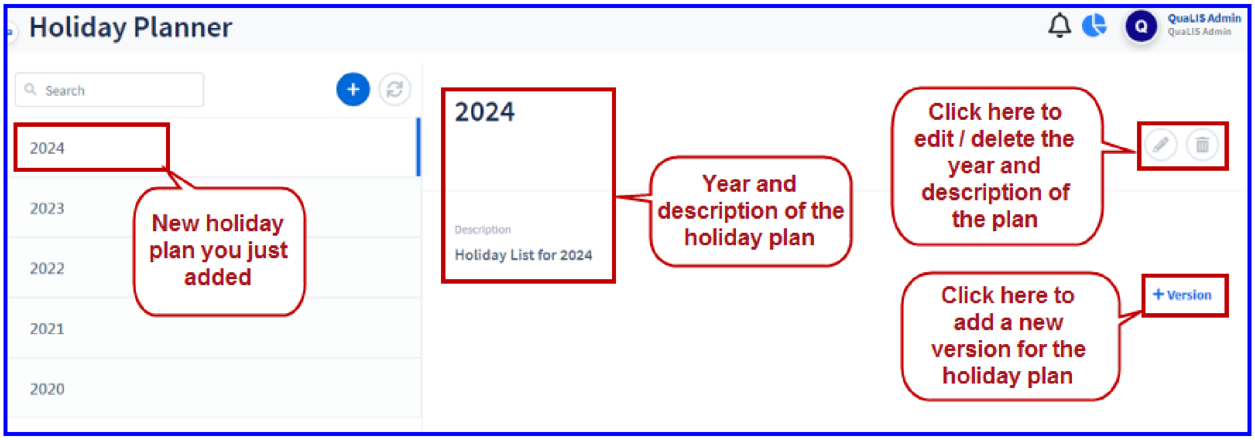


FIGURE: New Holiday Planner Added

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:

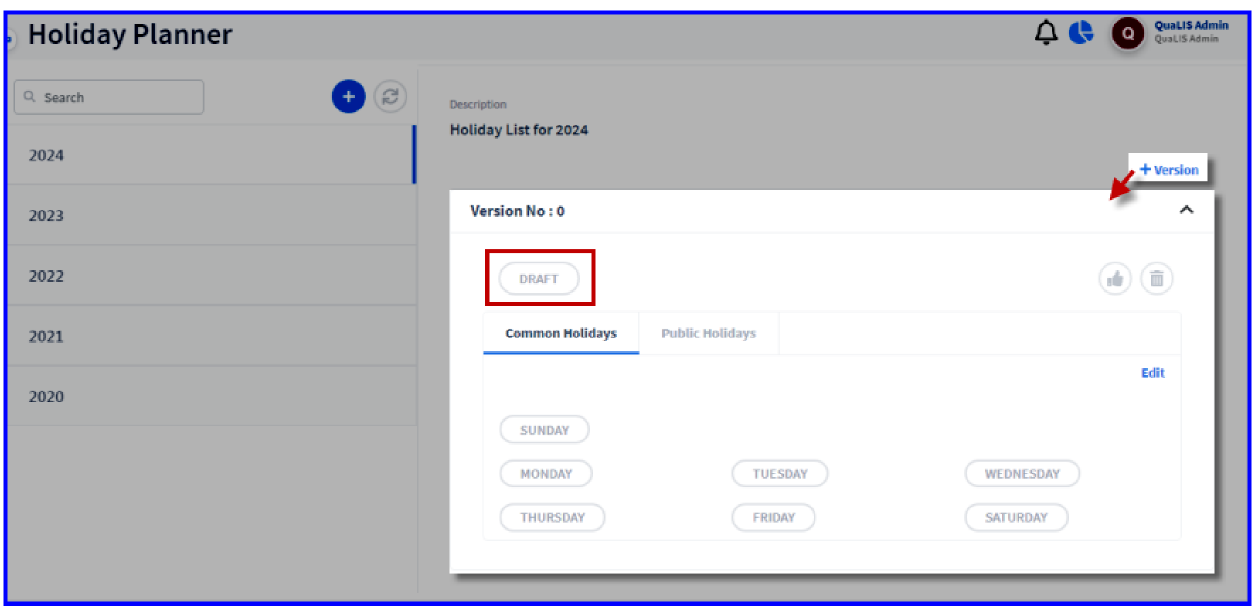


FIGURE: Adding New Version to the Holiday Plan

This section has Common Holidays and Public Holidays tabs.

3.4.3.3 Defining Common Holidays

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

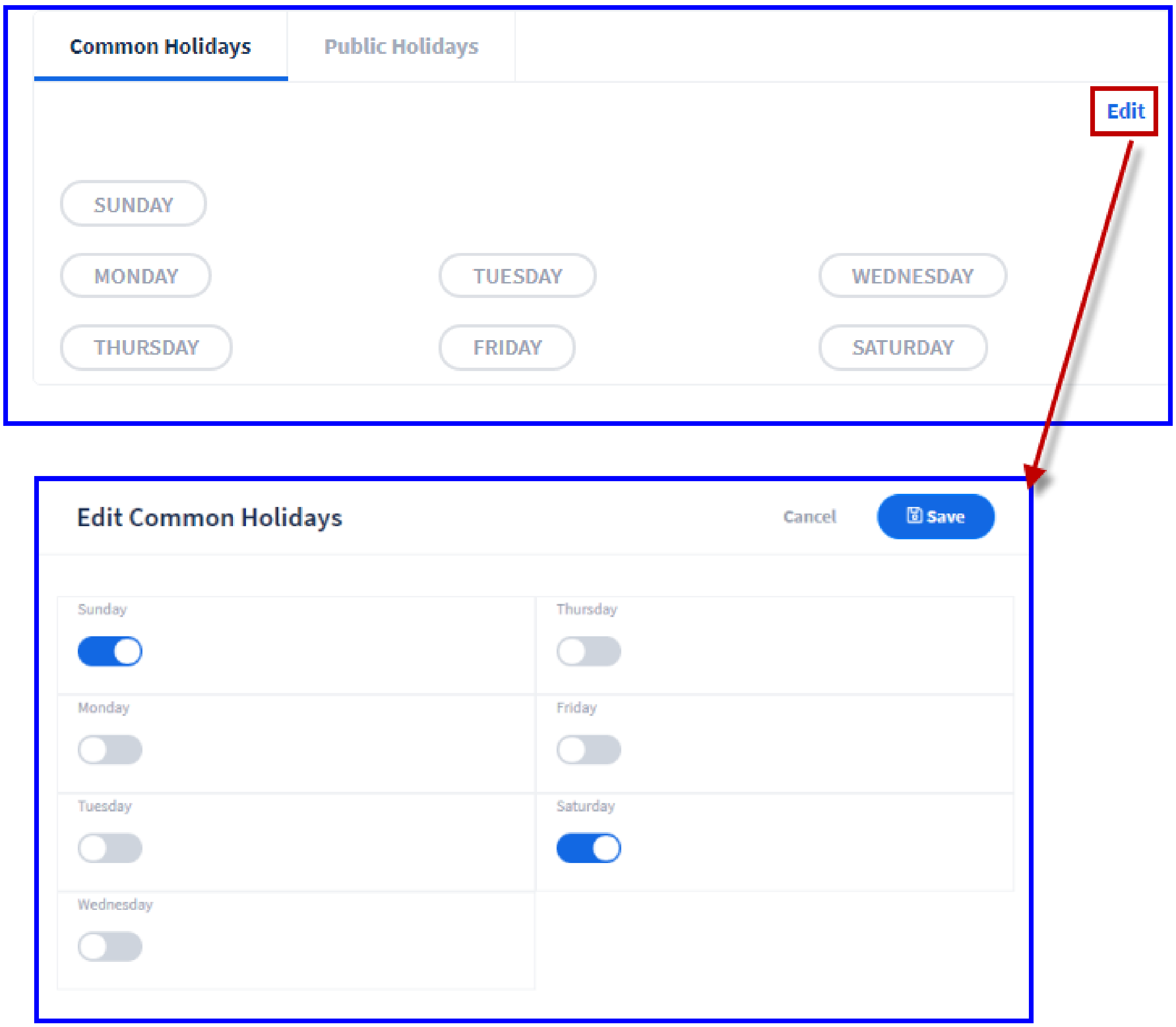


FIGURE: Defining Common Holidays

7. 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:

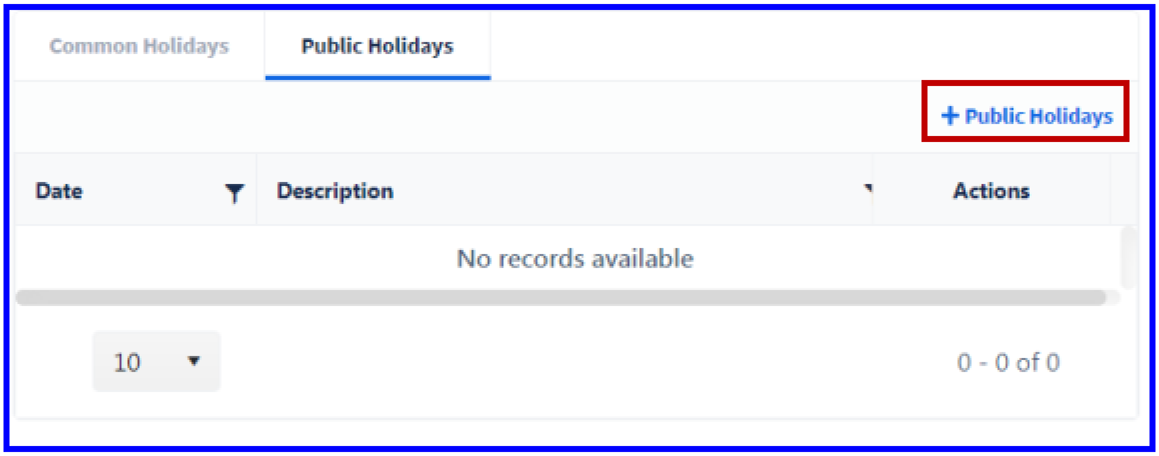


FIGURE: Public Holiday Tab

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

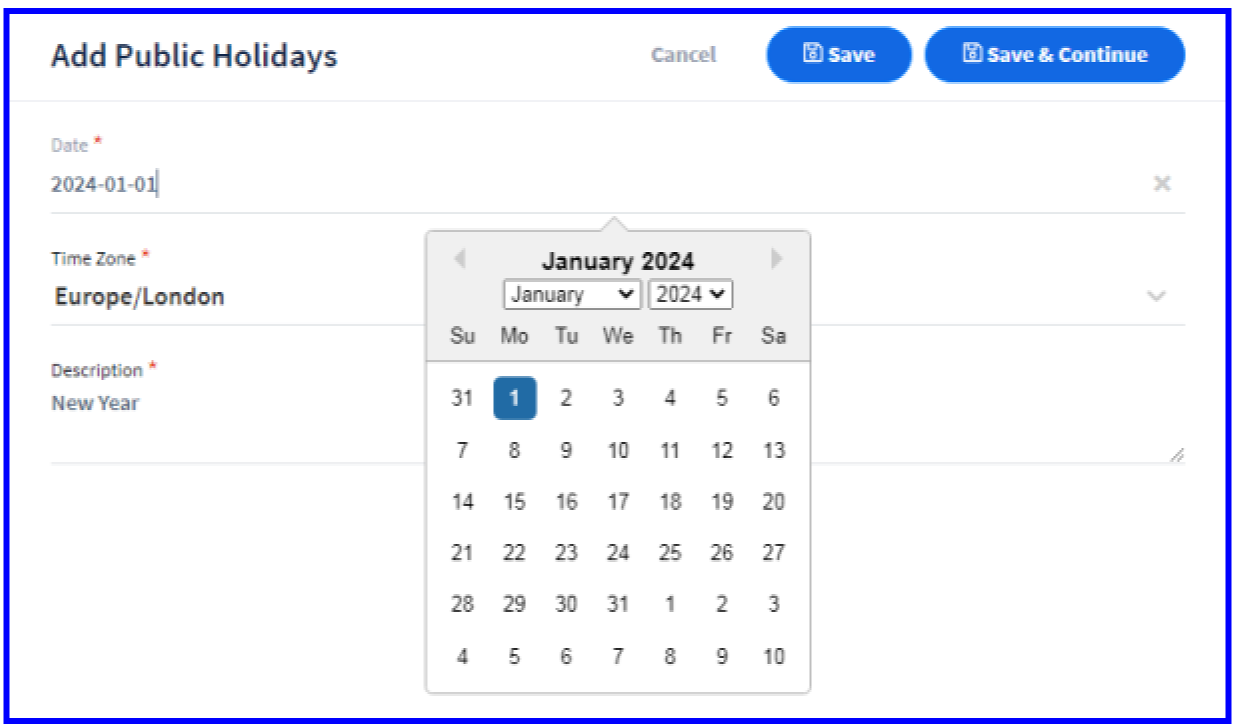


FIGURE: Add Public Holidays

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:

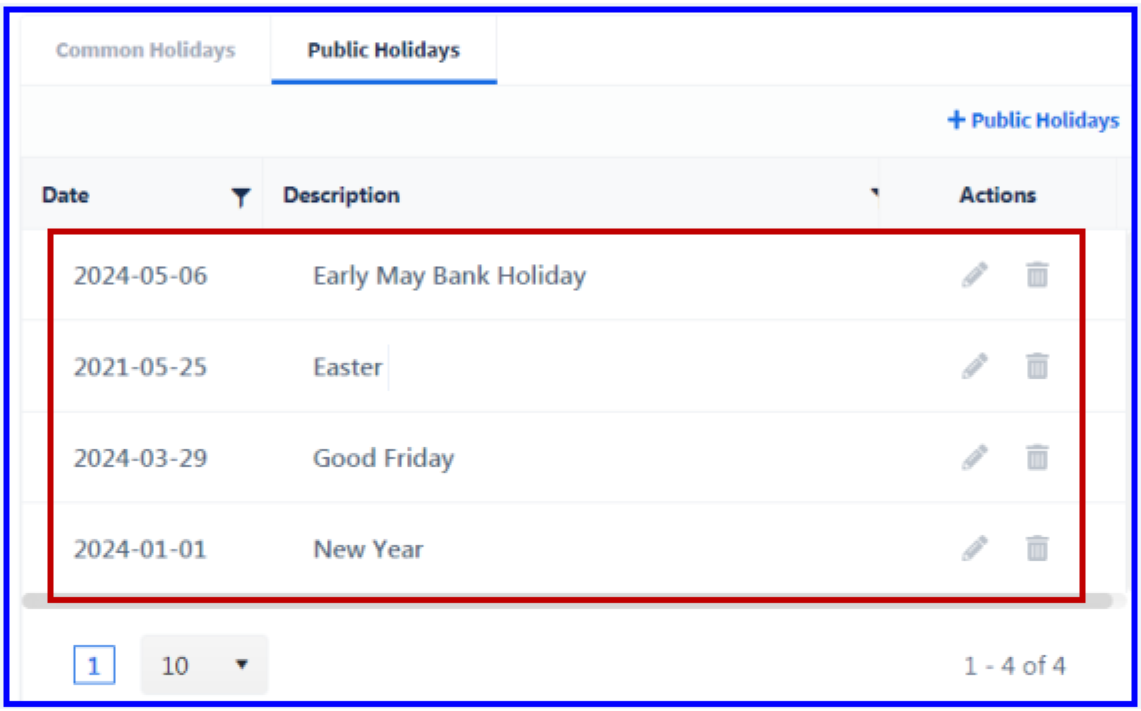


FIGURE: Public Holidays Added

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:

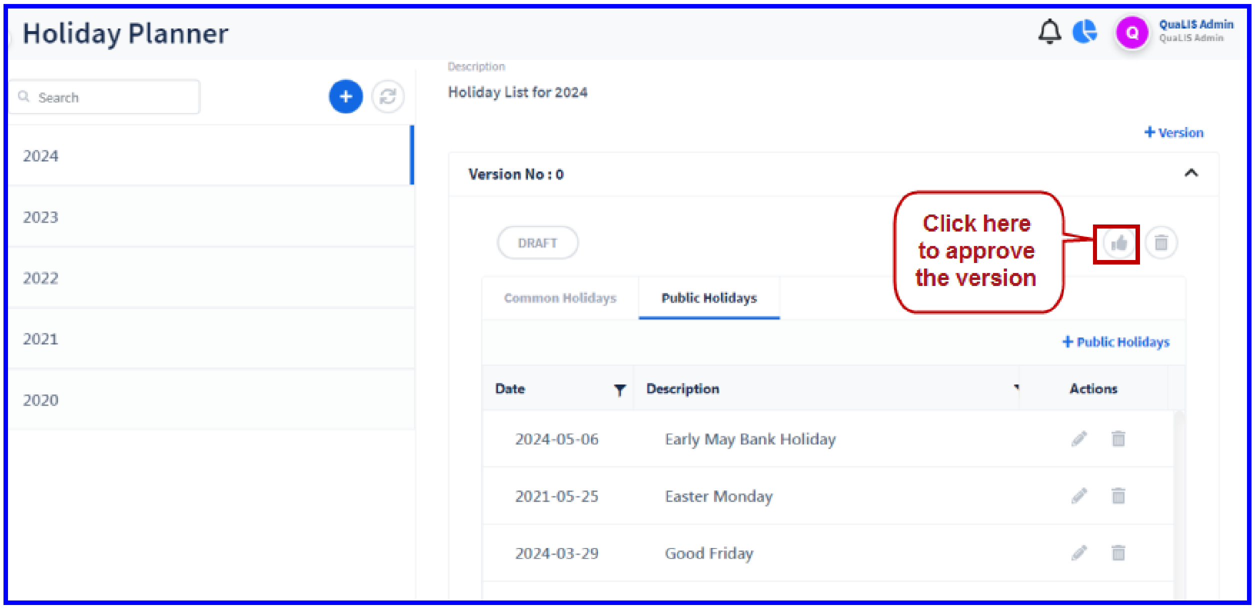


FIGURE: Approving a Version

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:

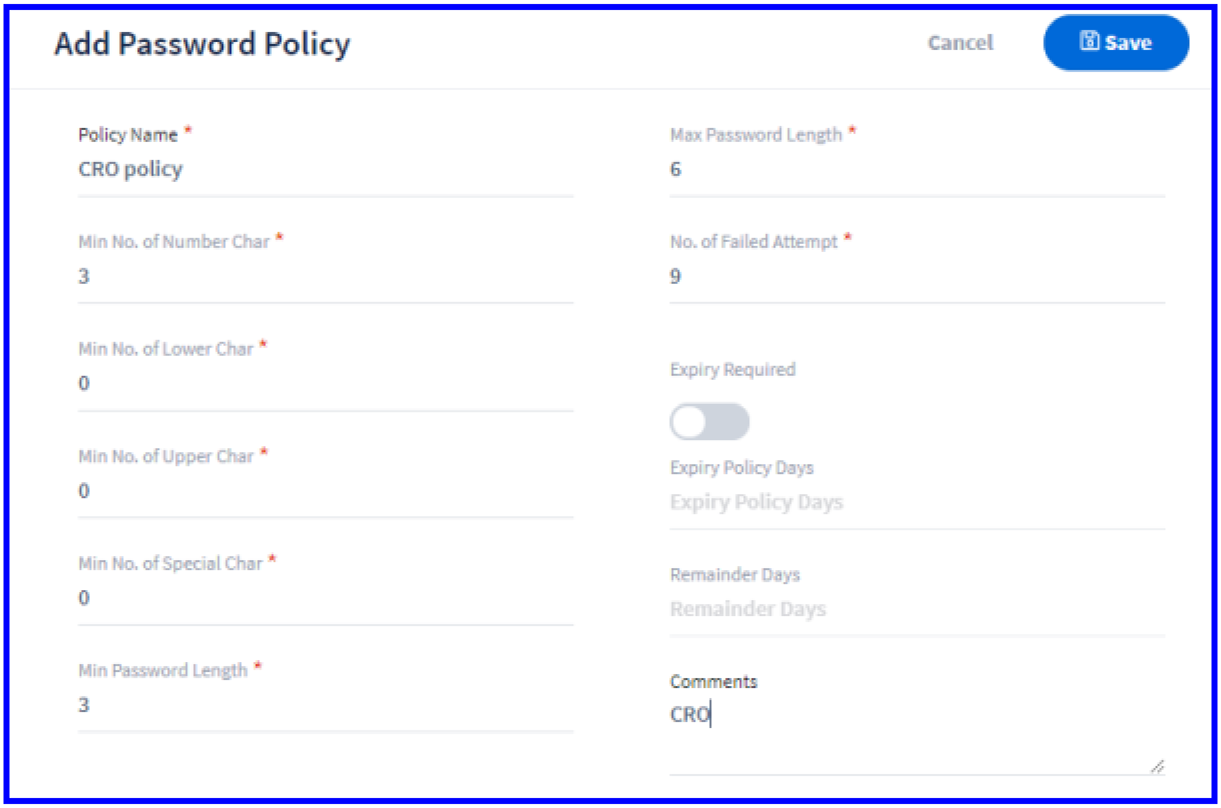


FIGURE: Add Password Policy Screen

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 .

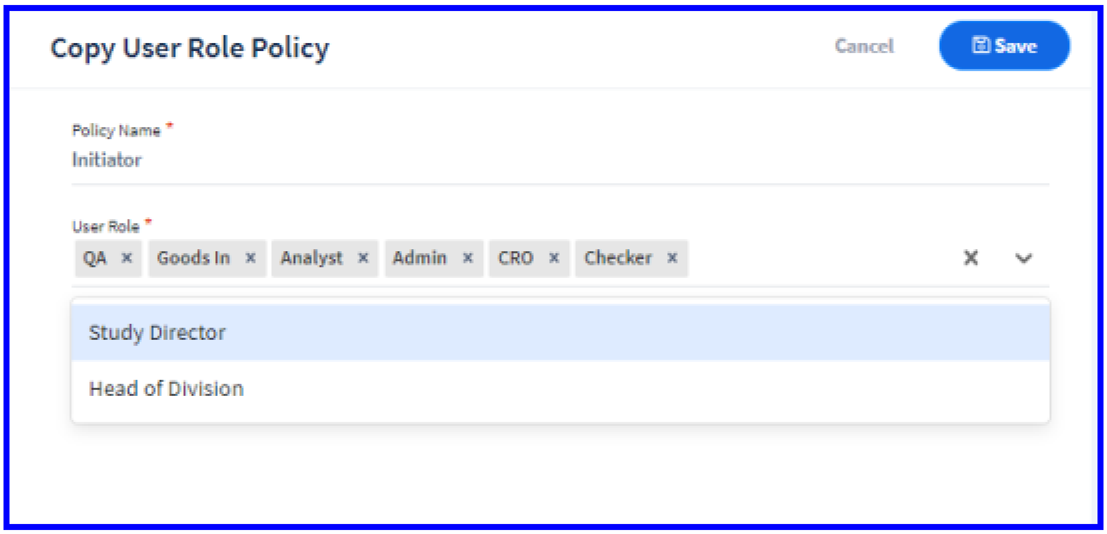


FIGURE: Copy Password Policy Dialog

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:

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:

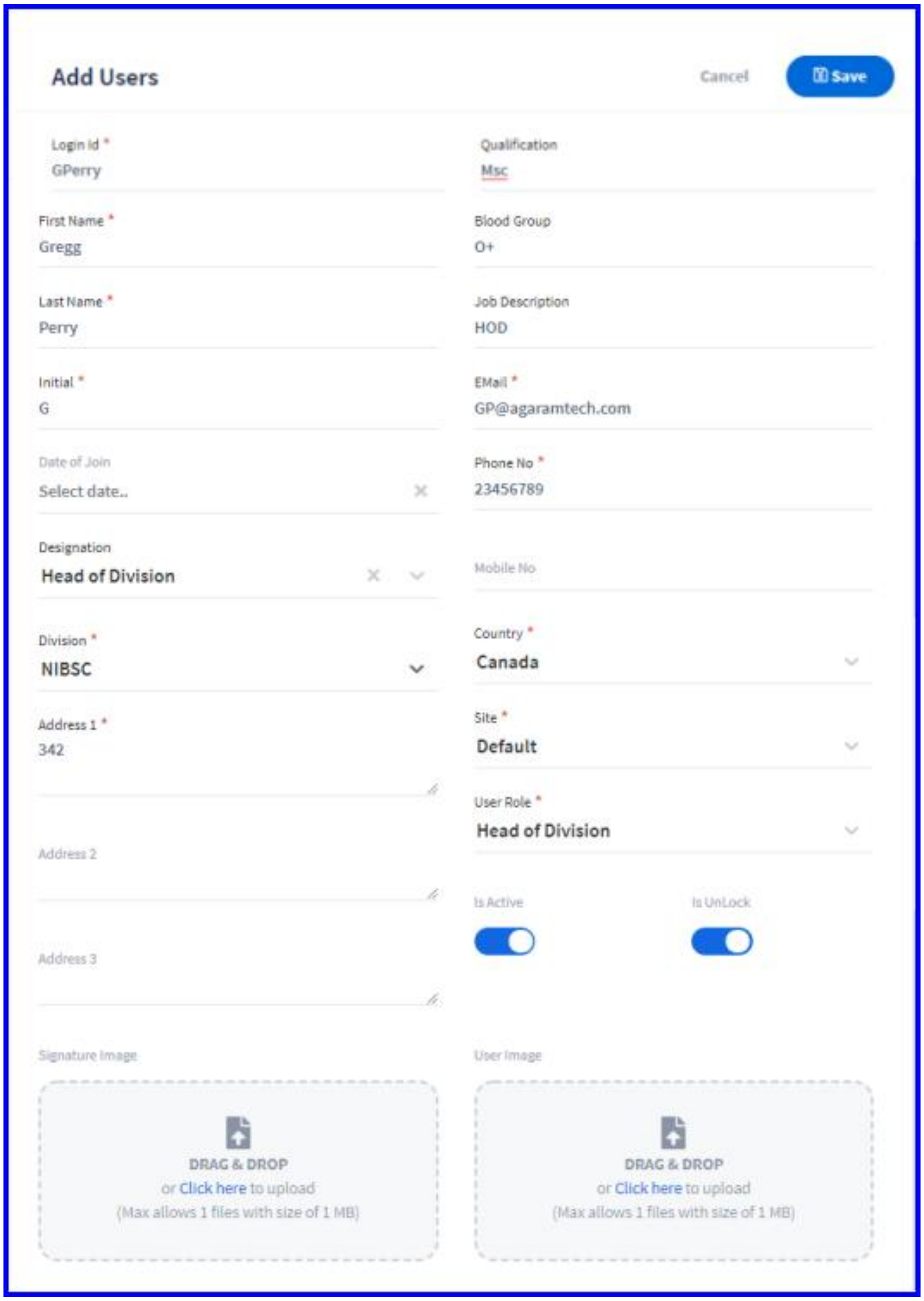


FIGURE: Add Users Screen

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:

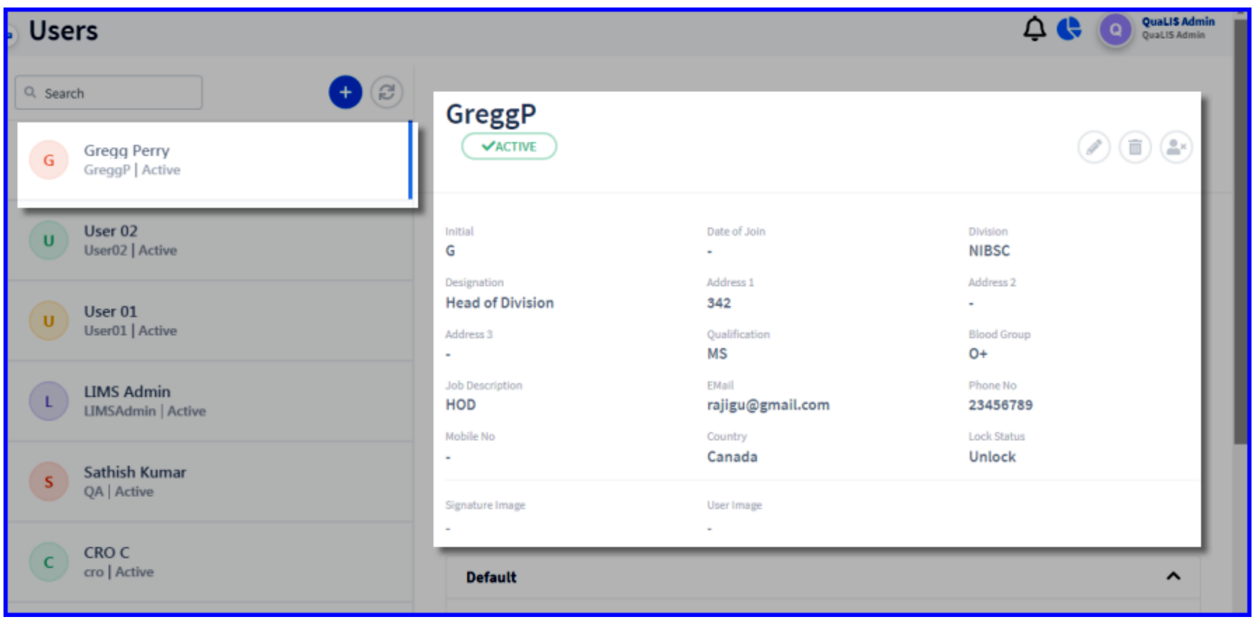


FIGURE: Users Screen Showing New User Added

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 form the list and then go to the **Role** tab. The **Role** tab appears as shown in the figure:

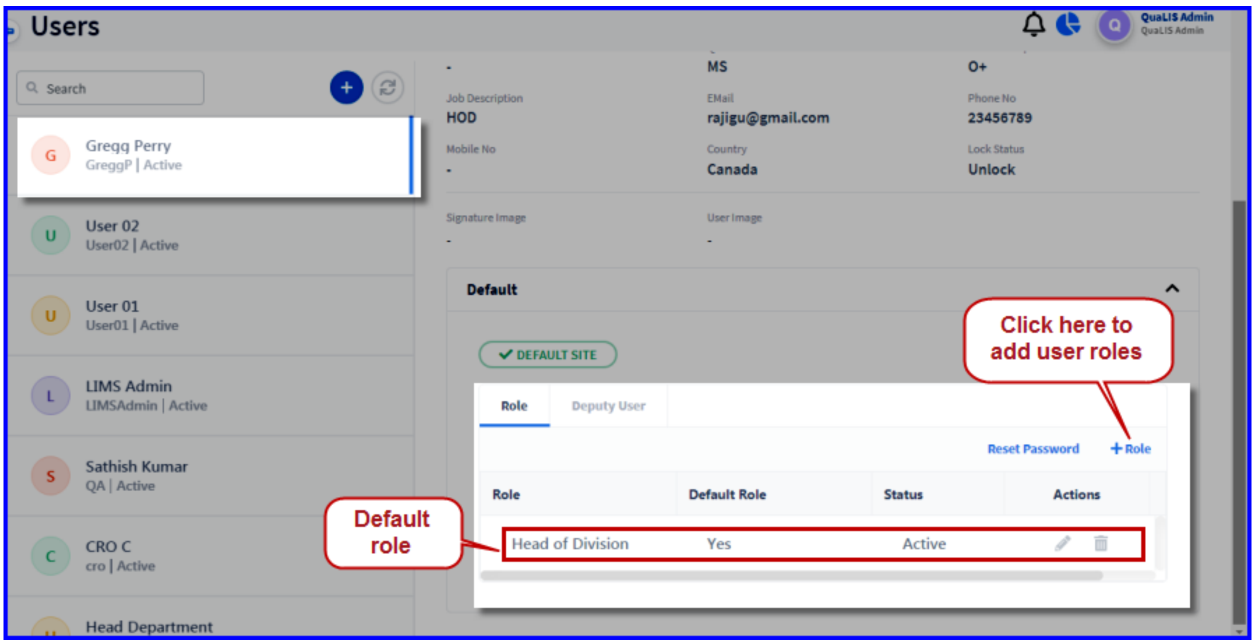


FIGURE: User Role Tab

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:

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:

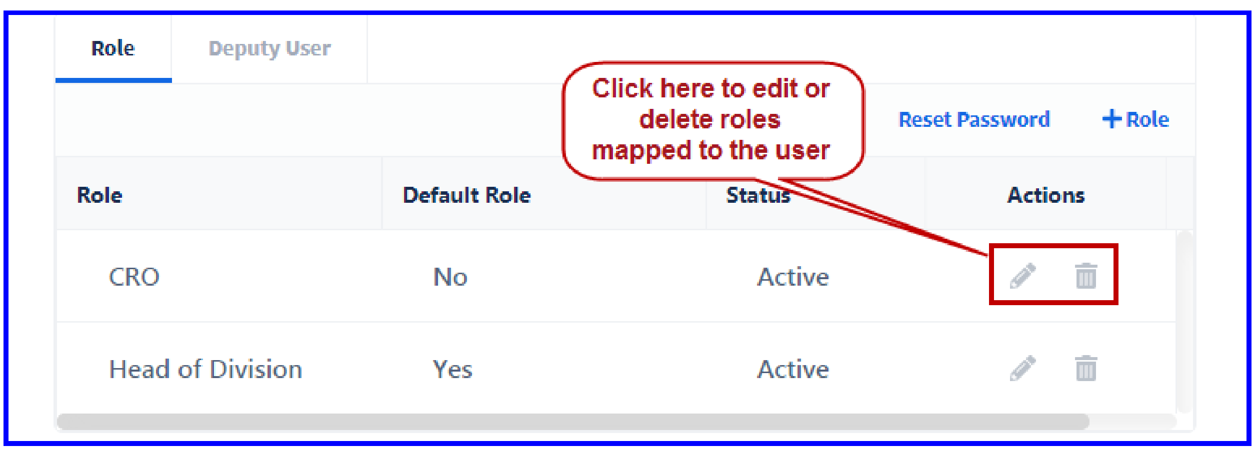


FIGURE: Role Tab Showing Roles Mapped to the User

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 form the list and then go to the **Deputy User** tab. The **Deputy User** tab appears as shown in the figure:

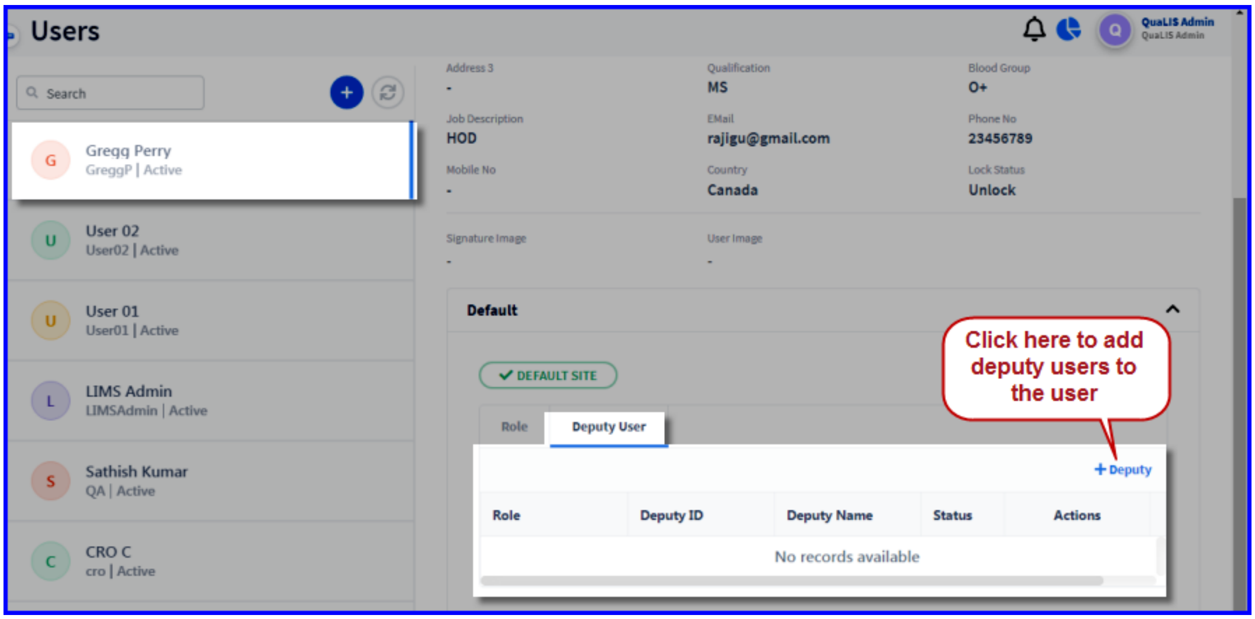


FIGURE: Deputy User Tab

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

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:

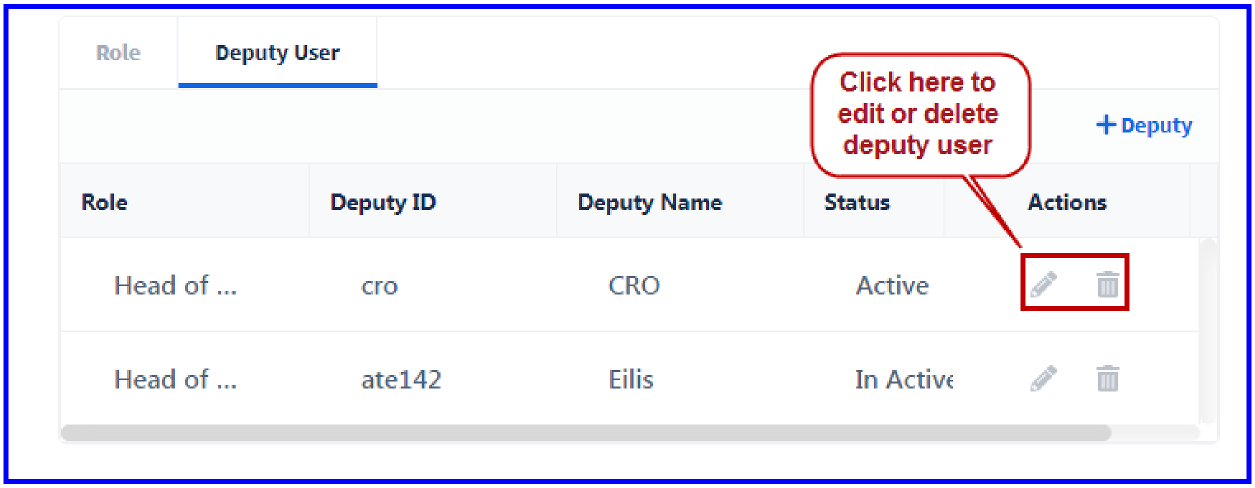


FIGURE: Deputy User Tab Showing Added Deputy Users

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:

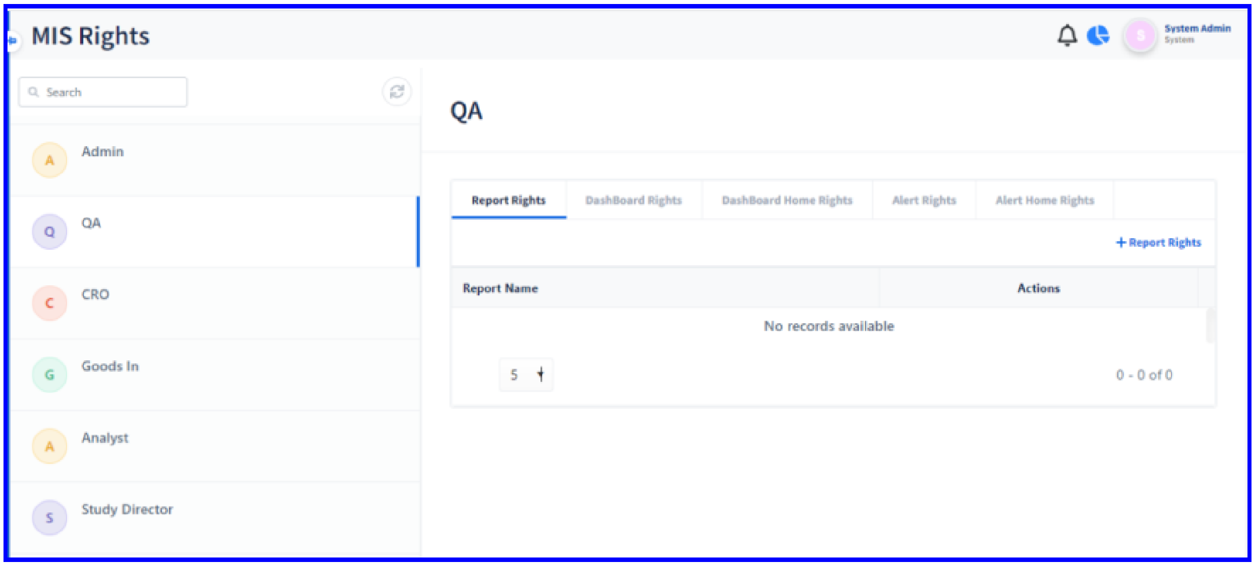


FIGURE: MIS Rights Screen

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:

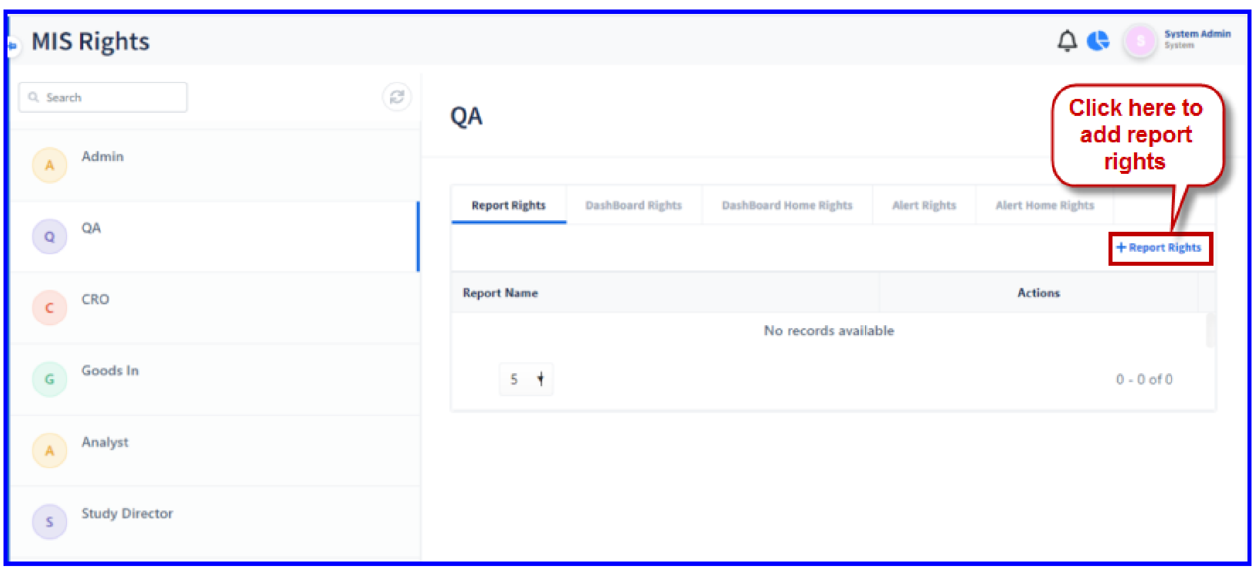


FIGURE: Report Rights Tab

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

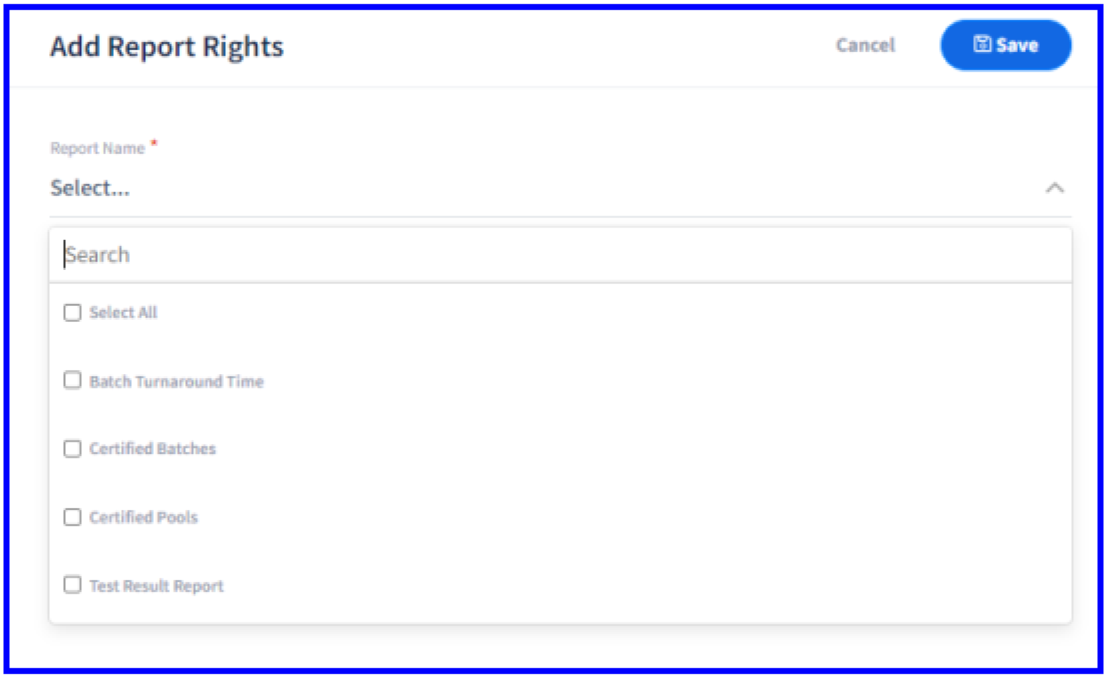


FIGURE: Add Report Rights Dialog

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:

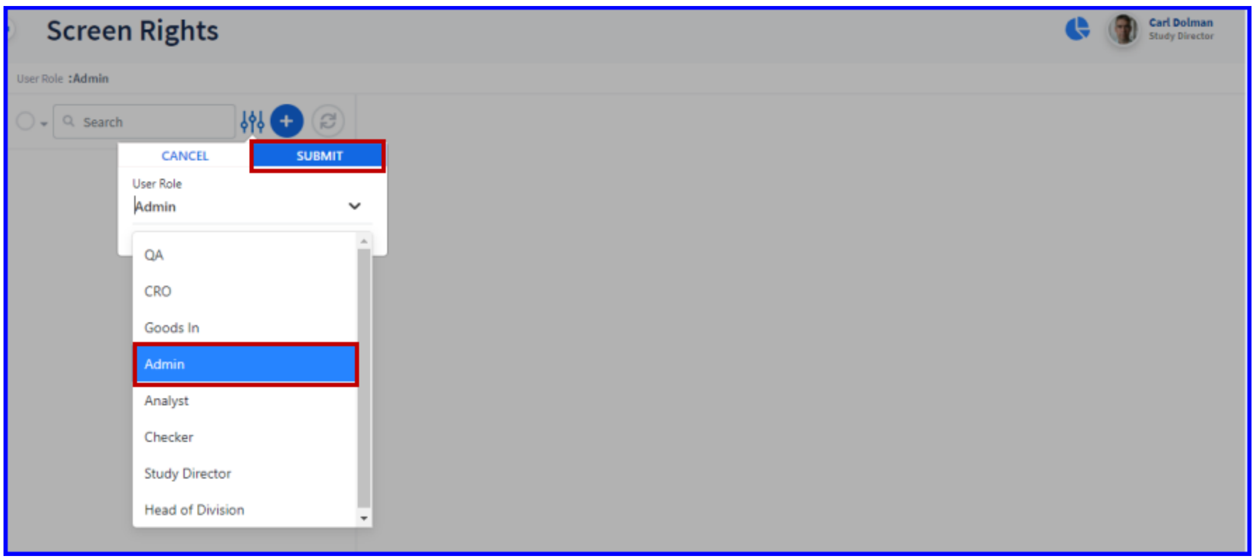


FIGURE: Selecting User Role to Define Screen Rights

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:

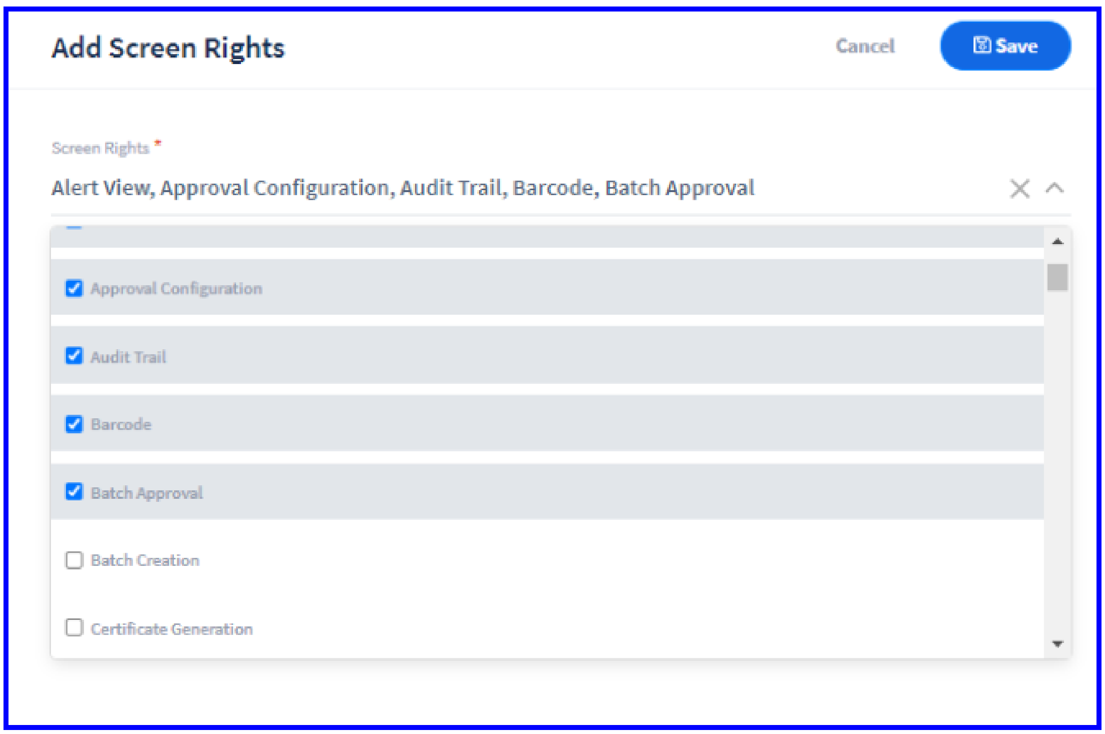


FIGURE: Add Screen Rights Screen

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:

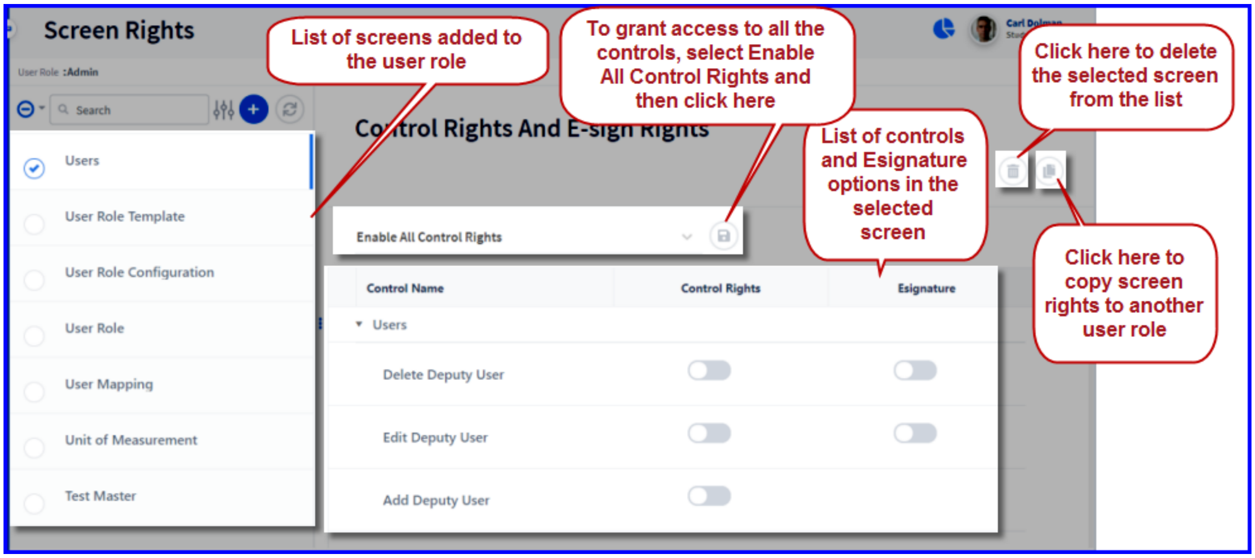


FIGURE: List of Screens, Controls and E-Sign Options

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:

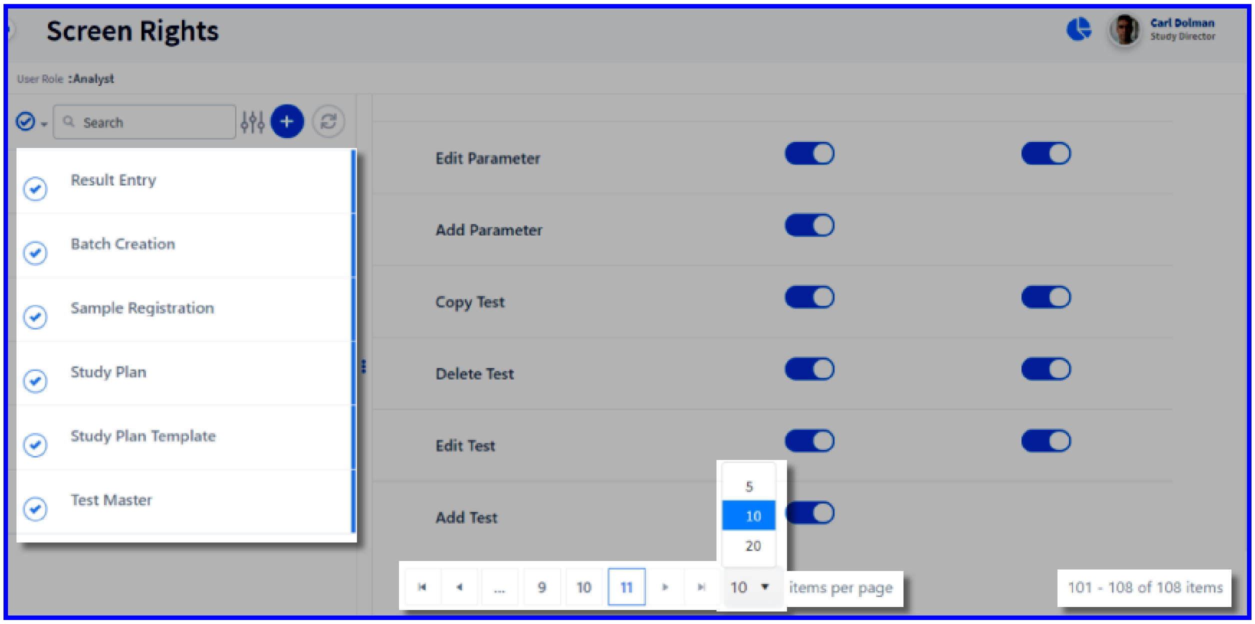
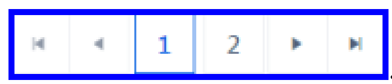


FIGURE: Screen Rights – Pagination

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 .

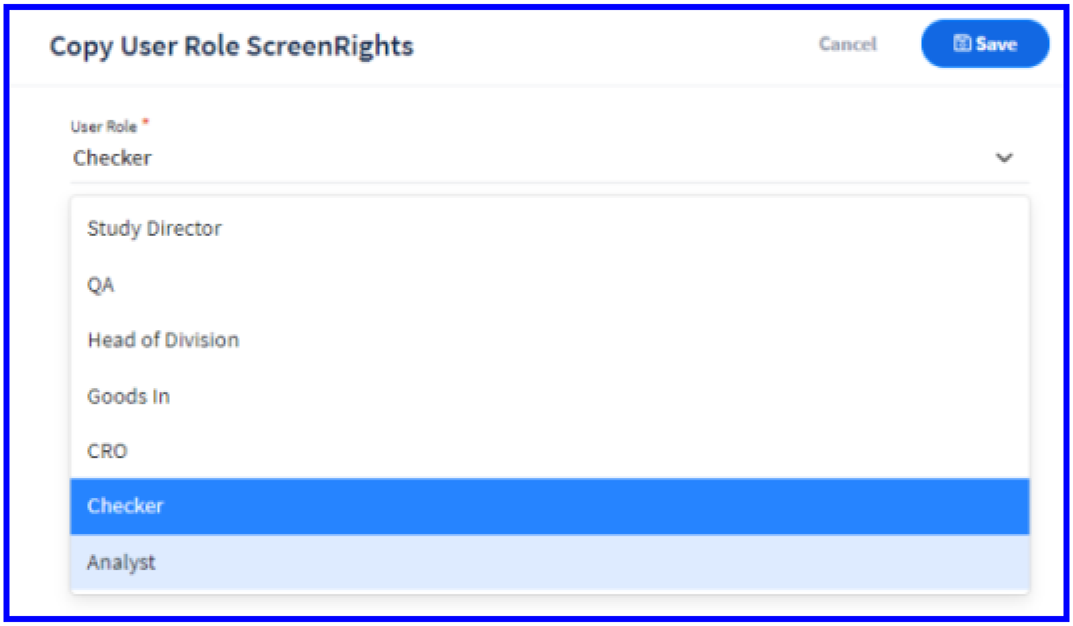


FIGURE: Copy User Role Screen Rights Screen

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:

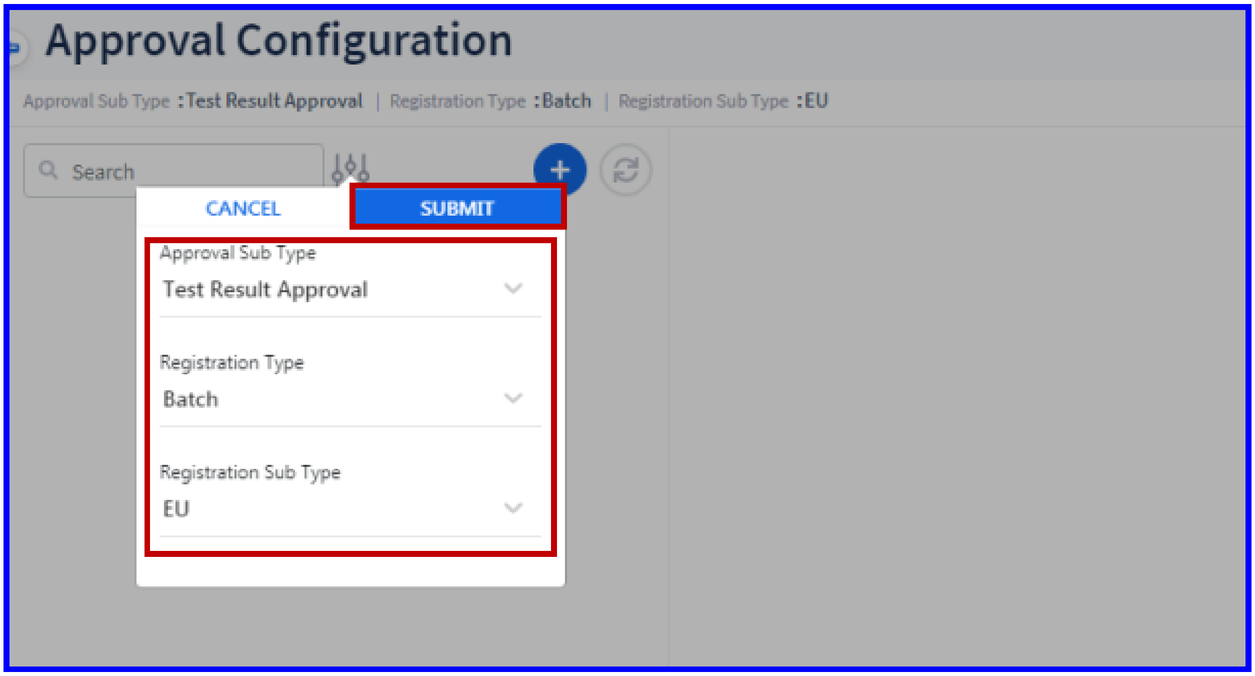


FIGURE: Approval Configuration Screen

2. In the 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:

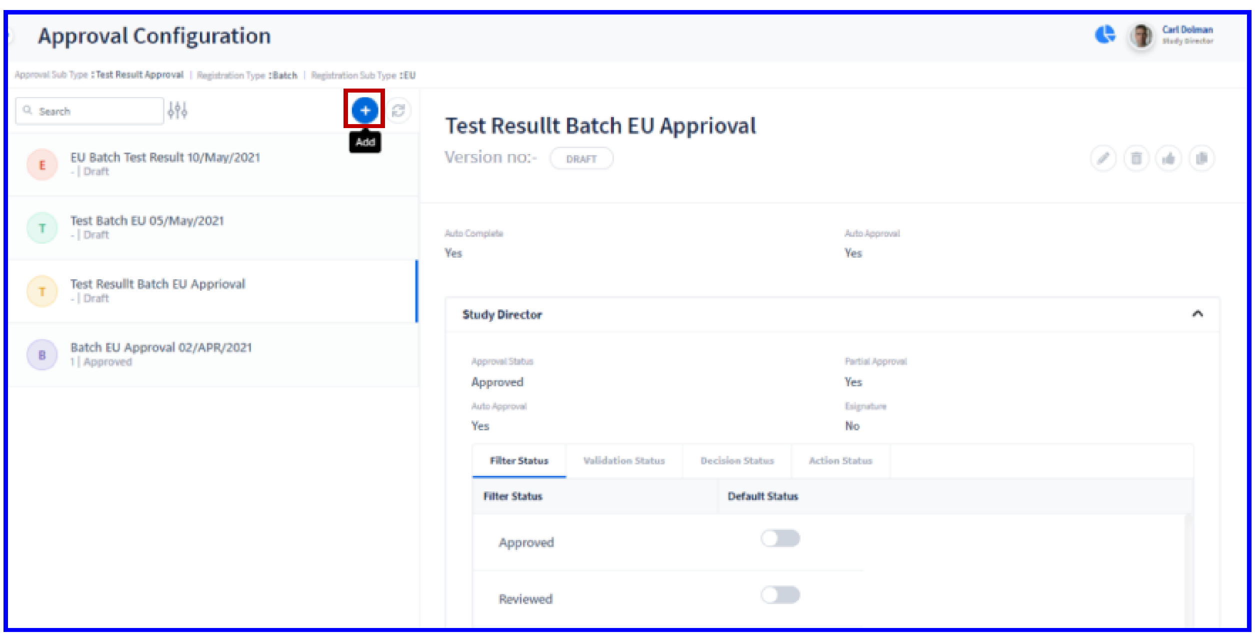


FIGURE: Approval Configuration Screen - Add

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

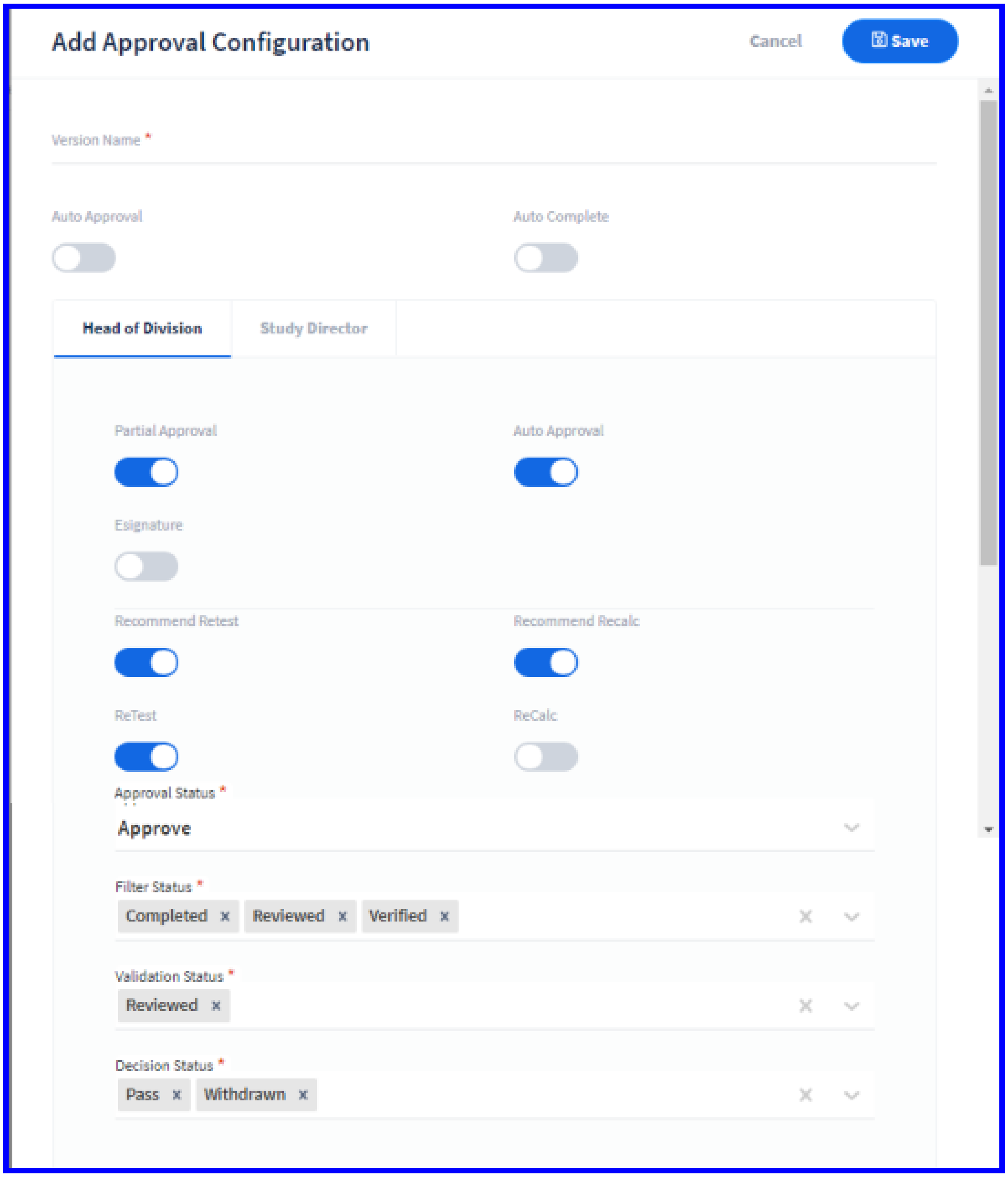


FIGURE: Add Approval Configuration Screen

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 .

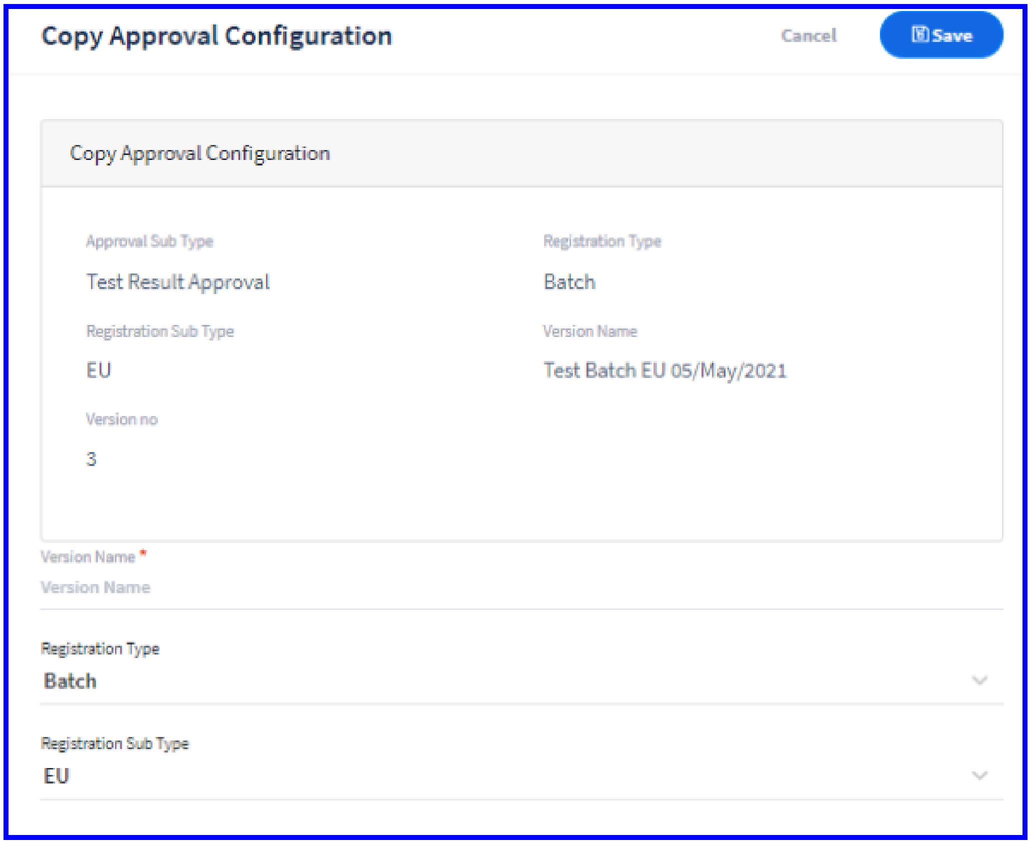


FIGURE: Copy Approval Configuration Screen

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:

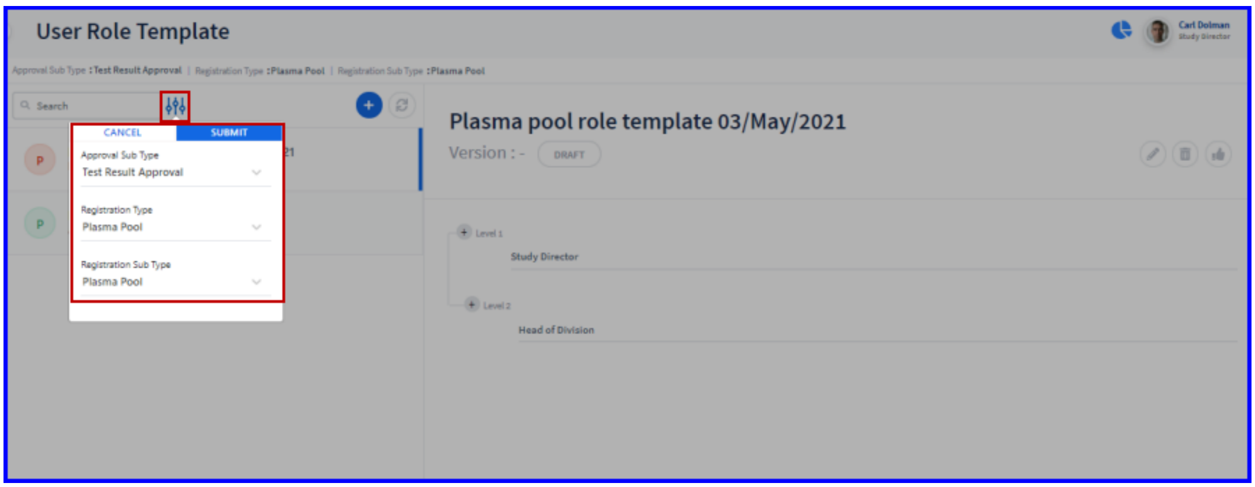


FIGURE: User Role Template Screen Showing Filter

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**.

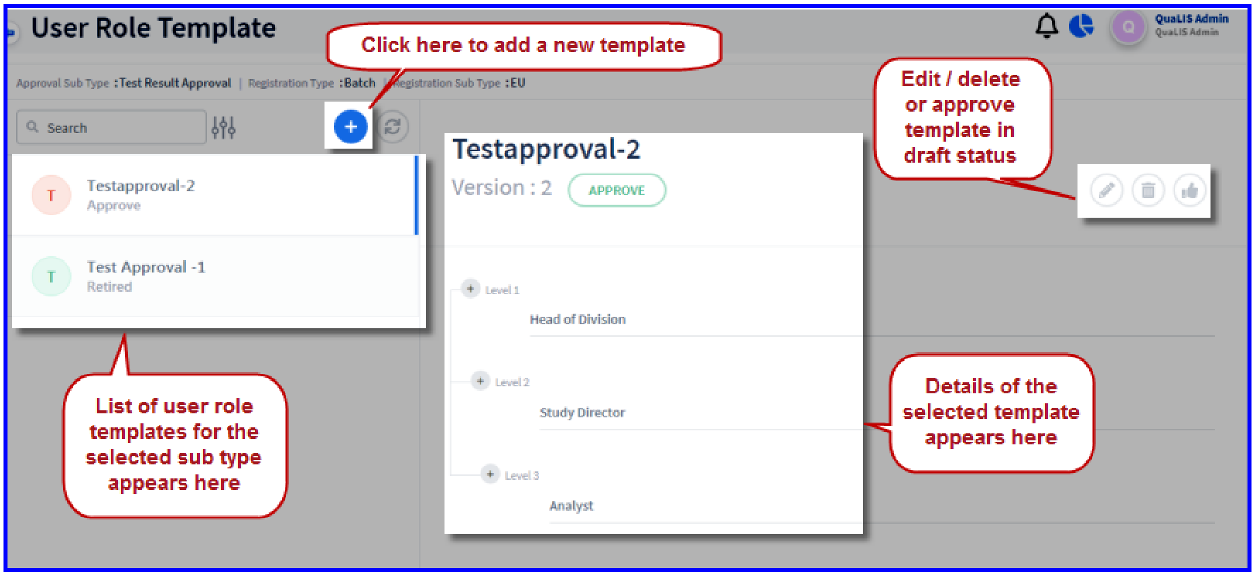


FIGURE: User Role Template Screen Showing List of Templates

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:

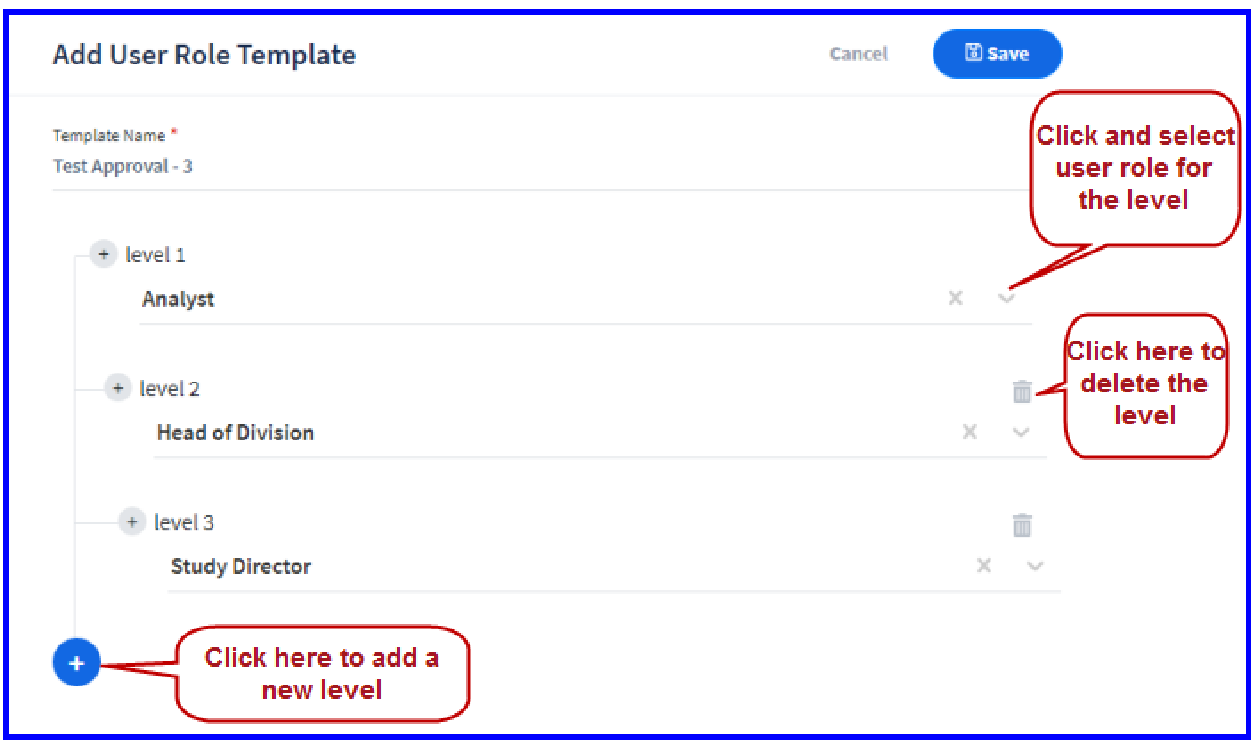


FIGURE: Add User Role Template Screen

4. In the **Template Name** field, type a name for the template.

5. + level 1 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:

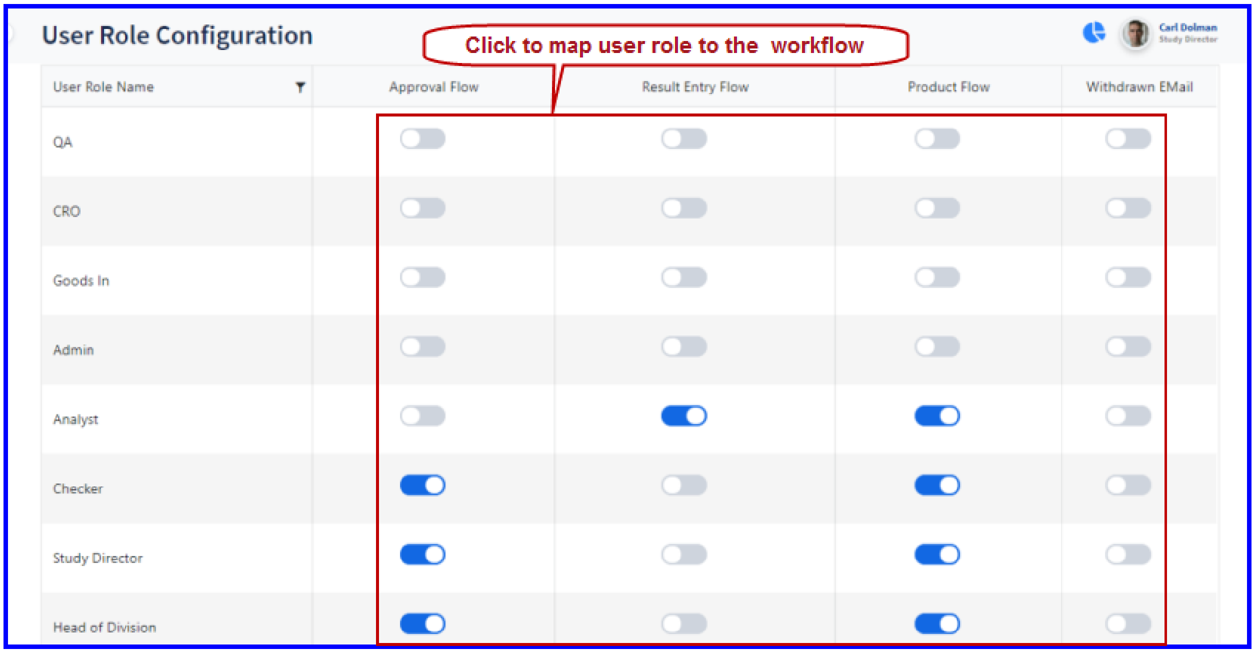


FIGURE: User Role Configuration Screen

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:

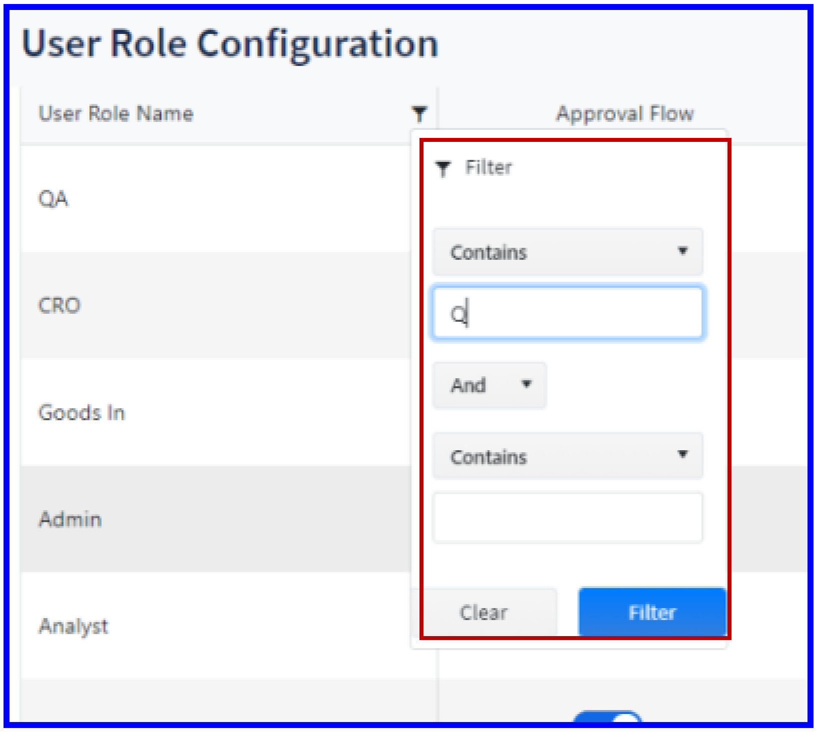


FIGURE: Filter User Role Name

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:

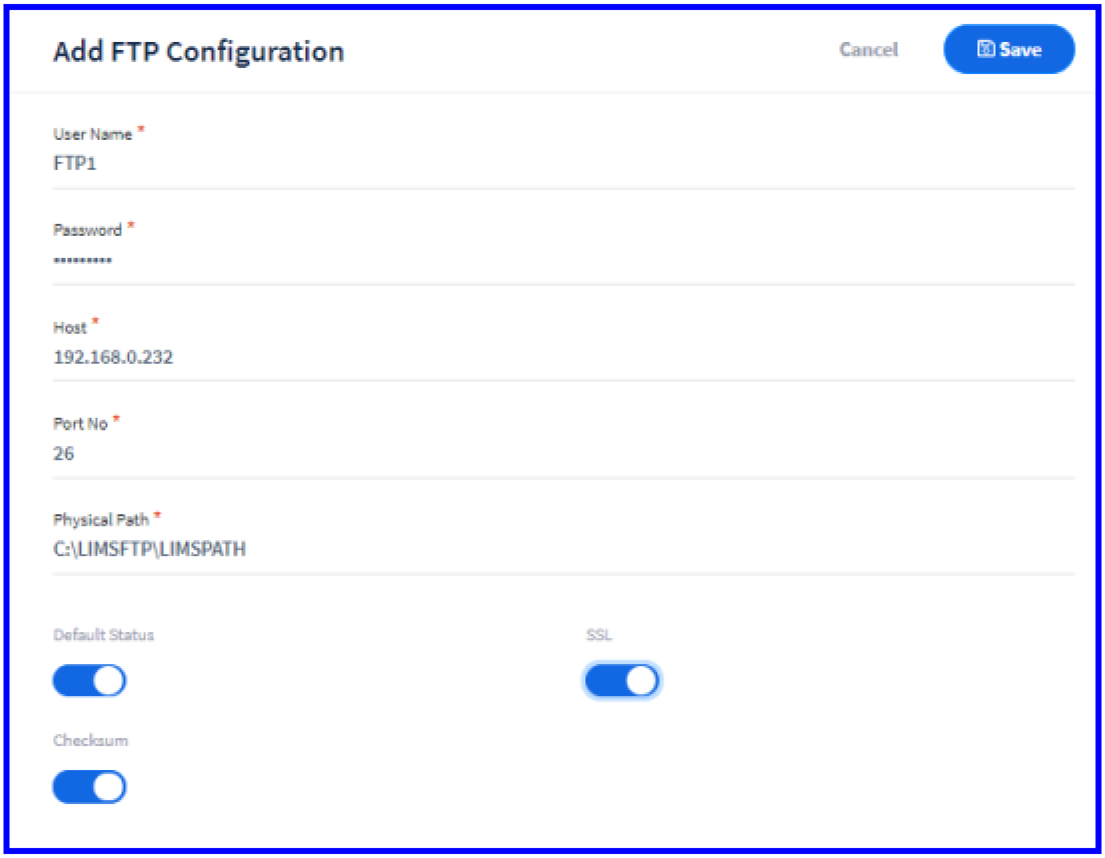


FIGURE: Add FTP Configuration Screen

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:

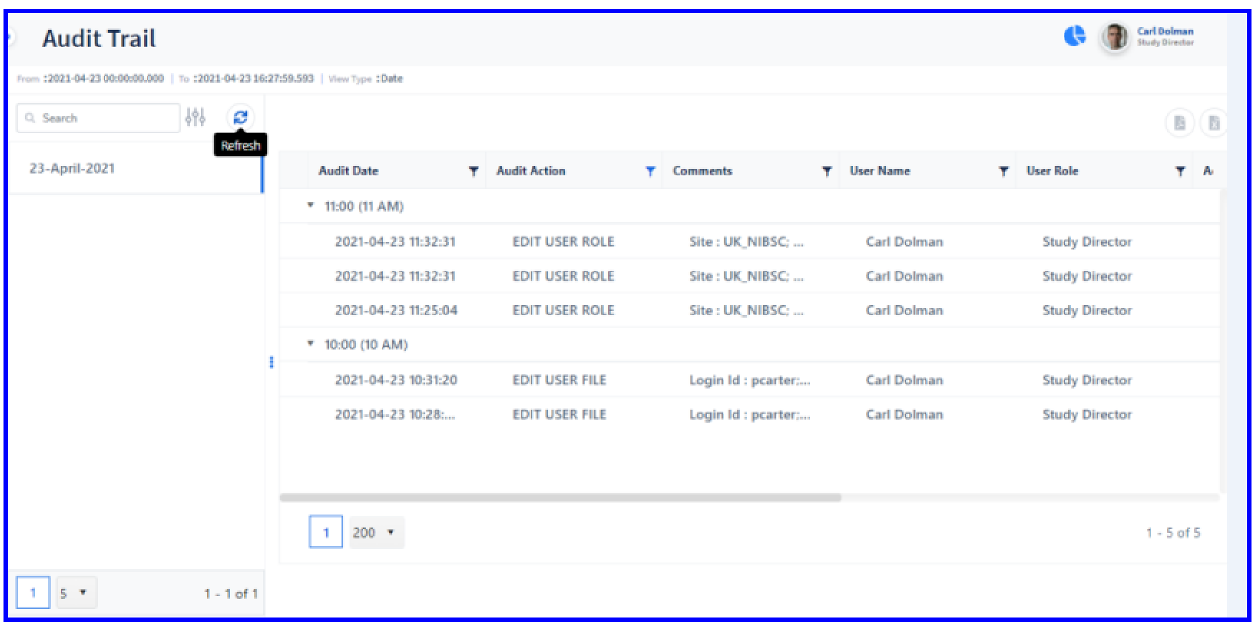


FIGURE: Audit Trail Screen

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:

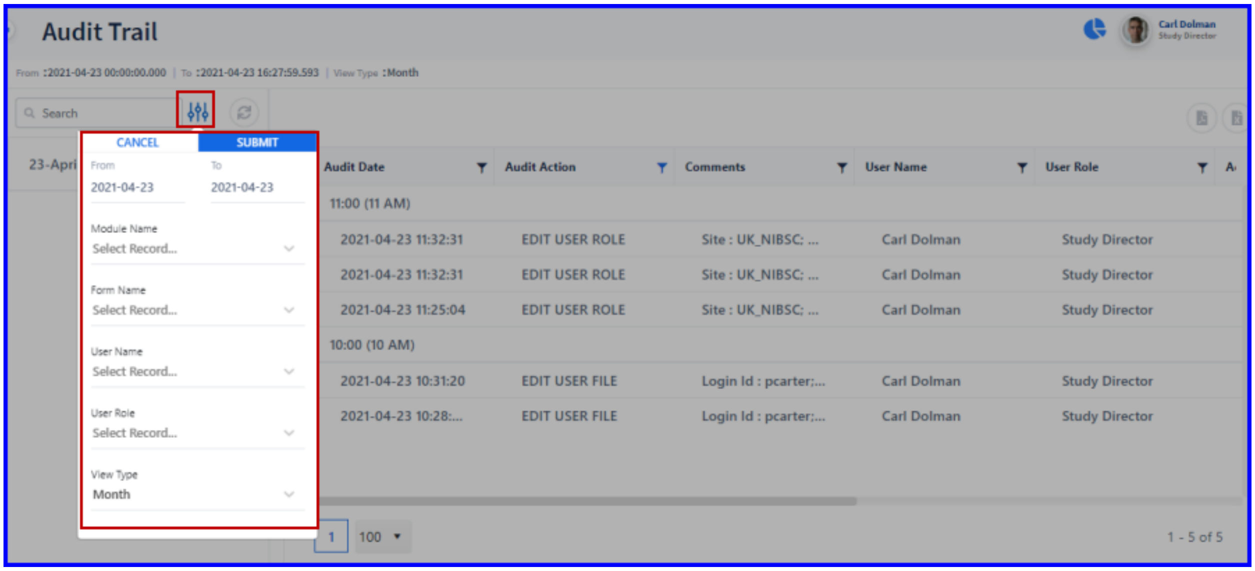


FIGURE: Filter audit Trail Records

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:

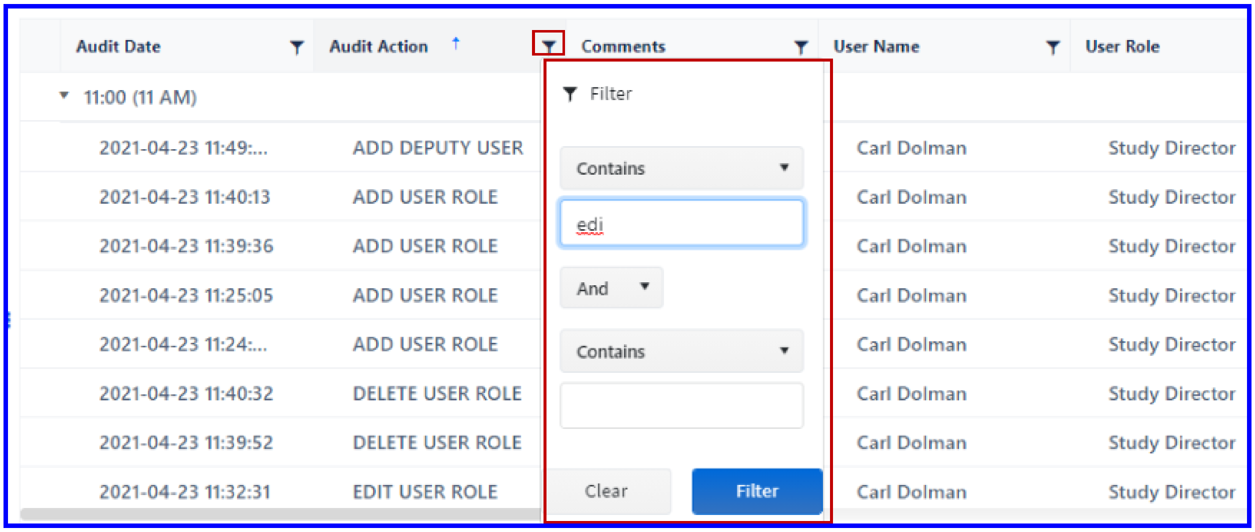


FIGURE: Filter audit Records Based on Fields

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:

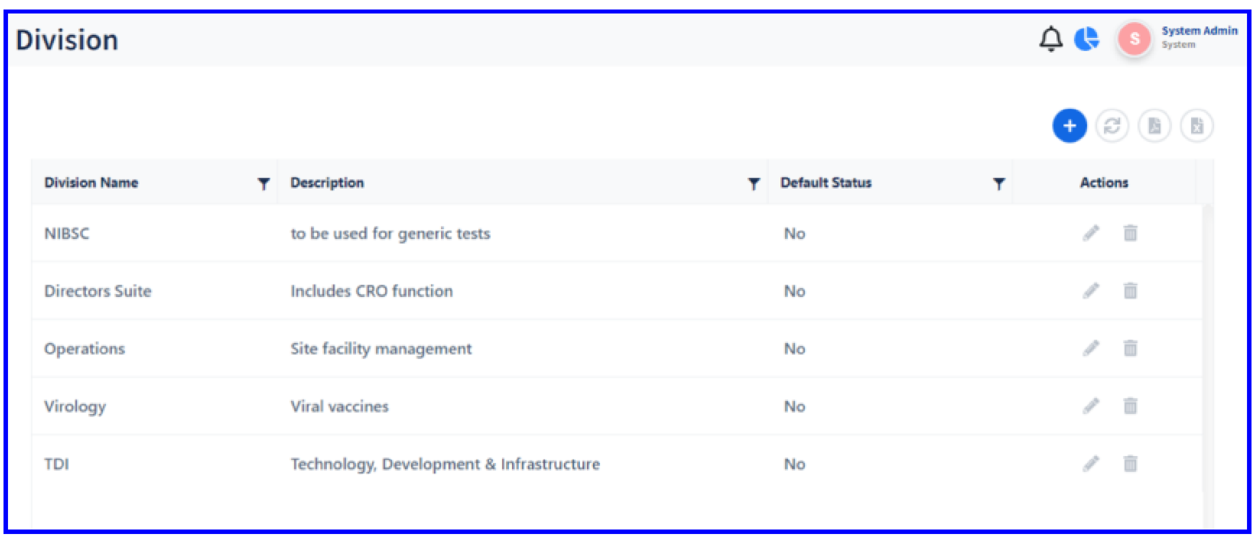


FIGURE: Division Master Screen

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:

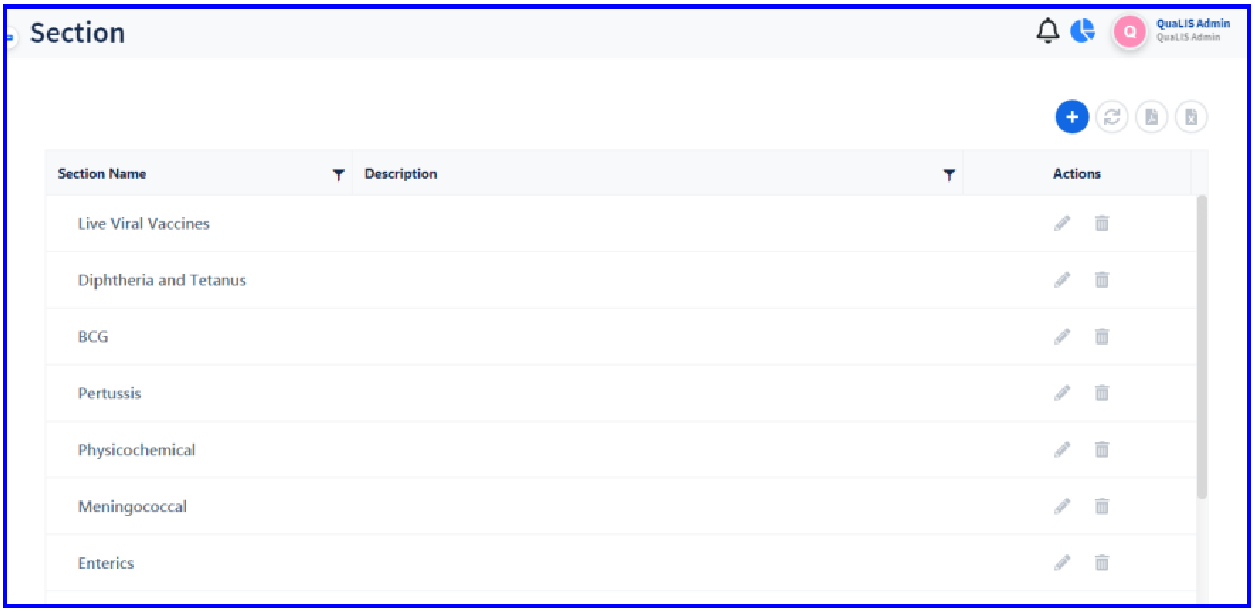


FIGURE: Section Master Screen

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:

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:

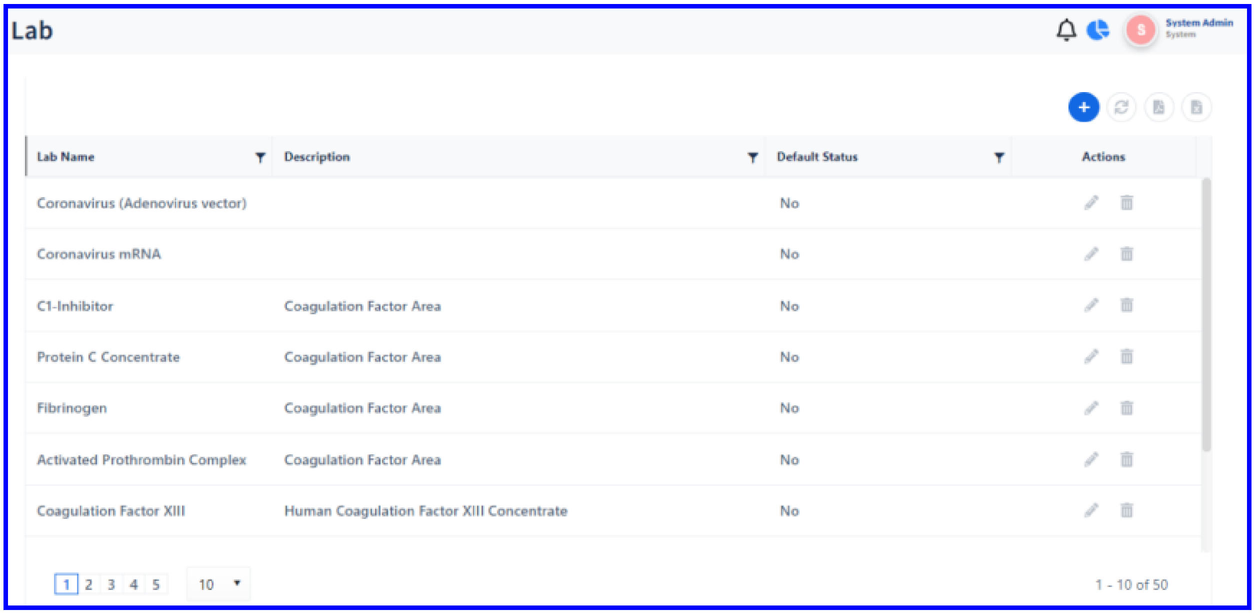


FIGURE: Lab Master Screen

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:

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:

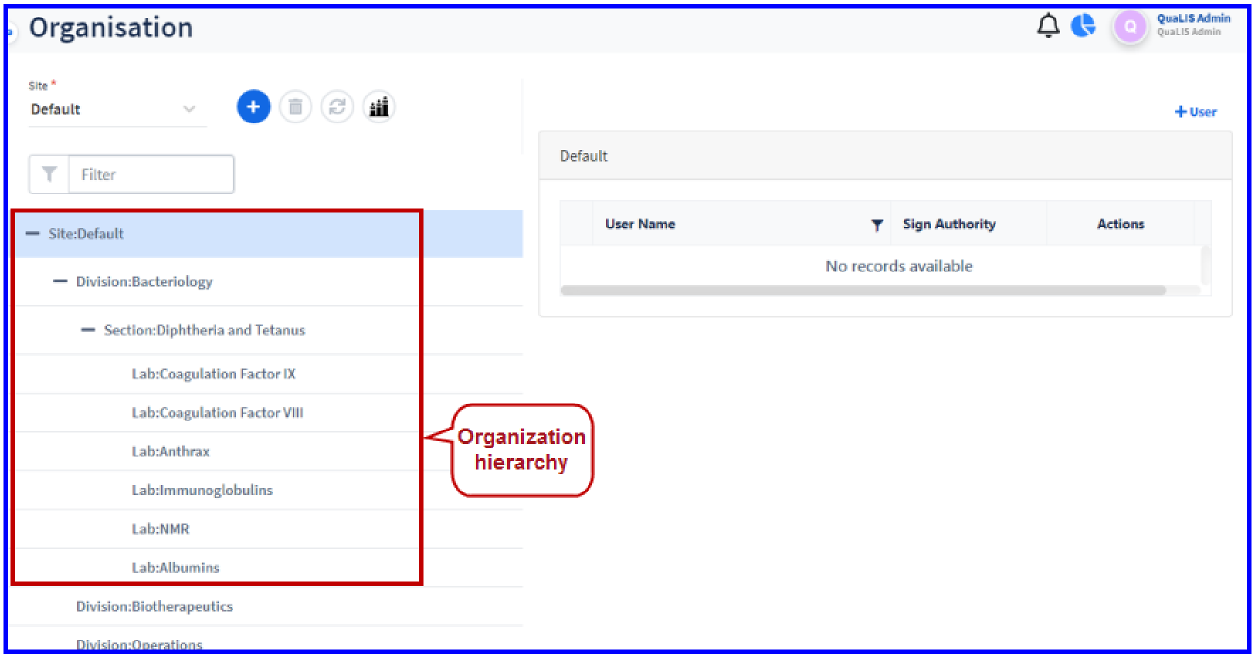


FIGURE: Organisation Master

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:

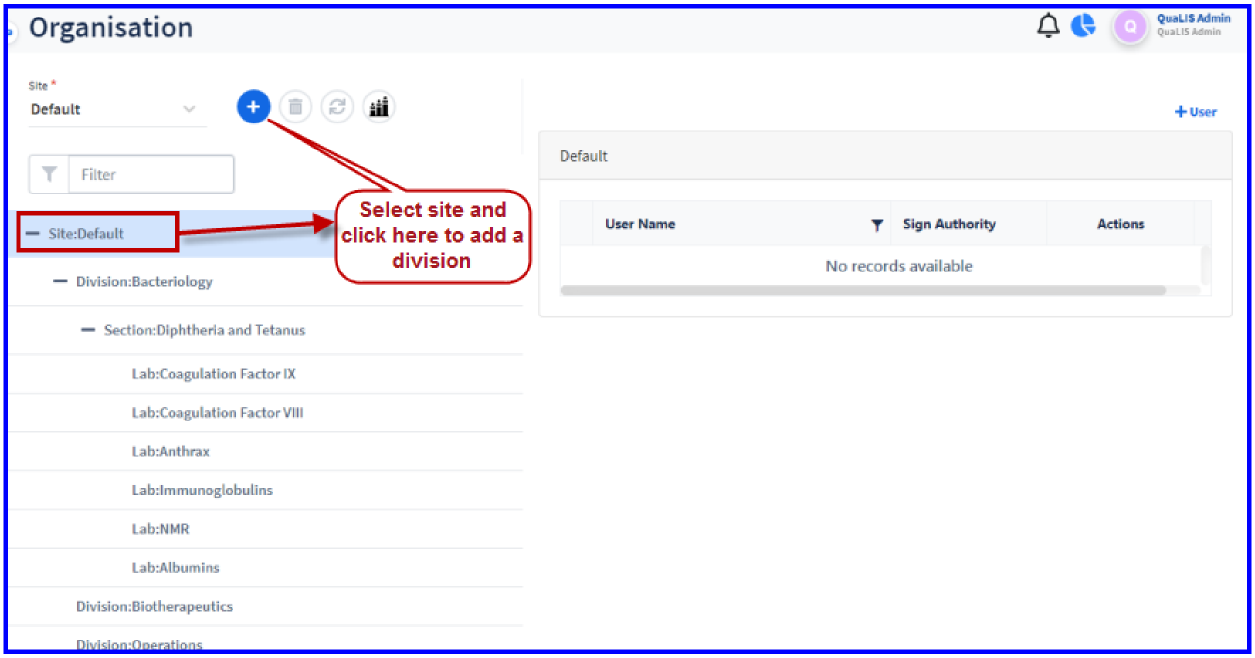


FIGURE: Adding Division to Site

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

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:

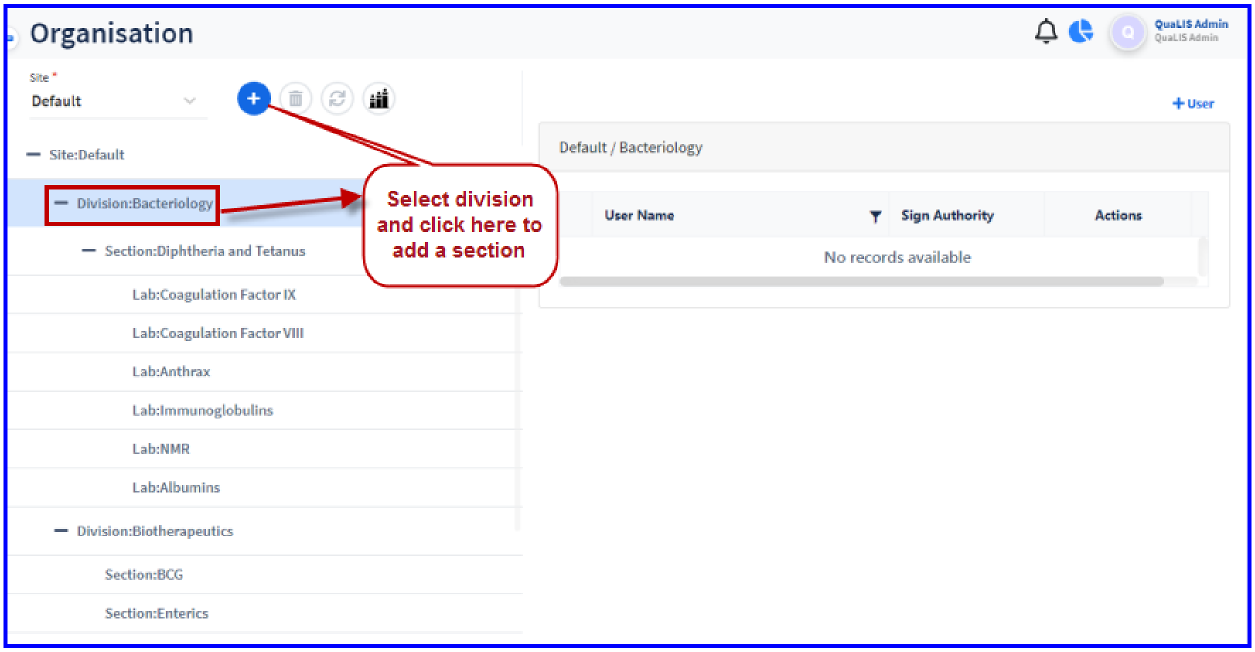


FIGURE: Adding Section to Division

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

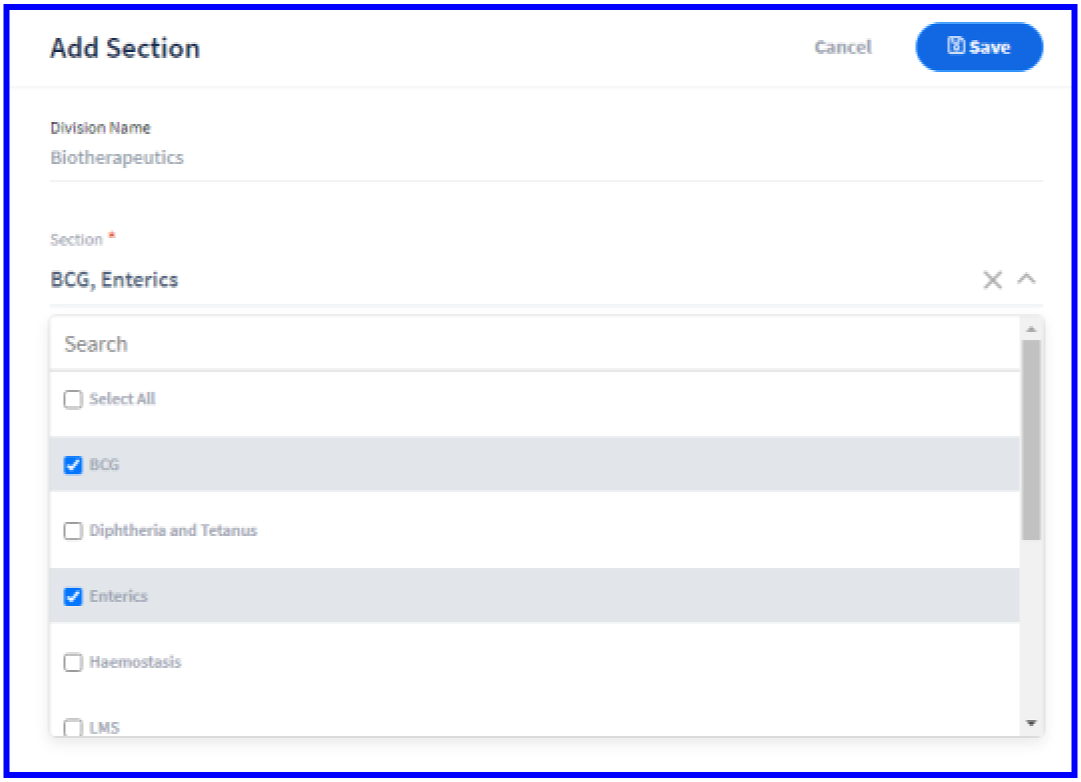


FIGURE: Add Section Dialog

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:

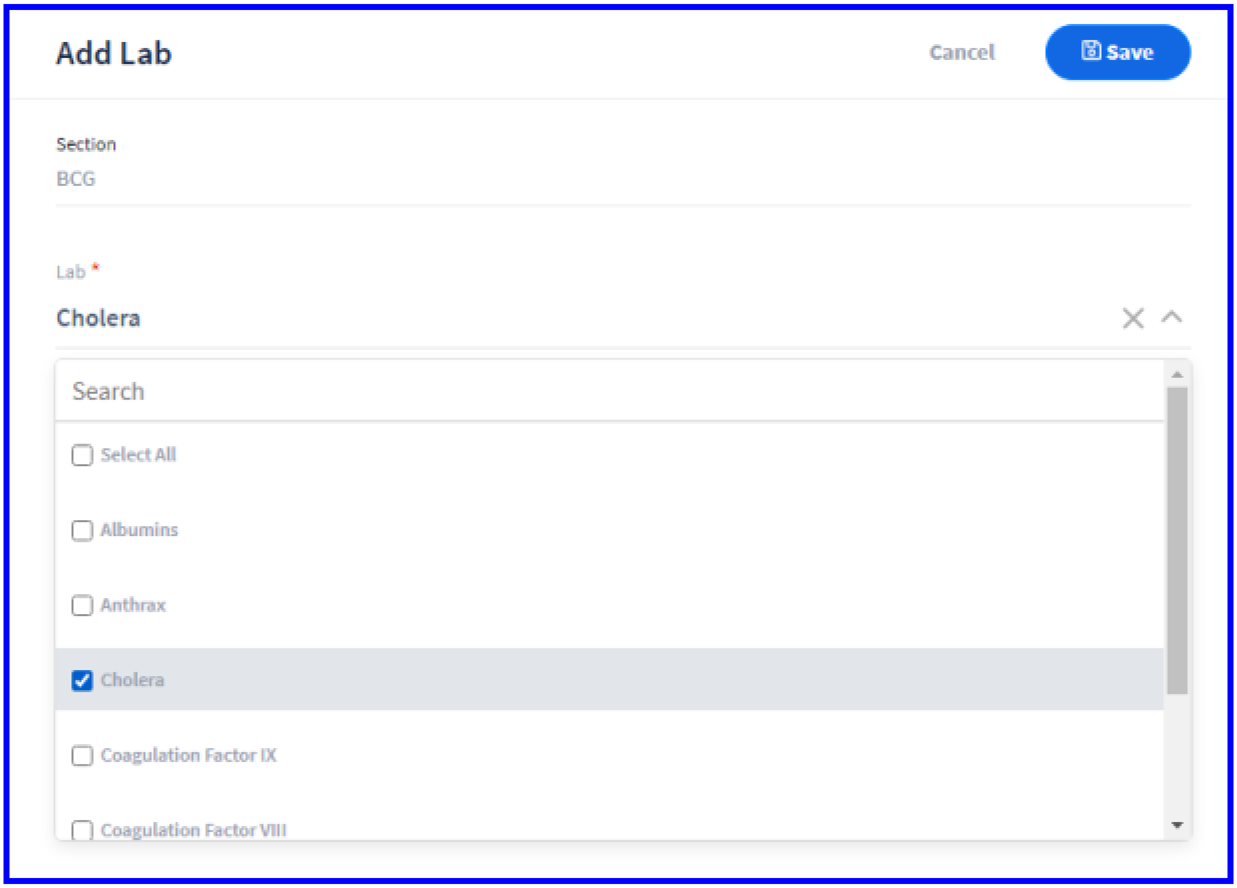


FIGURE: Add Lab Dialog

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:

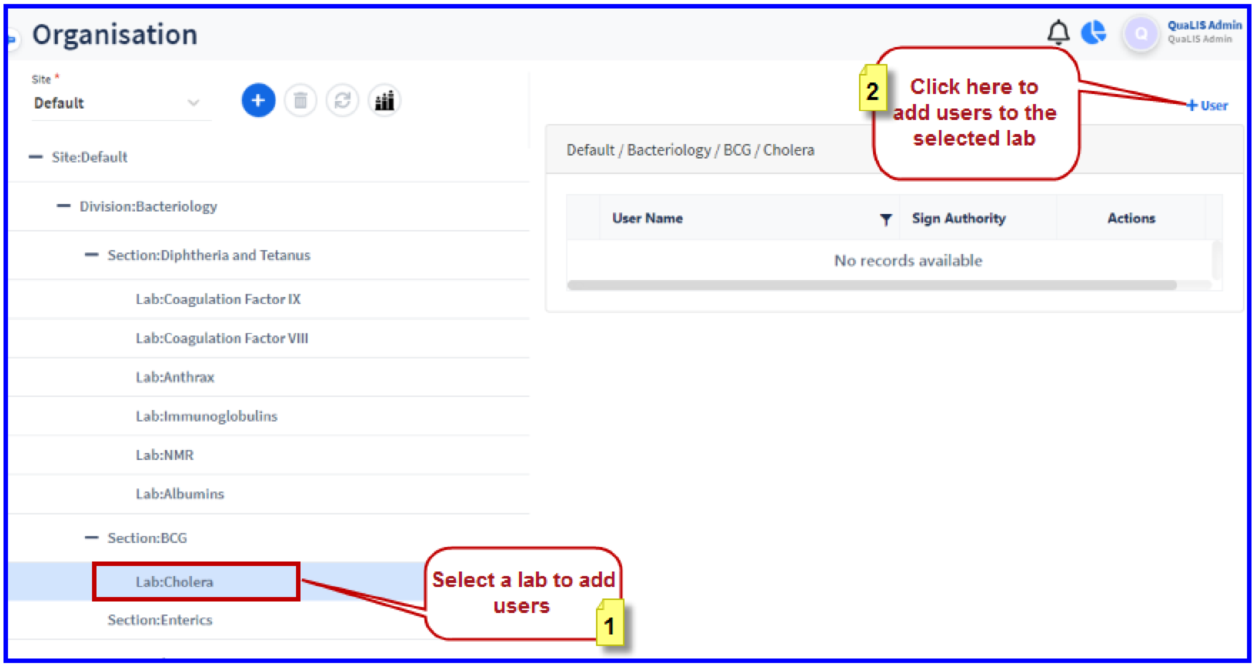


FIGURE: Adding Users to Lab

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

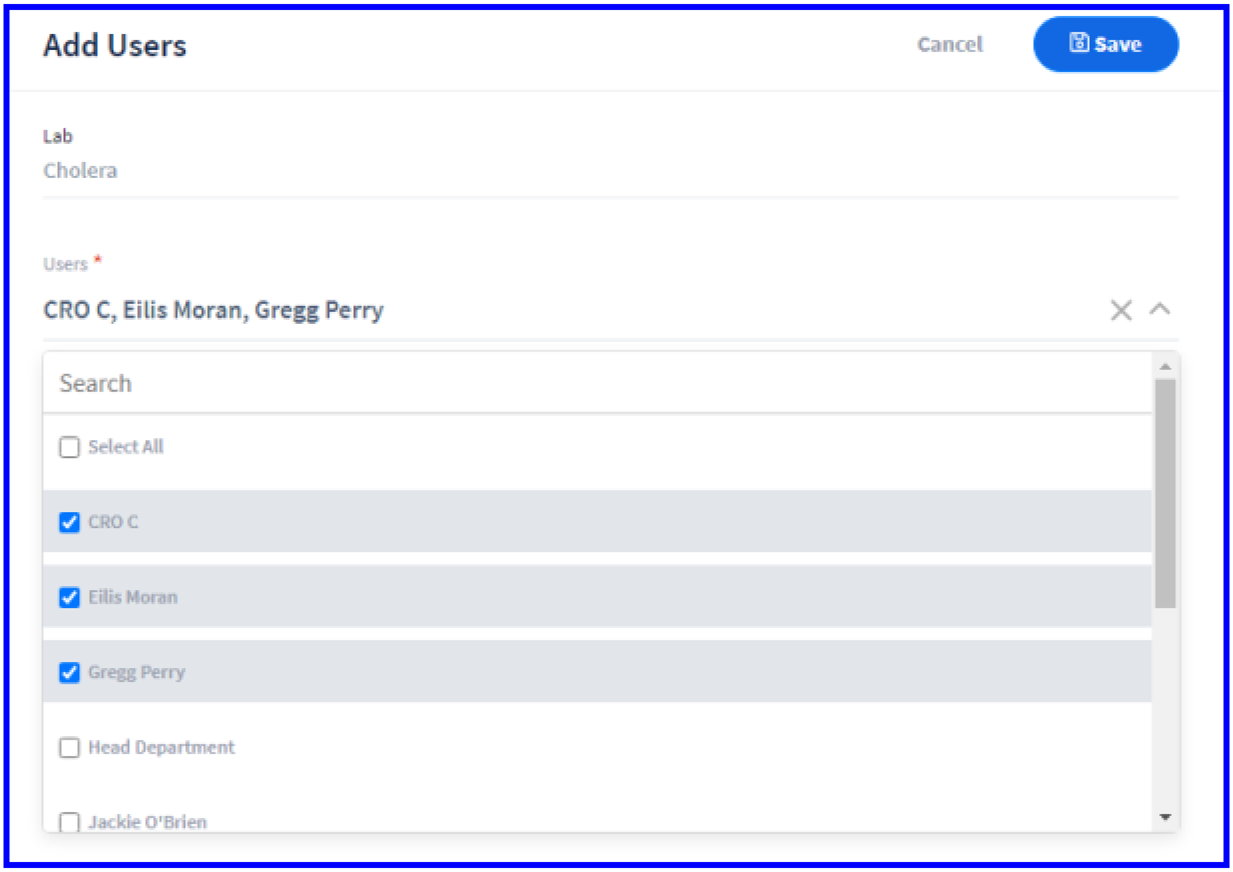


FIGURE: Add Users Dialog

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:

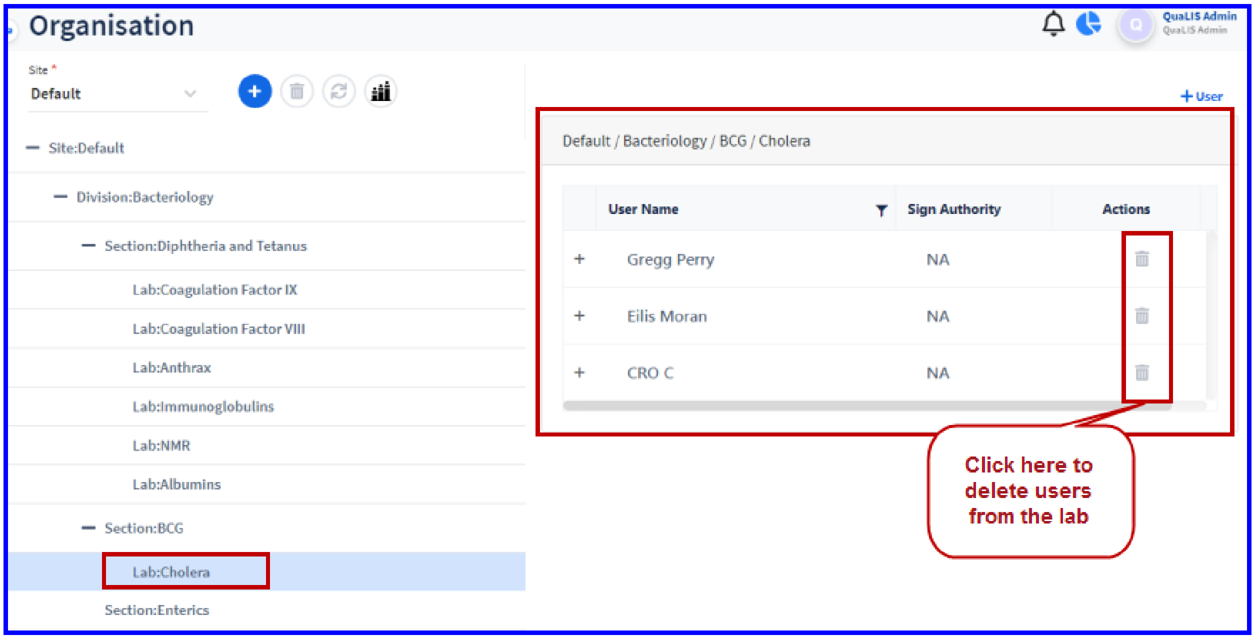


FIGURE: Users Added to the Lab

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:

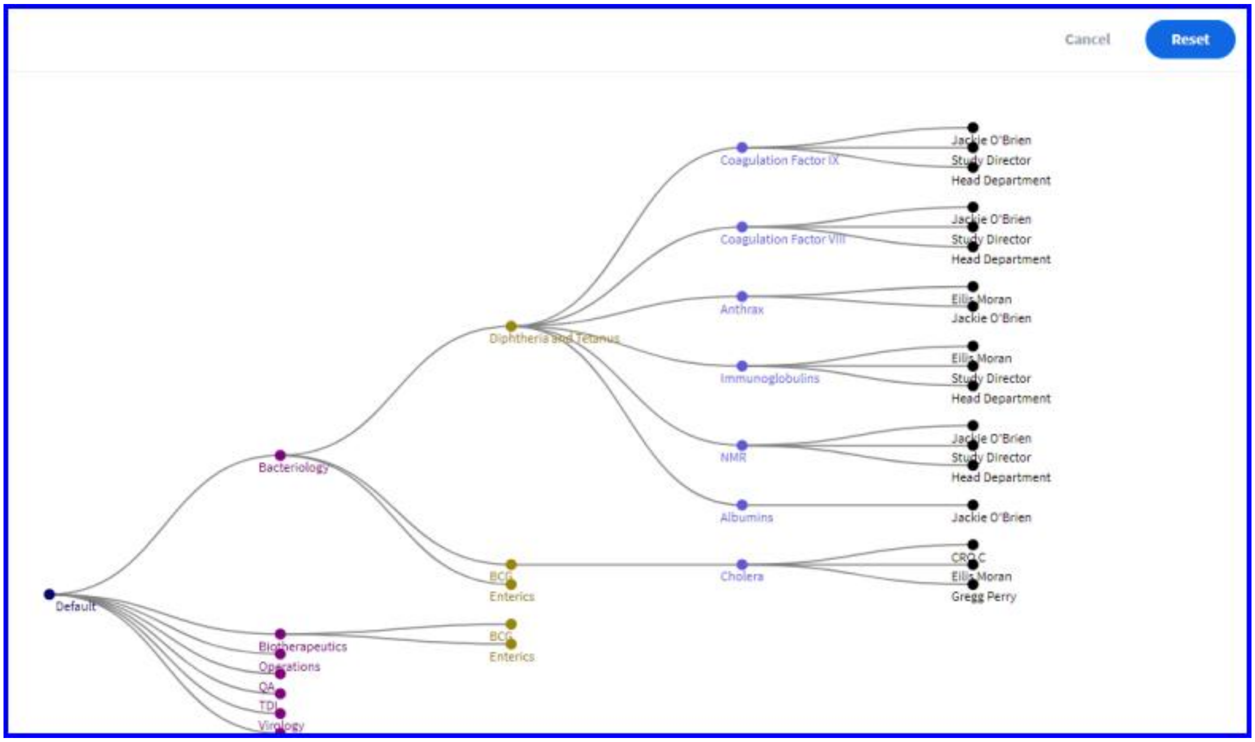


FIGURE: Graphical View of Organisation Setup

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:

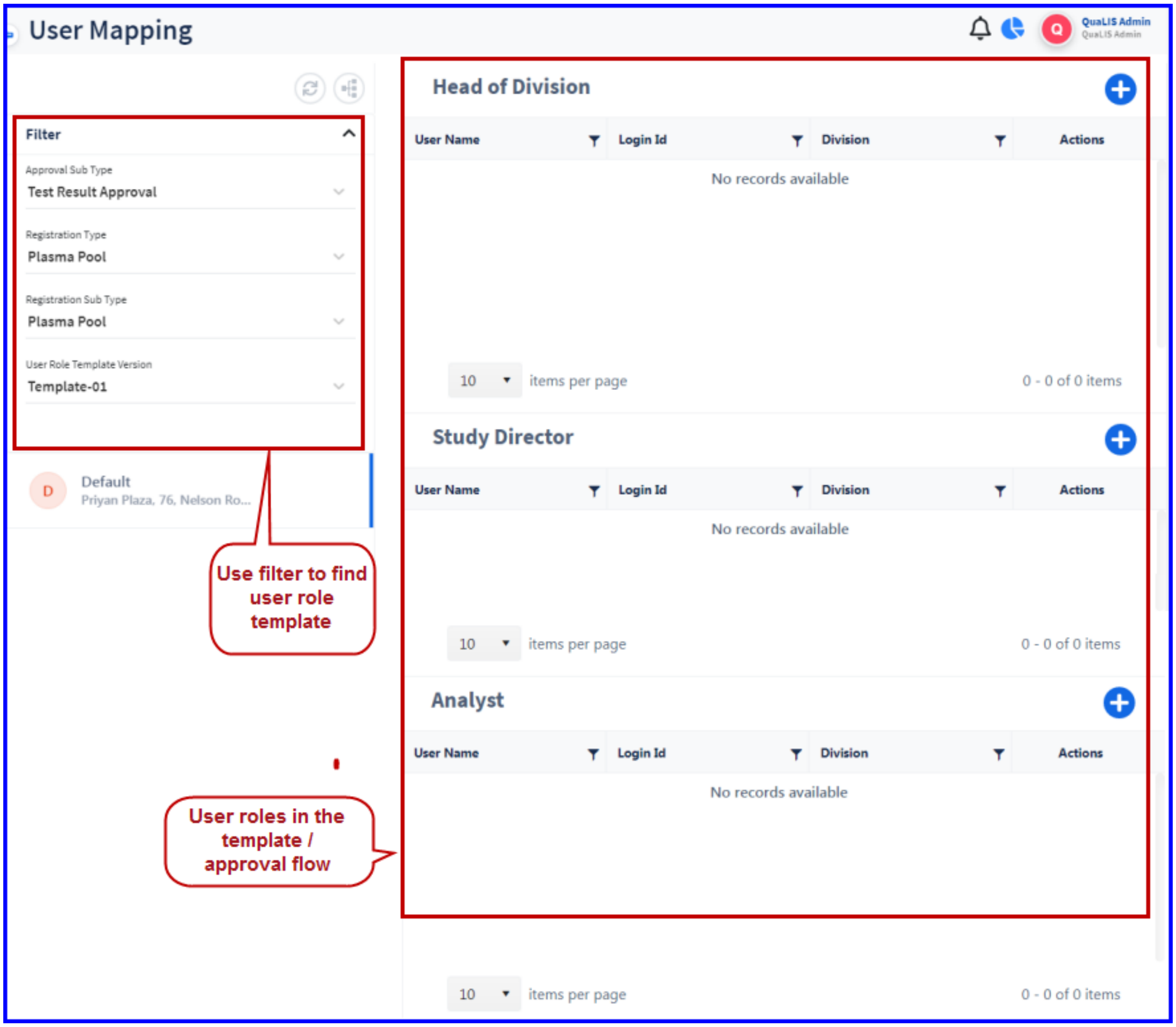


FIGURE: User Mapping Screen

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:

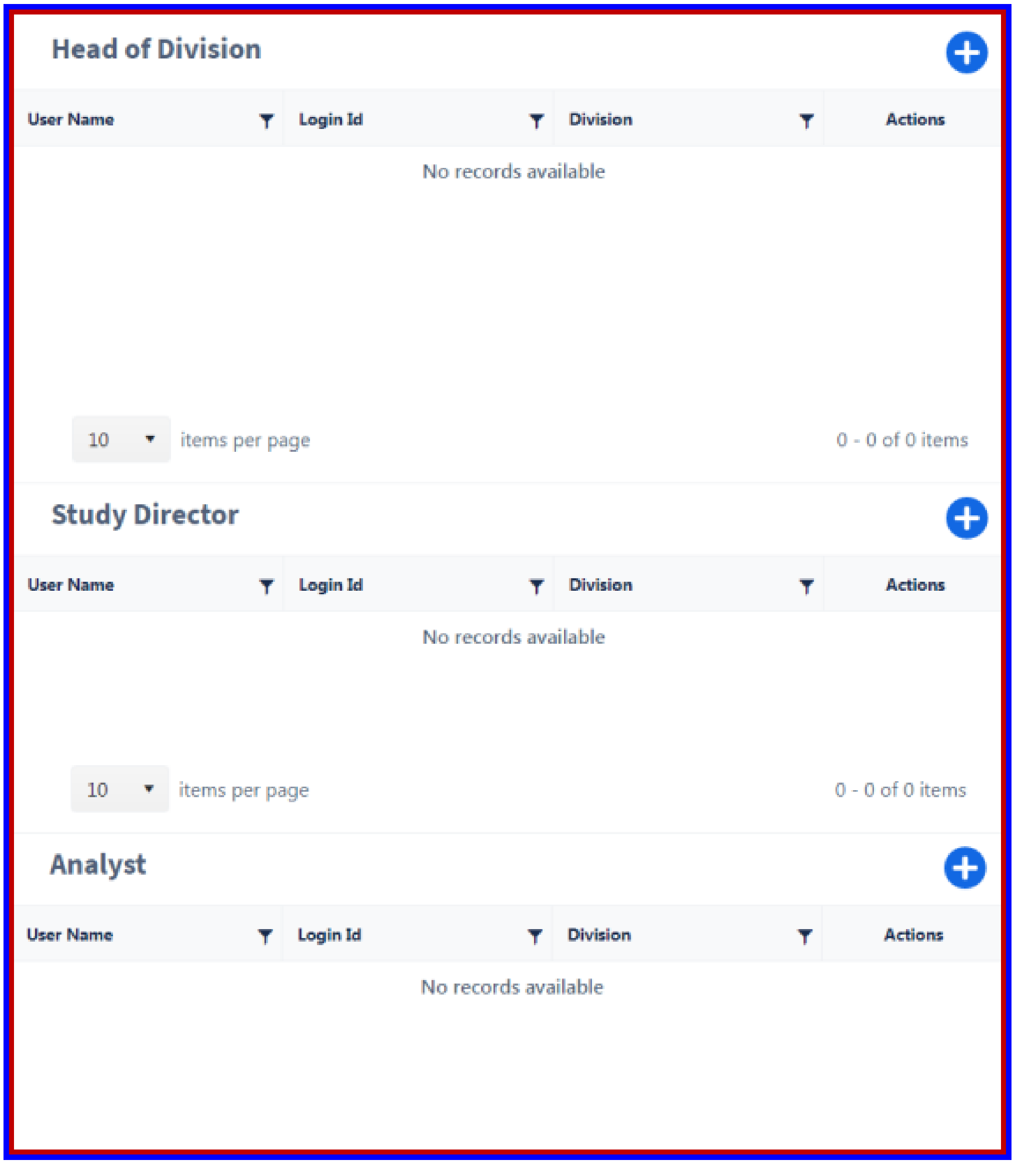


FIGURE: User Mapping Screen

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:

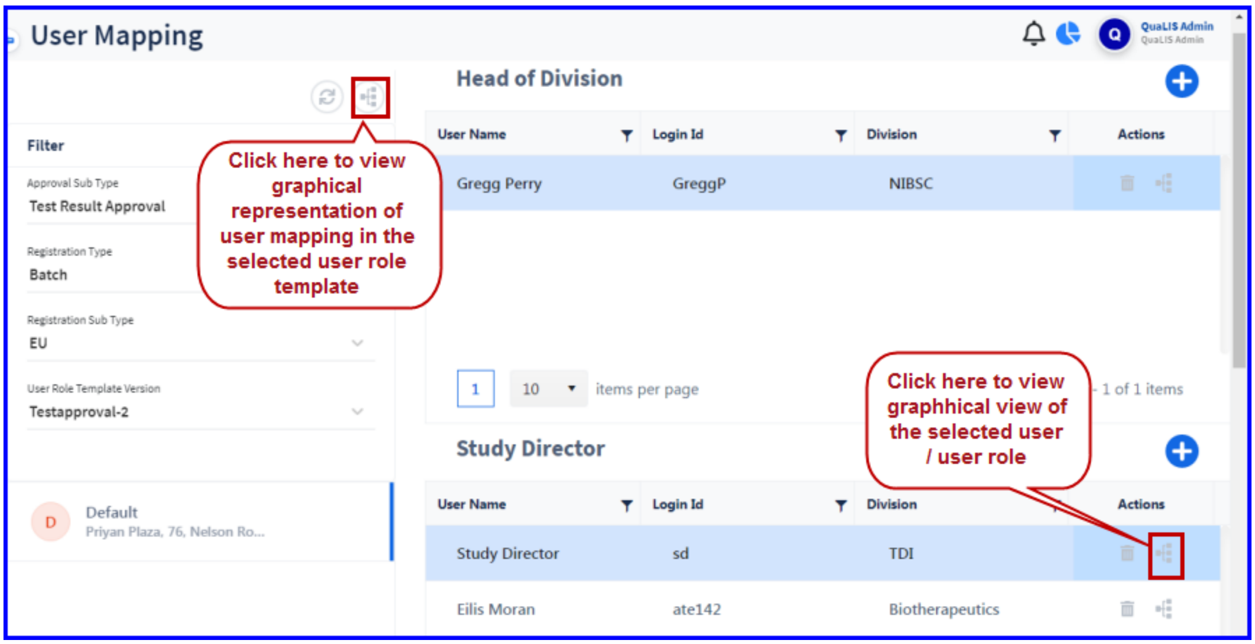


FIGURE: Graphical View of User Mapping - 1

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

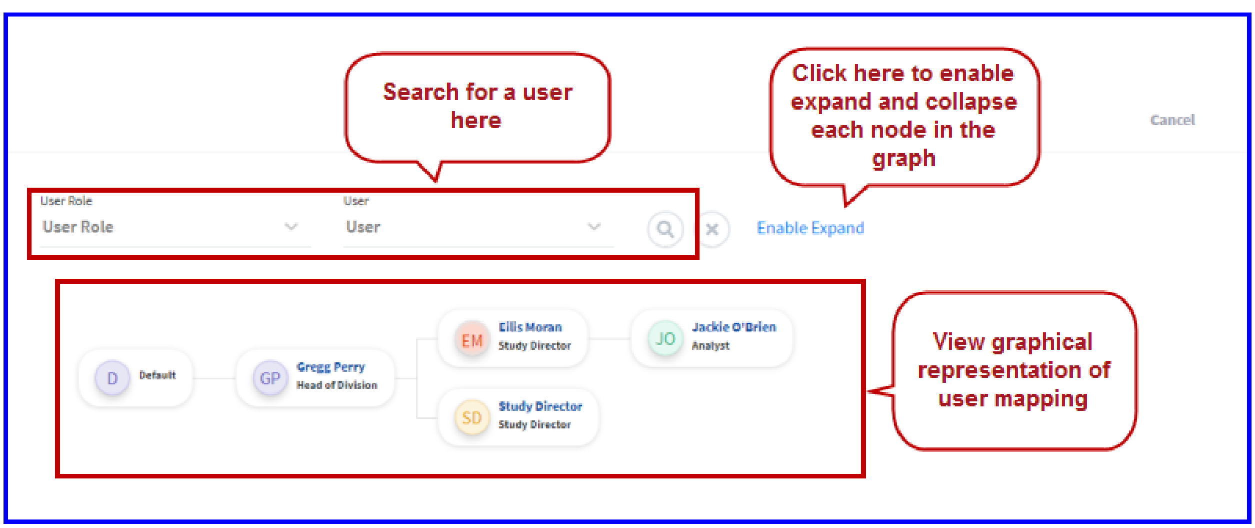


FIGURE: Graphical view of User Mapping – 2

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:

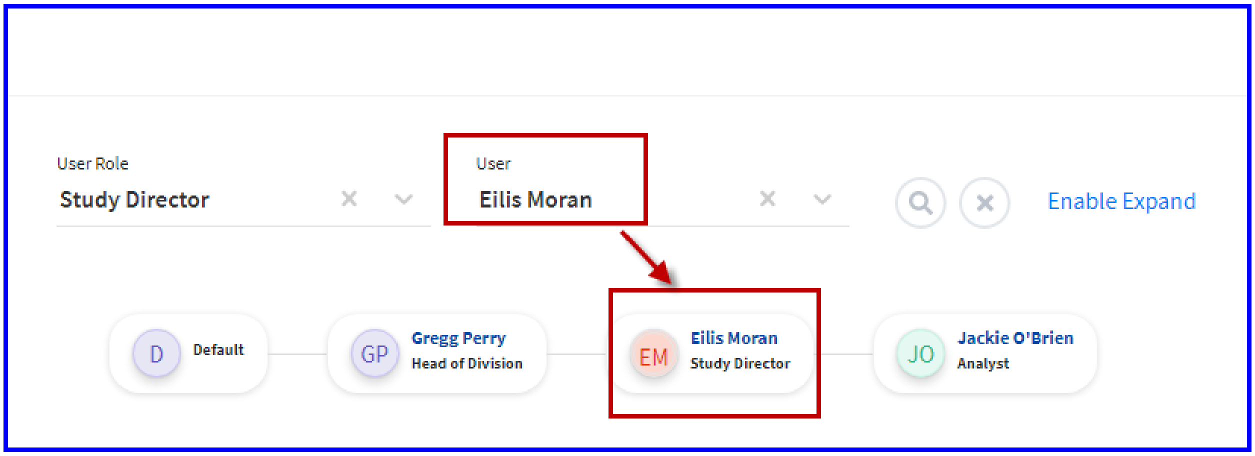


FIGURE: Graphical View - Search User

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:

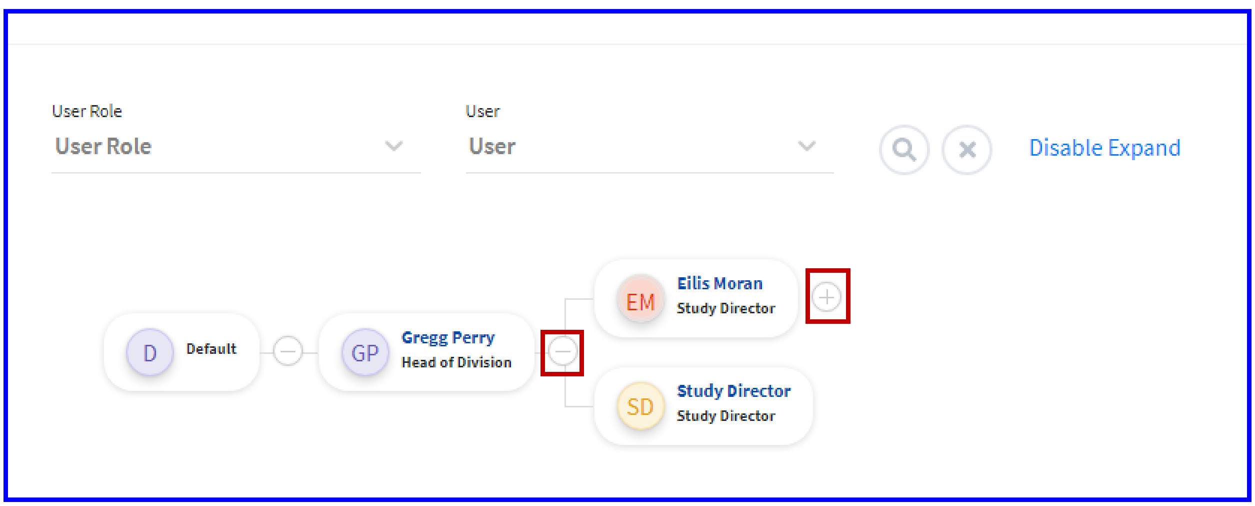


FIGURE: Graphical View of User Mapping – Enable Expand View

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

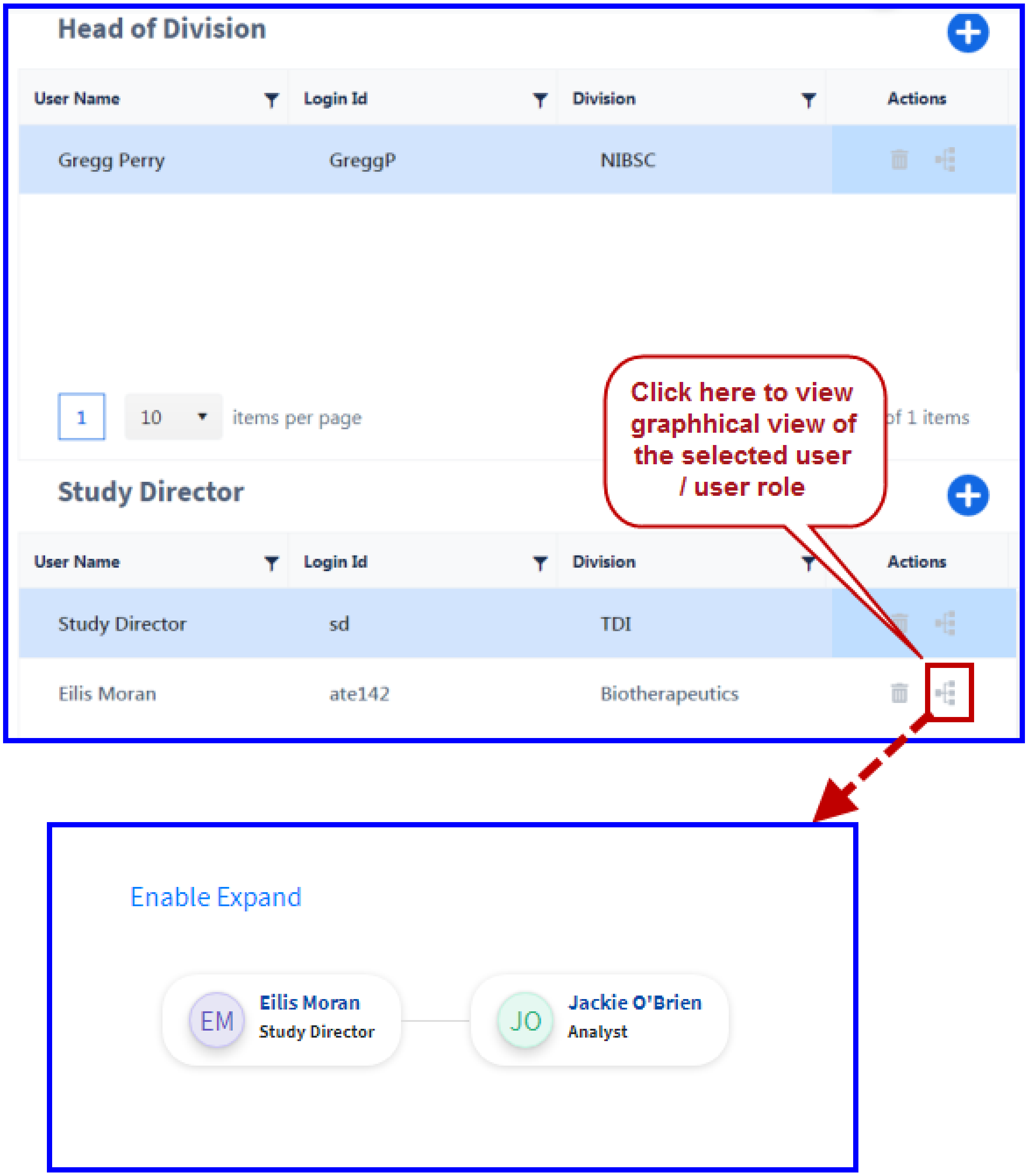


FIGURE: Graphical View of a Selected User

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:

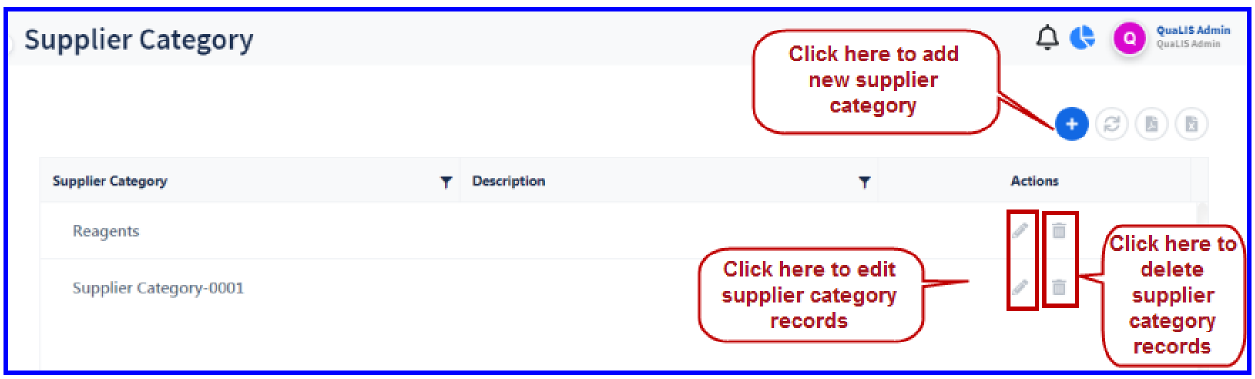


FIGURE: Supplier Category Master Screen

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:

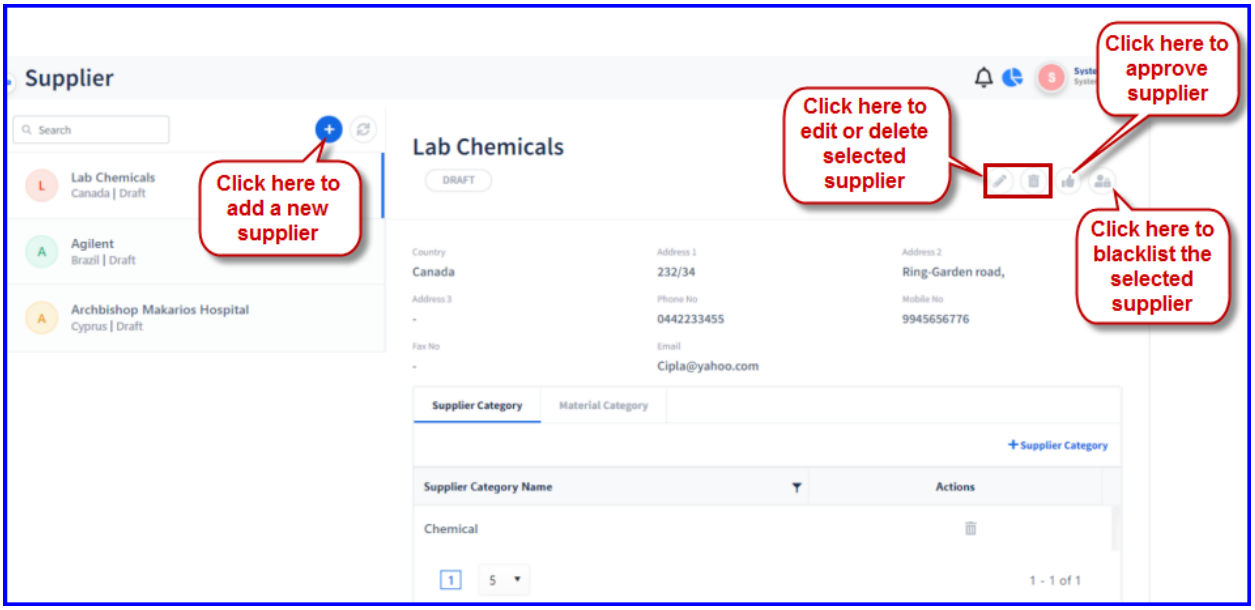


FIGURE: Supplier Master Screen

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

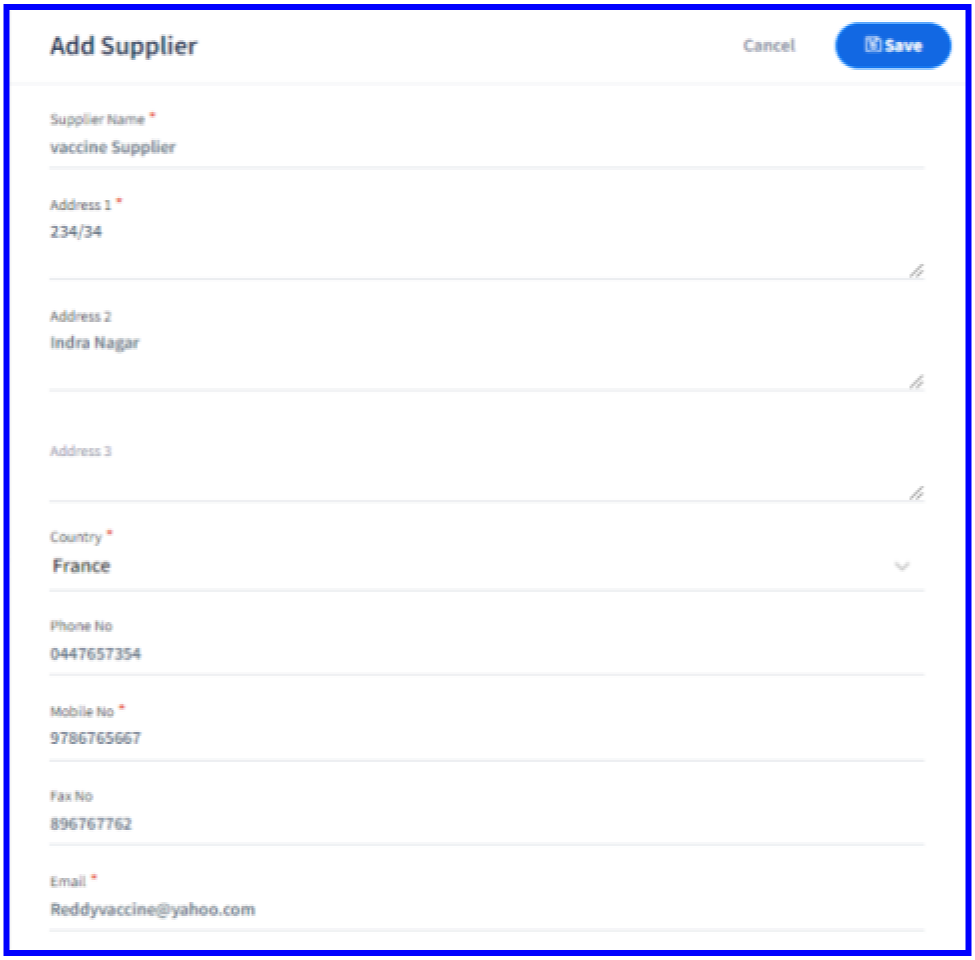


FIGURE: Add Supplier Screen

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 **+Supplier Category** as shown in the figure:

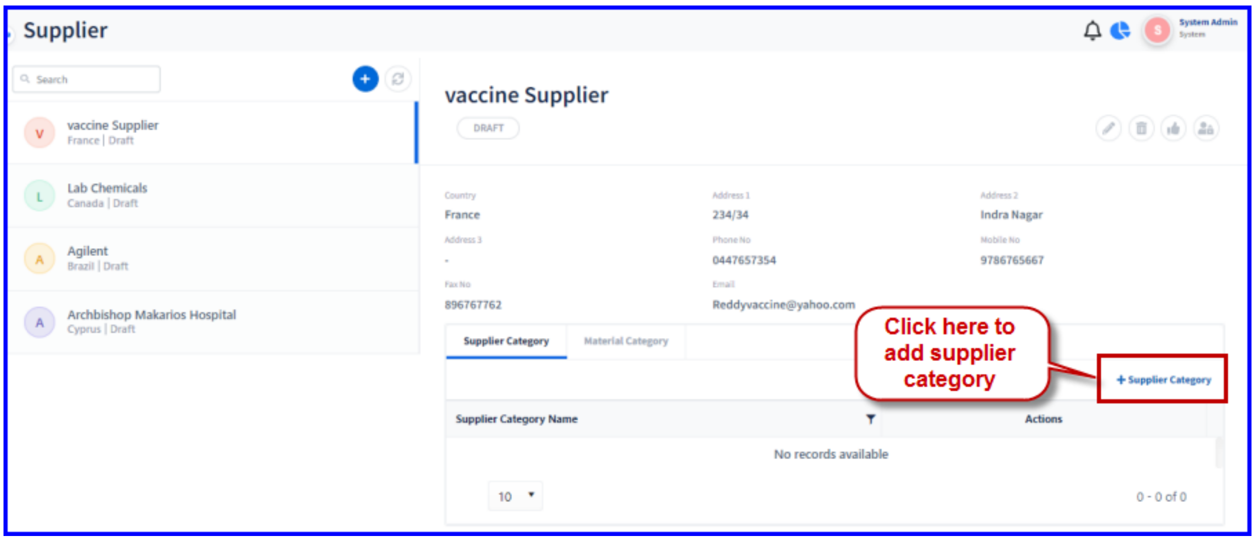


FIGURE: Adding Supplier Category to Supplier

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

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:

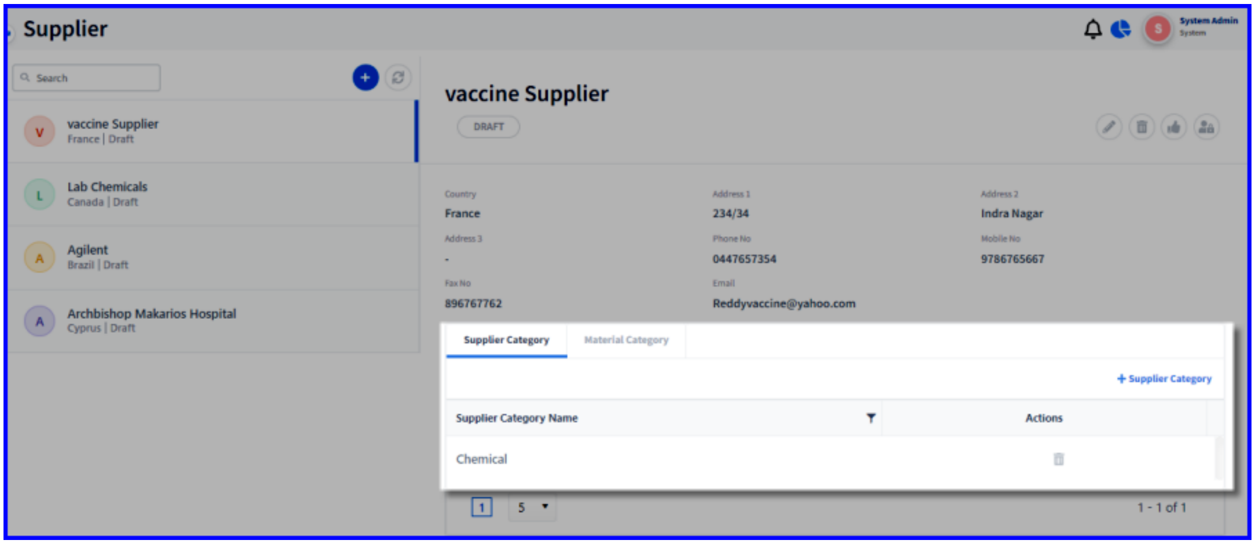


FIGURE: Supplier Categories Added to the Supplier

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:

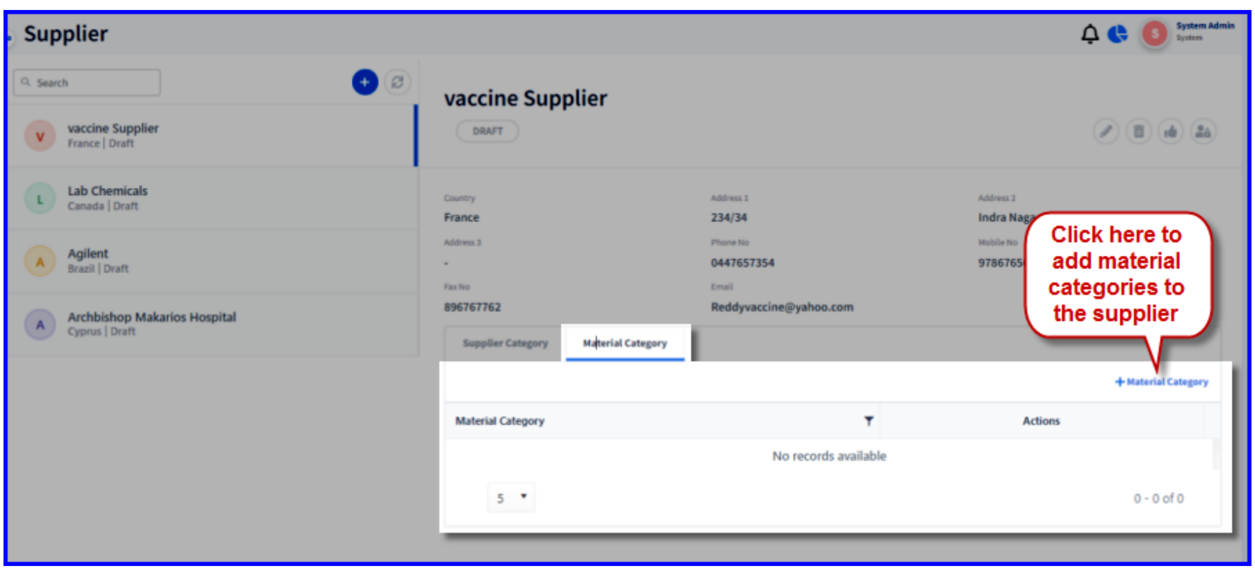


FIGURE: Adding Material Category to Supplier

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:

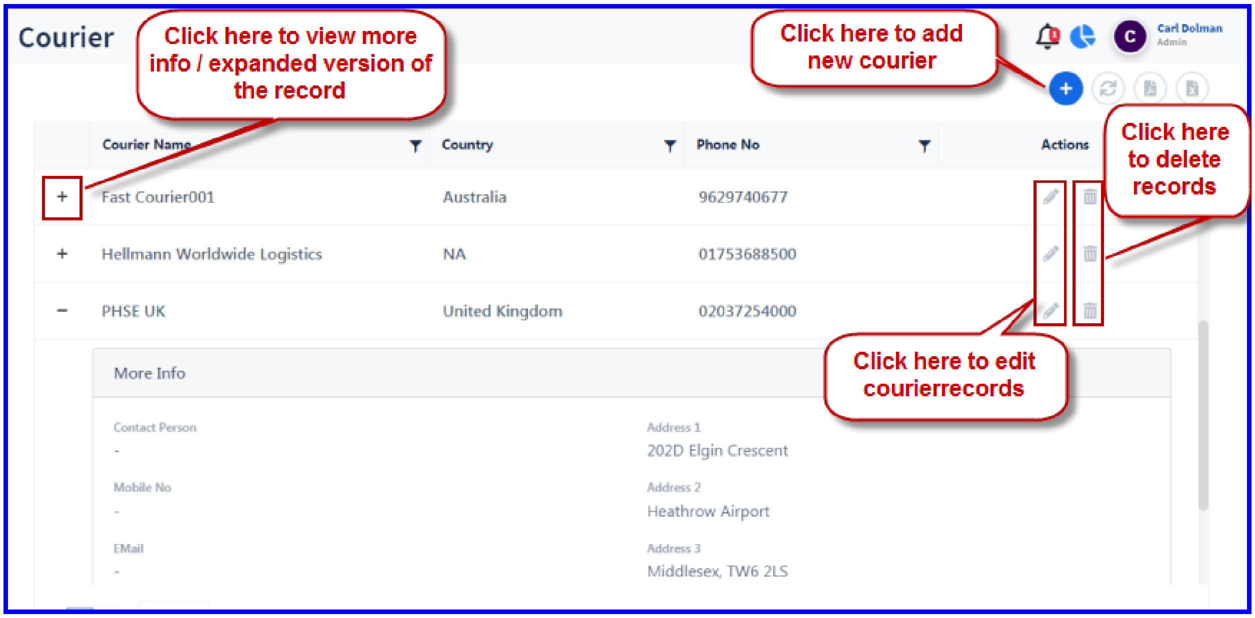


FIGURE: Courier Master Screen

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:

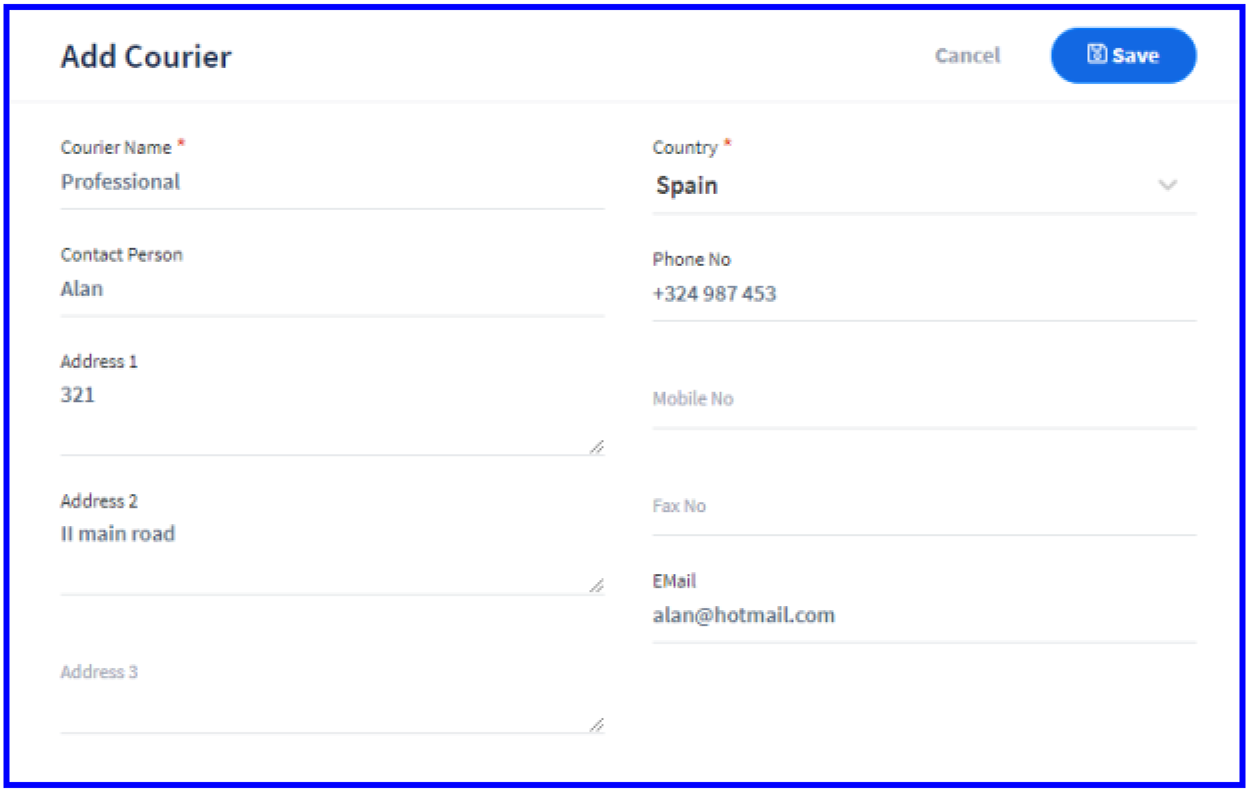


FIGURE: Add Courier Screen

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:

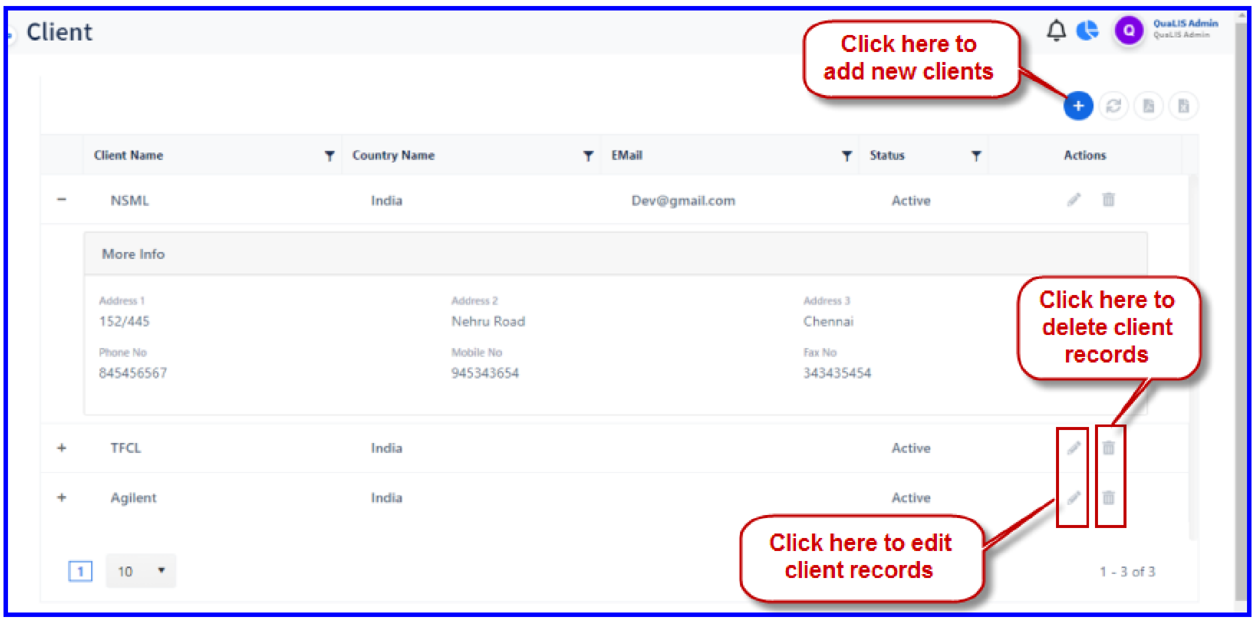


FIGURE: Client Master Screen

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:

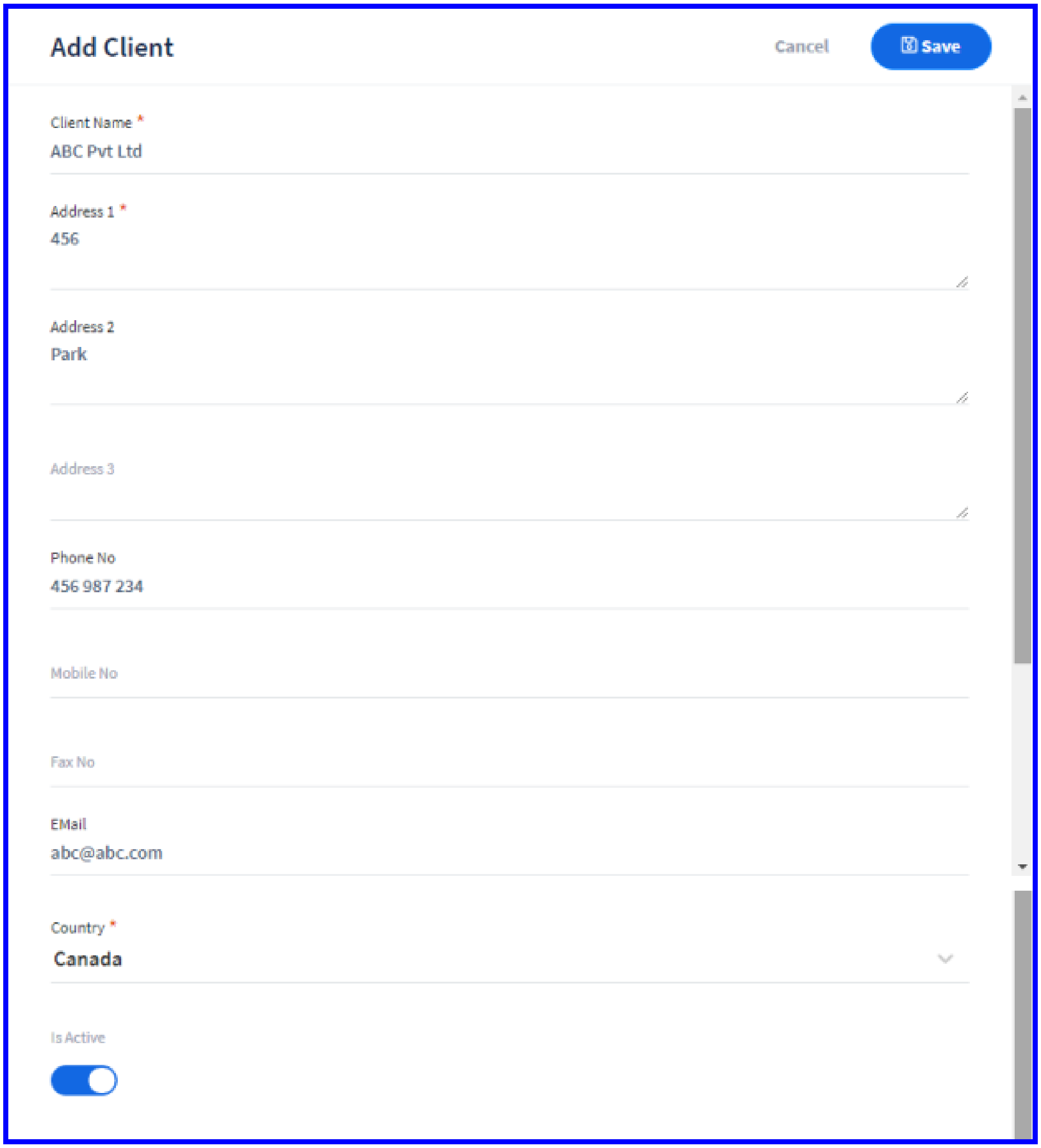


FIGURE: Add Client Screen

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:

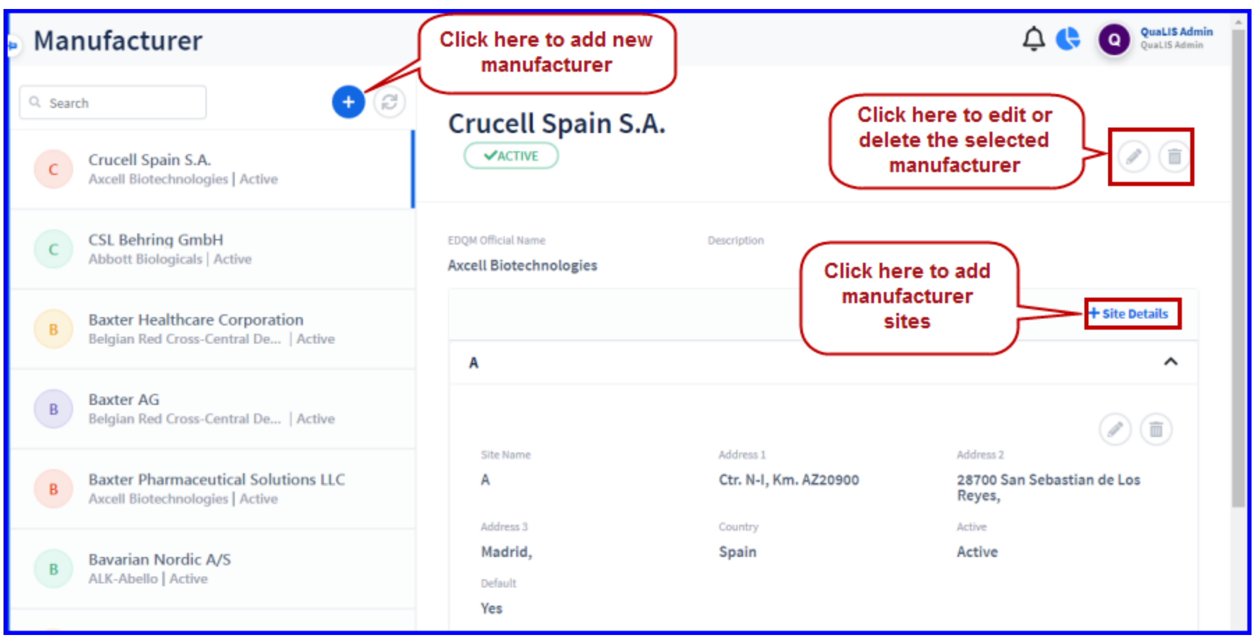


FIGURE: Manufacturer Master Screen

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:

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:

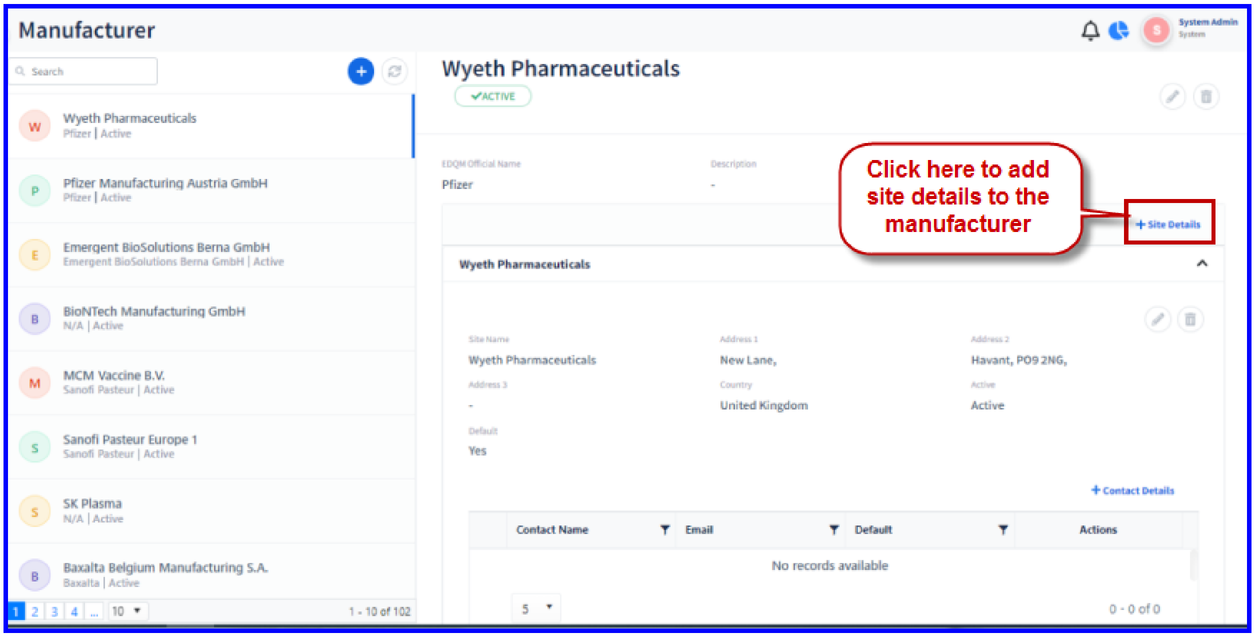


FIGURE: Adding Sites to the Manufacturer

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

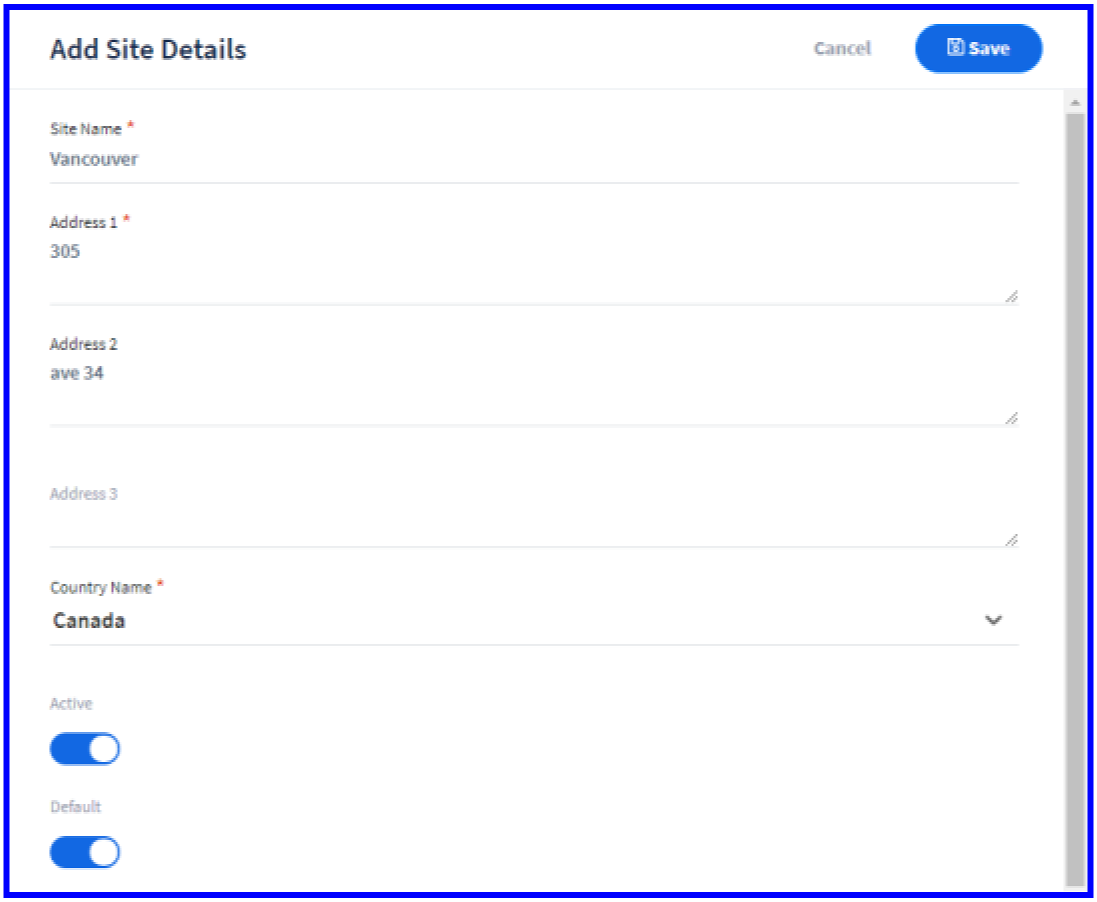


FIGURE: Add Site Details Dialog

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:

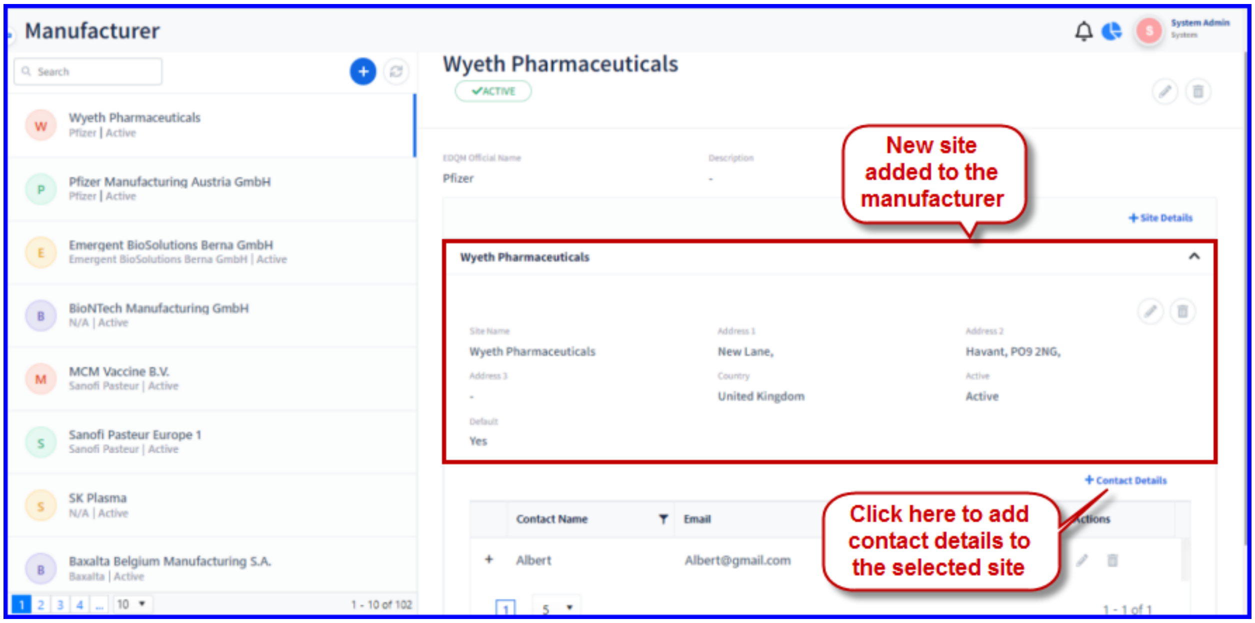


FIGURE: Adding Contact Details to the Selected Site

Same way, you can add more sites to the manufacturer. For each sited 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:

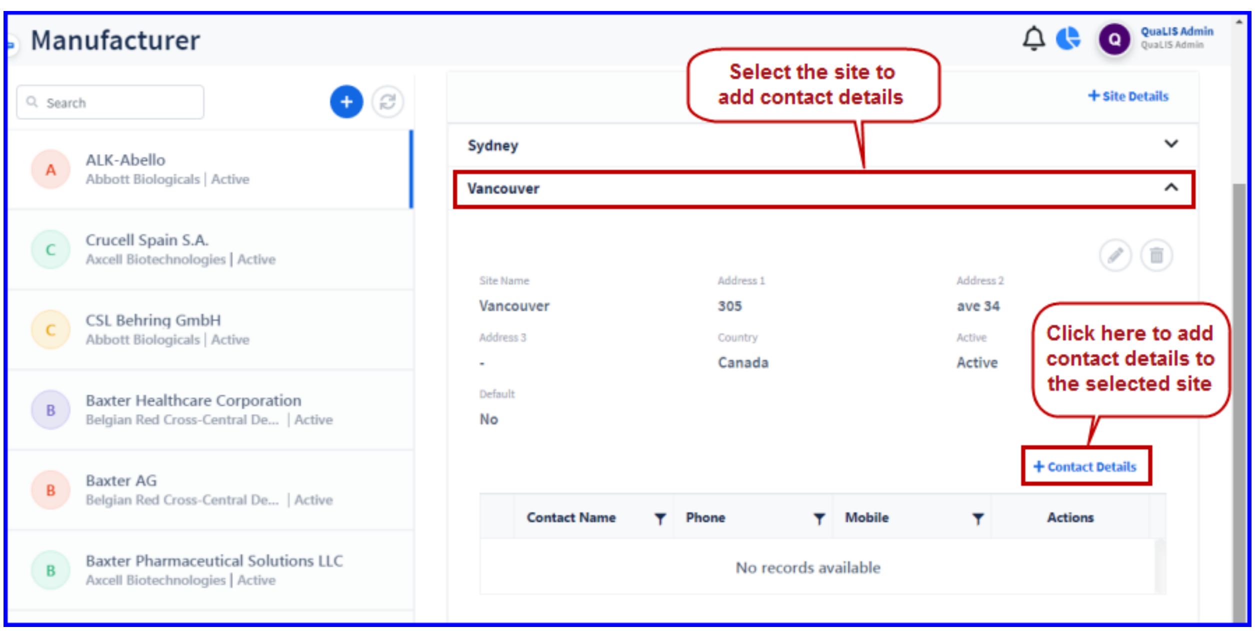


FIGURE: Adding Contact Details to the Site

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

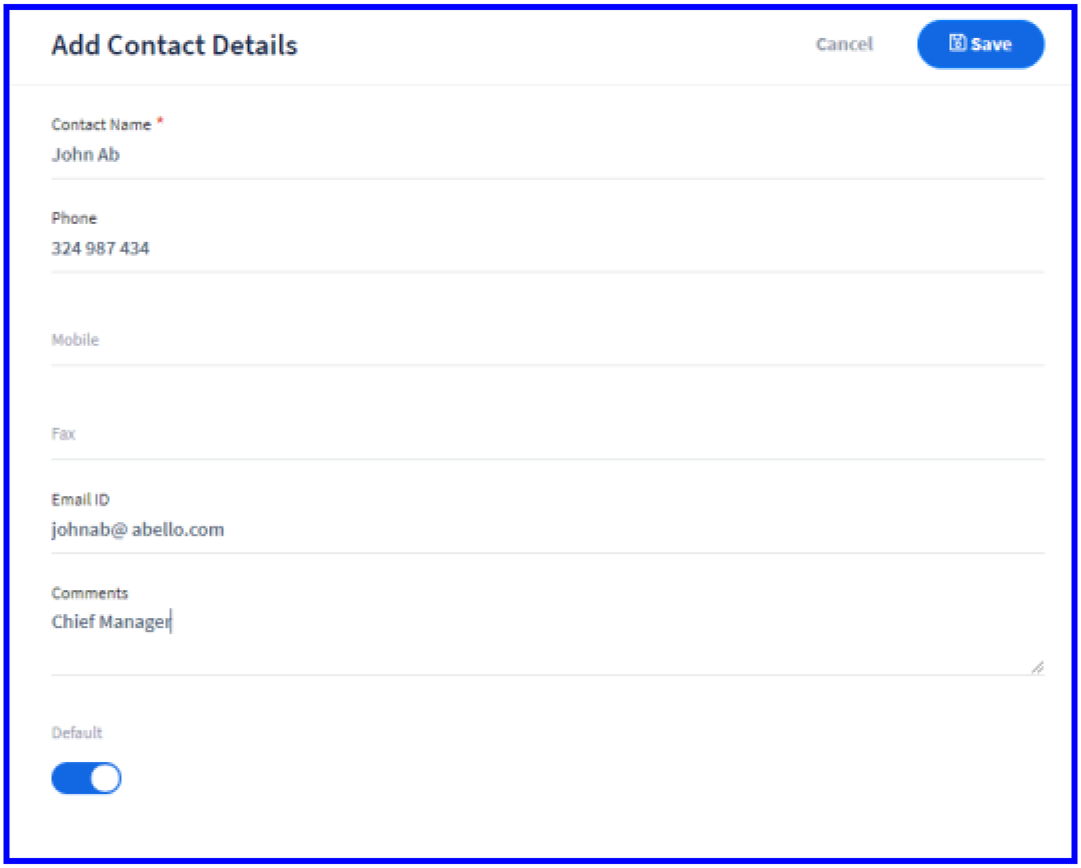


FIGURE: Add Contact Details Dialog

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:

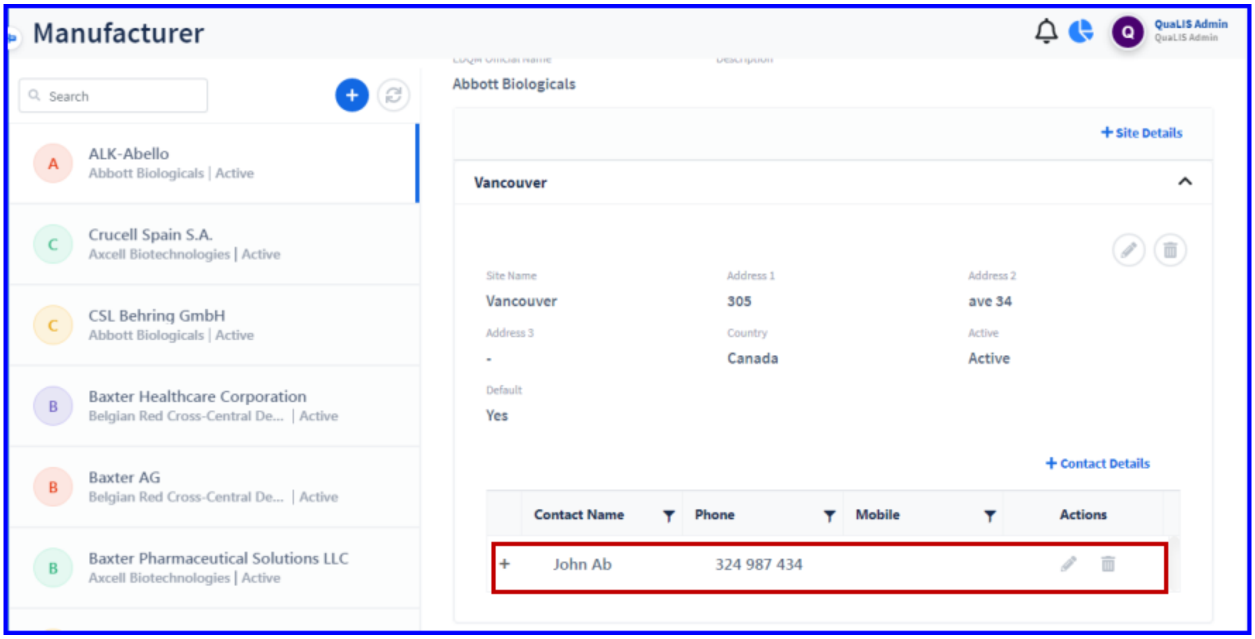


FIGURE: Added Contact Details

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:

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:

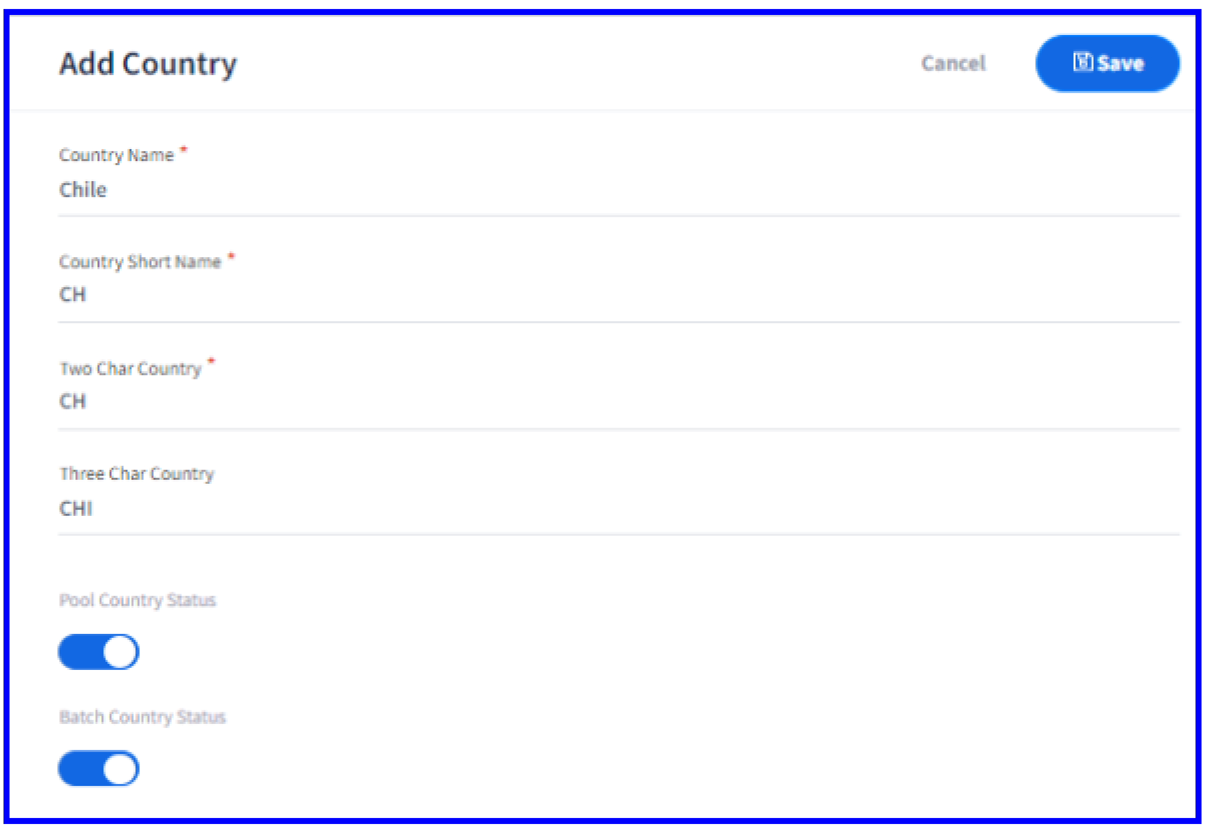


FIGURE: Add Country Screen

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:

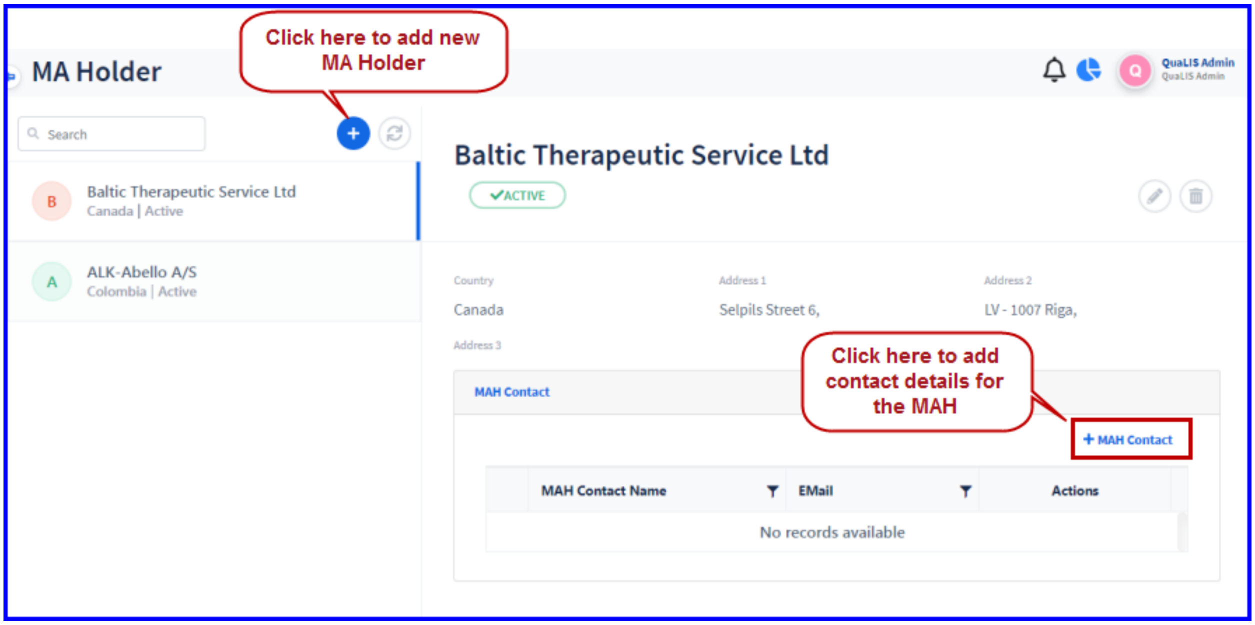


FIGURE: MA Holder Master Screen

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:

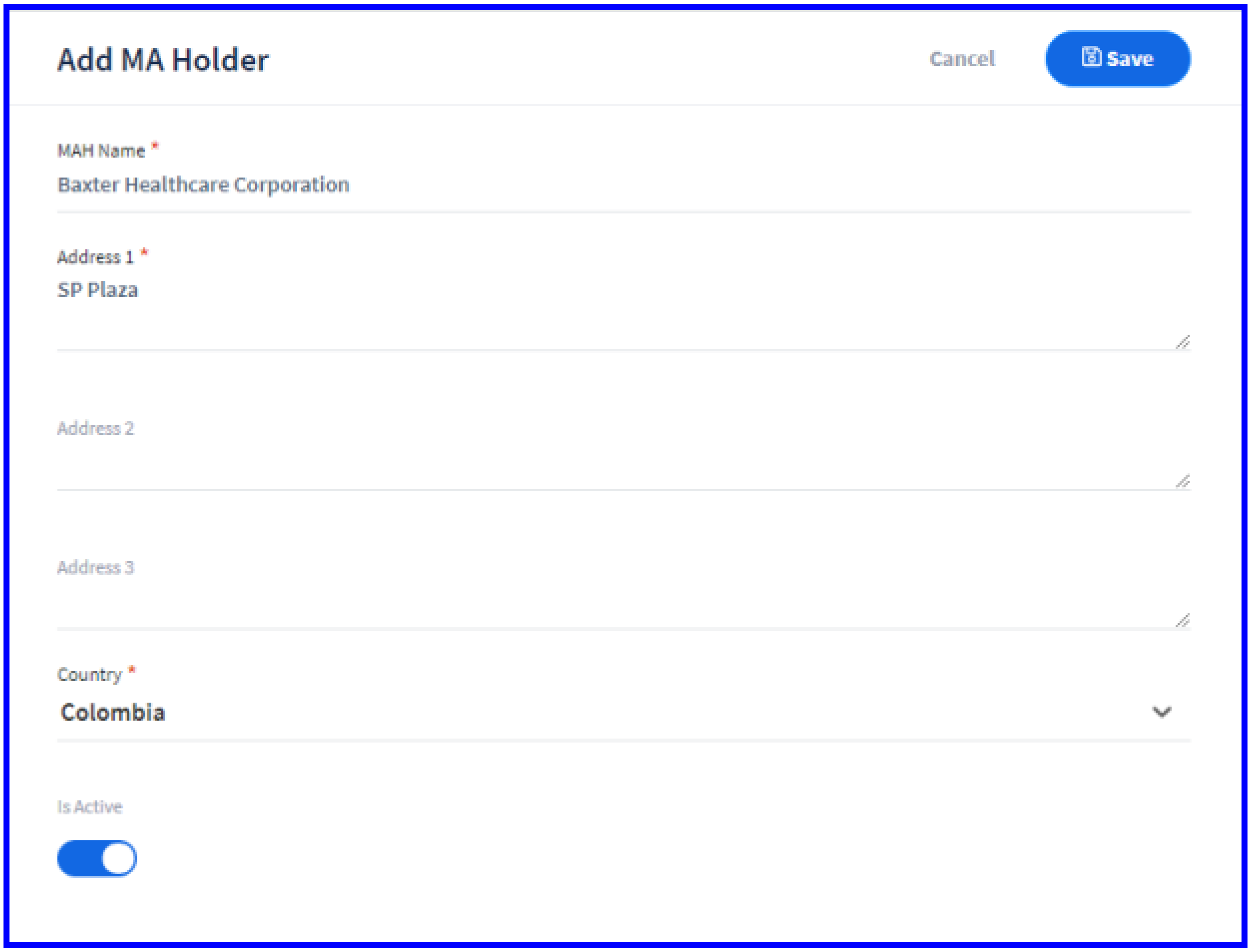


FIGURE: Add MA Holder Screen

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:

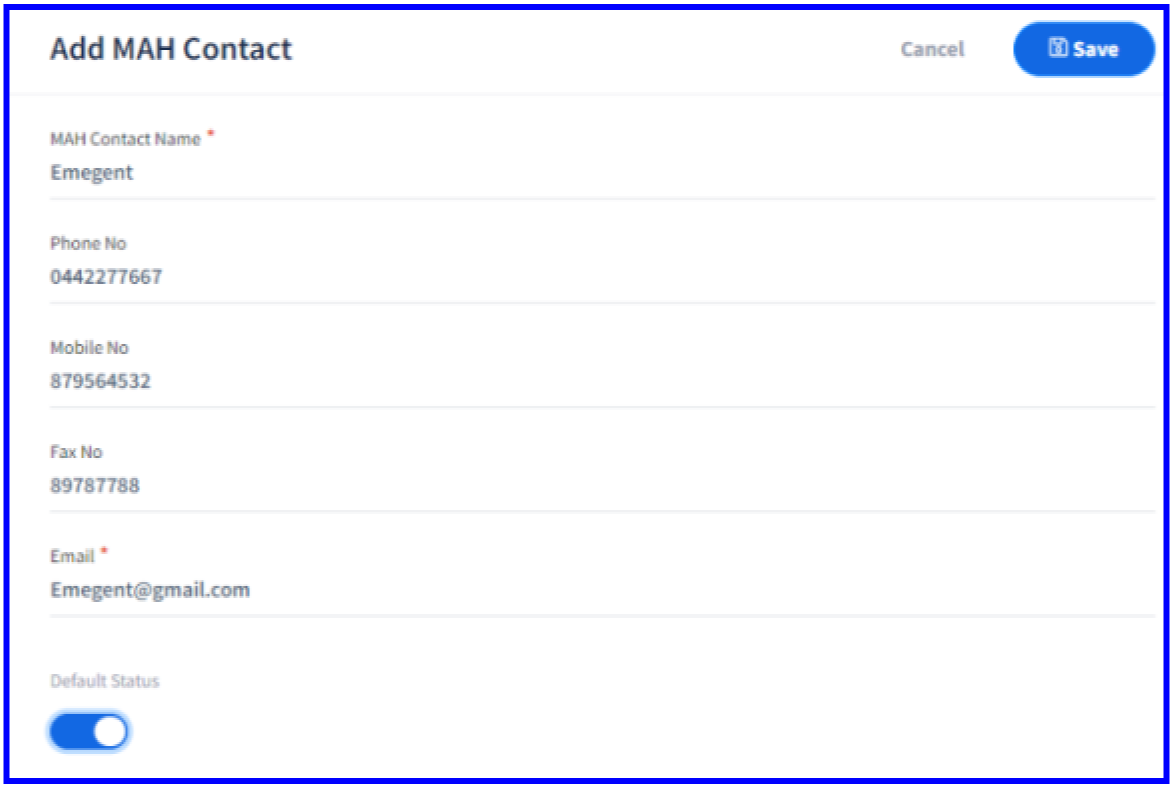


FIGURE: Add MAH Contact Dialog

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:

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:

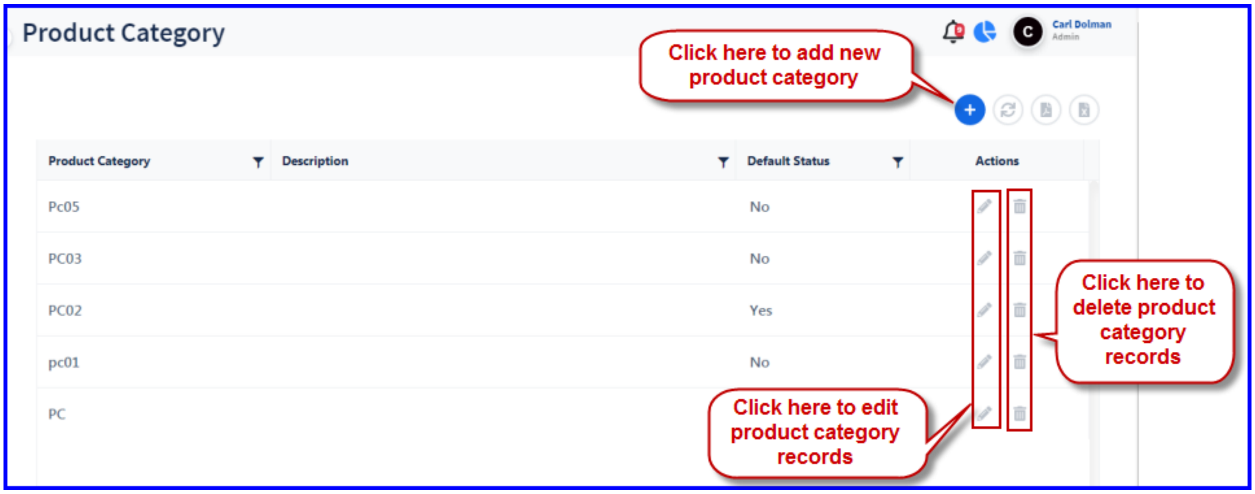


FIGURE: Product Category Master Screen

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:

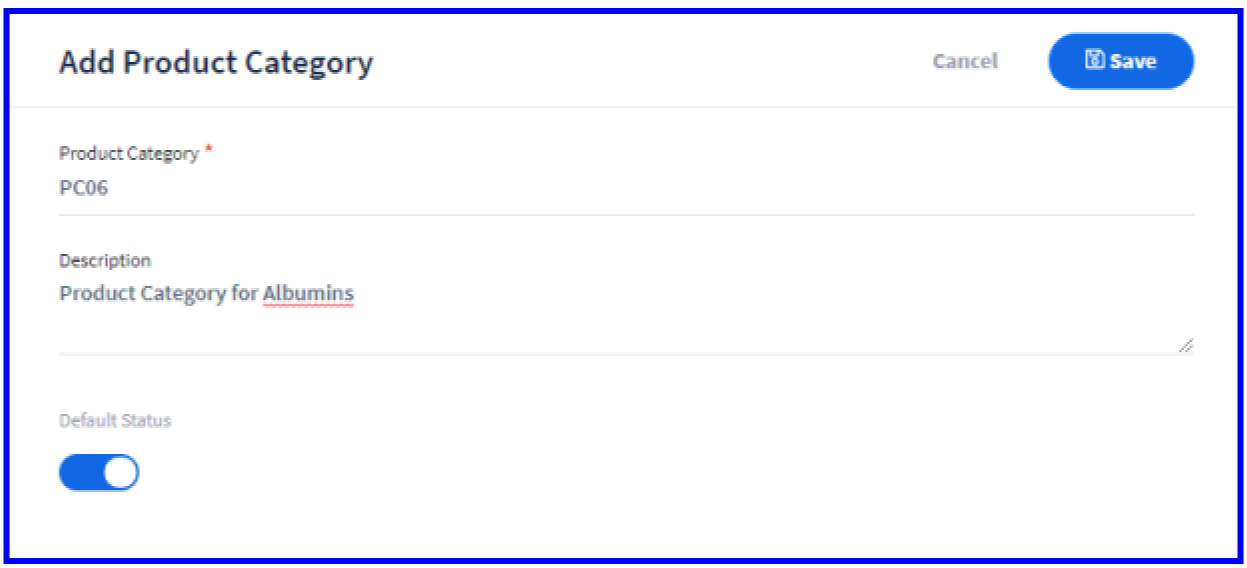


FIGURE: Add Product Category Dialog

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:

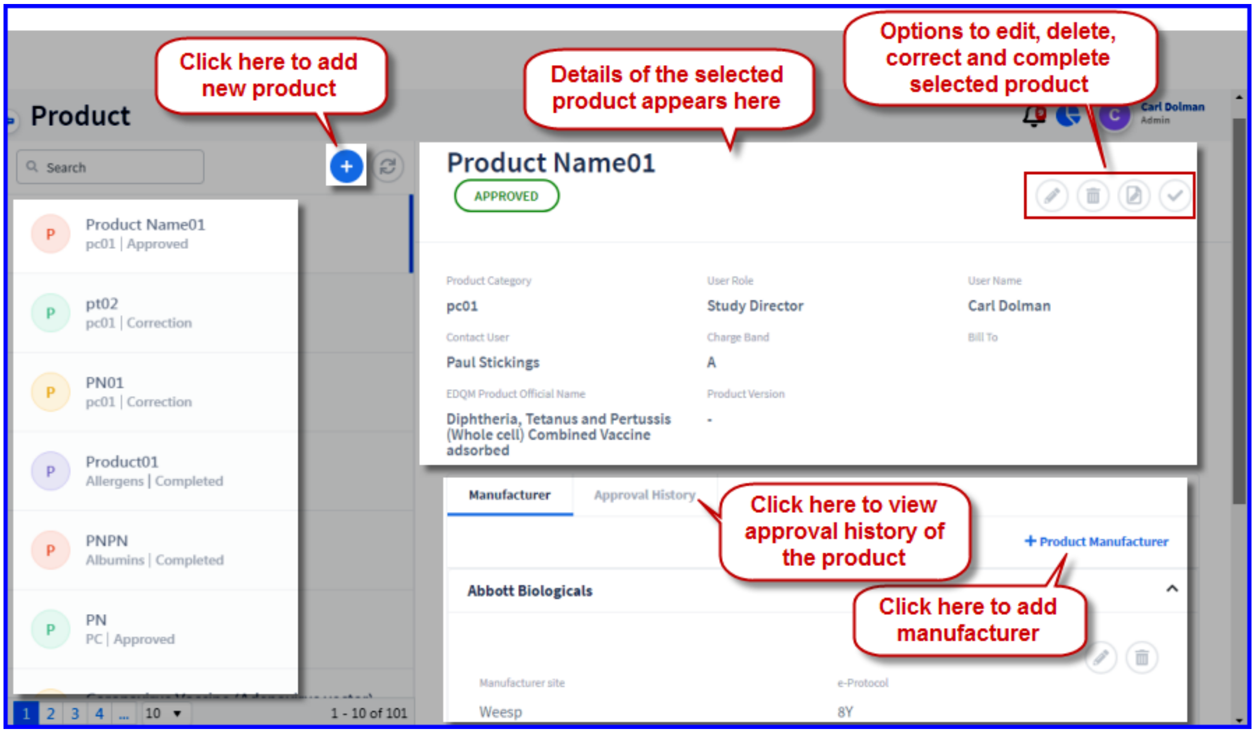


FIGURE: Product Master Screen

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:

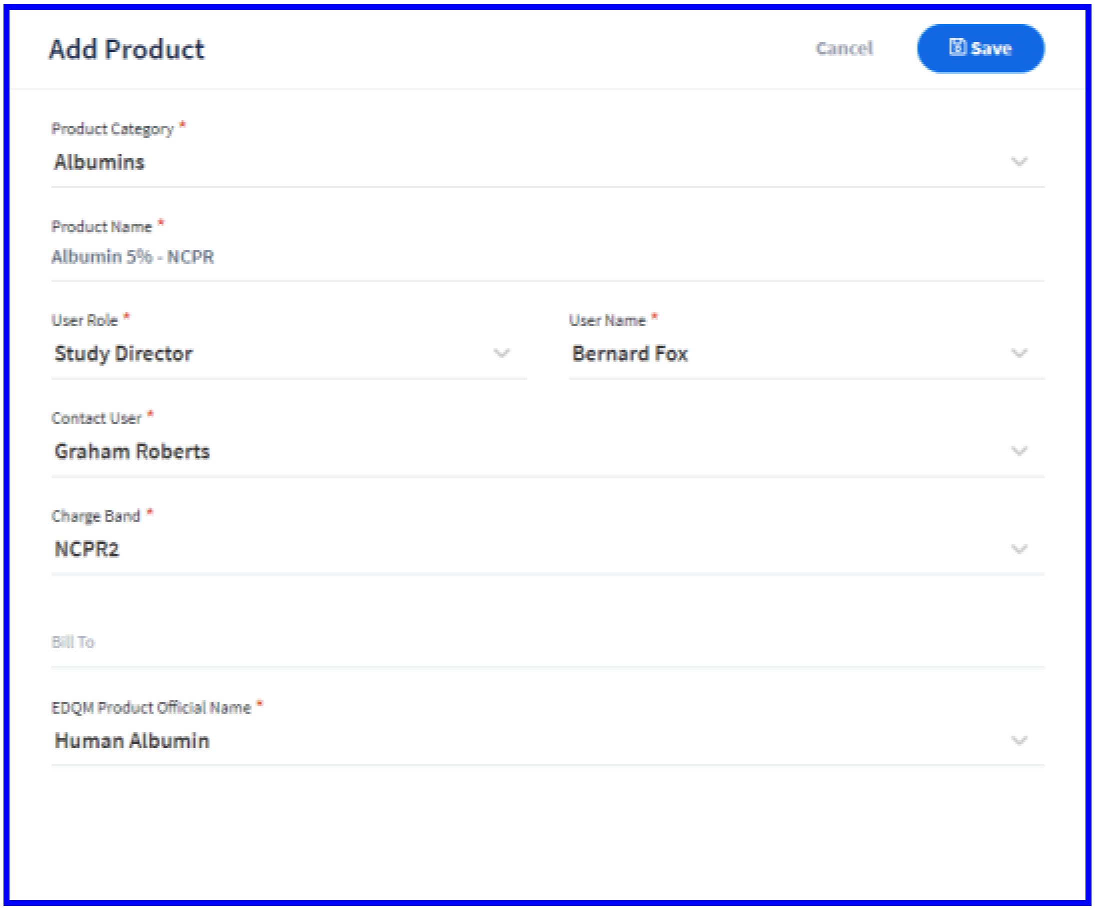


FIGURE: Add Product Screen

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:

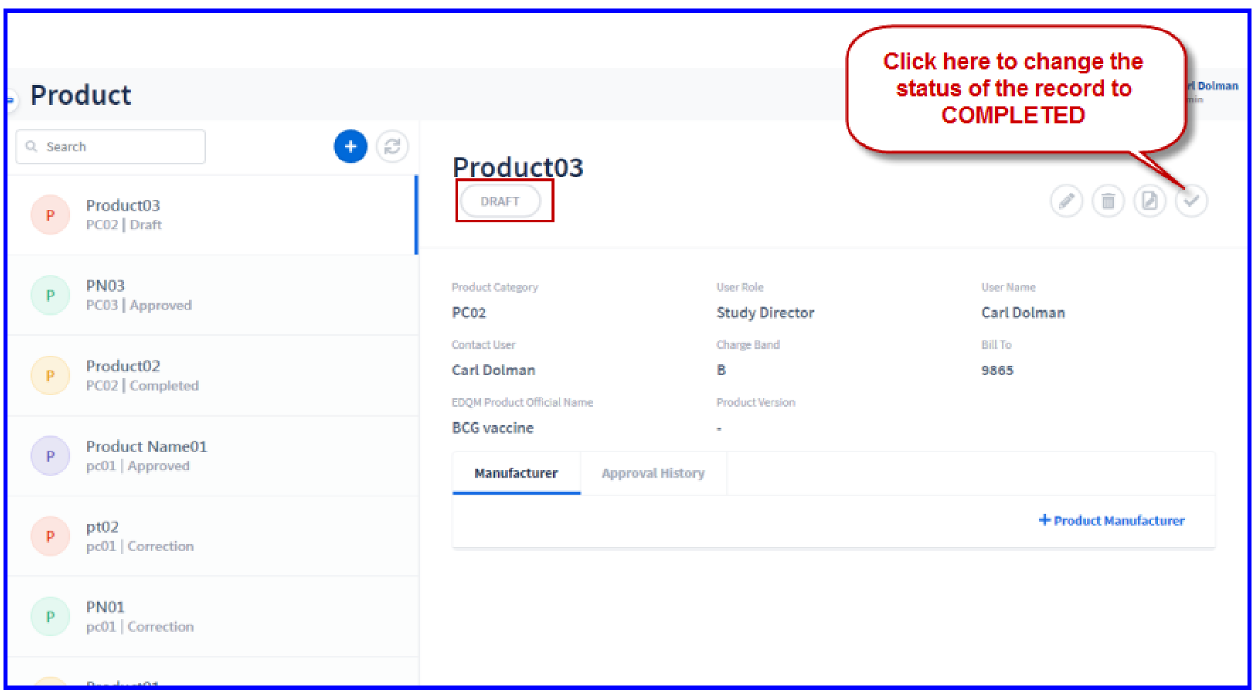


FIGURE: Changing the Status of the Product Record to COMPLETED

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

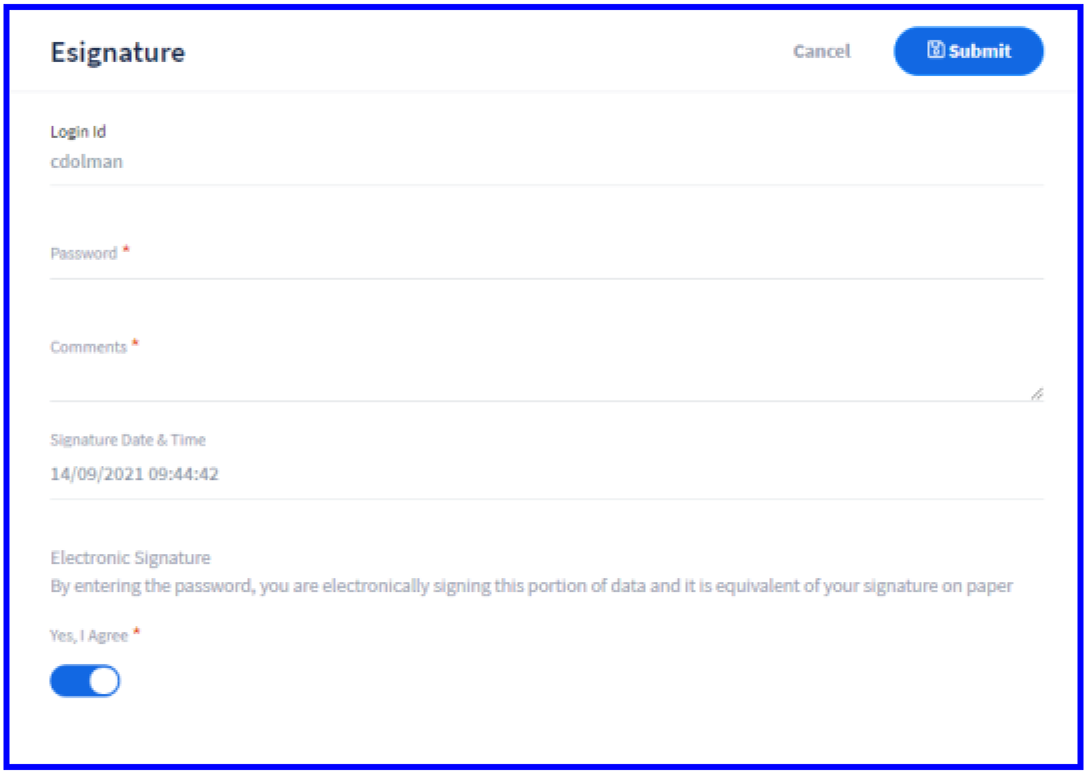


FIGURE: Esignature Dialog

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:

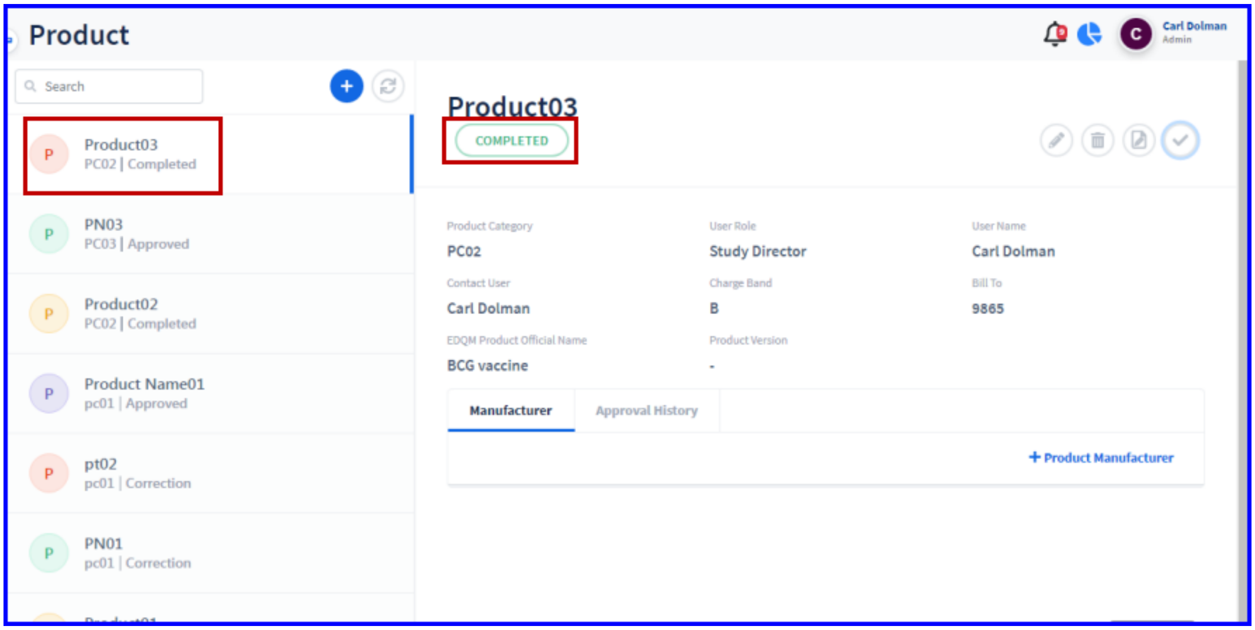


FIGURE: Product Record in the COMPLETED State

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:

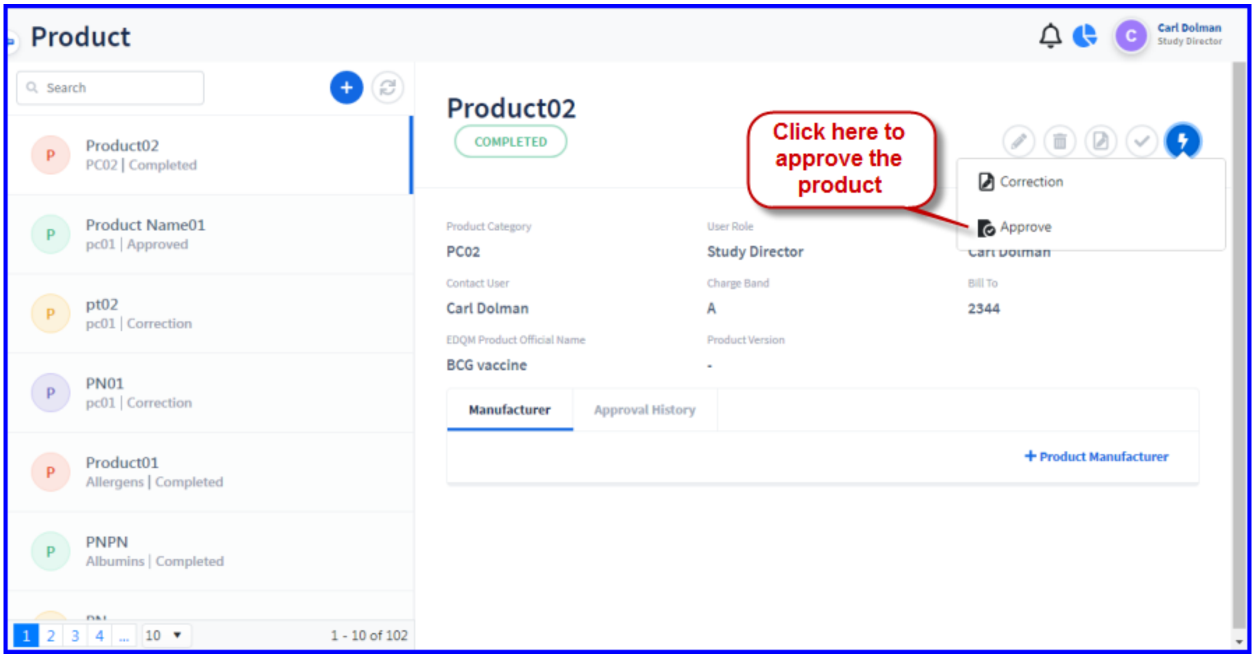


FIGURE: Approving Product Record

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

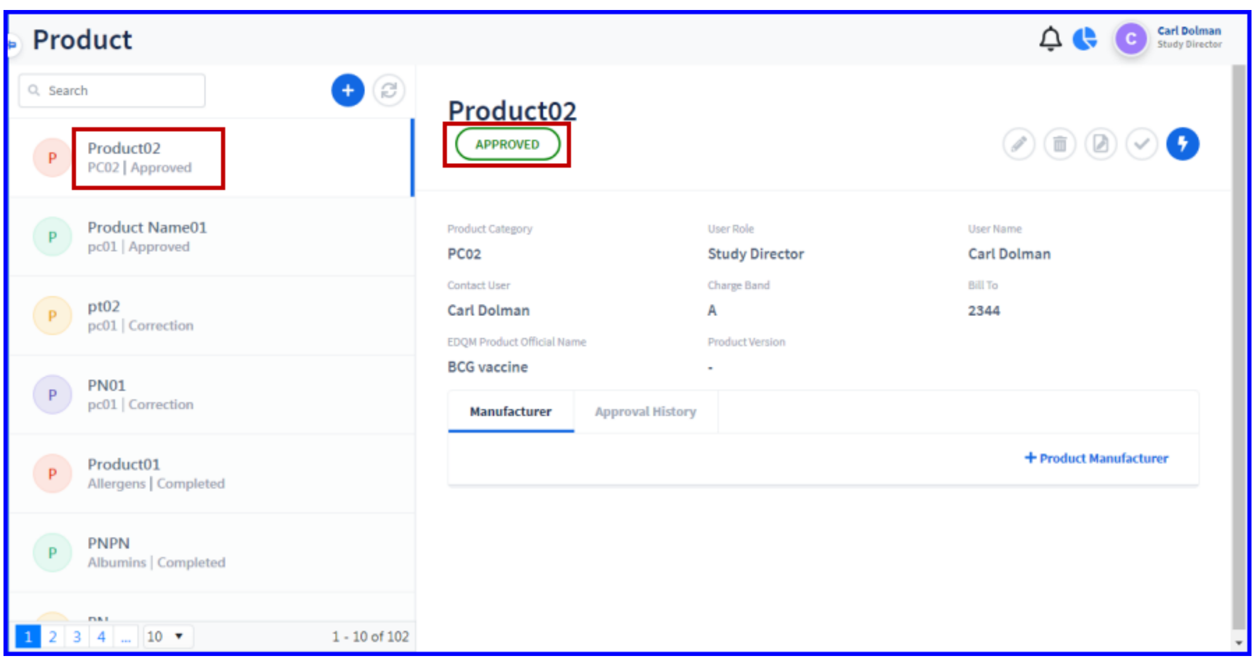


FIGURE: Product in the APPROVED State

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:

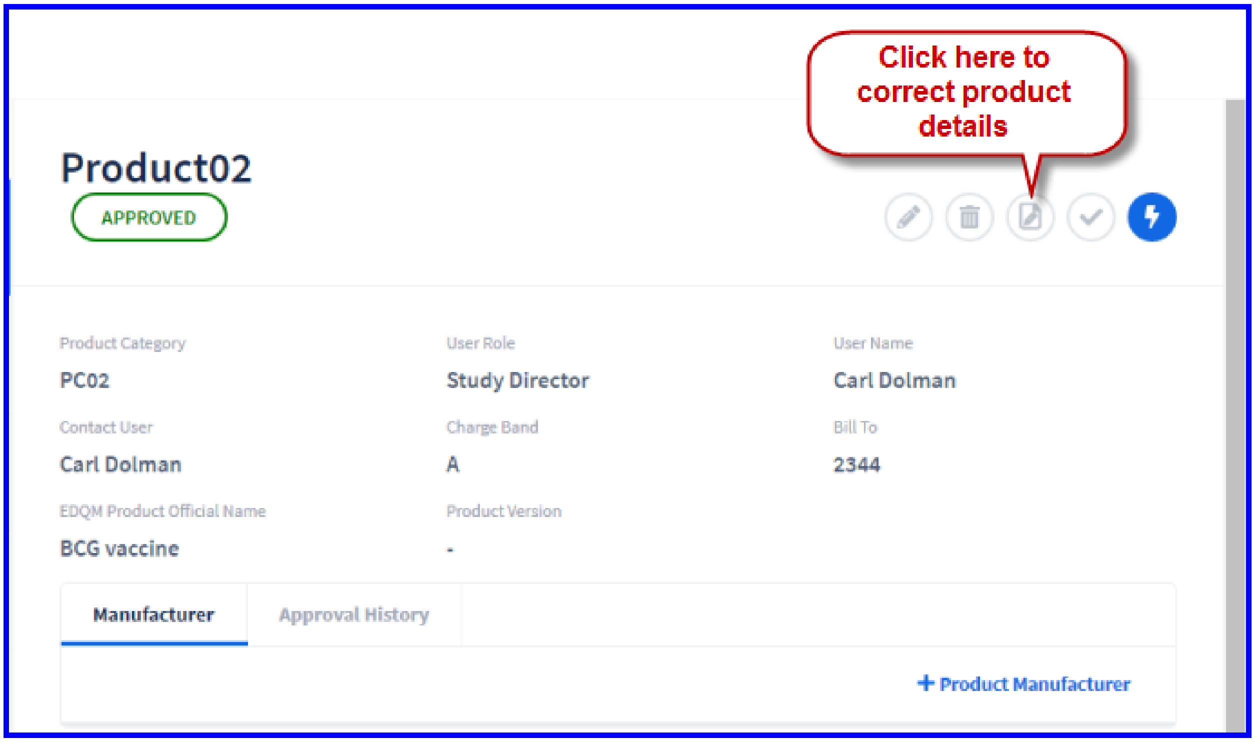


FIGURE: Correcting Product Details

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

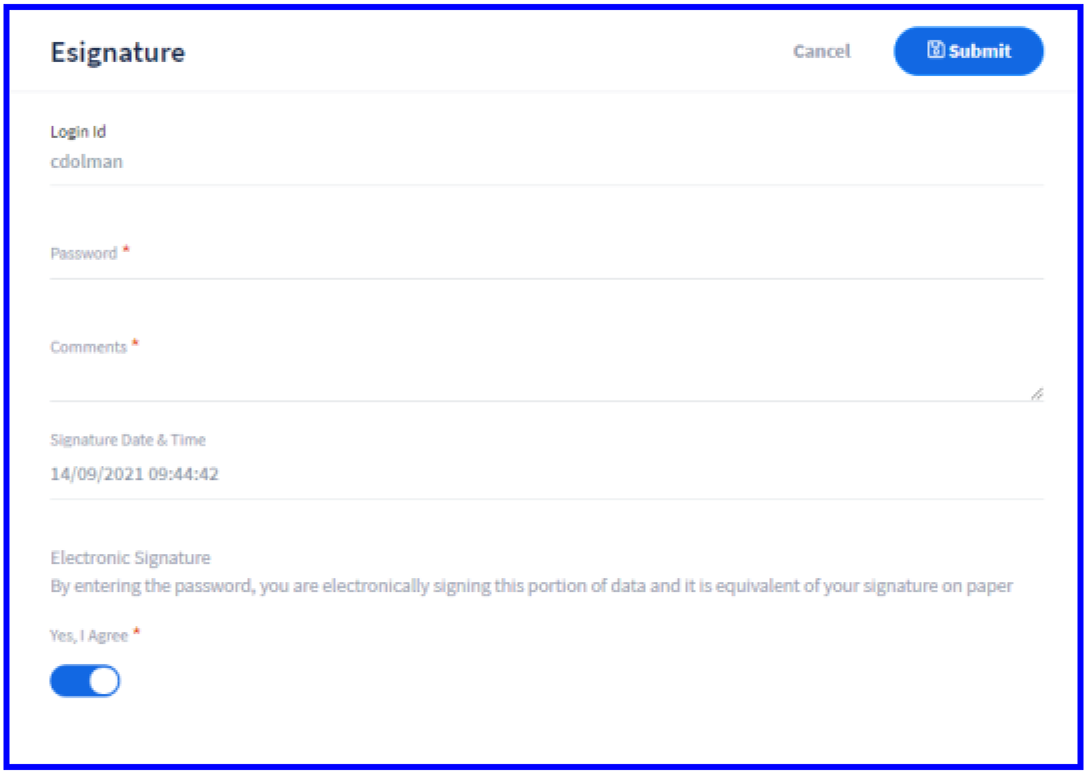


FIGURE: Esignature Dialog

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:

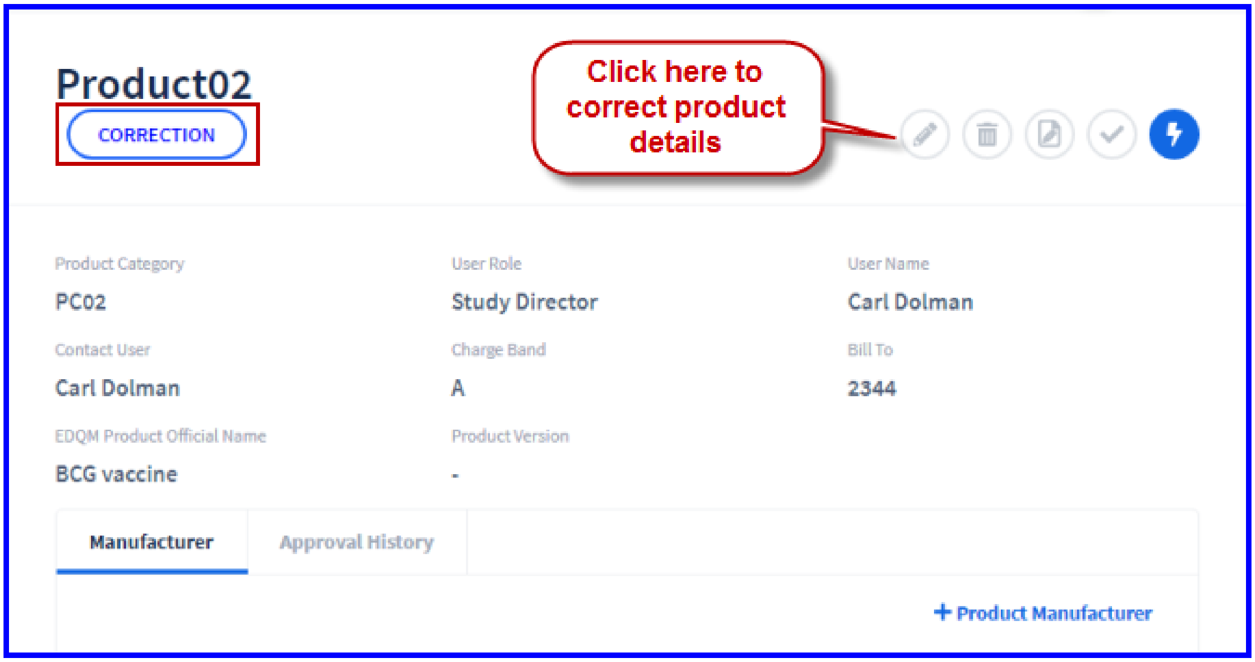


FIGURE: Product Record in the CORRECTION State

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:

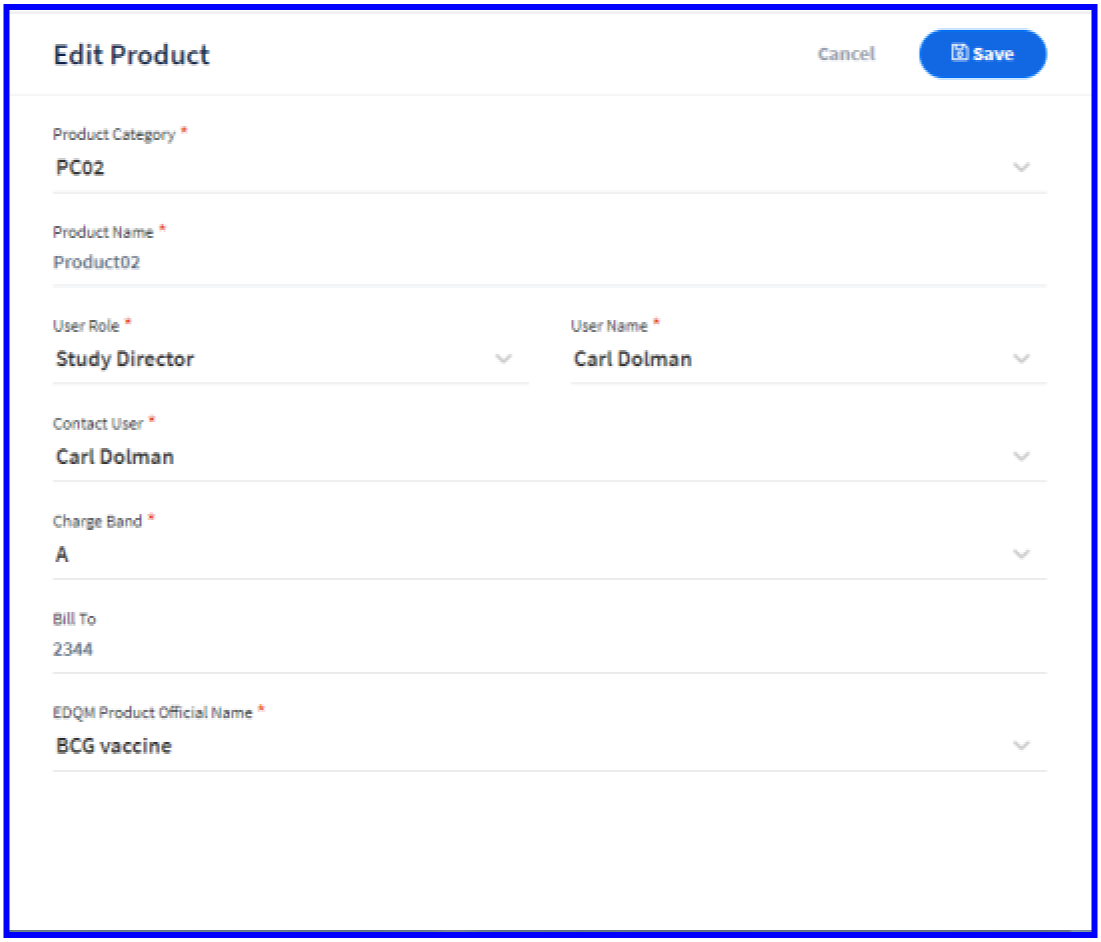


FIGURE: Edit Product Dialog

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 the click **+ Product Manufacturer** as shown in the figure:

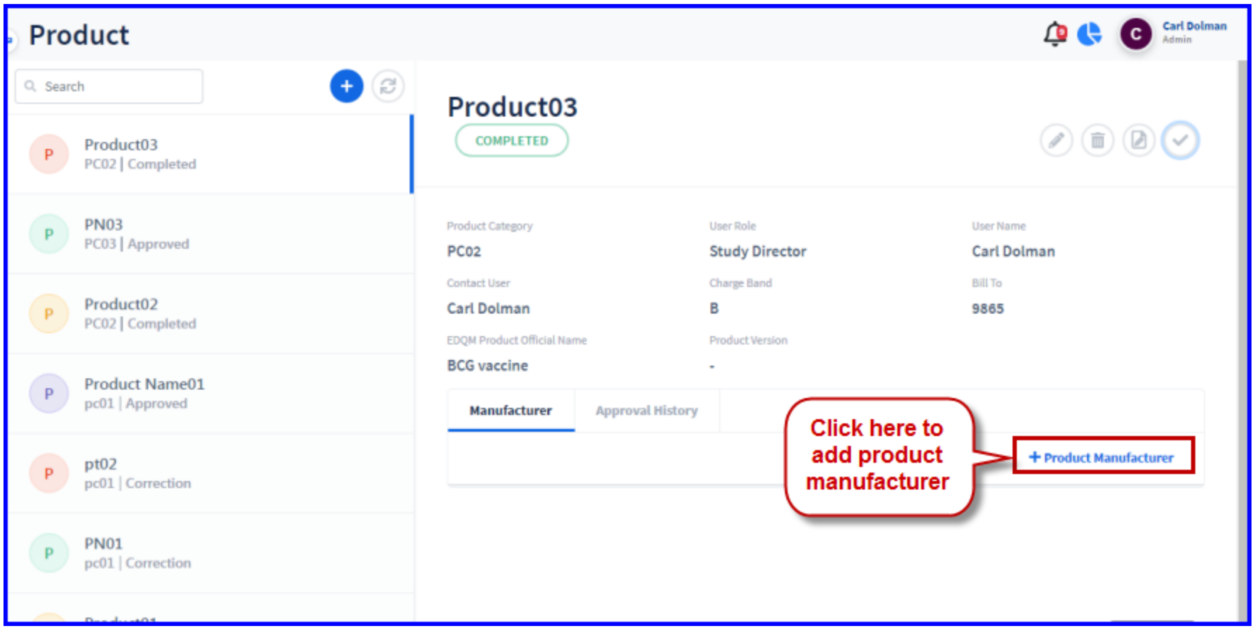


FIGURE: Adding Product Manufacturer to the Product

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

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:

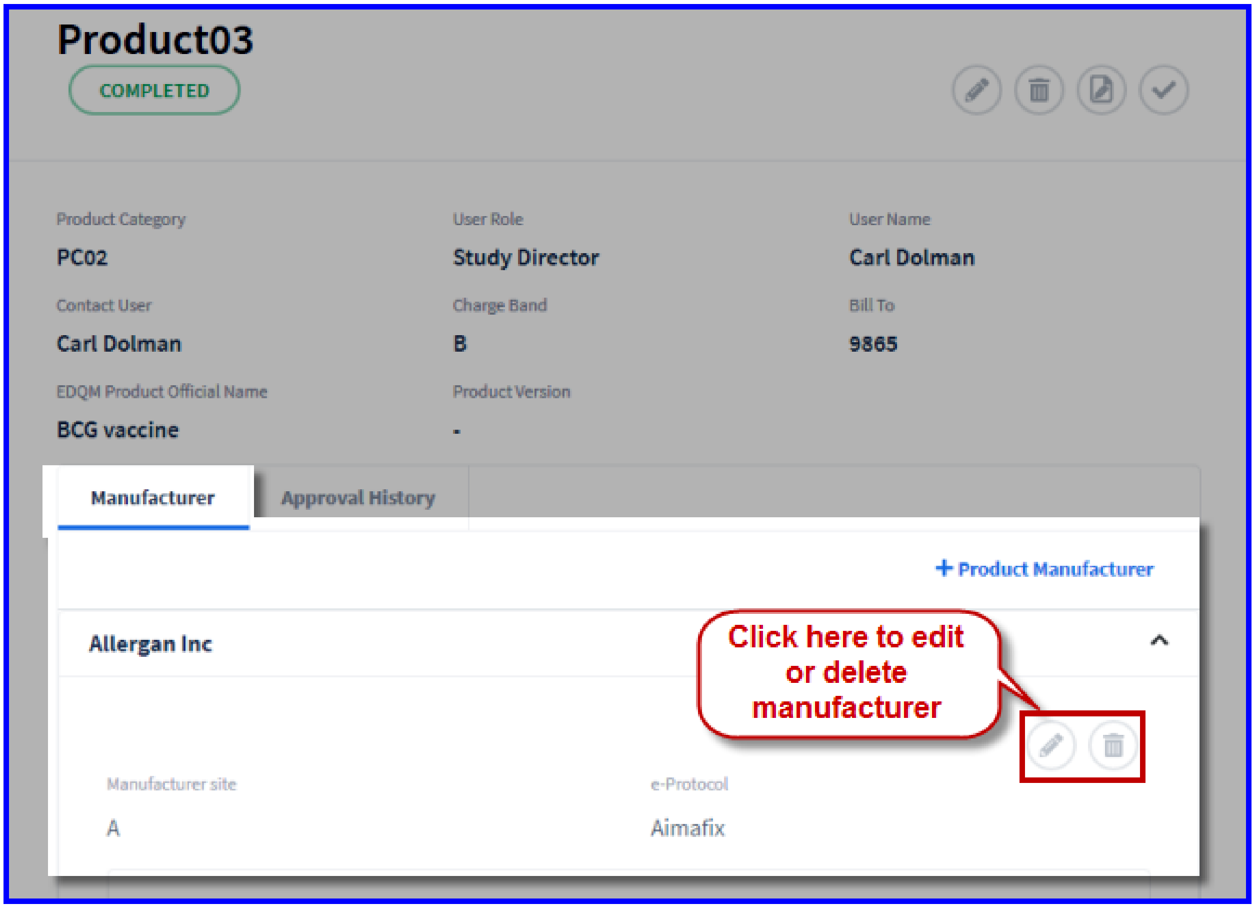


FIGURE: Added Manufacturer to the Selected Product

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:

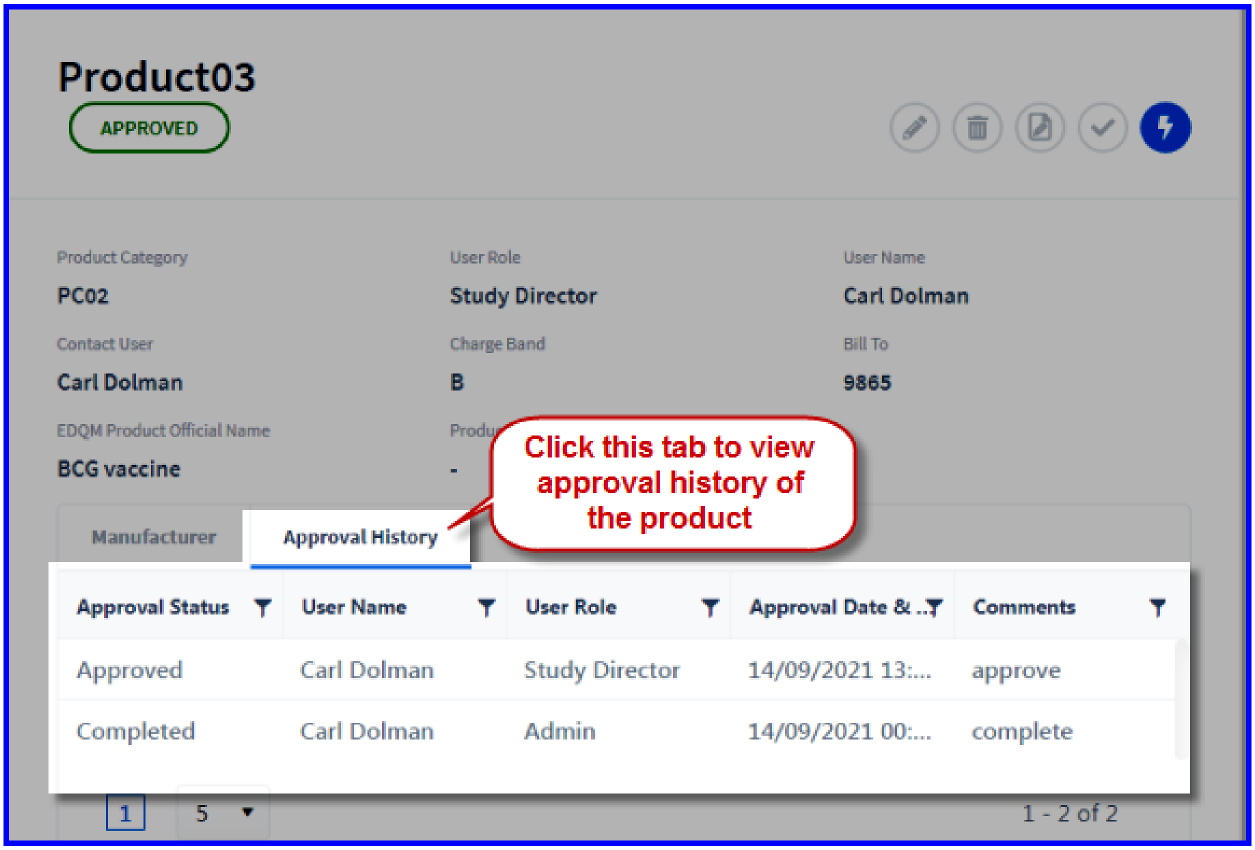


FIGURE: Viewing Approval History of the Product

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:

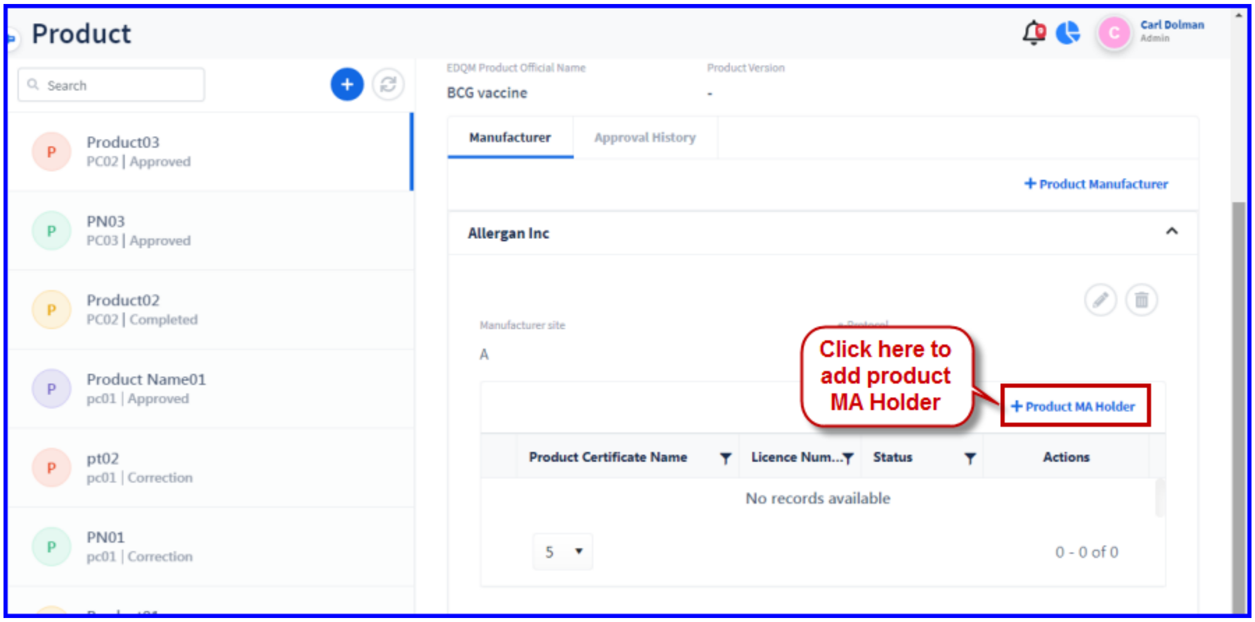


FIGURE: Adding Product MA Holder

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

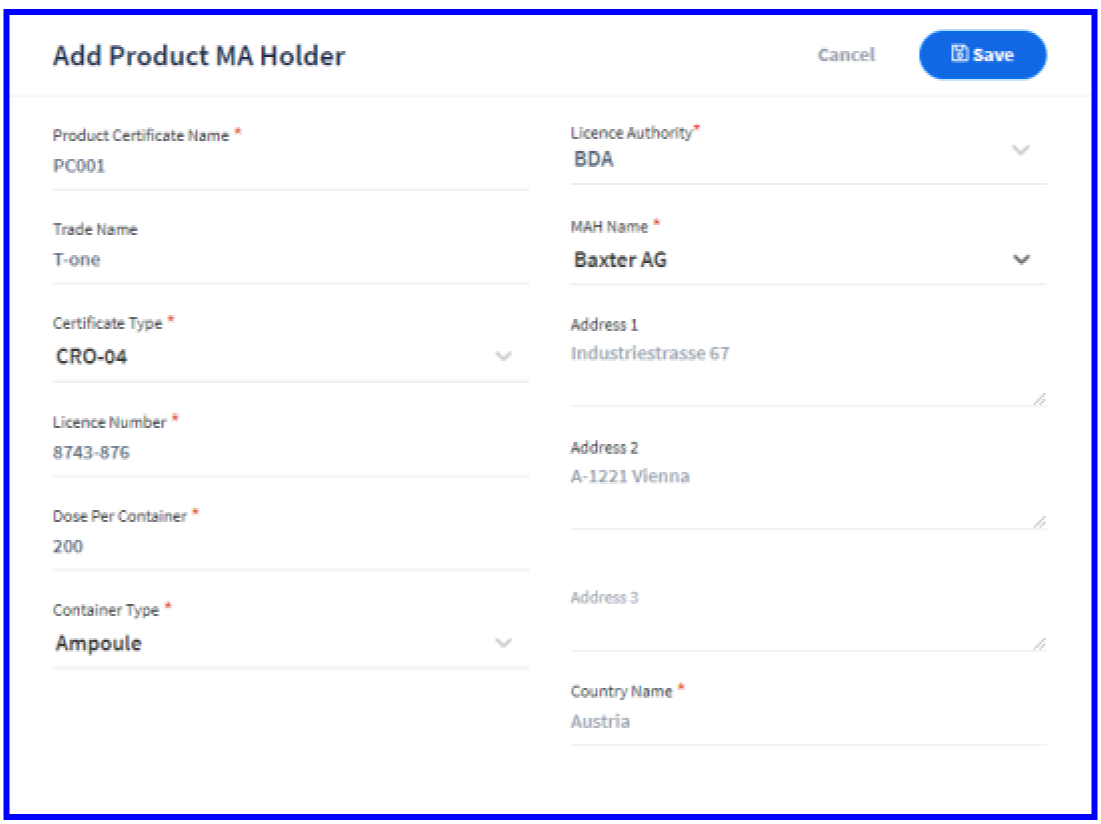


FIGURE: Add Product MA Holder Dialog

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:

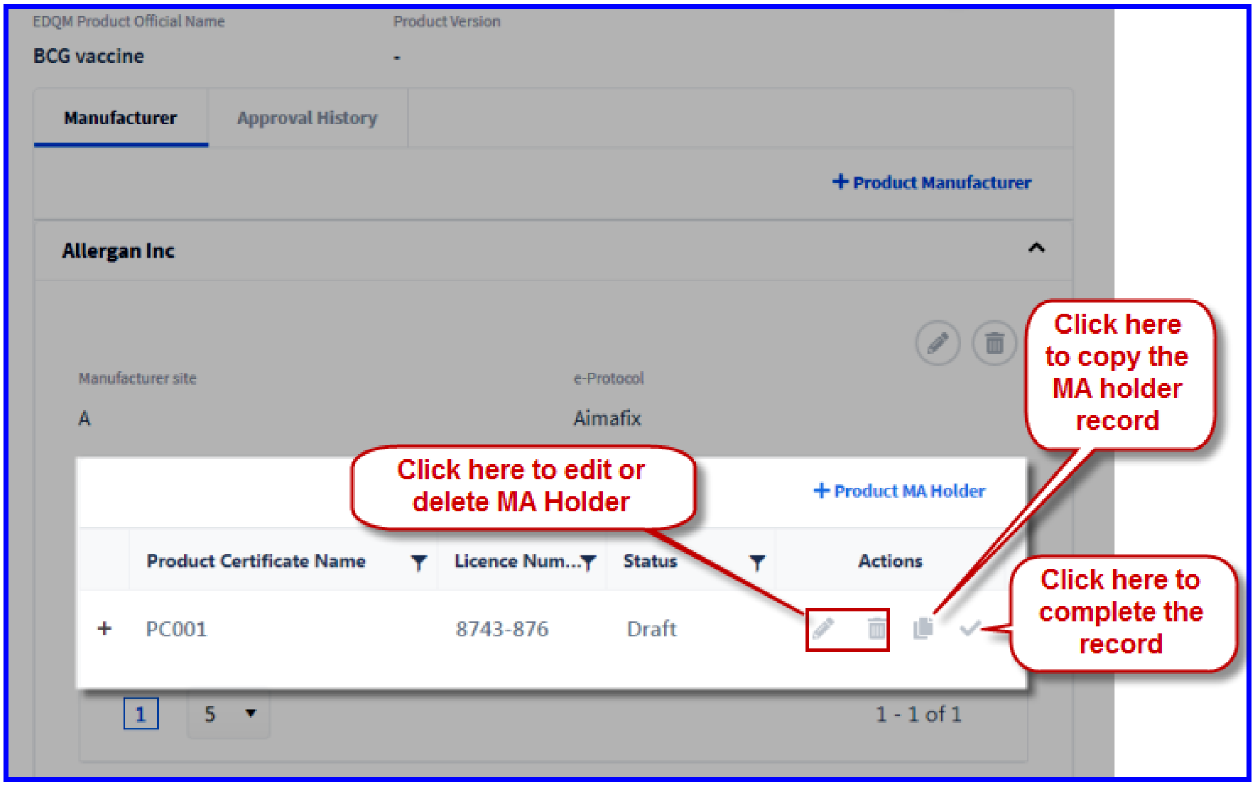


FIGURE: Added MA Holder for the Product

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:

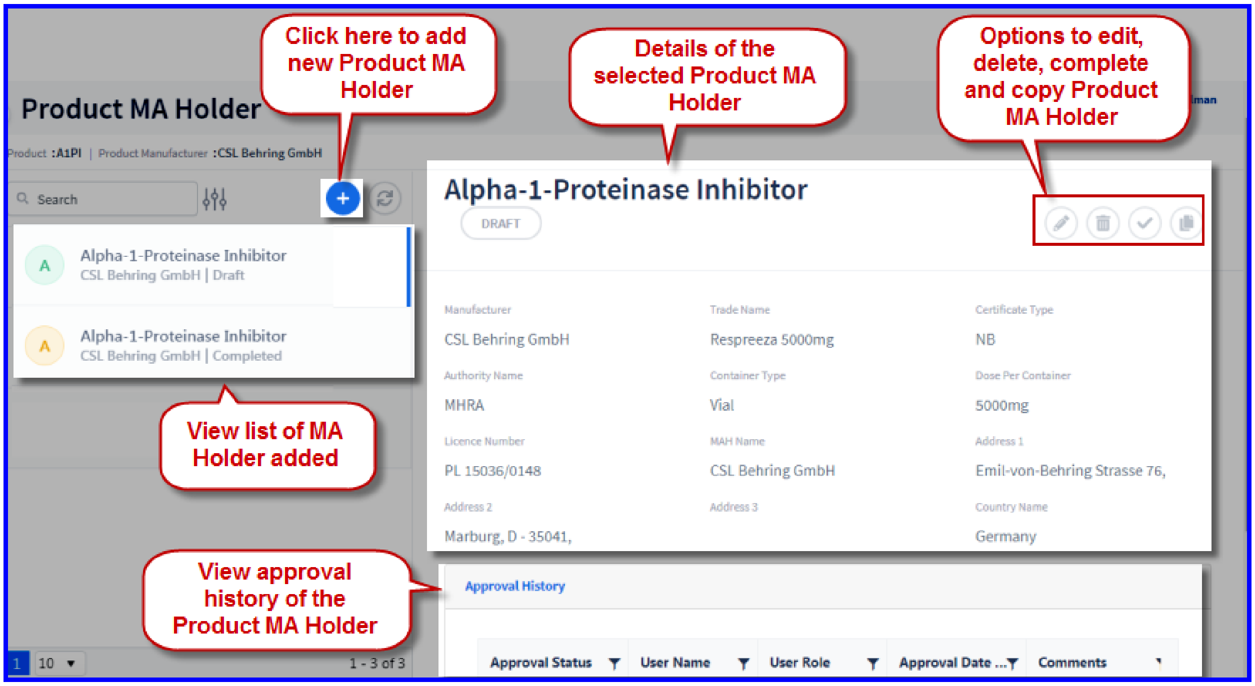


FIGURE: Product MA Holder Master Screen

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:

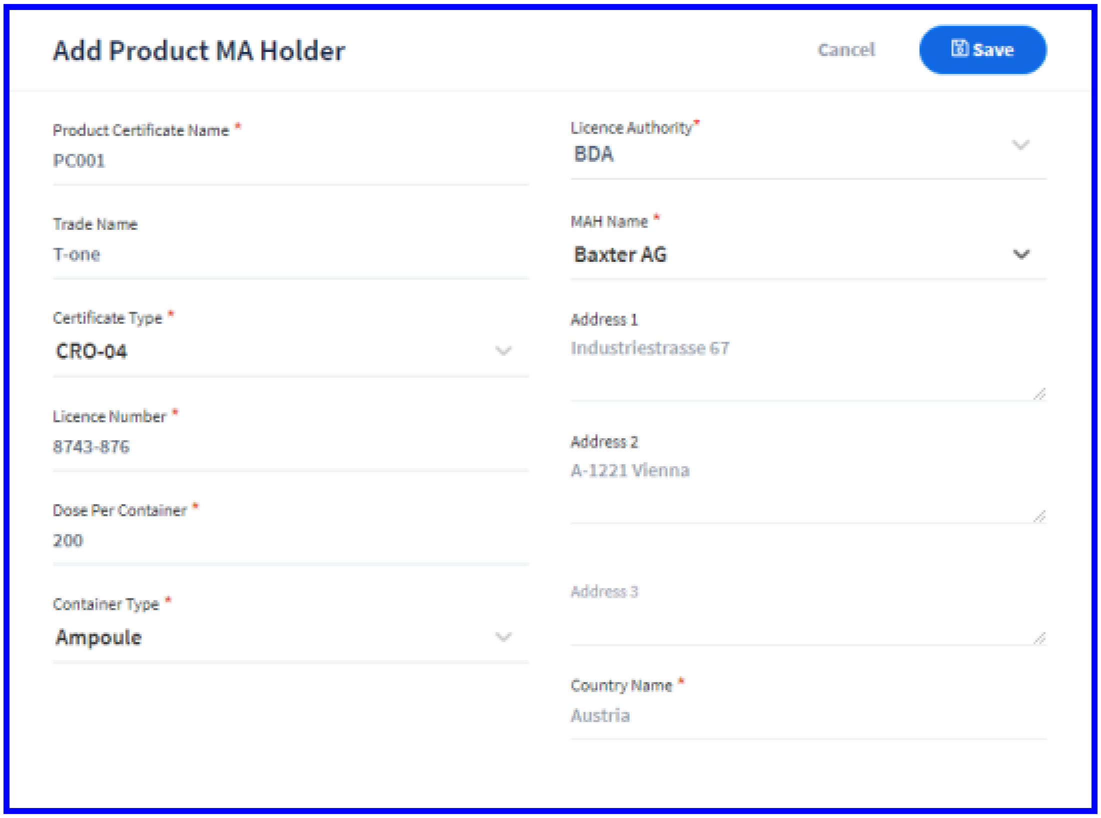


FIGURE: Add Product MA Holder Dialog

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 m MA Holder aster 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:

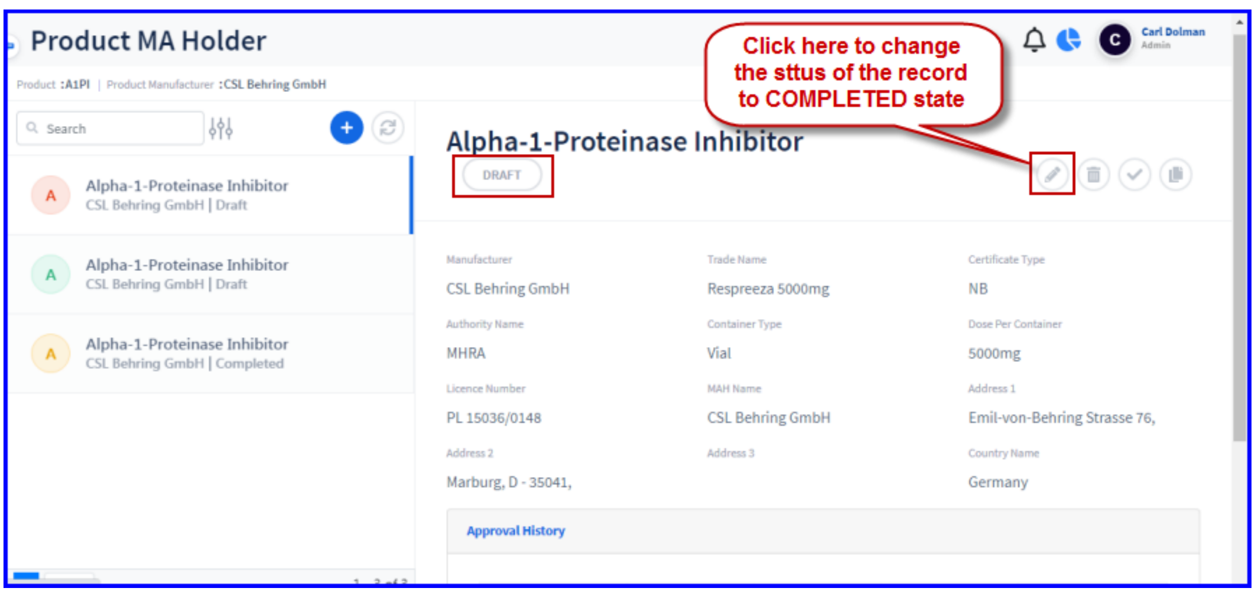


FIGURE: Changing the Status of the Product MA Holder Record to COMPLETED State

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

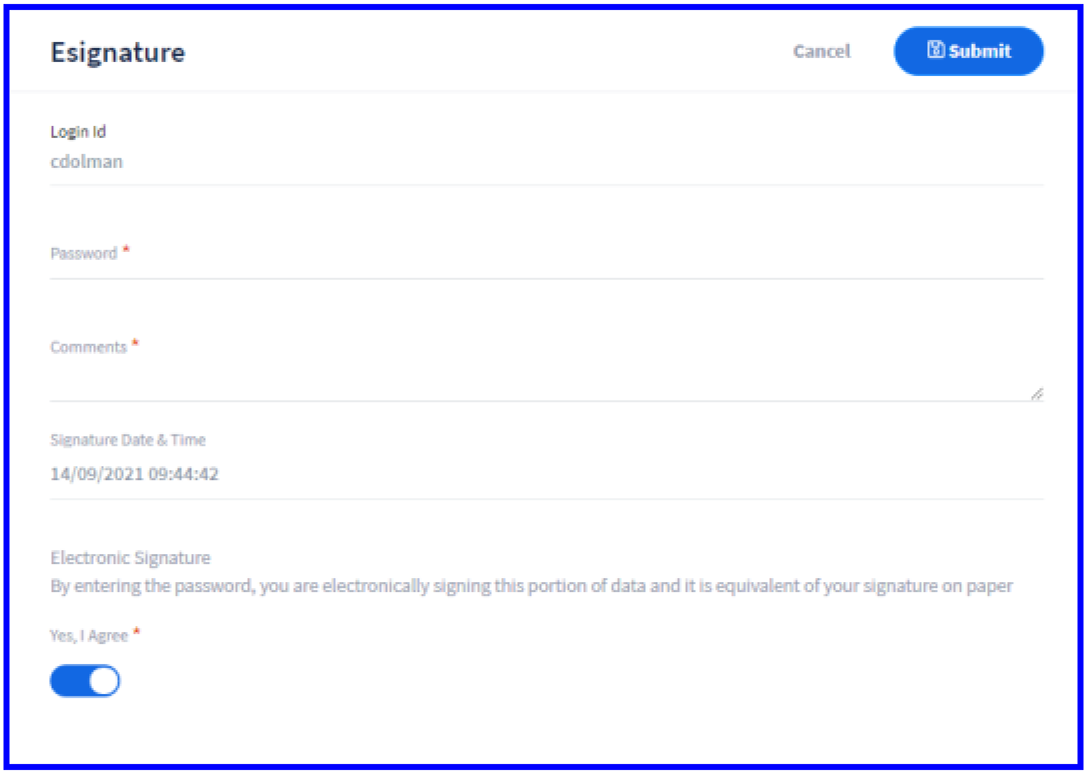


FIGURE: Esignature Dialog

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:

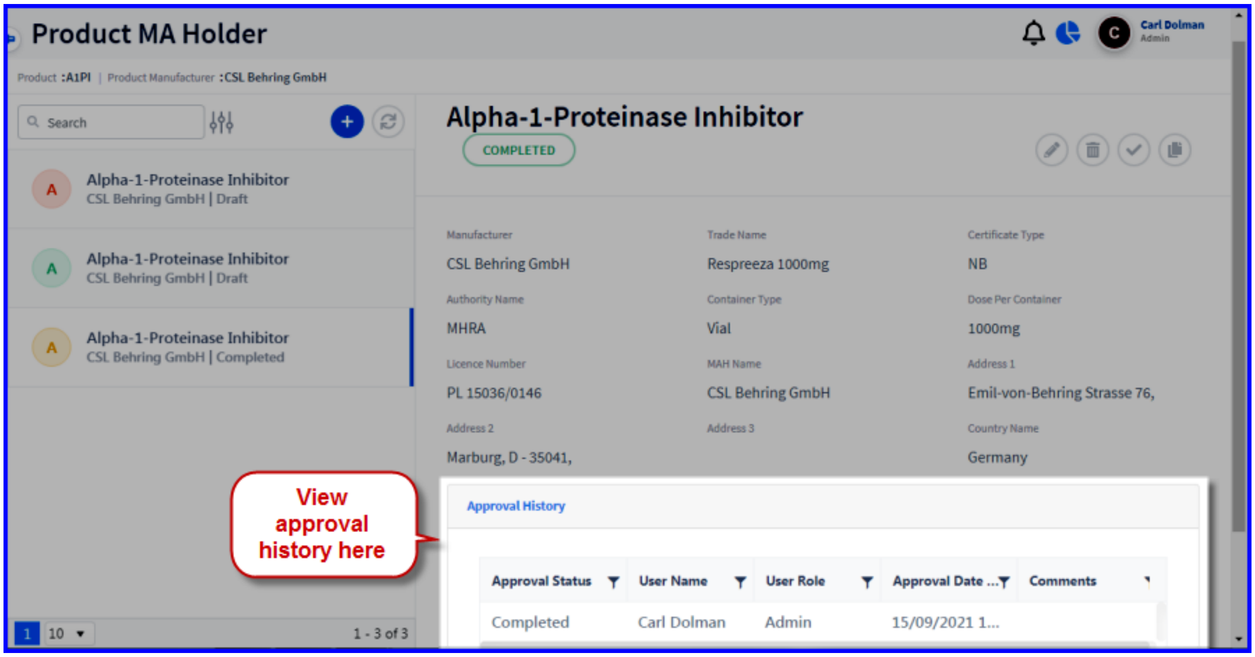


FIGURE: Viewing Approval History of the Product MA Holder Record

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:

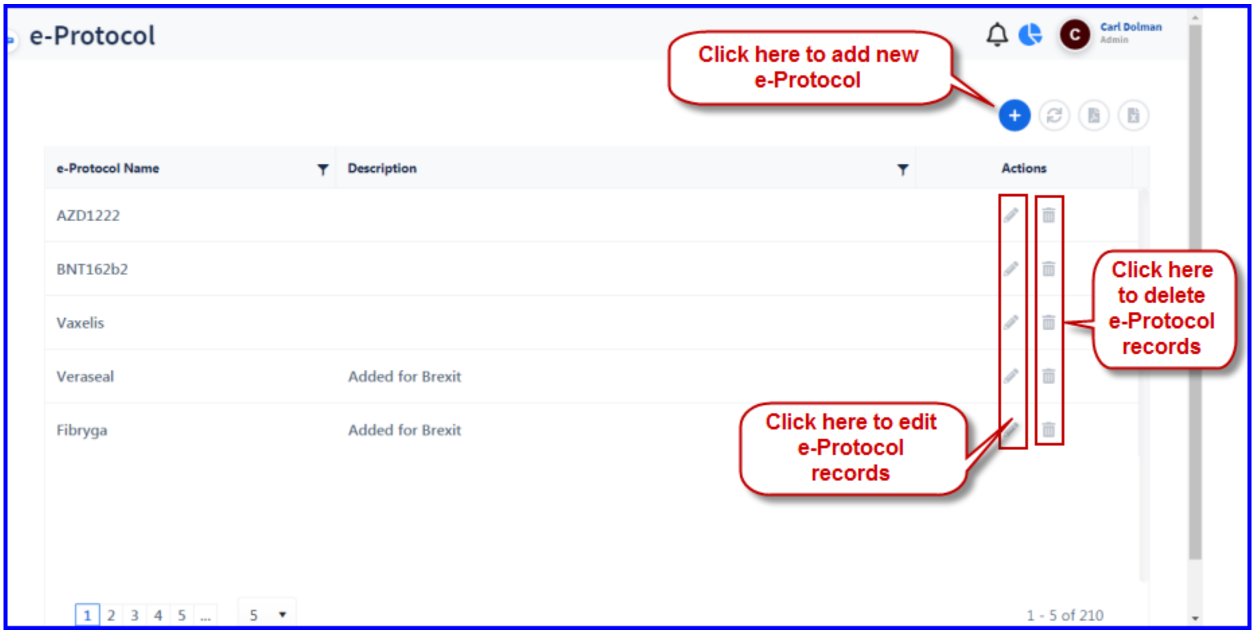


FIGURE: e-Protocol Master Screen

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:

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:

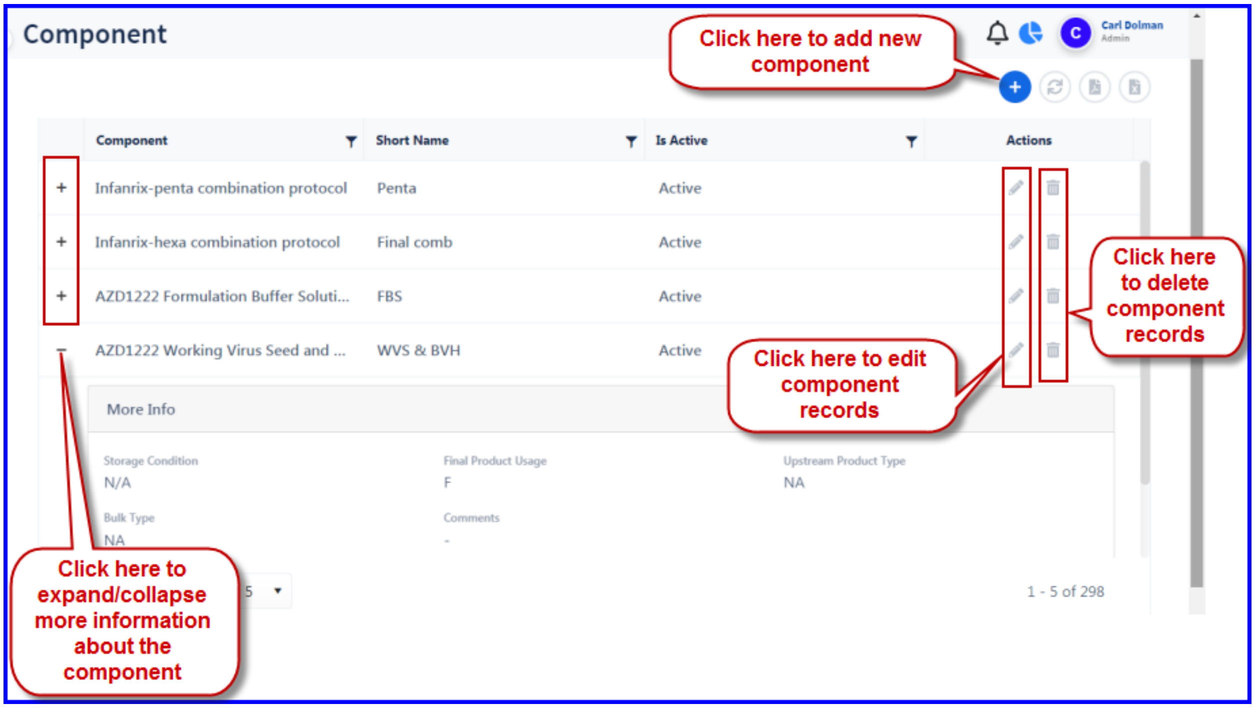


FIGURE: Component Master Screen

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:

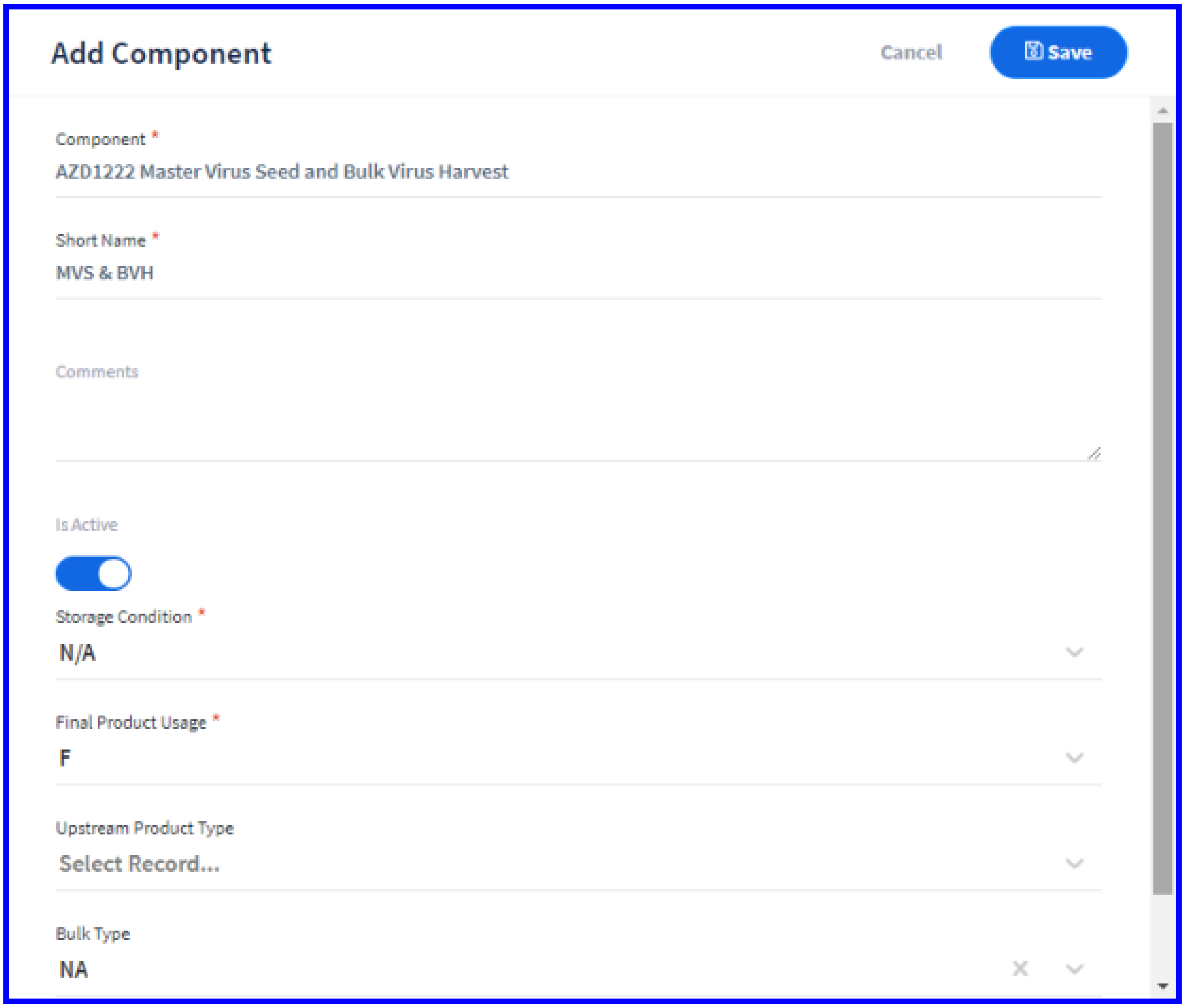


FIGURE: Add Component Dialog

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:

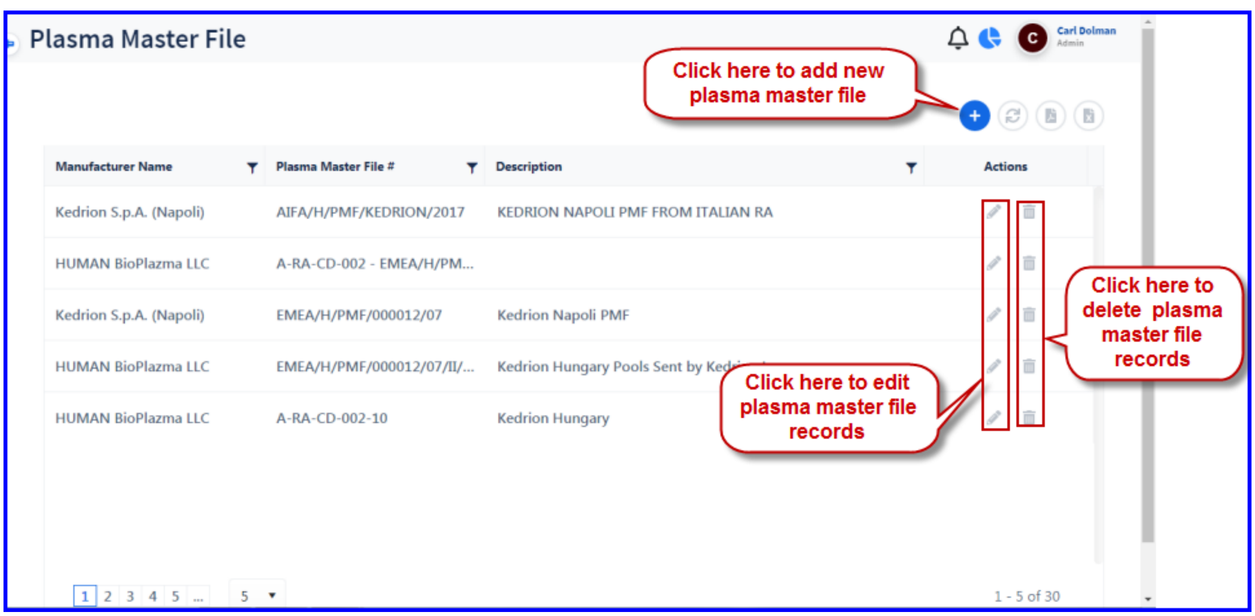


FIGURE: Plasma Master File Master Screen

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:

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:

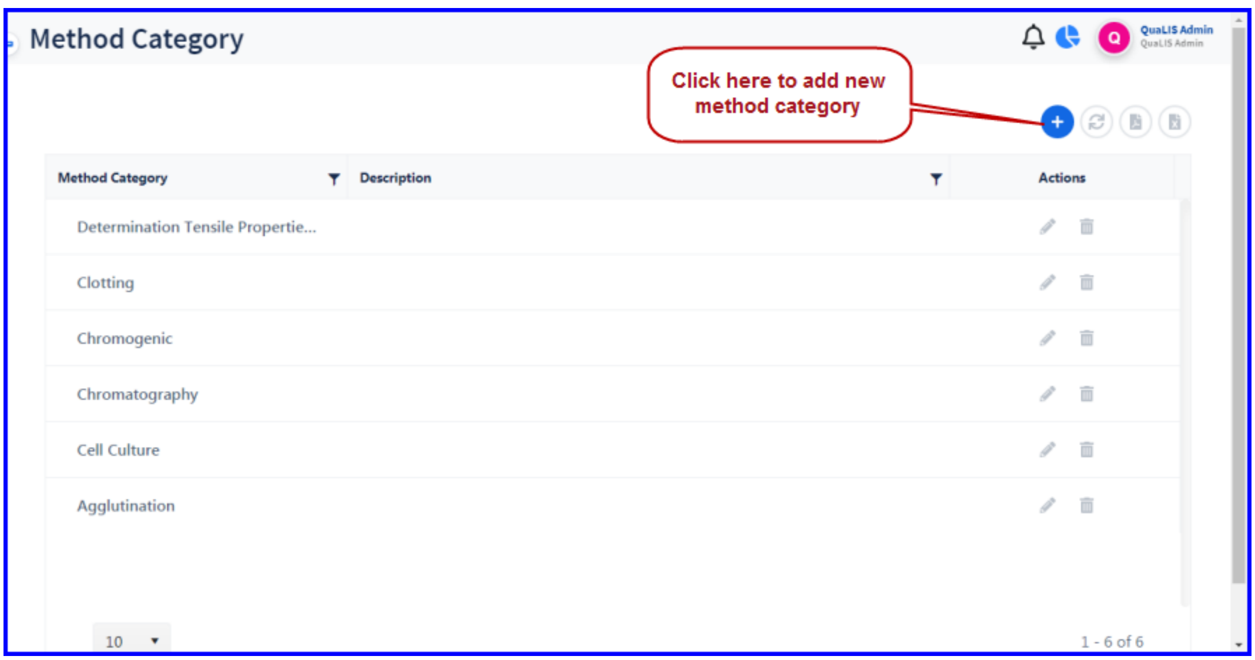


FIGURE: Method Category Master Screen

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 . 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:

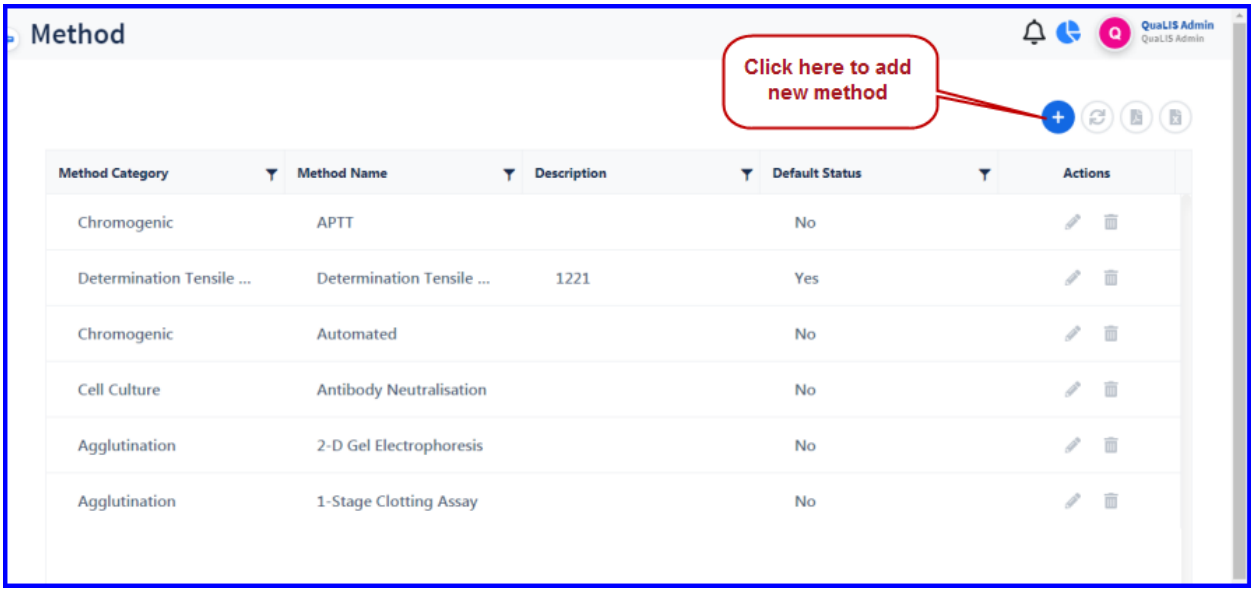


FIGURE: Method Master Screen

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:

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:

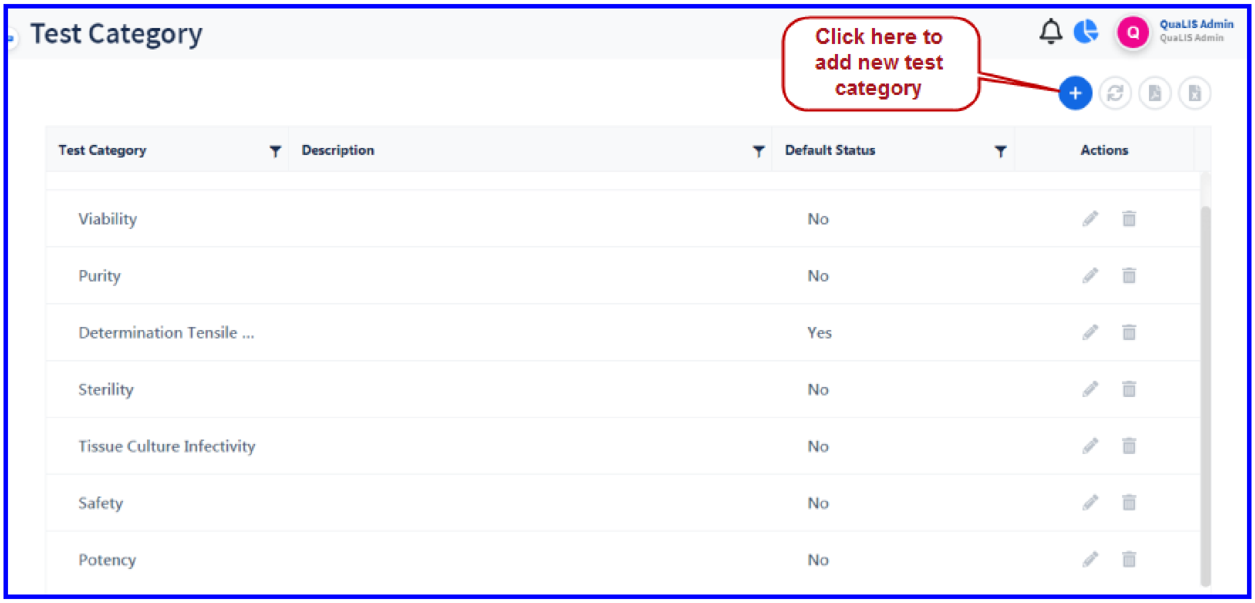


FIGURE: Test Category Master Screen

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:

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:

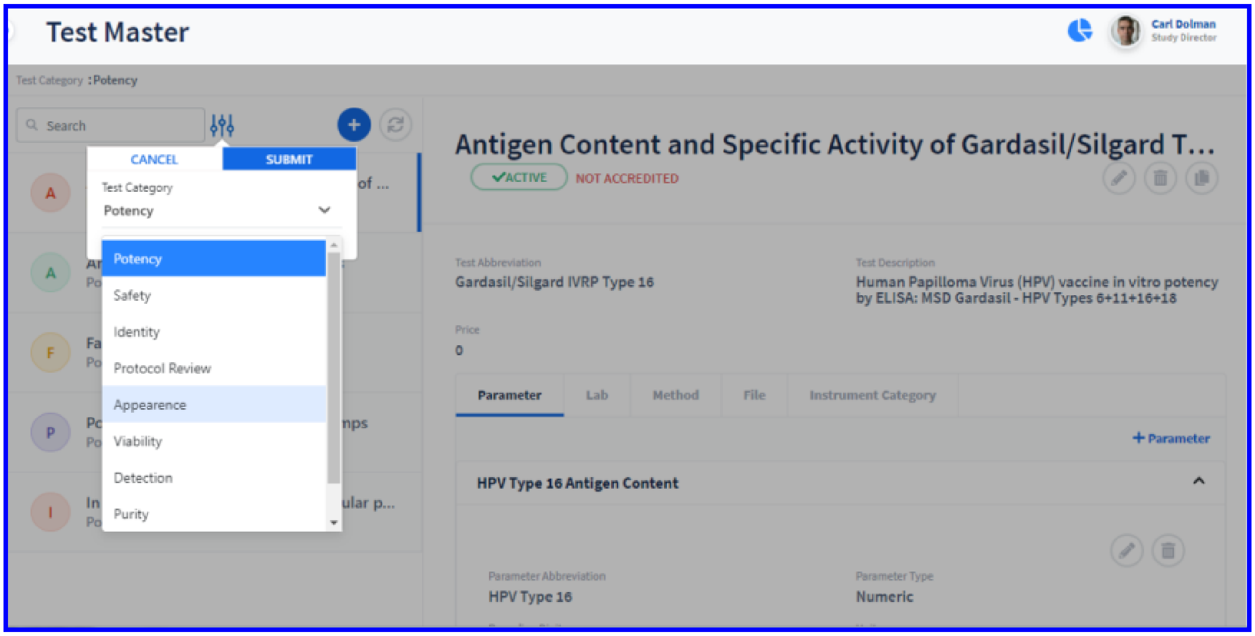


FIGURE: Test Master Screen

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:

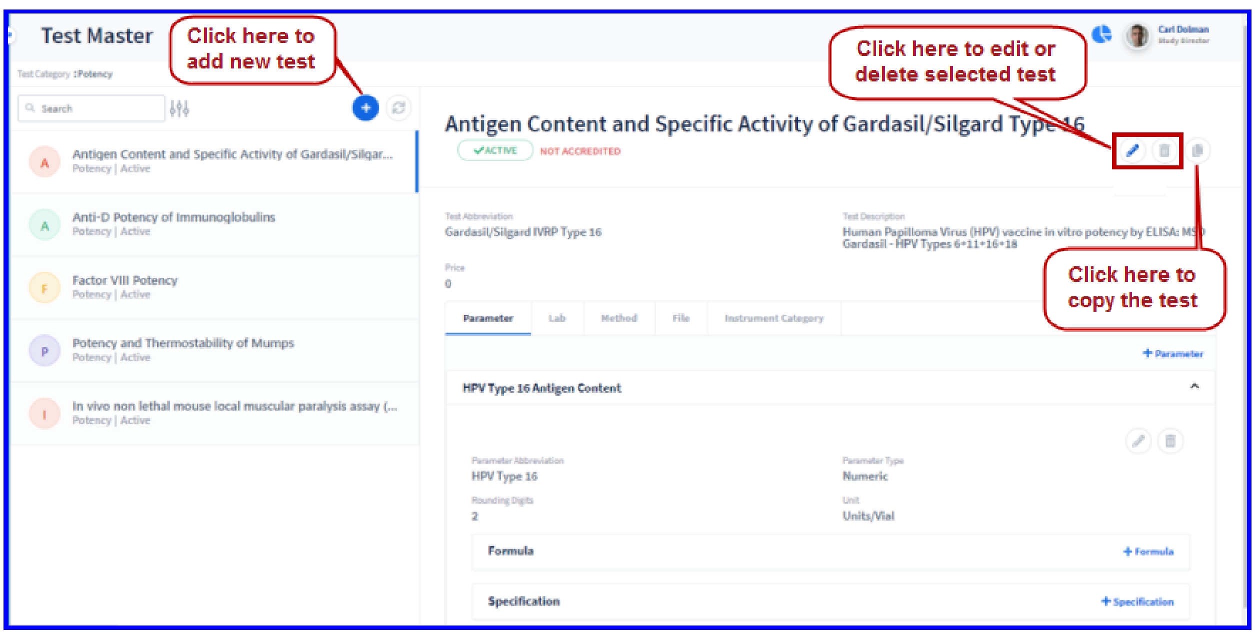


FIGURE: Test Master Showing Tests in the Selected Test Category

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:

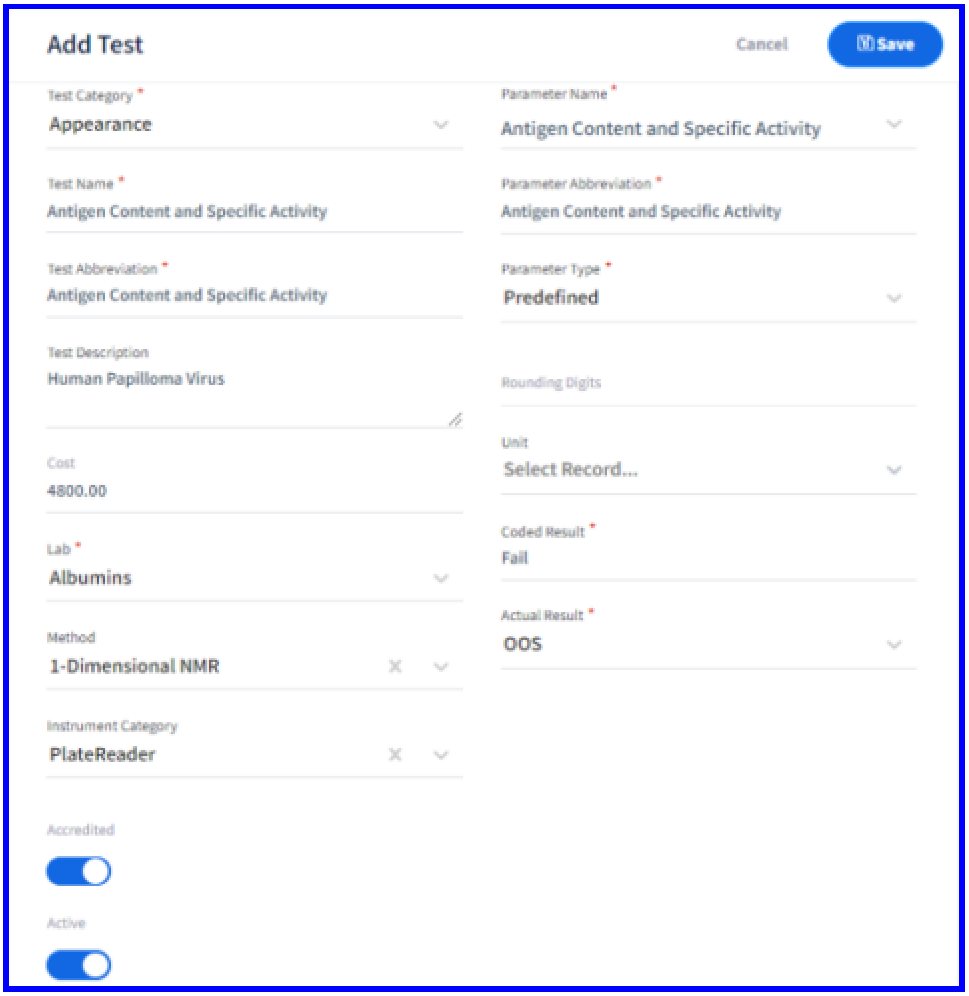


FIGURE: Add Test Dialog

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:

FIGURE: Parameter Tab

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

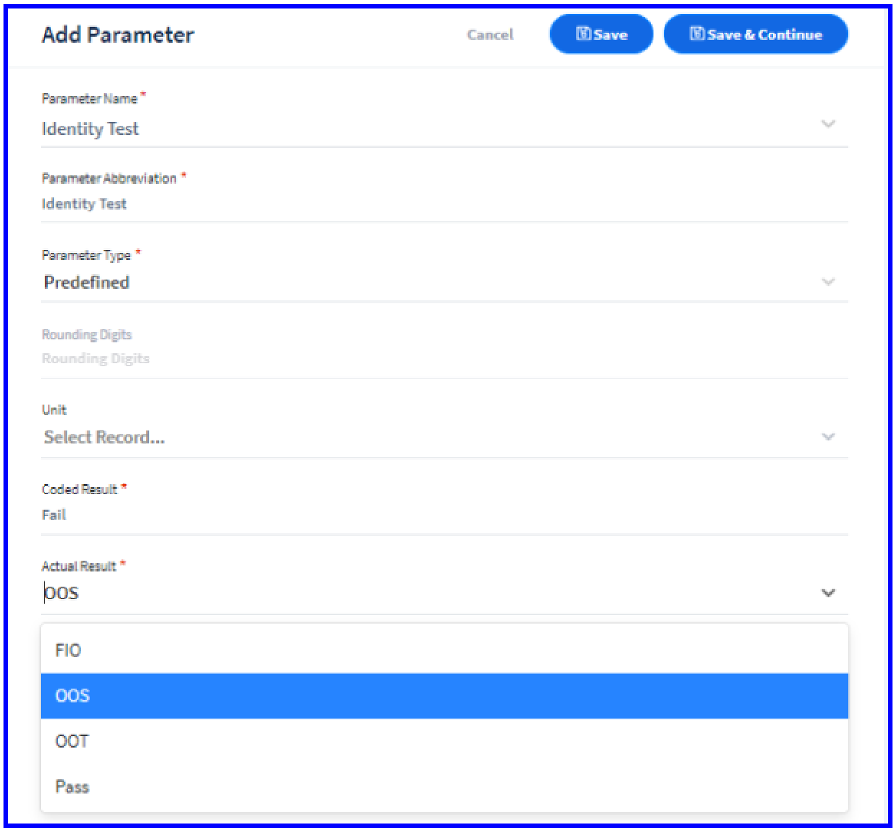


FIGURE: Add Parameter Dialog

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:

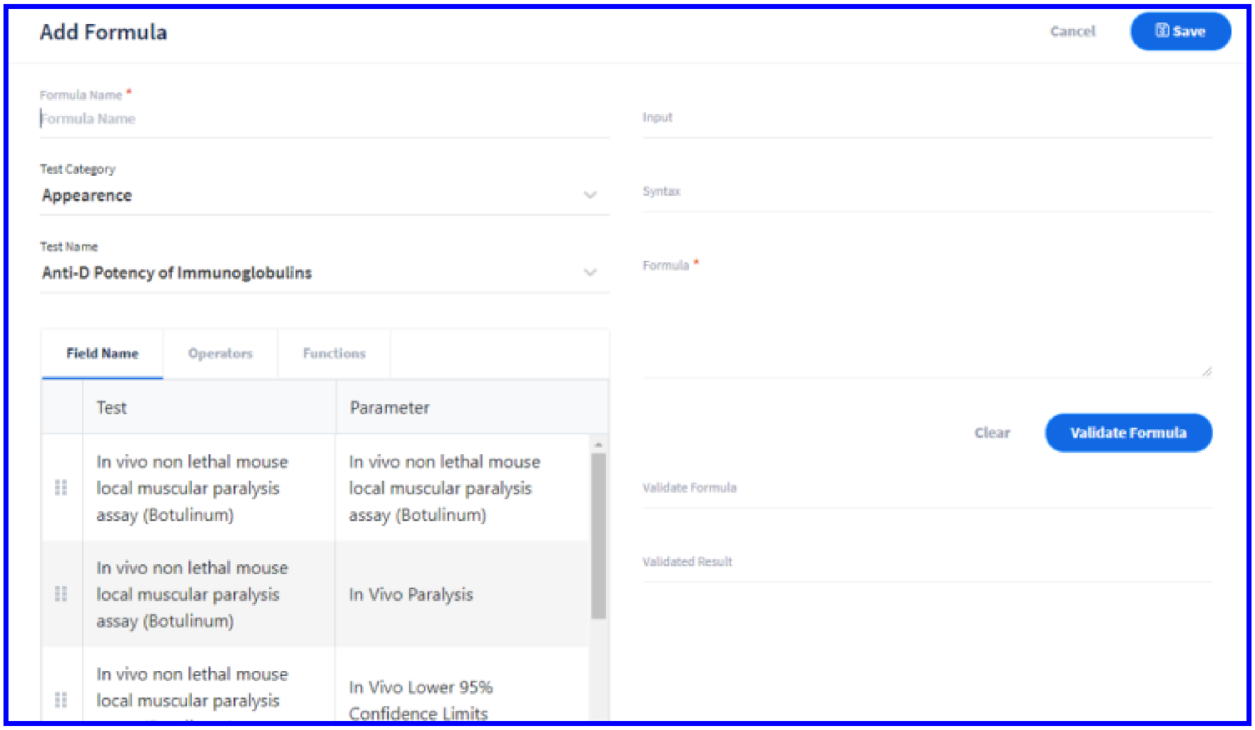


FIGURE: Add Formula Screen

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** filed.

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:

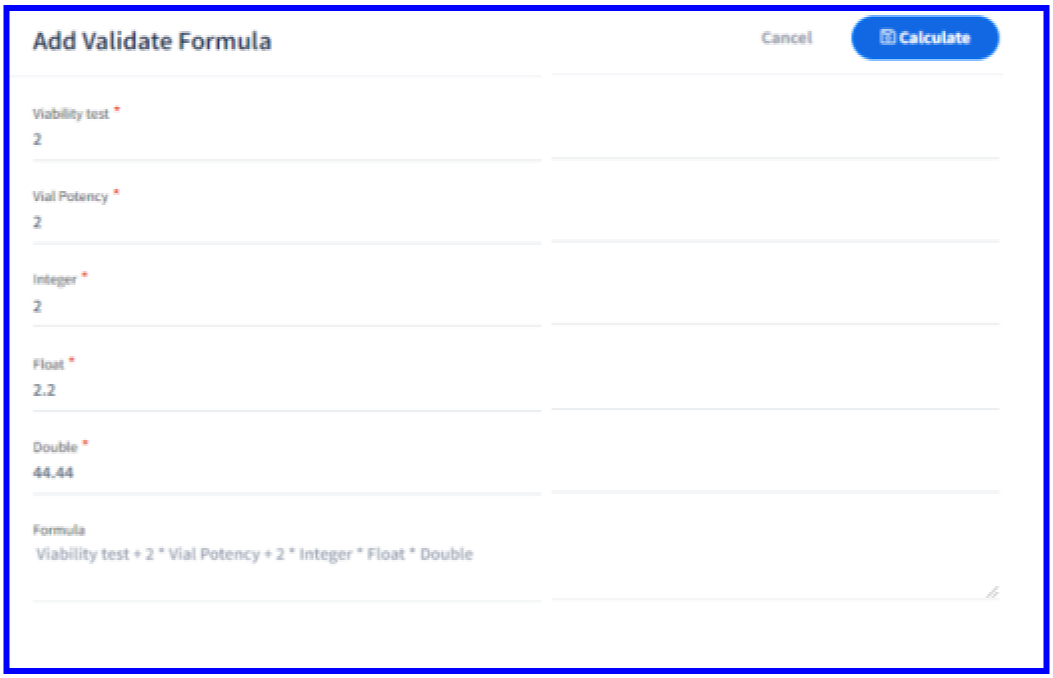


FIGURE: Validate Formula

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:

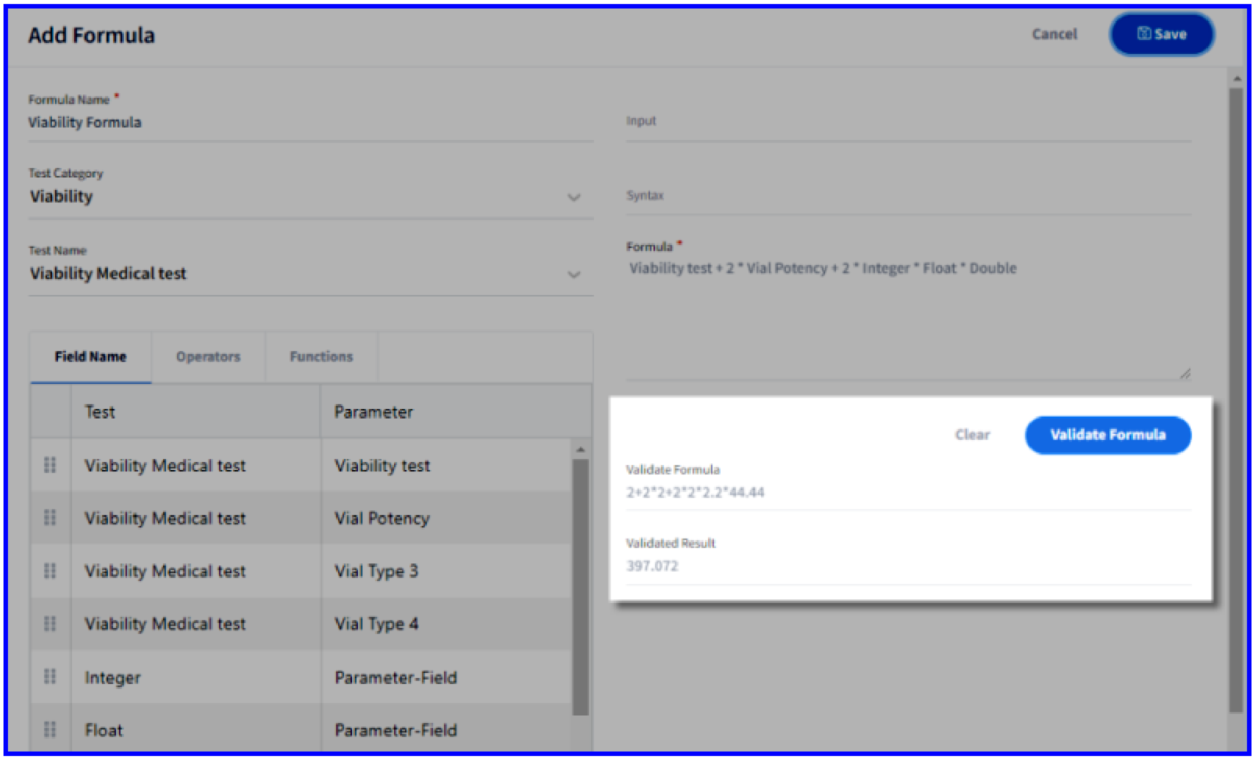


FIGURE: Result Calculated

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:

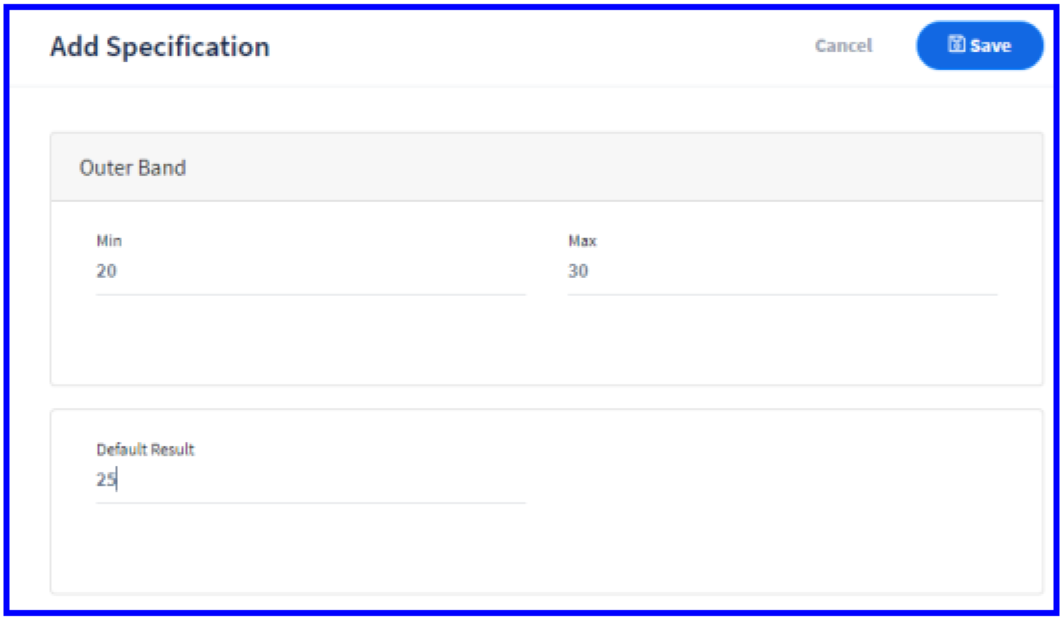


FIGURE: Add Specification Dialog

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:

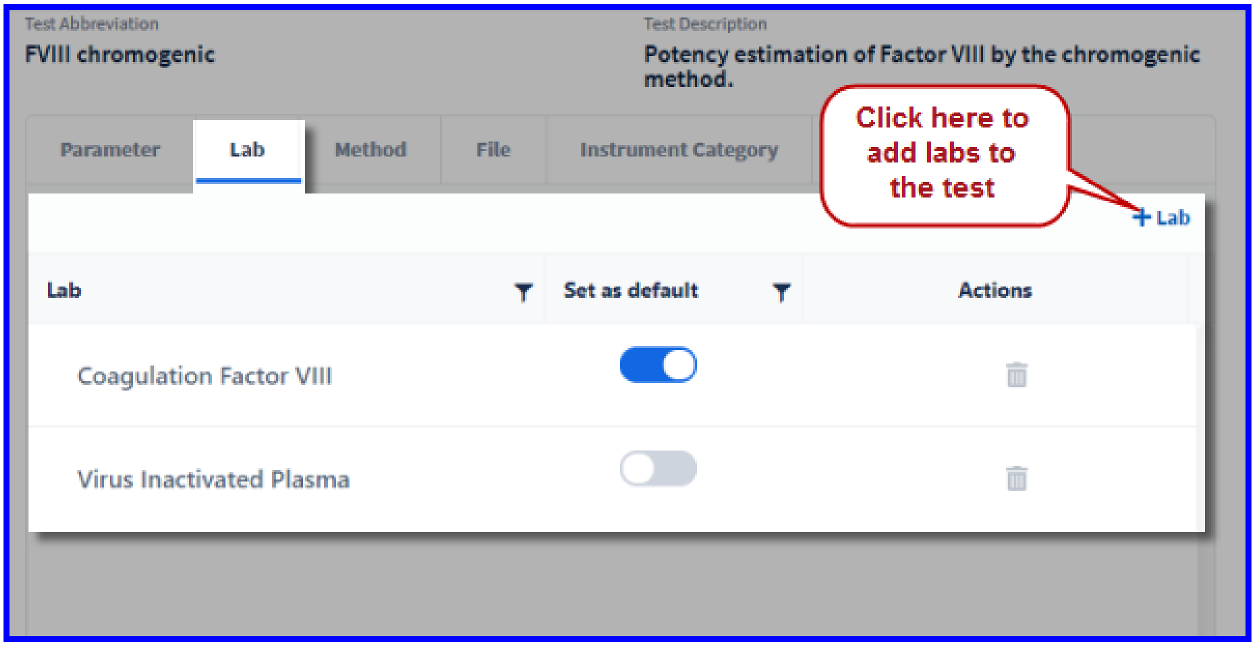


FIGURE: Test master – Lab Tab

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:

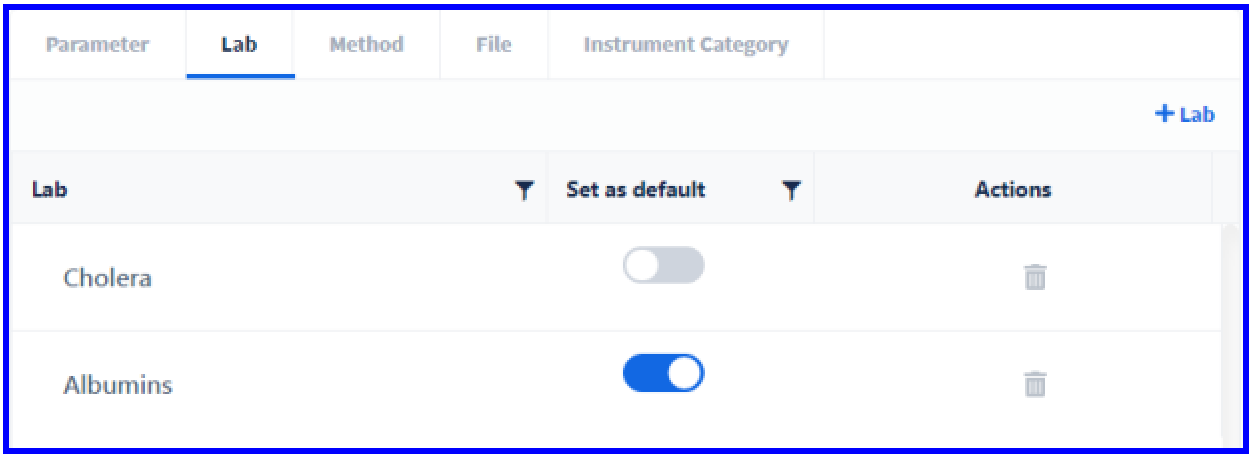


FIGURE: Labs Added to the Selected Test

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 + Method. The **Add Method** screen appears as shown in the figure:

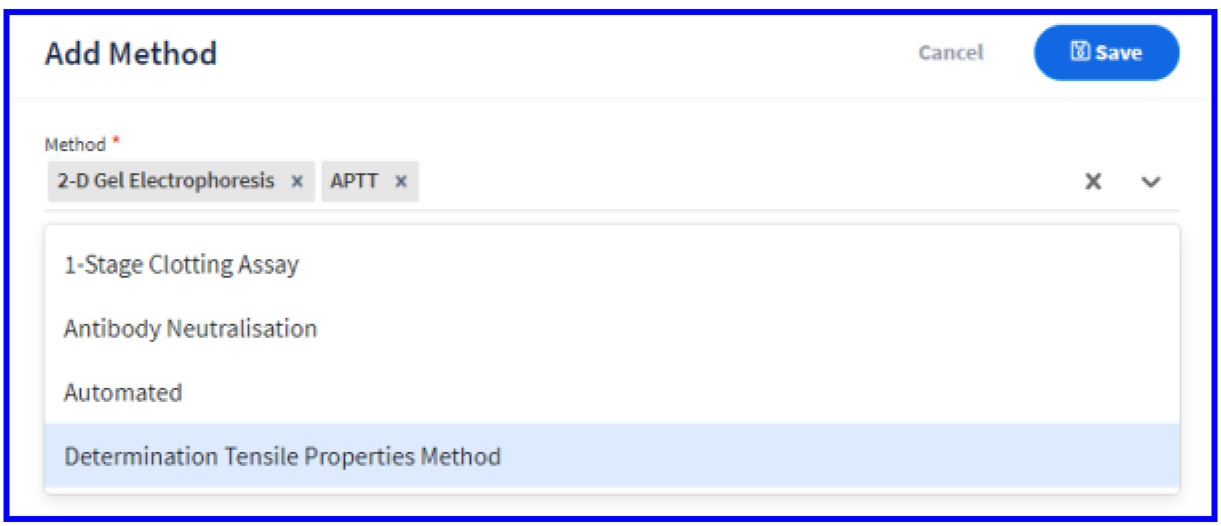


FIGURE: Test master – Add Method Screen

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:

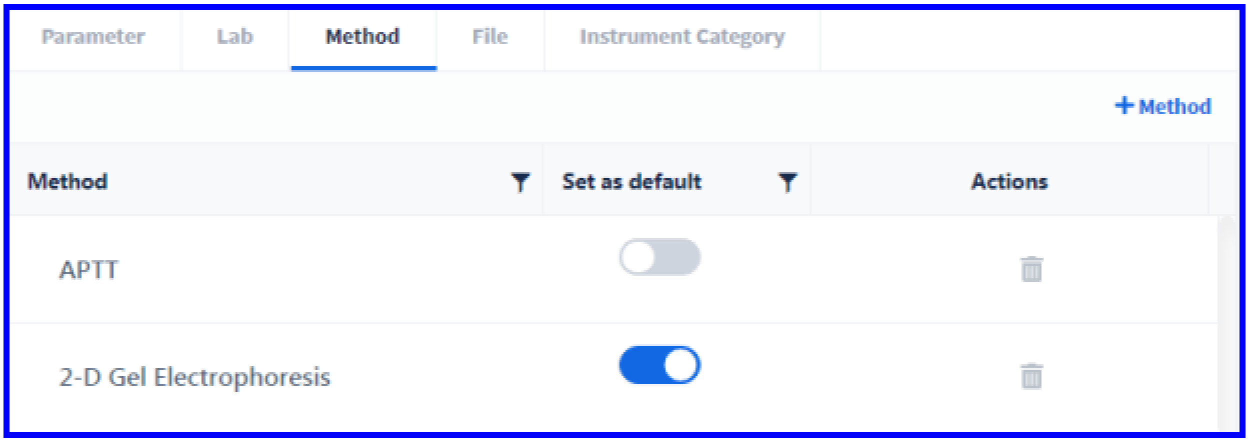


FIGURE: Test master – List of Add Methods Added to the Test

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:

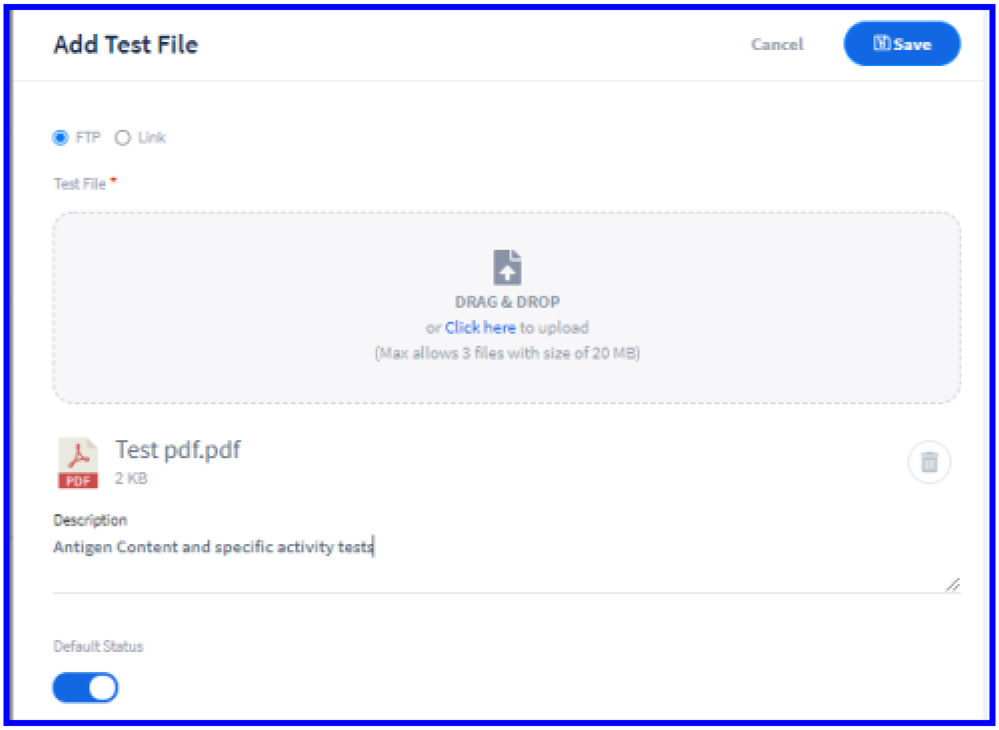


FIGURE: Test master – Add Test File Screen

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:

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:

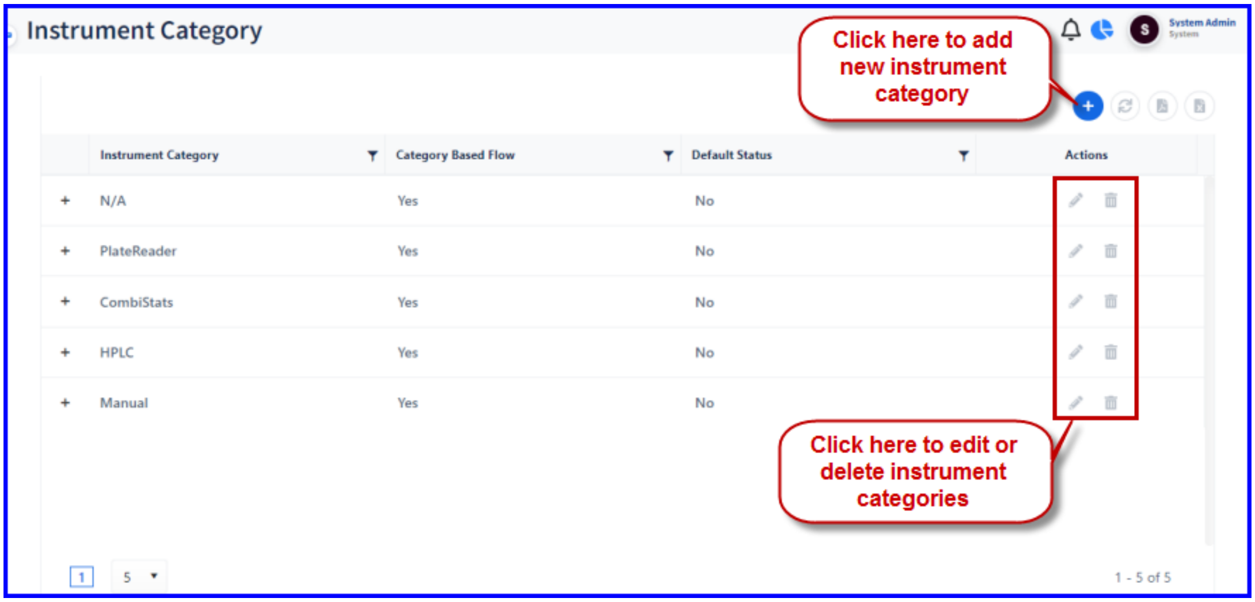


FIGURE: Instrument Category Master Screen

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:

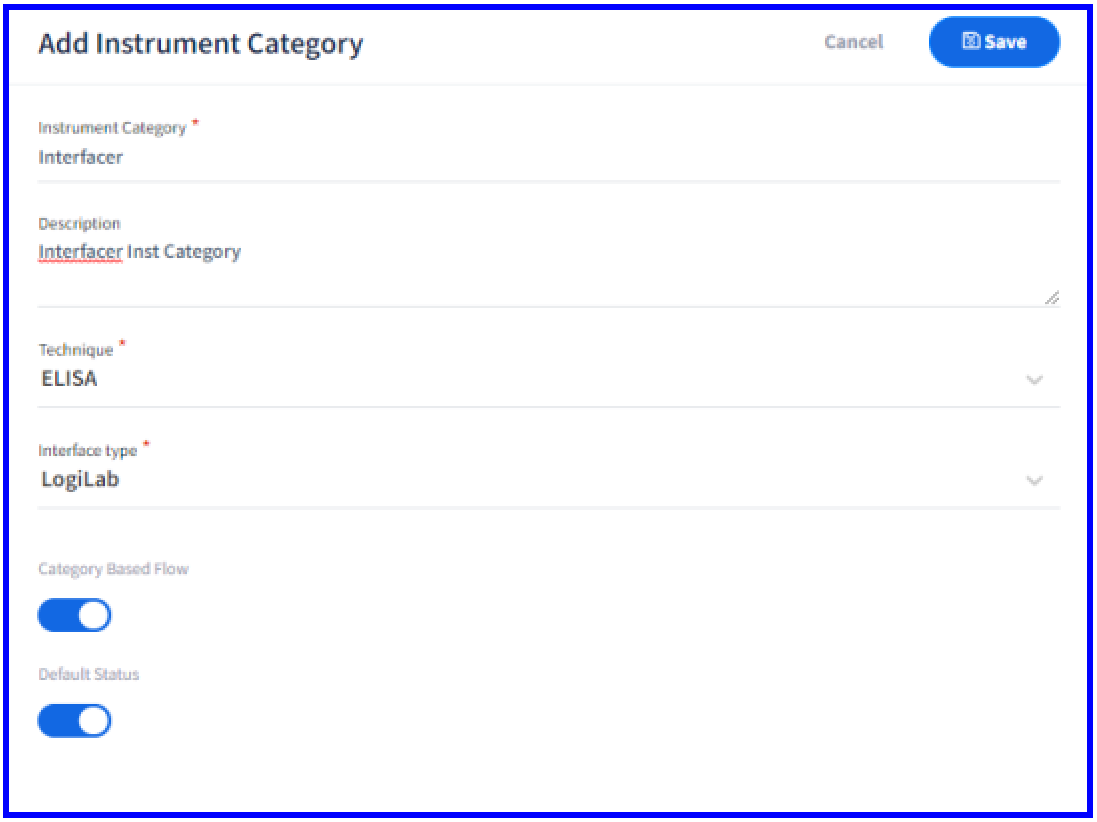


FIGURE: Add Instrument Category Dialog

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:

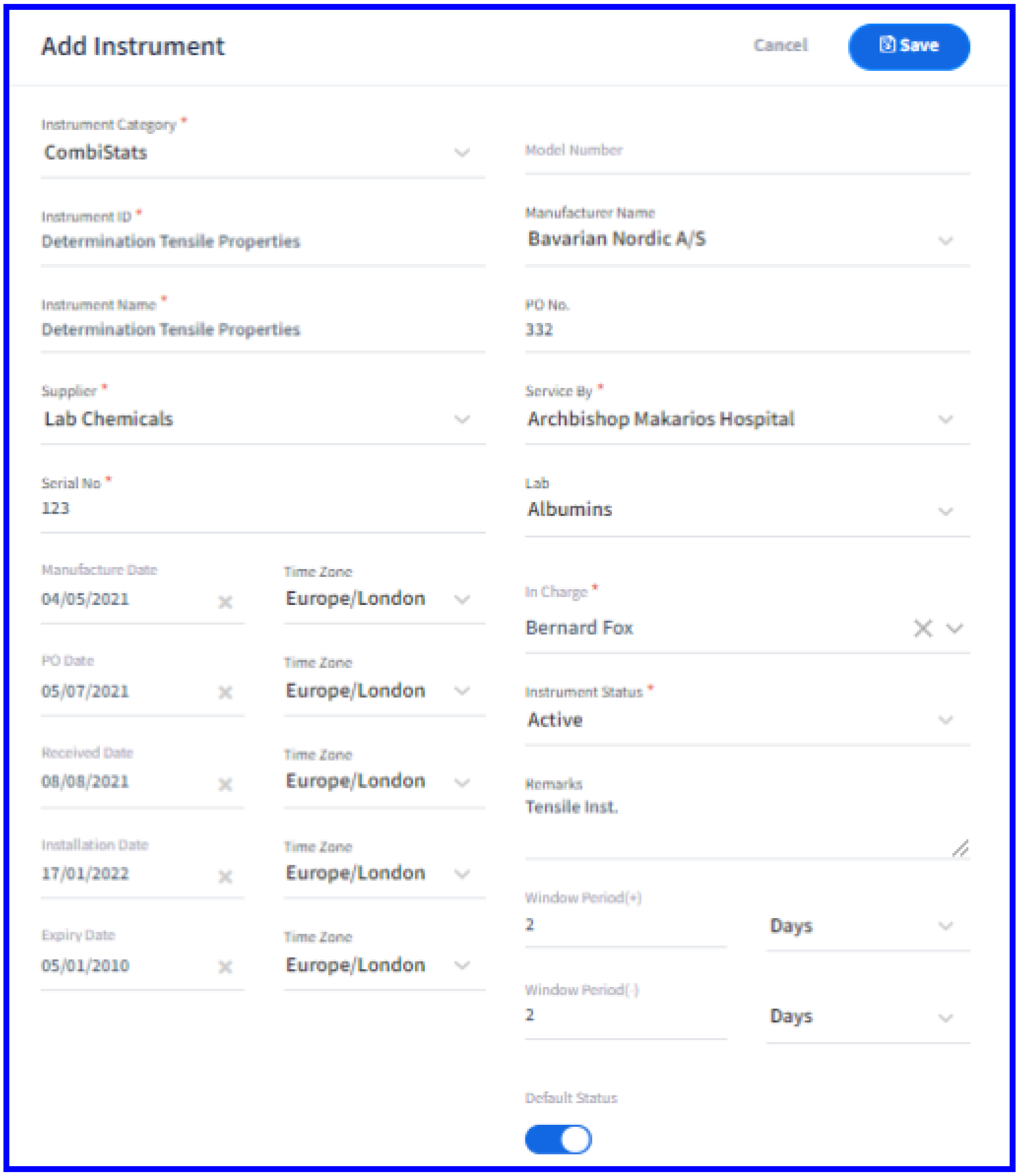


FIGURE: Add Instrument Dialog

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:

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:

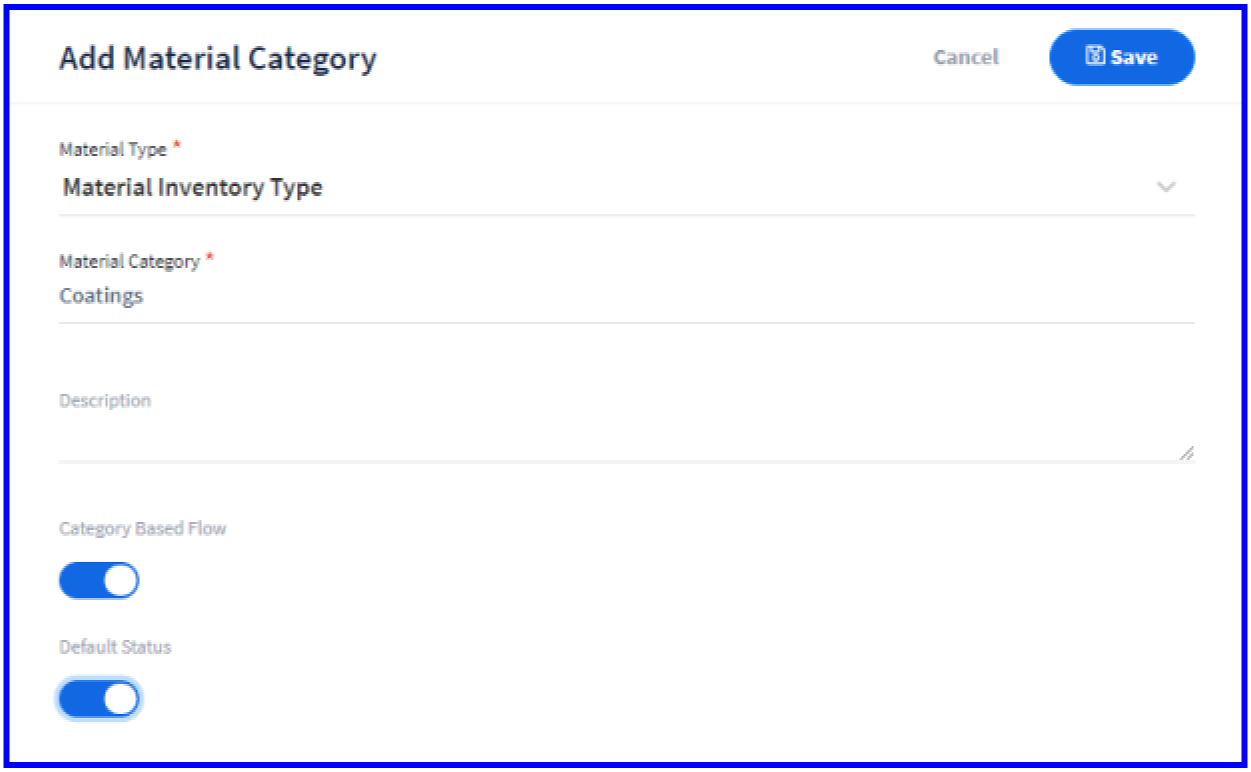


FIGURE: Add Material Category Screen

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:

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:

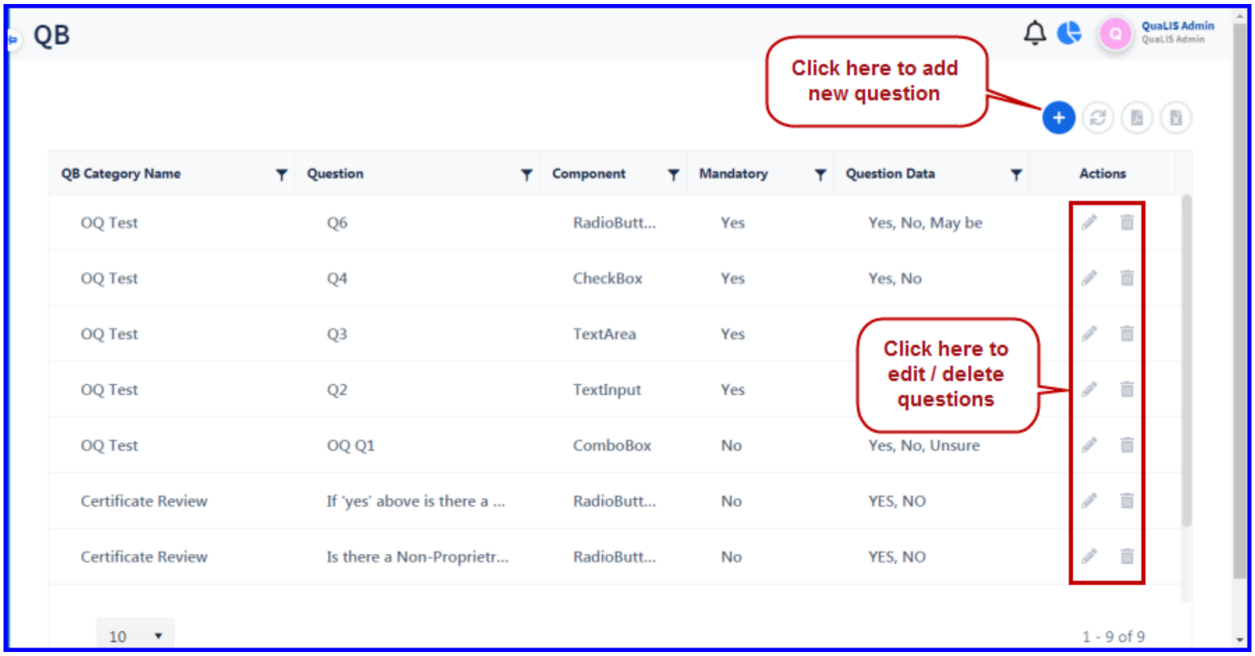


FIGURE: QB Master Screen

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:

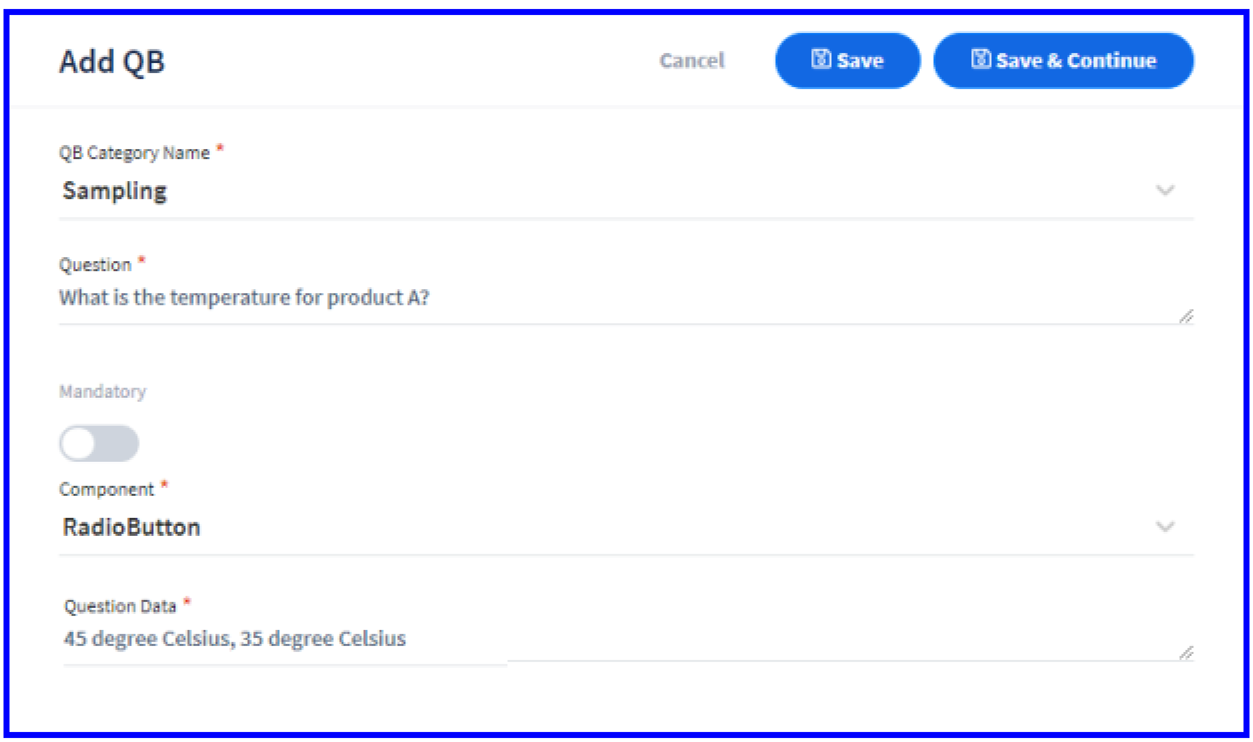


FIGURE: Add Question Screen

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:

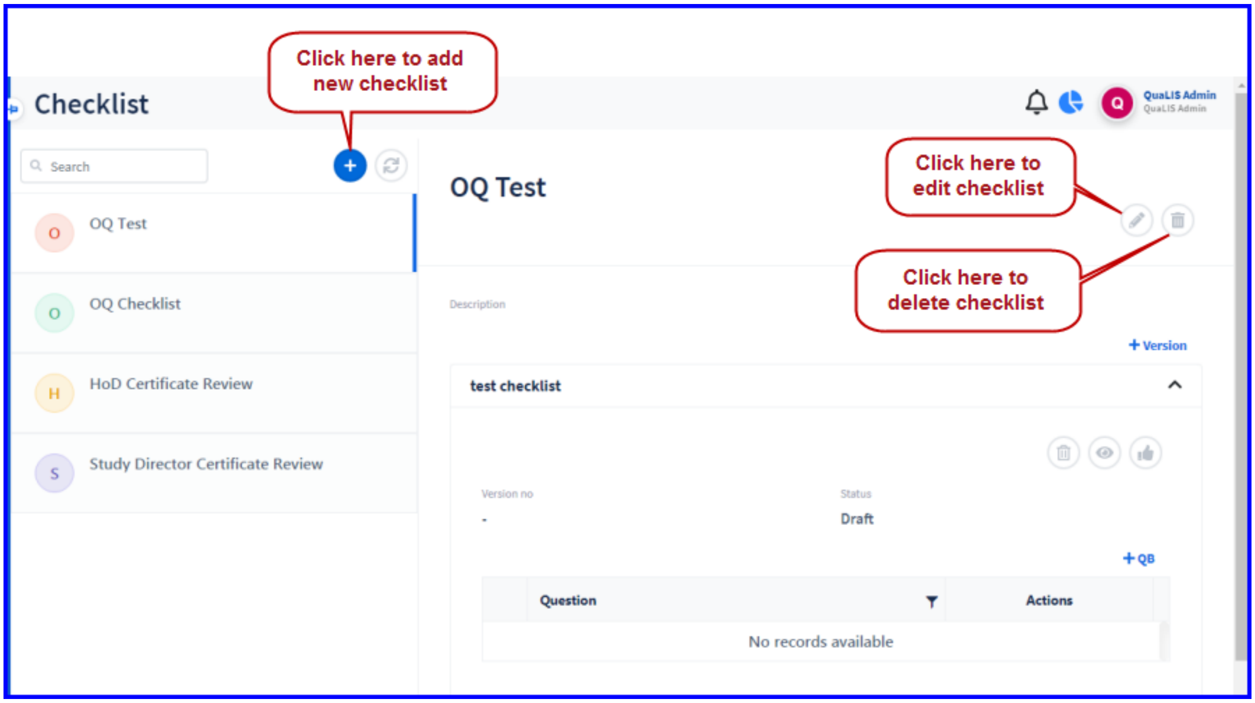


FIGURE: Checklist Master Screen

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:

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:

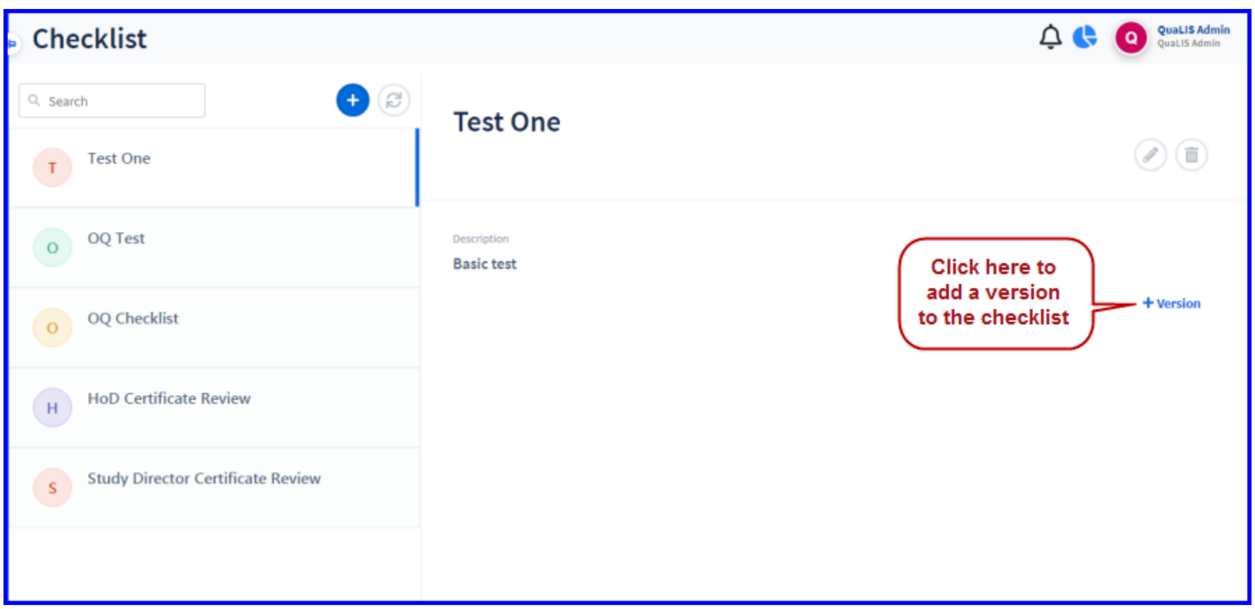


FIGURE: Adding Version to the Checklist

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

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:

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:

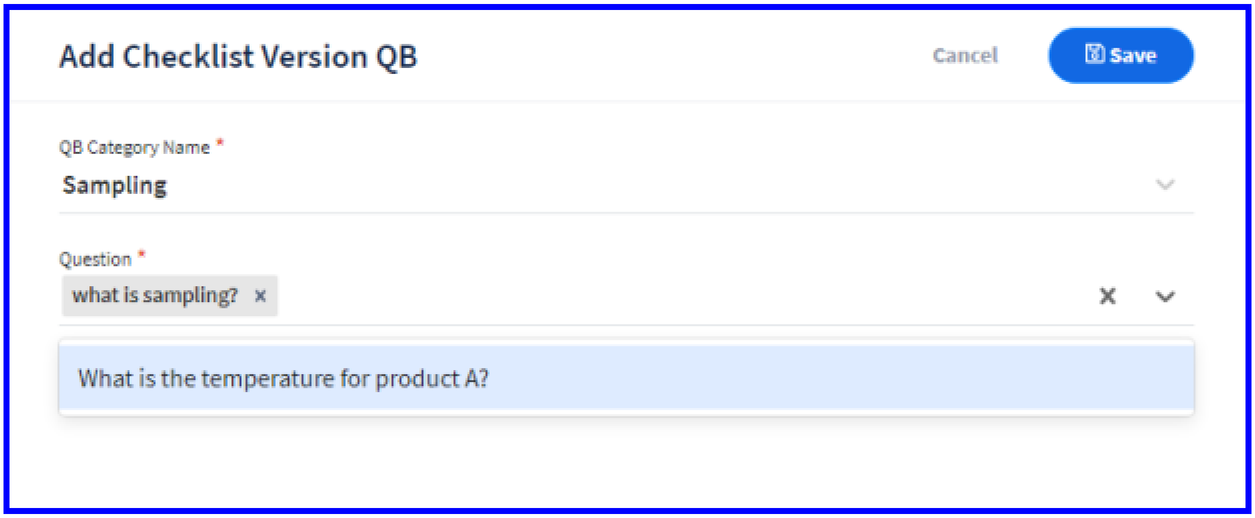


FIGURE: Add Question to Checklist Screen

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:

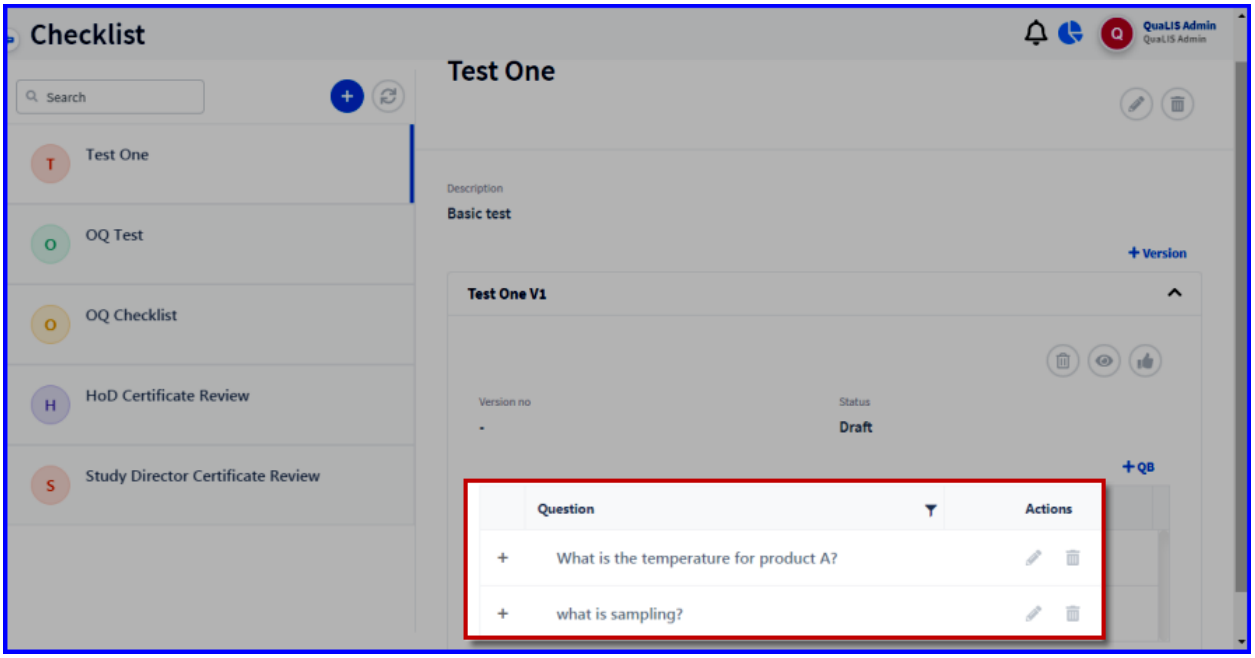


FIGURE: Questions Added to the Checklist Version

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:

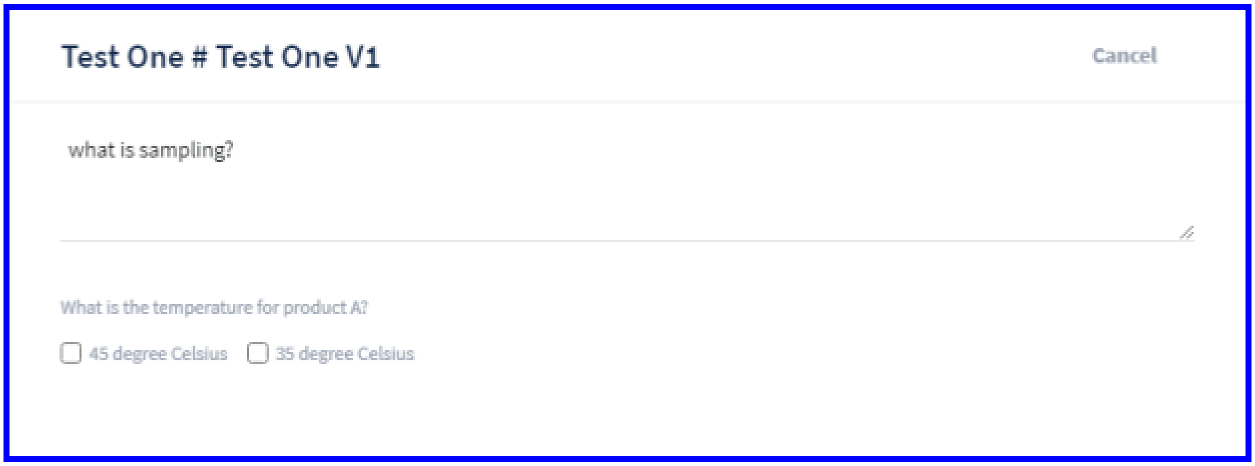


FIGURE: View Checklist Items

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:

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.

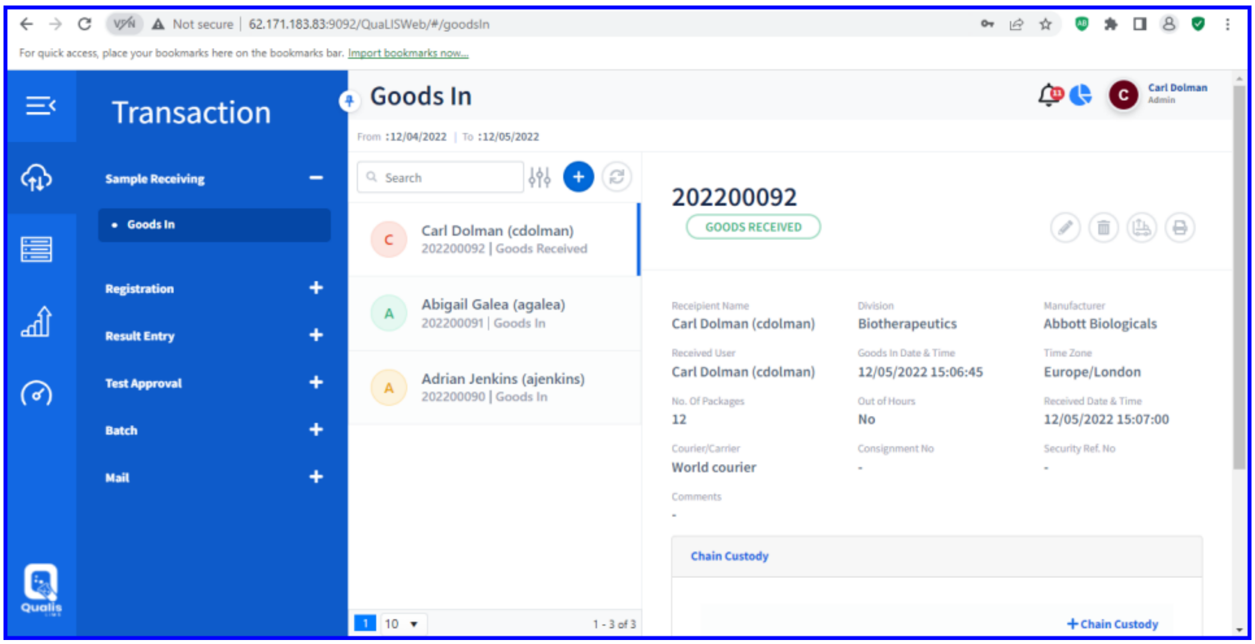
4 Transactions

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:

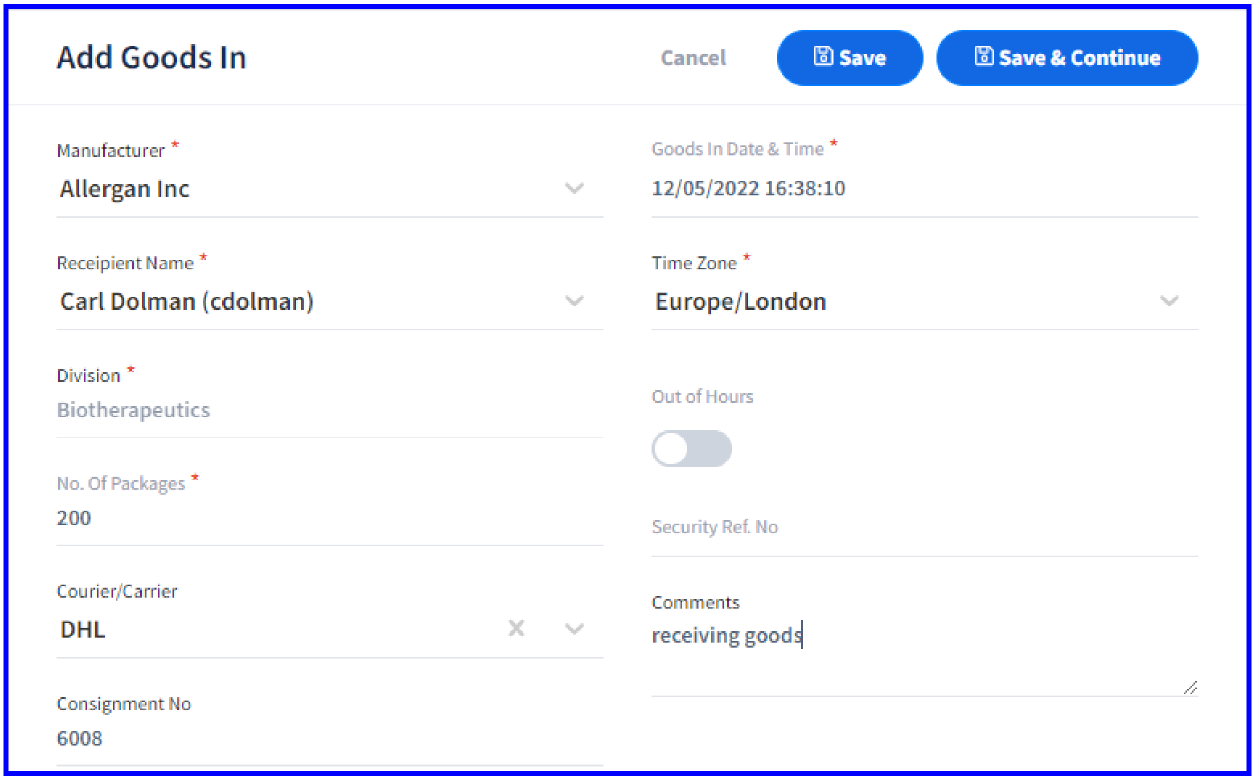
1. On the main menu, click **Transaction**, **Sample Receiving** and then click **Goods In**. The **Goods In** screen appears as shown in the figure:



Goods In Screen

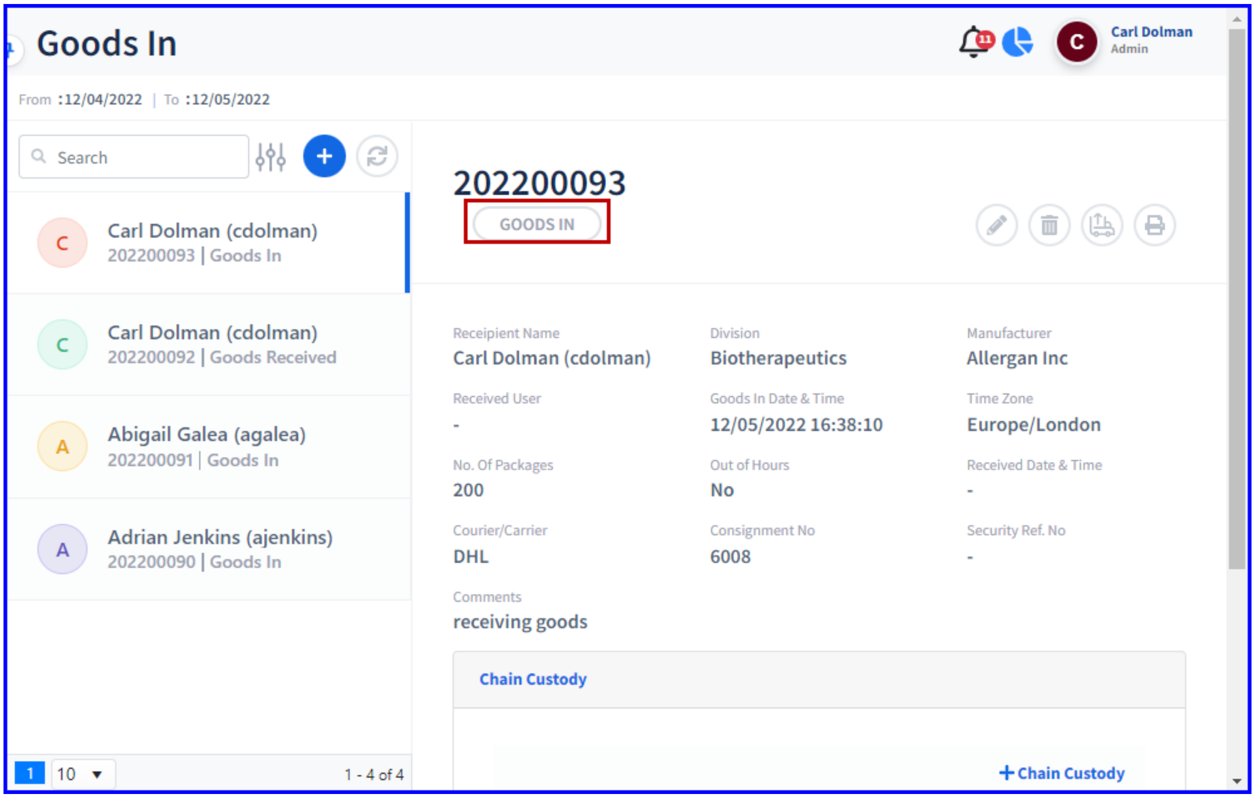
To add goods details, follow these steps:

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



Add Goods In Screen

3. In the **Manufacturer Name** field, type the manufacturer of the goods.
4. In t he **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:



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:

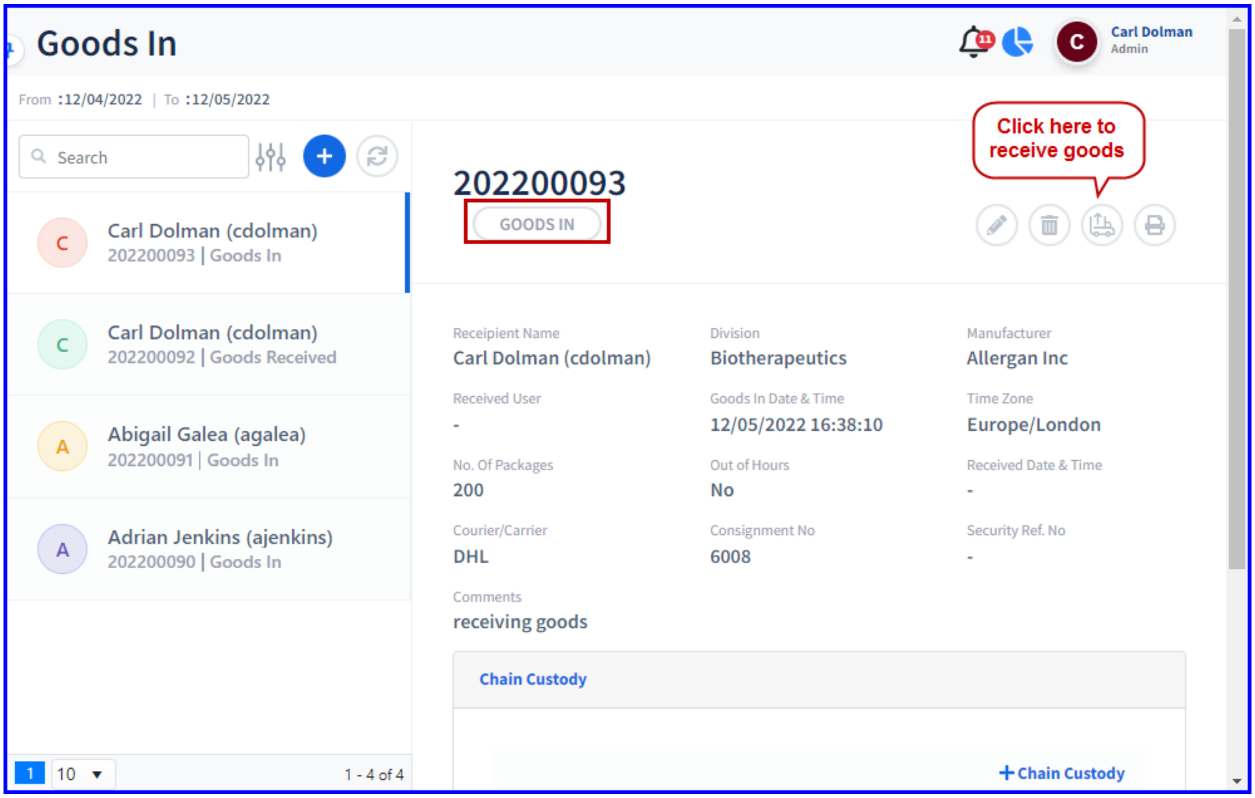


FIGURE: Receiving Goods

The status will turn to **GOODS RECEIVED** as shown in the figure:

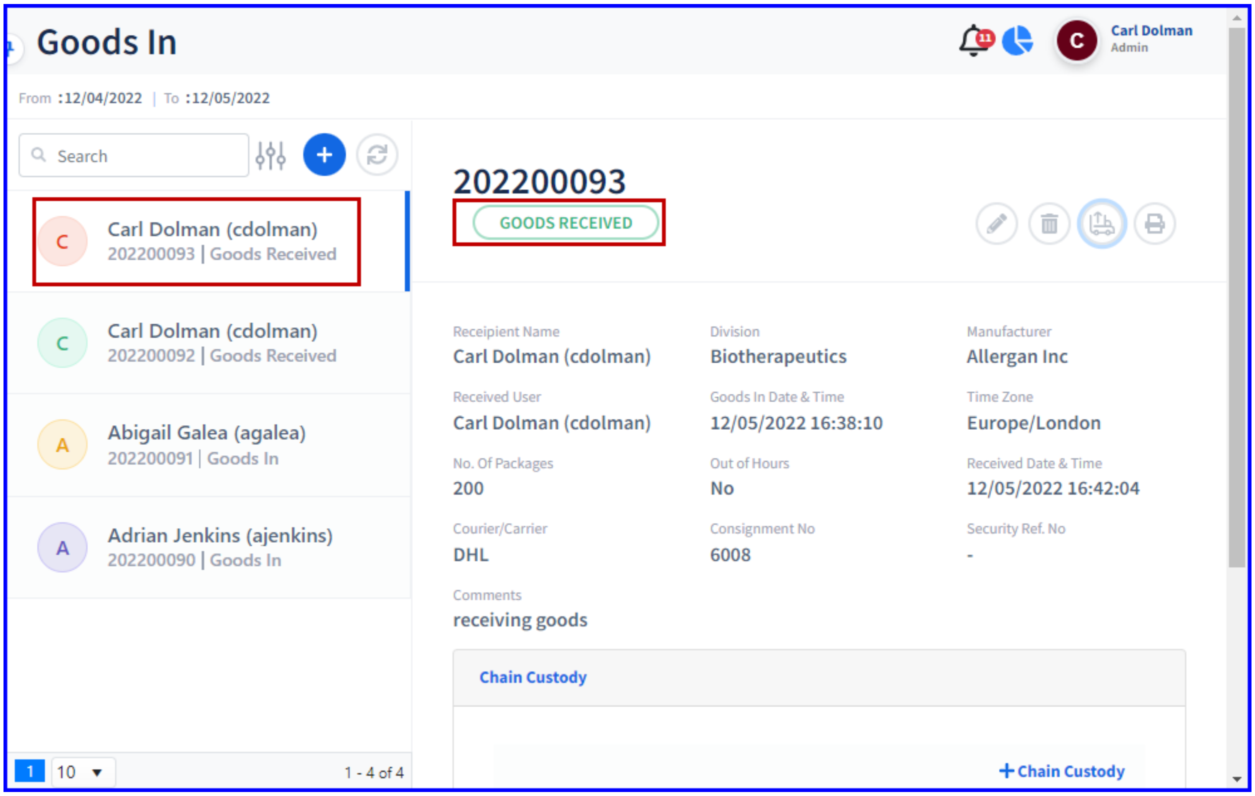


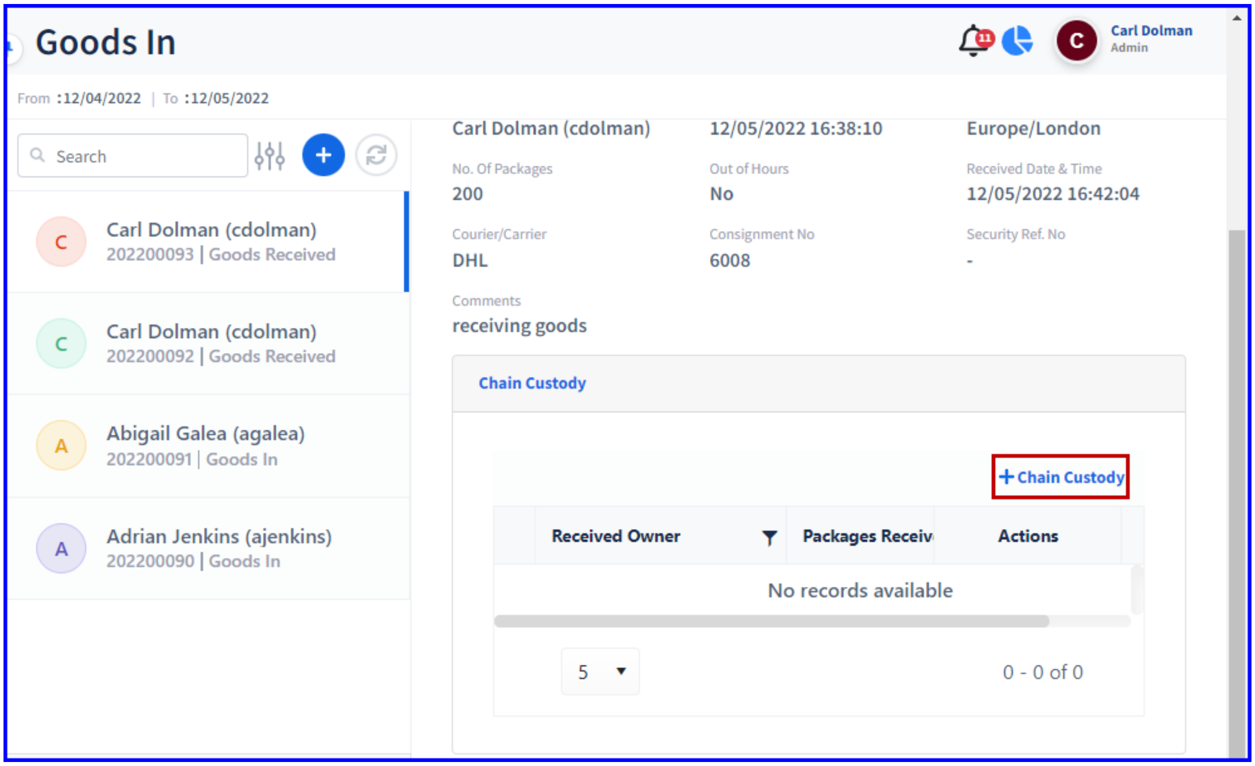
FIGURE: Record in GOODS RECEIVED State

4.1.3 Chain Custody

The Chain Custody option in the Goods In screen enables the user to split and receive goods in storage.

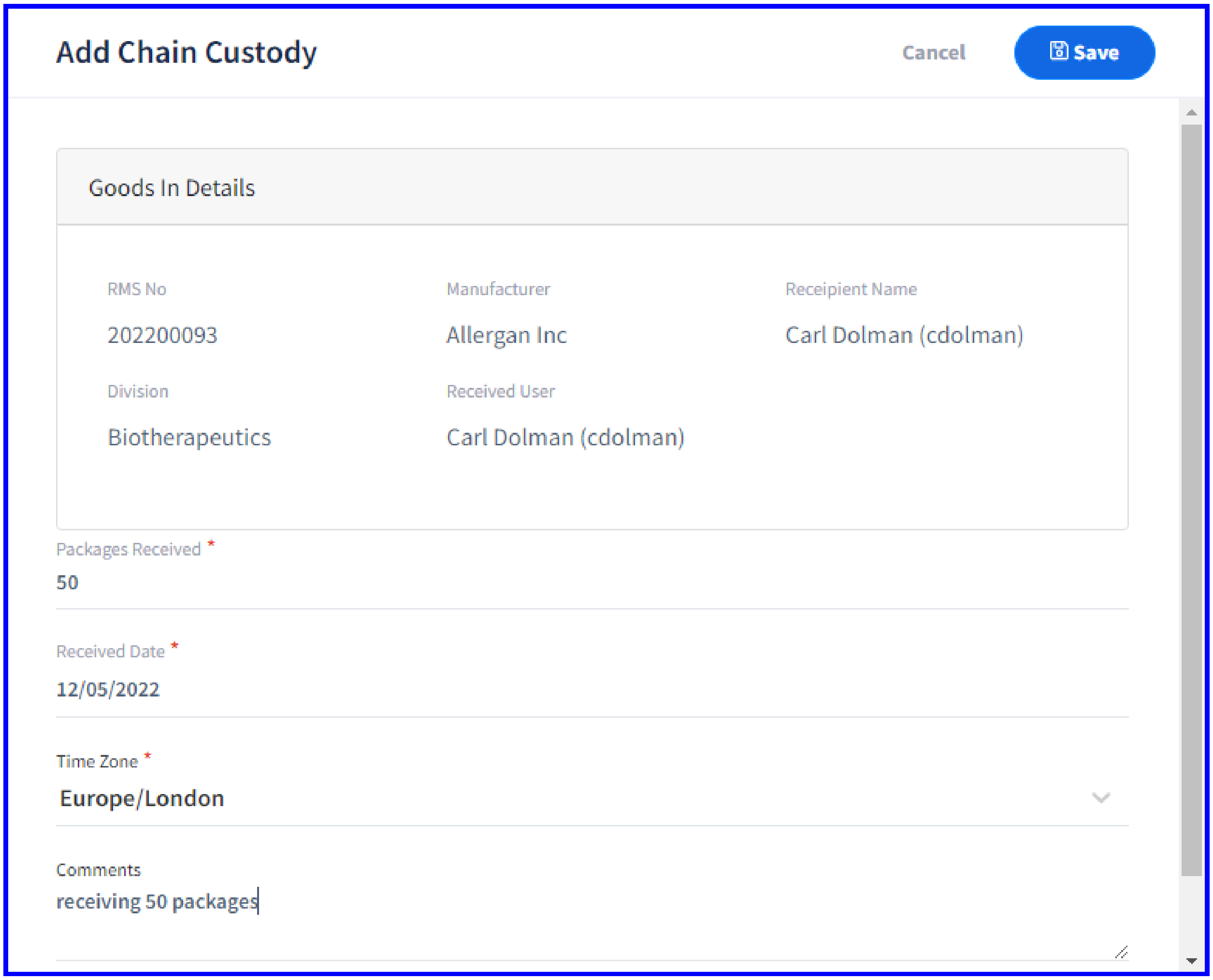
To receive goods in storage, follow these steps:

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:



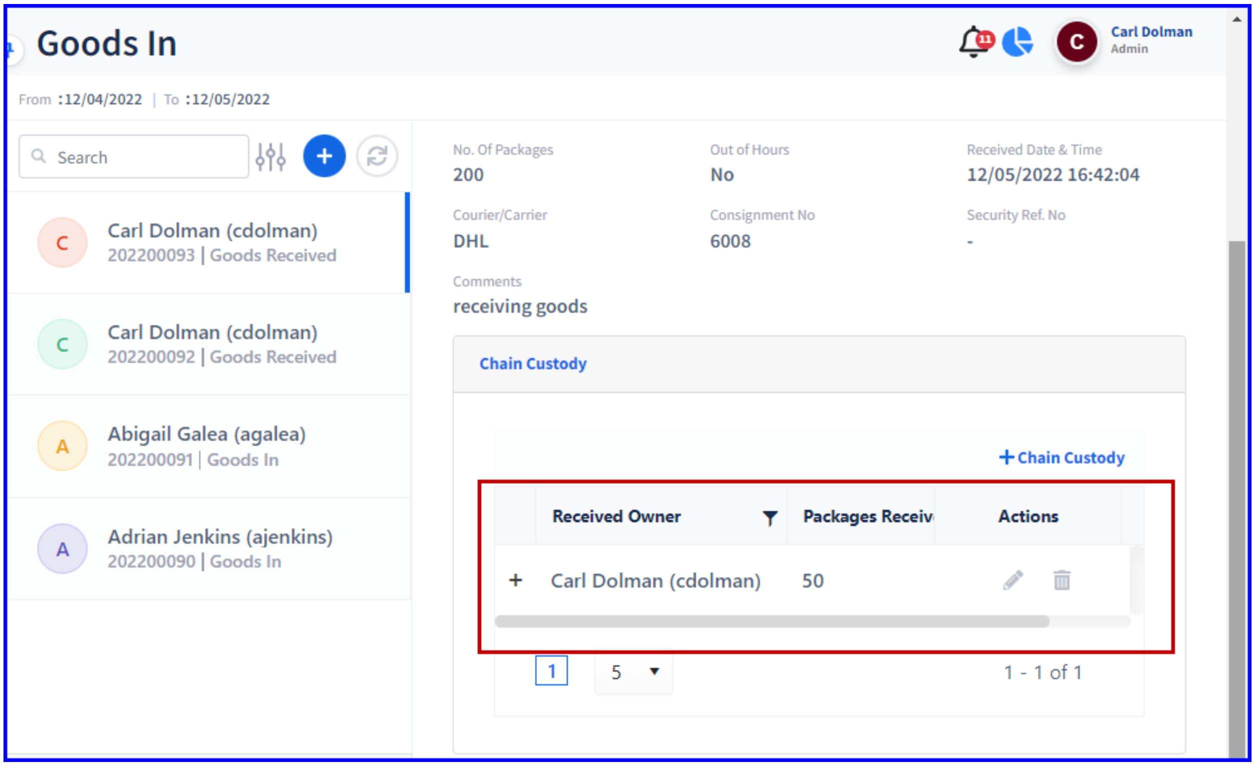
Chain custody Option

The **Add Chain Custody** dialog appears as shown in the figure:



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:



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:

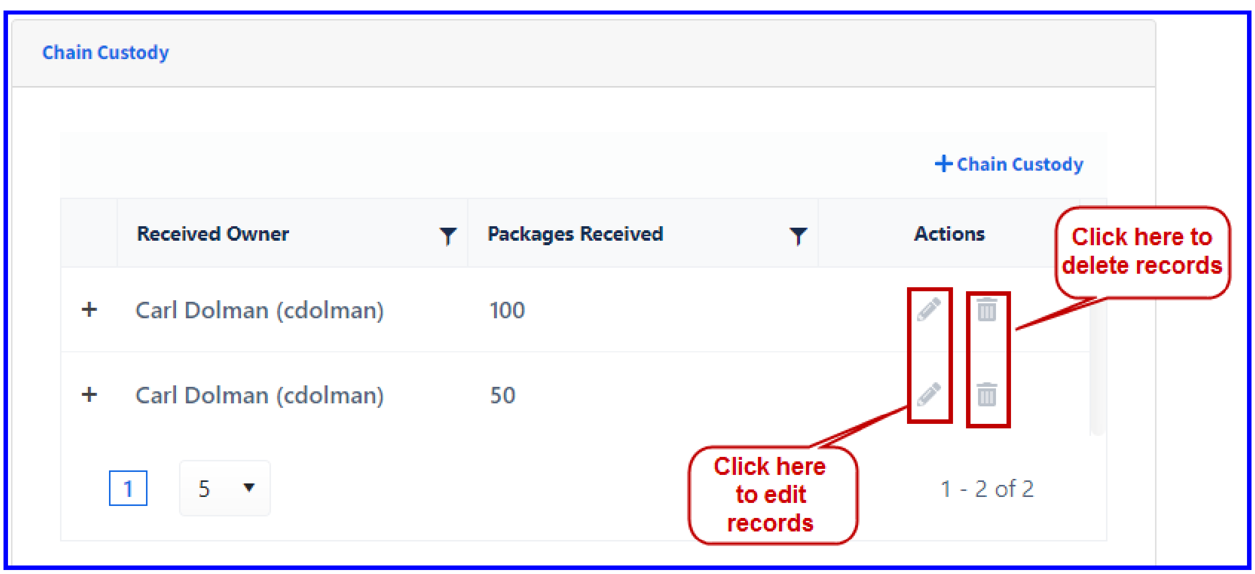


FIGURE: Edit and Delete Options for Chain Custody Records

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:

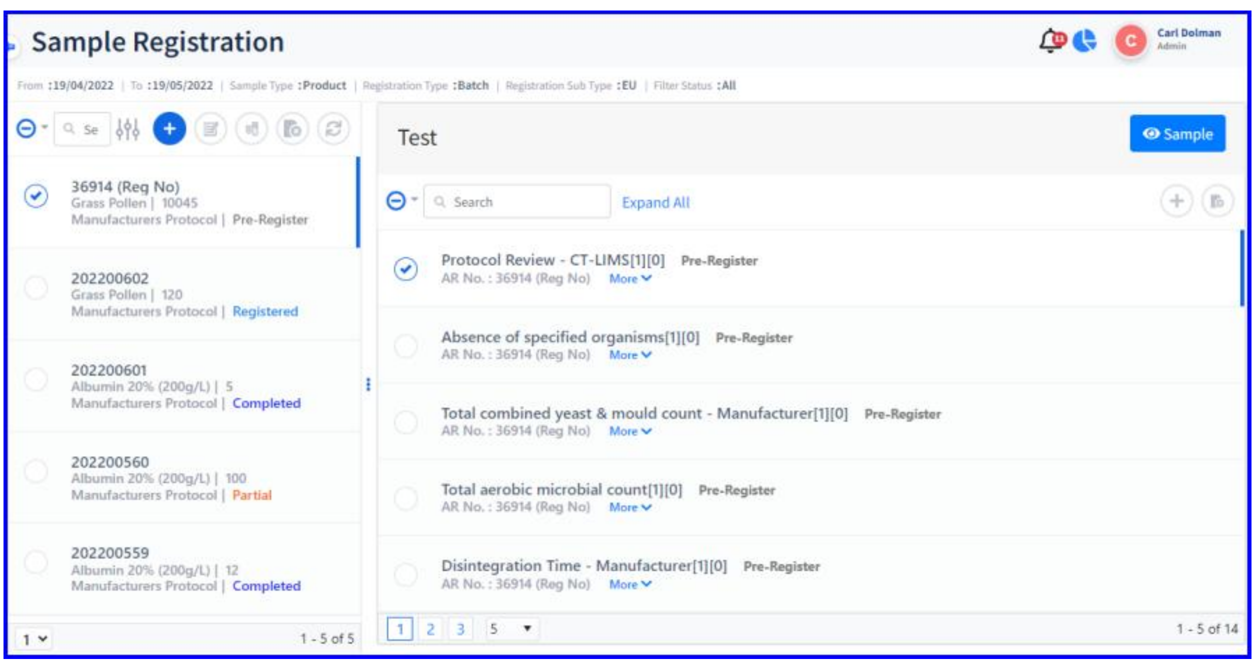


FIGURE: Sample Registration Screen

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:

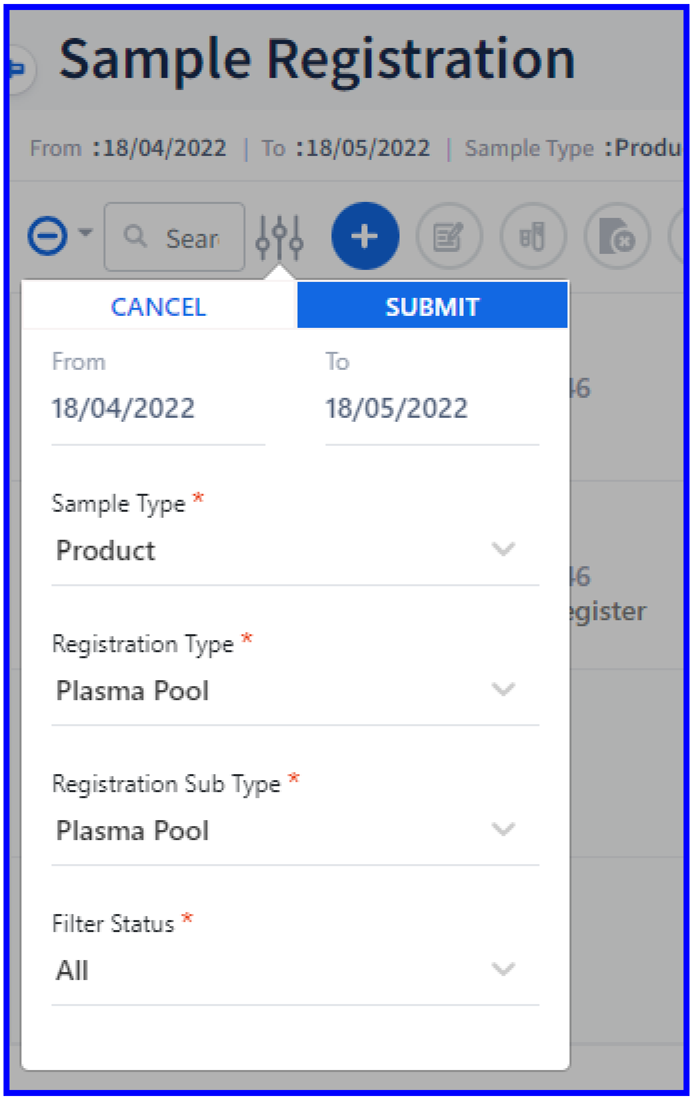
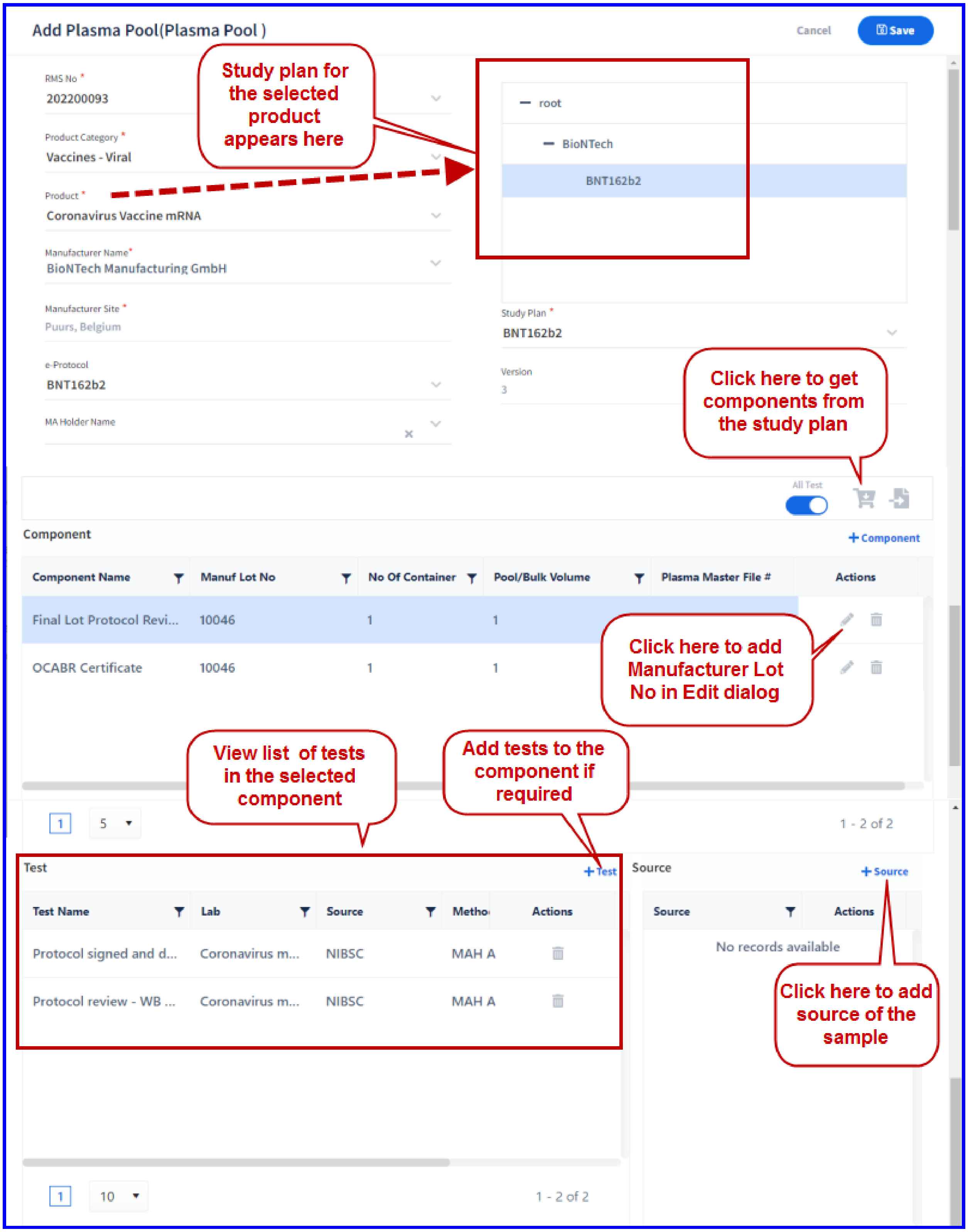


FIGURE: Using Filter in Registration Screen

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:



Registration Add Screen

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:

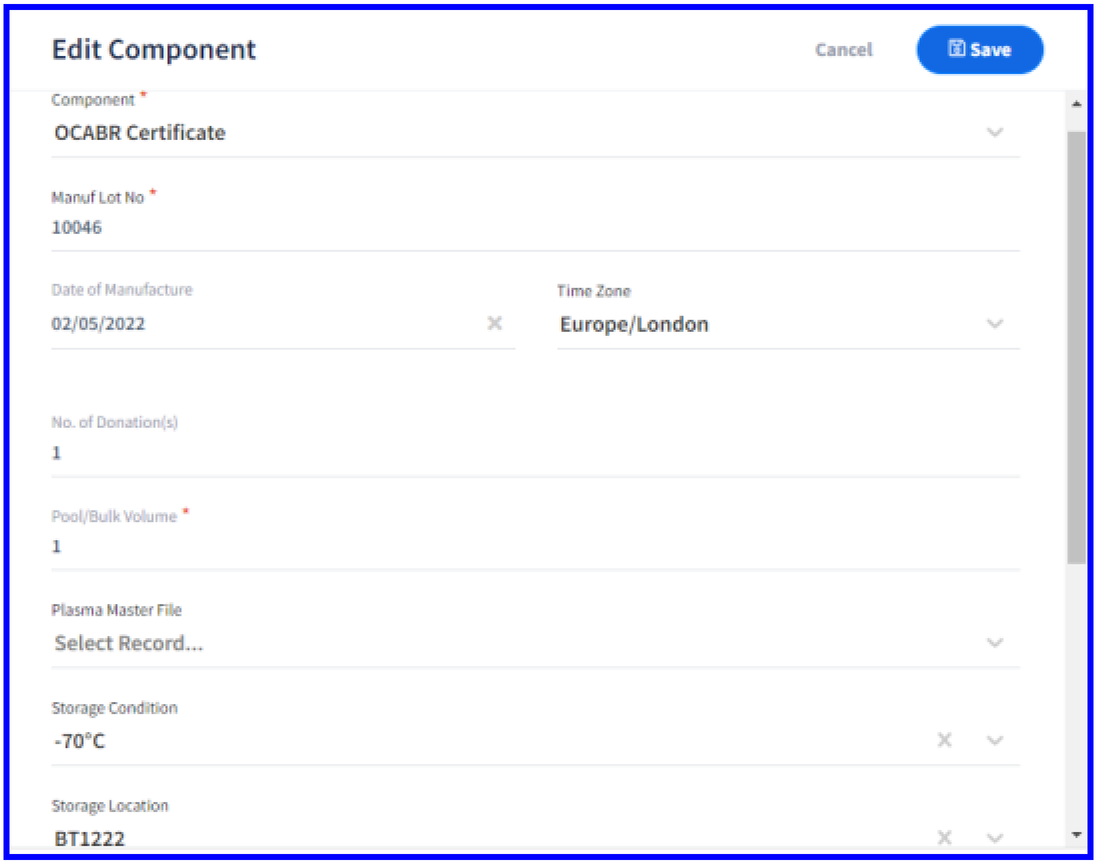


FIGURE: Edit Component Dialog

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:

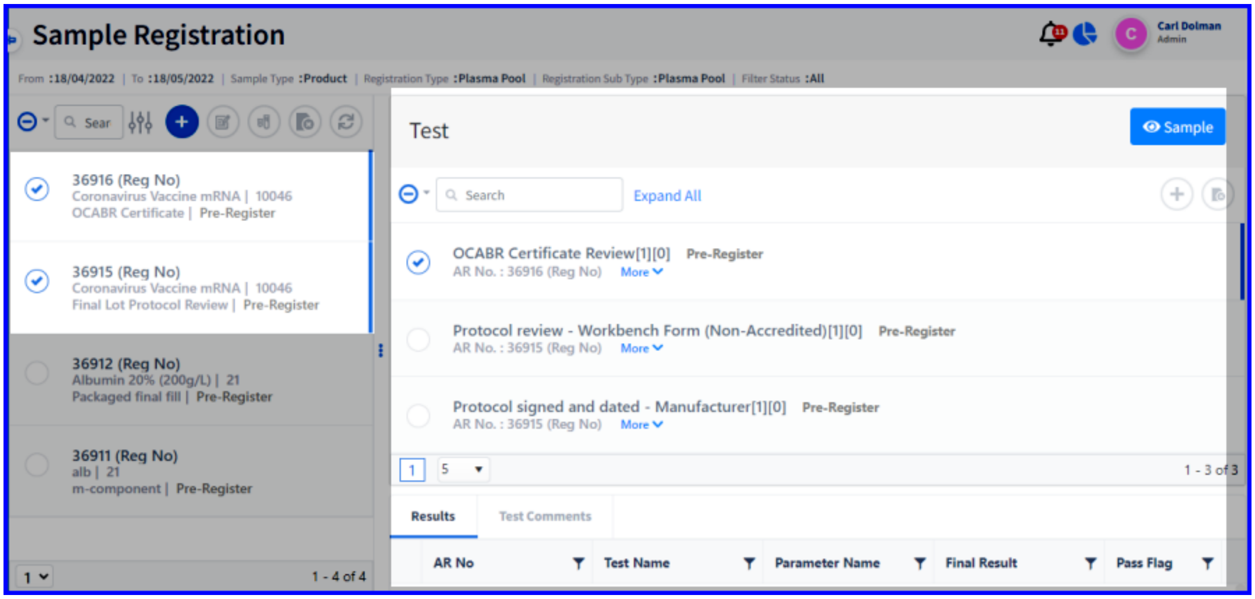


FIGURE: Registered Sample

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:

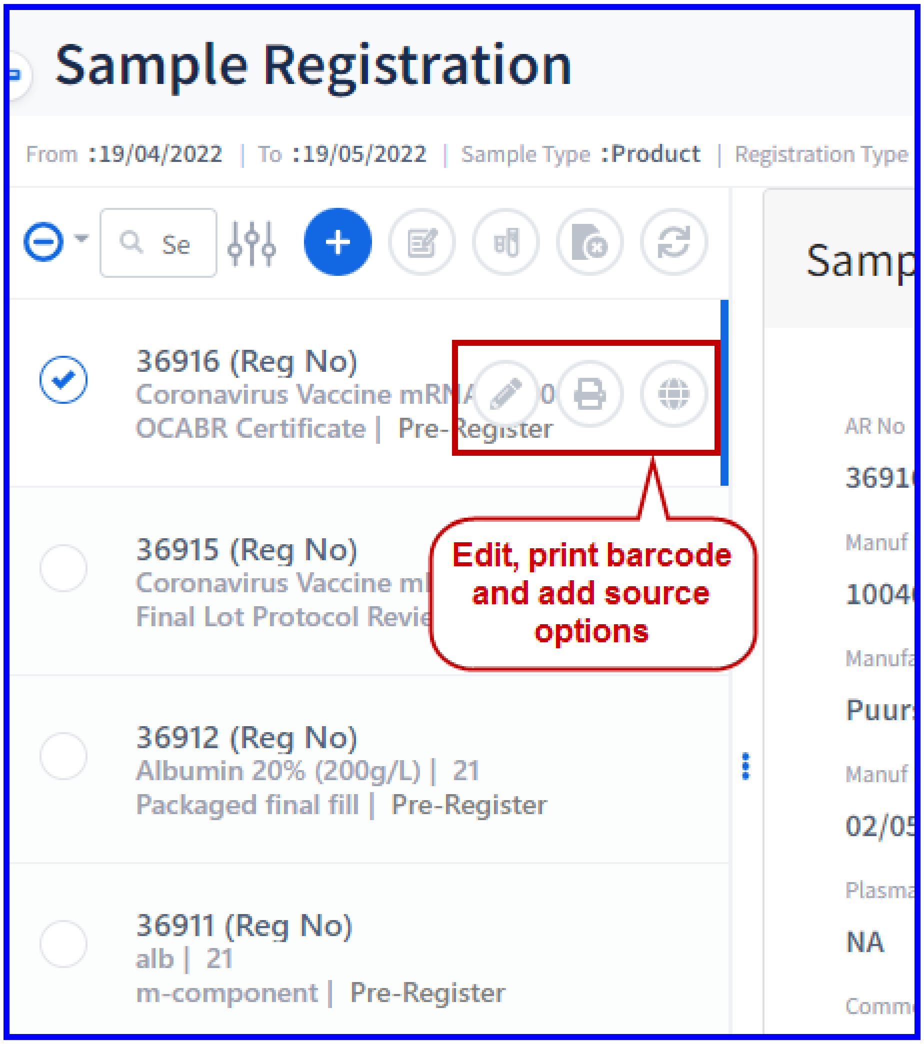


FIGURE: Registered Sample Showing Edit, Print Barcode and Add Source Options

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:

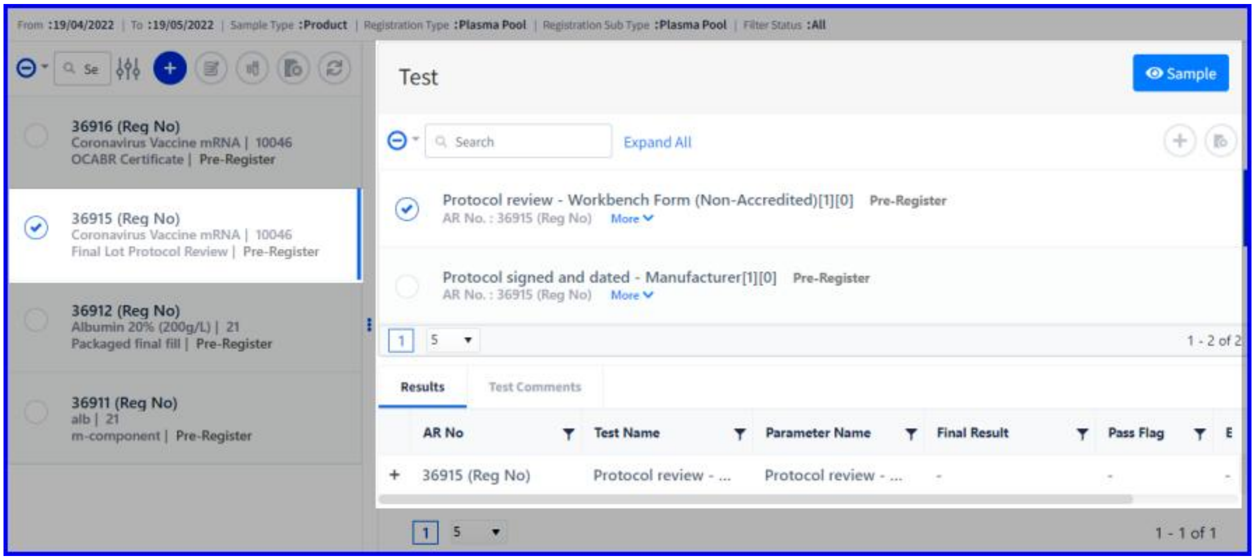


FIGURE: Viewing Tests Added to the Sample

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 Sample to view sample details. The sample details appear as shown in the figure:

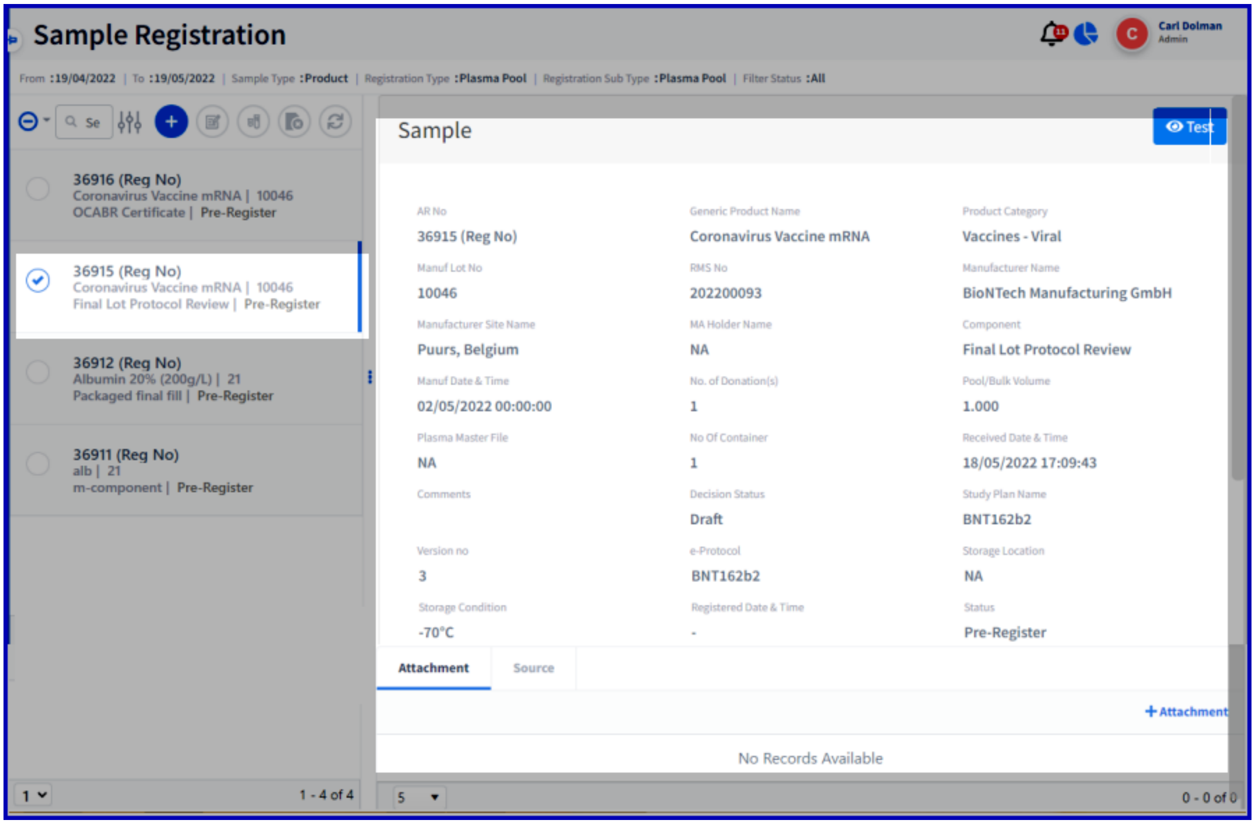


FIGURE: Viewing Sample Details

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:

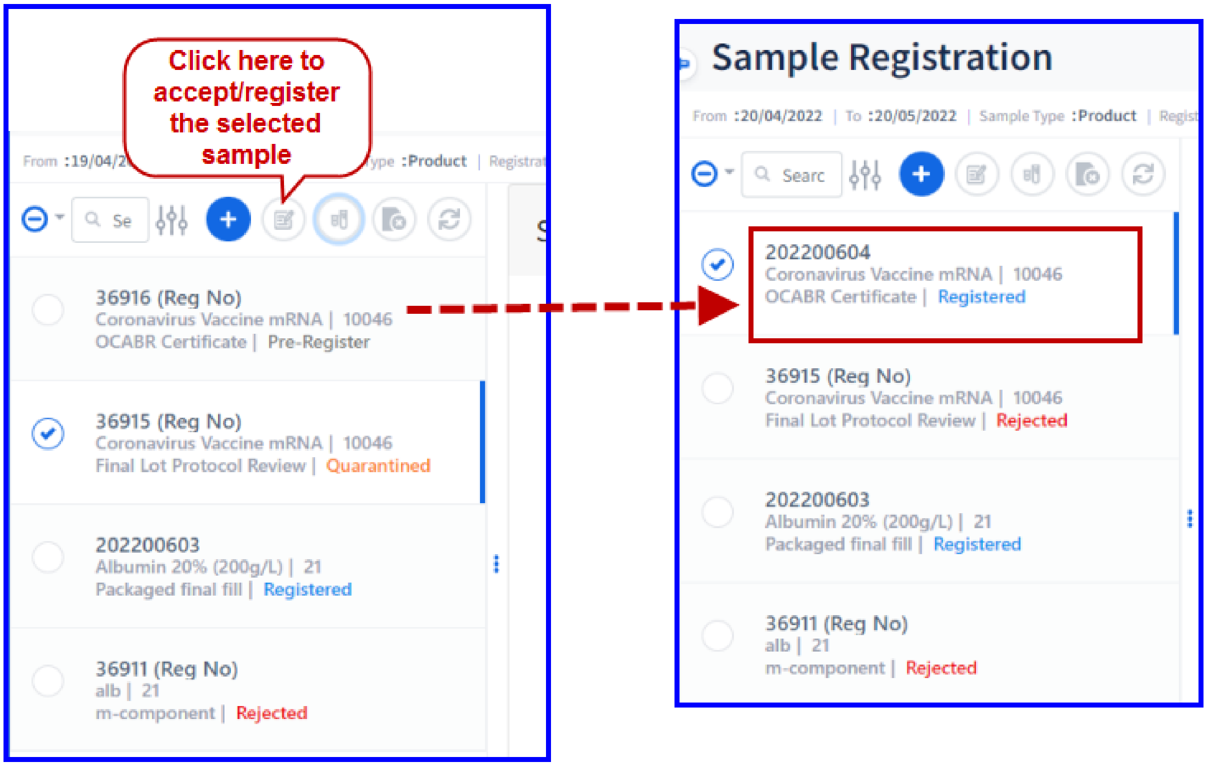


FIGURE: Accepting Sample

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:

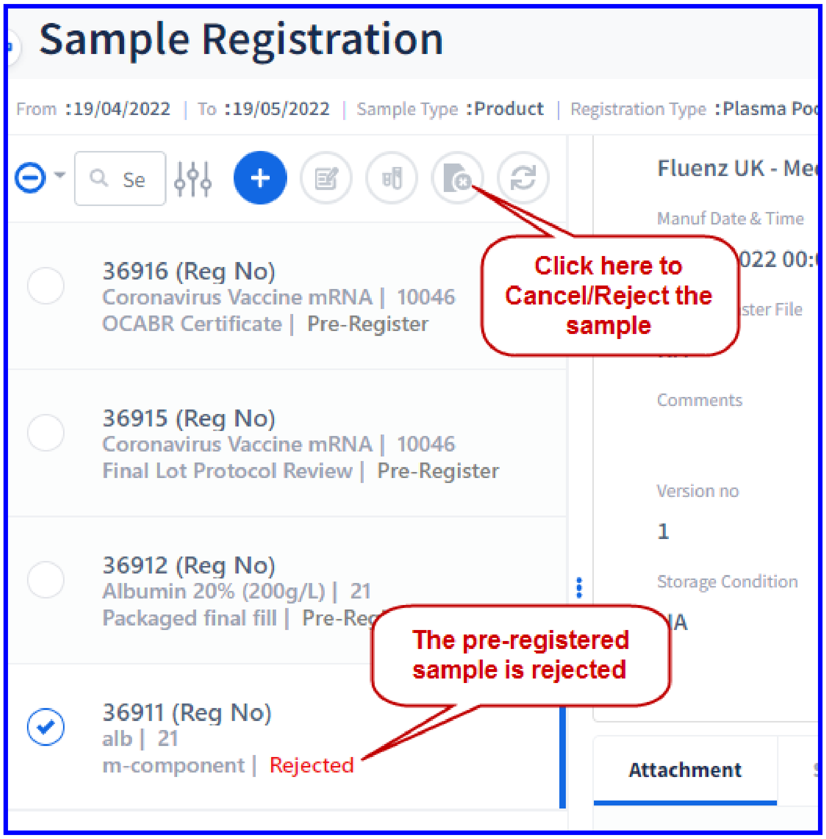


FIGURE: Cancel / Reject Sample

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:

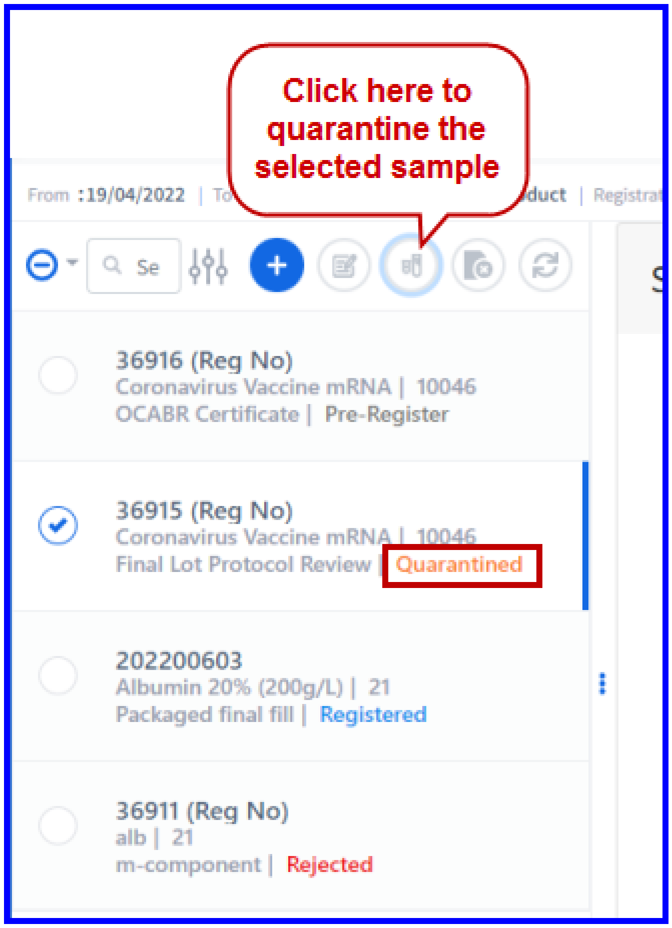


FIGURE: Quarantine Sample

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:

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:

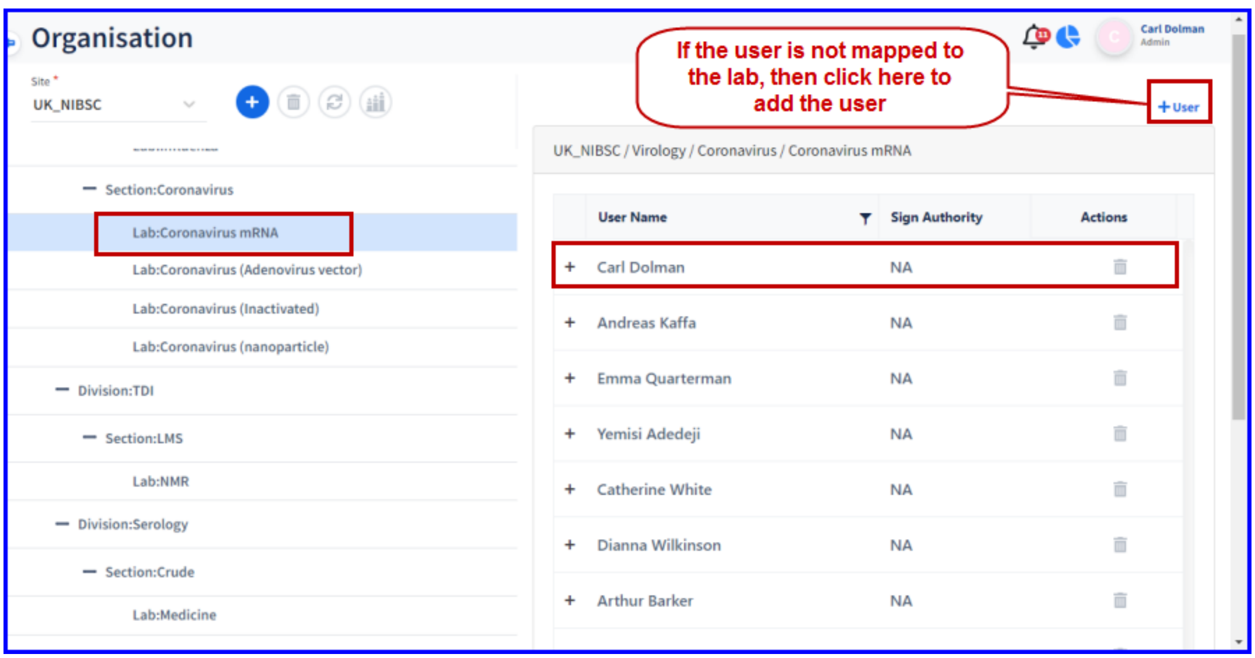


FIGURE: Organisation Screen Showing User Mapped to the Test Lab

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:

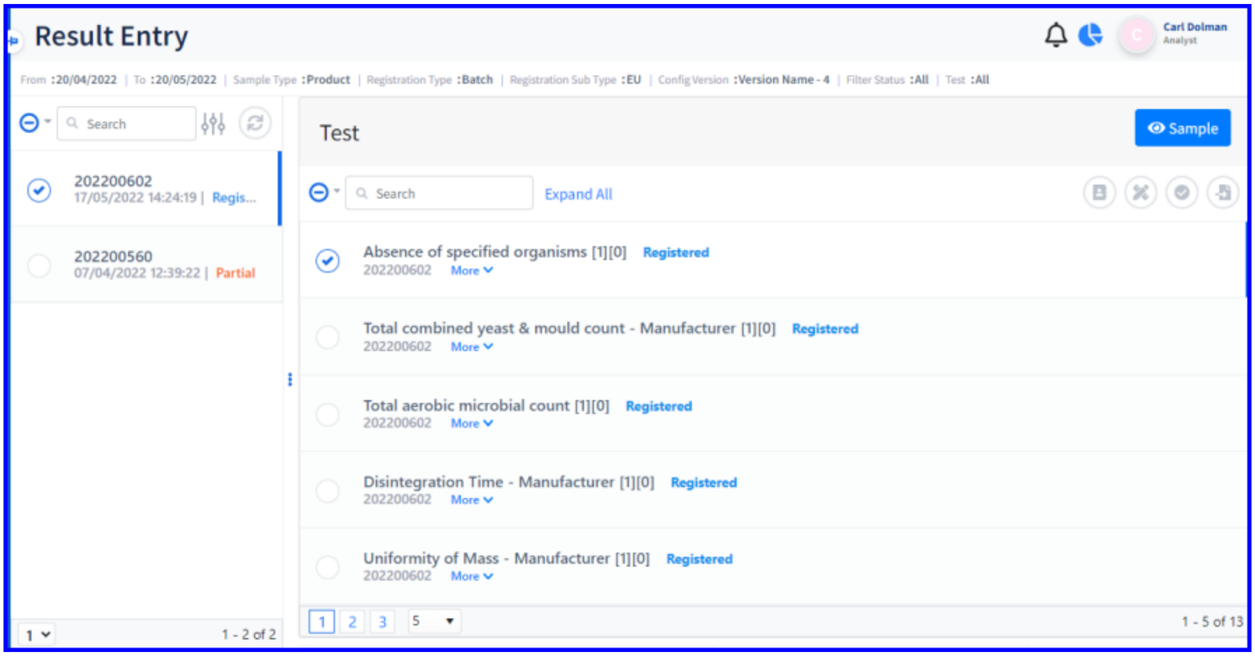


FIGURE: Result Entry Screen

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:

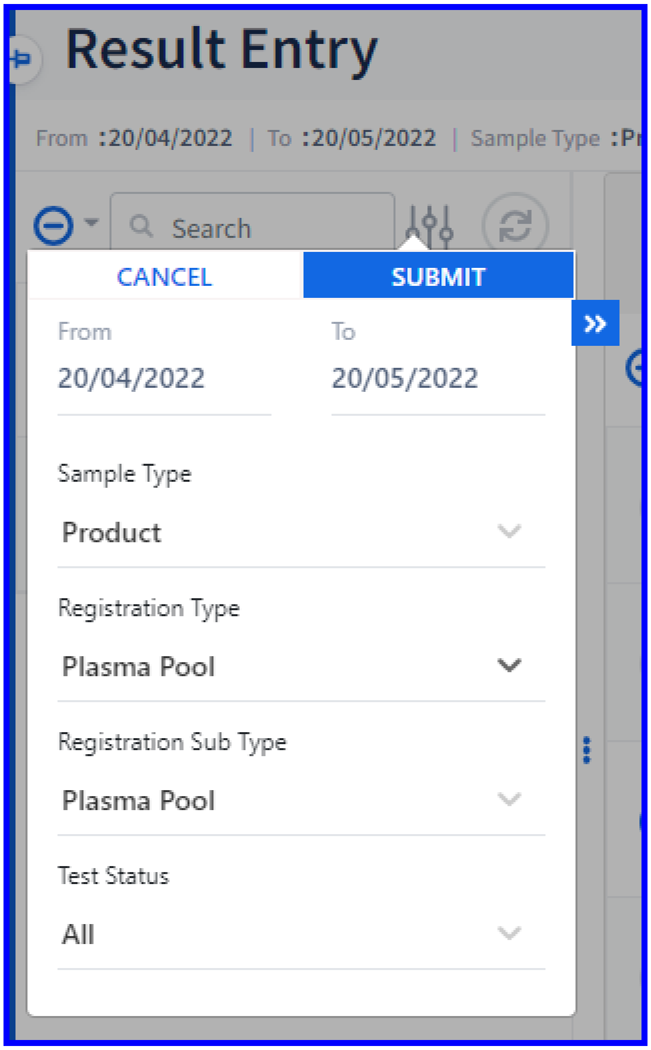


FIGURE: Using Filter in Result Entry Screen

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:

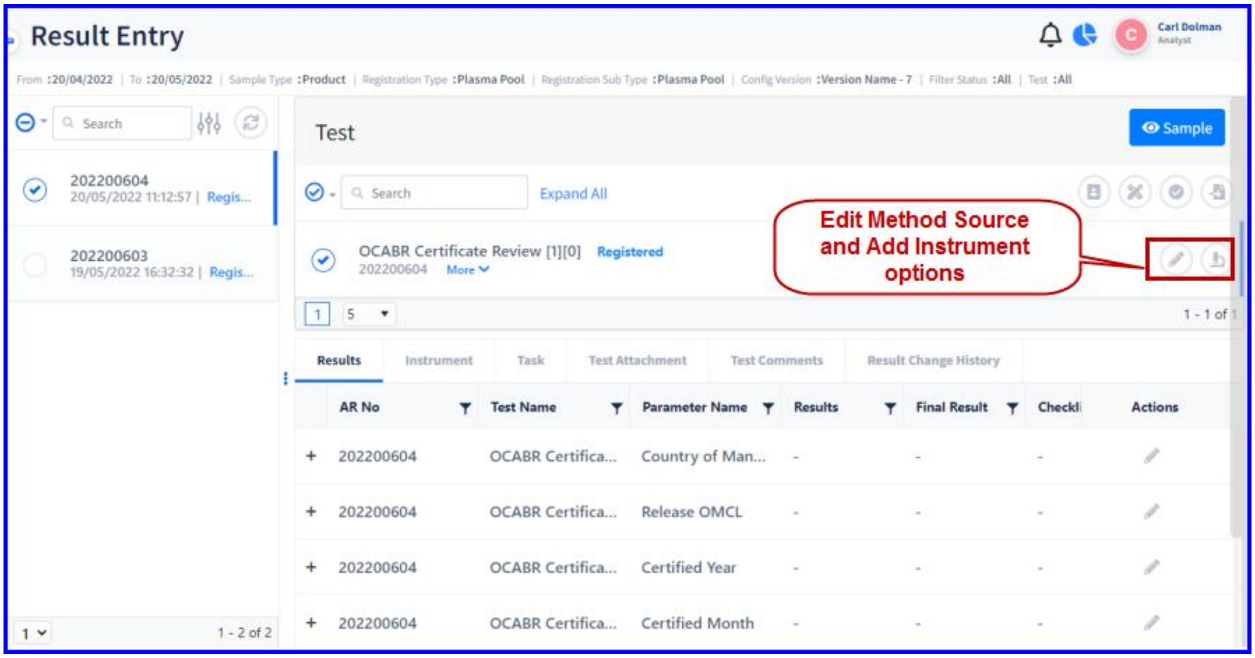


FIGURE: Result Entry Screen Showing Registered Sample and the List of Tests

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:

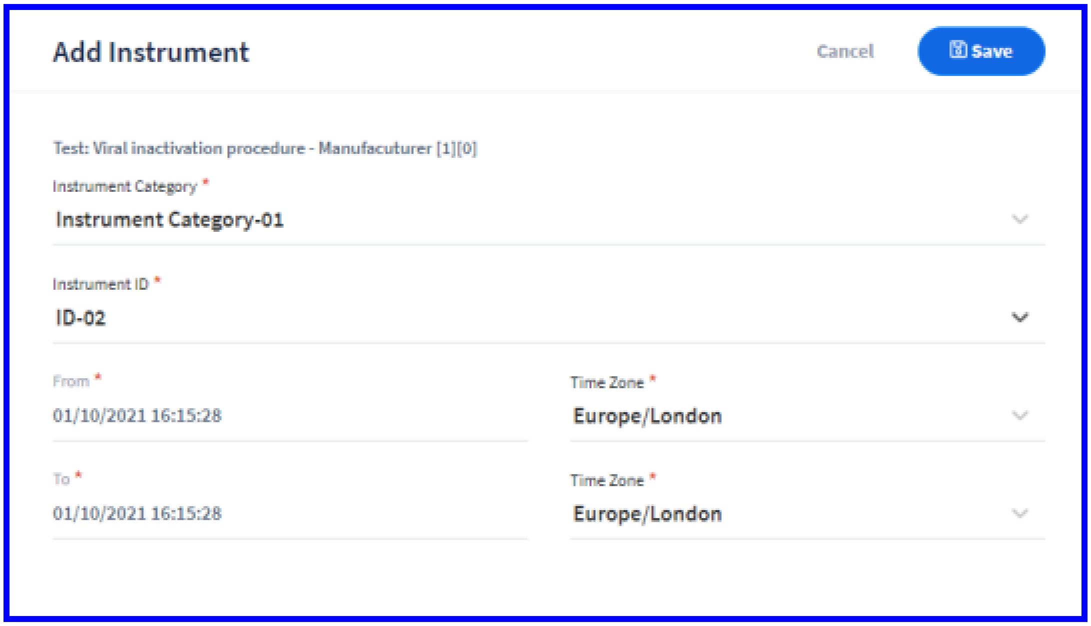


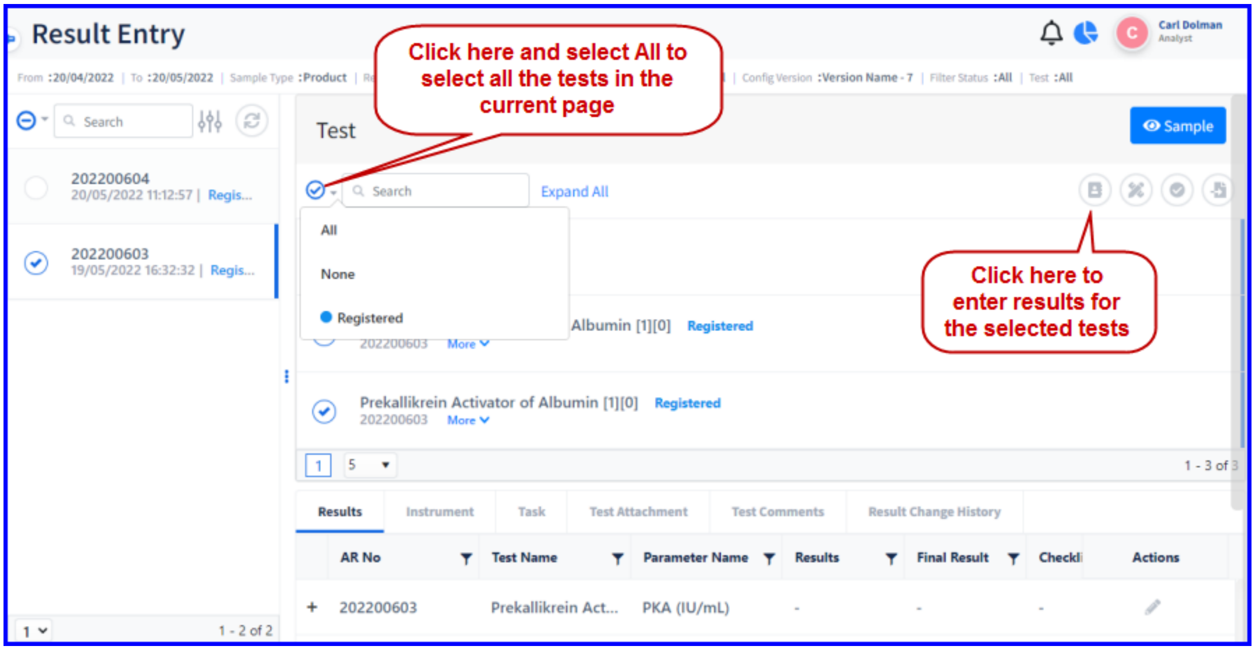
FIGURE: Add Instrument Dialog

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:



2. Click  . The **Result Entry** dialog appears prompting for result entry for all the selected tests as shown in the figure:

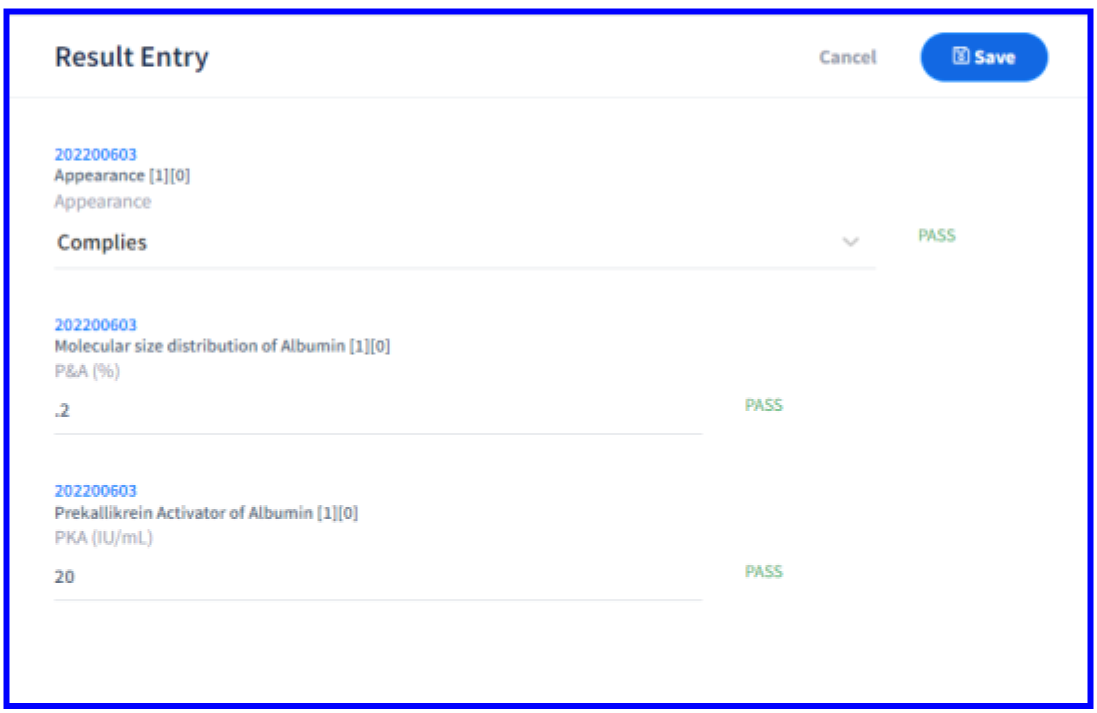


FIGURE: Result Entry for Multiple Tests

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

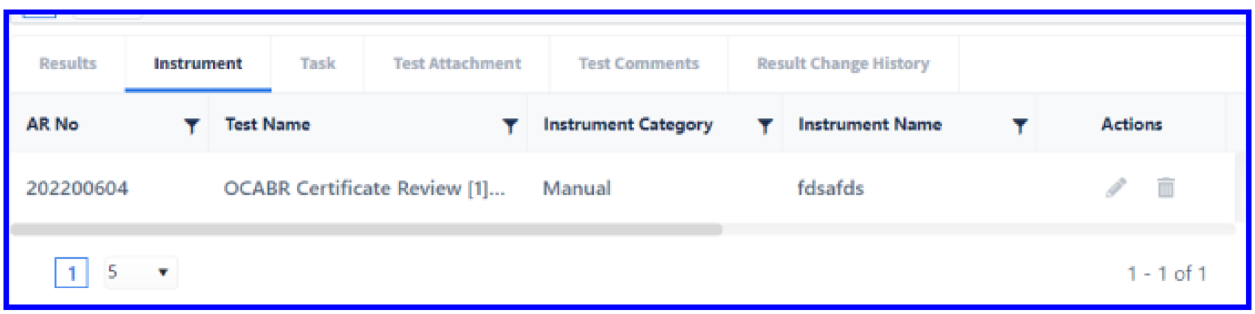
Following tabs are available in the Result Entry screen:

Results: View results entered for selected tests as shown in the figure:

	AR No	Test Name	Parameter Name	Results	Final Result	Checkl	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	-	

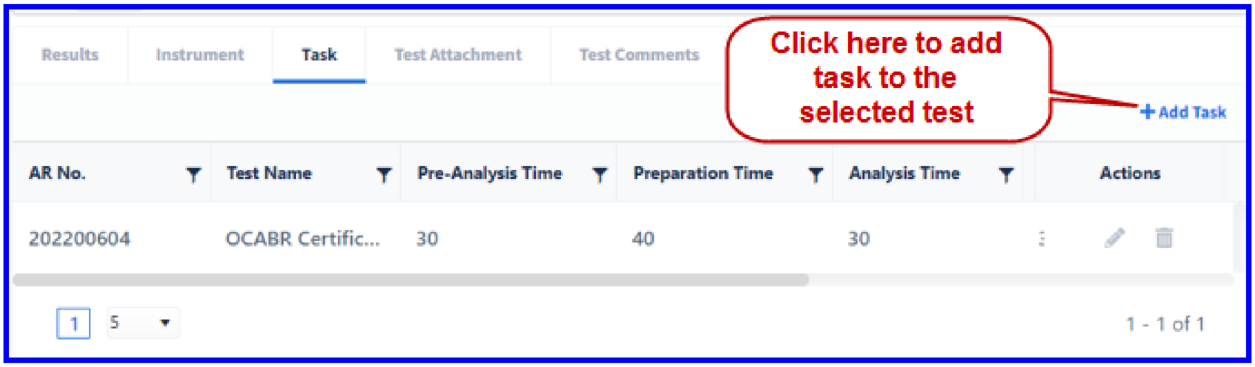
4.2.3.1 Instruments

View instruments added to the selected tests.



AR No	Test Name	Instrument Category	Instrument Name	Actions
202200604	OCABR Certificate Review [1]...	Manual	fdsafds	

Add Task: Add efforts/time taken to complete the test(s)



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:

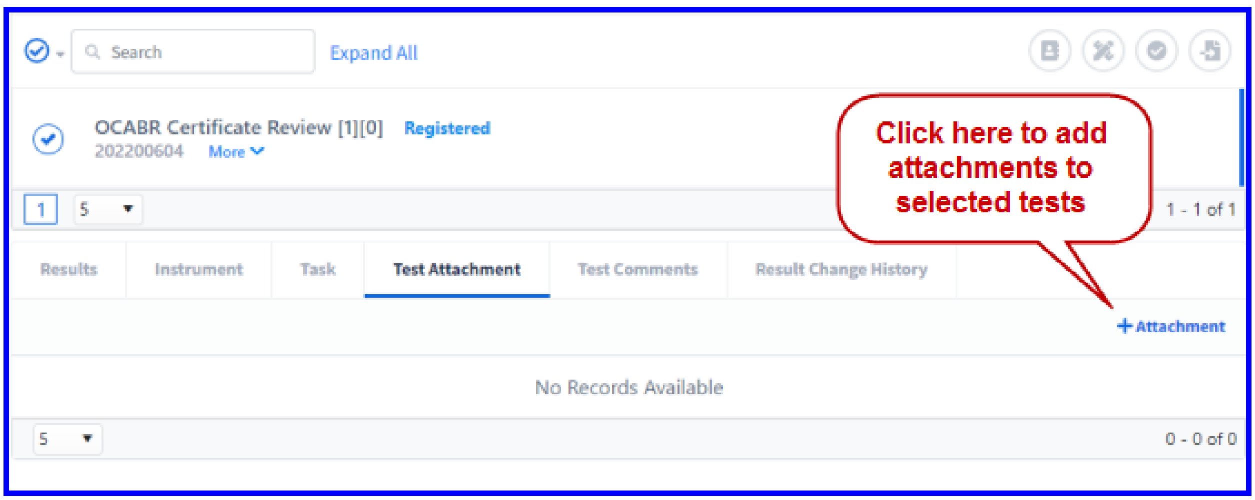


FIGURE: Attaching files to tests

The **Add Test Attachment** dialog appears as shown in the figure:

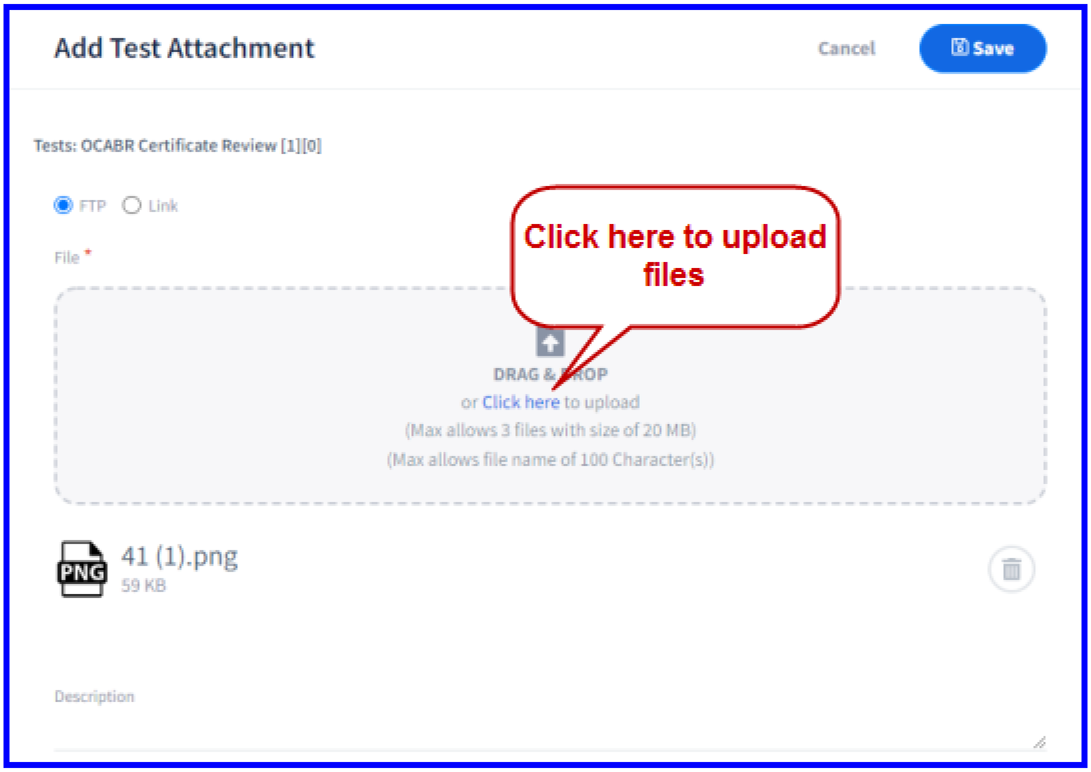


FIGURE: Add Test Attachment Dialog

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:

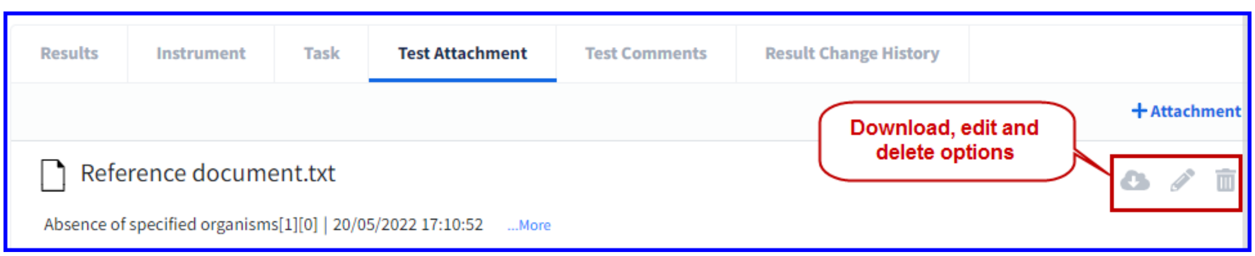


FIGURE: Attachment Added to the selected Test(s)

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:

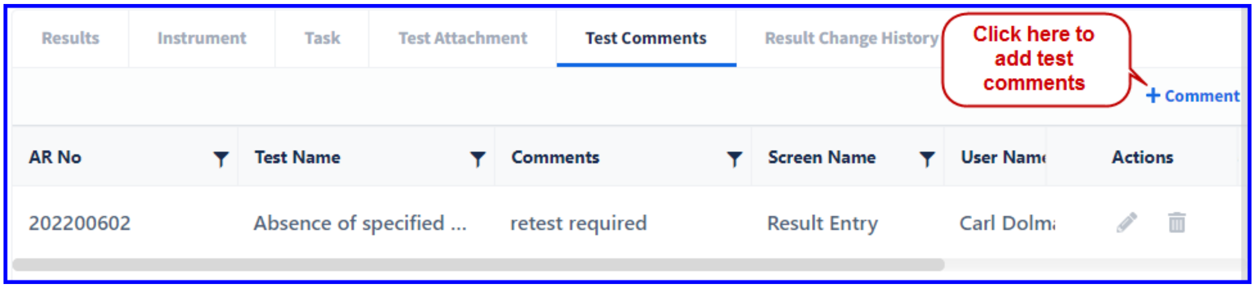


FIGURE: Adding Test Comments

The **Add Test Comments** dialog appears as shown in the figure:

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.

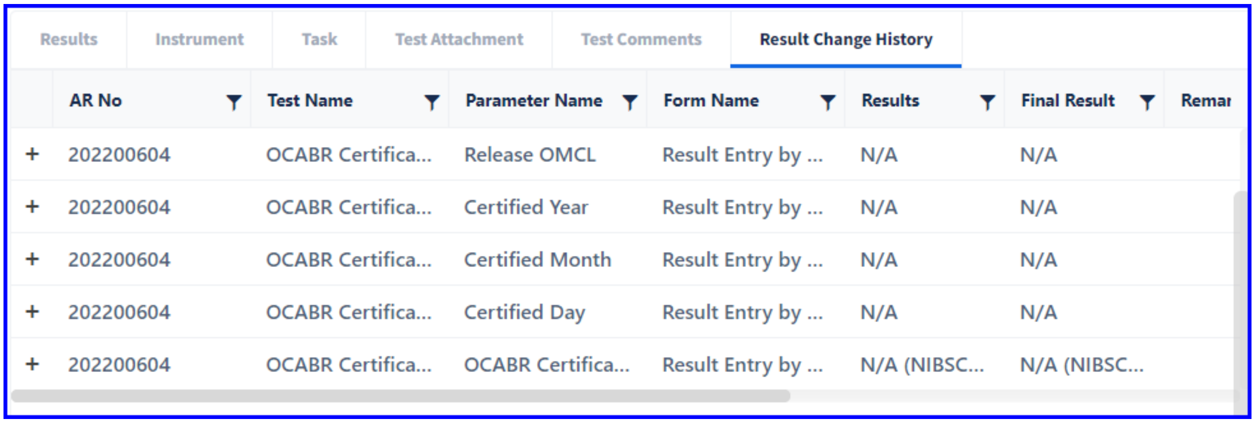


FIGURE: Result Change History Tab

4.2.3.5 Fill Default Results

Select test(s) and then click to fill default results as shown in the figure:

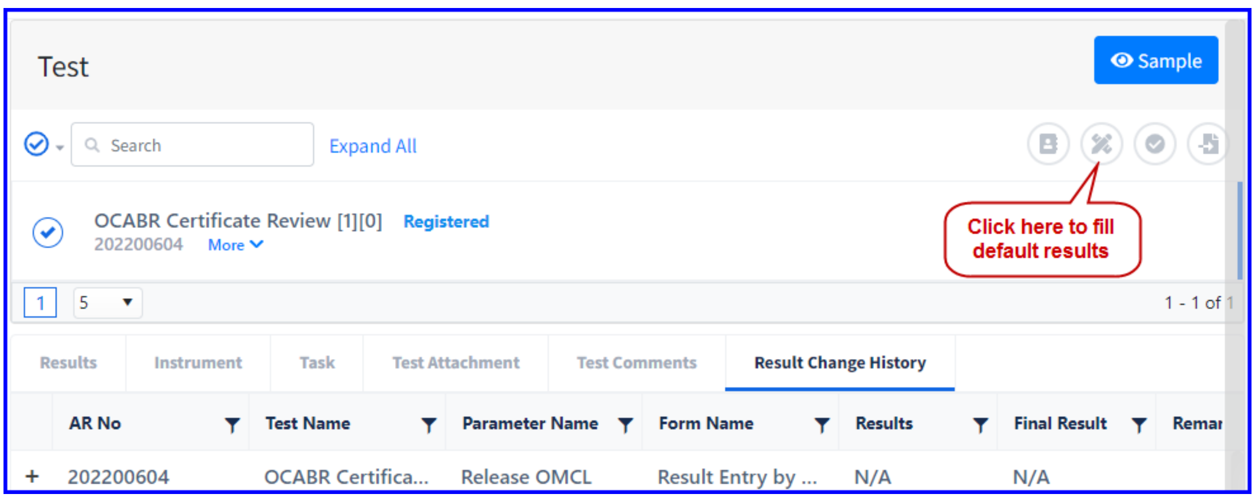


FIGURE: Filling Default Results to Selected Test(s)

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:

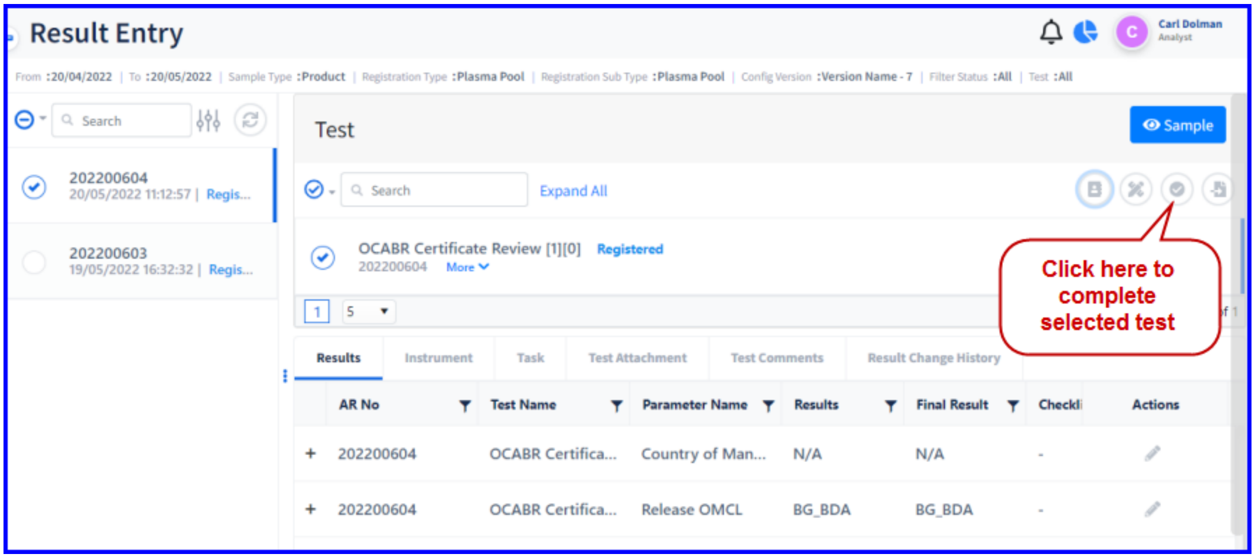


FIGURE: Completing Tests

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:

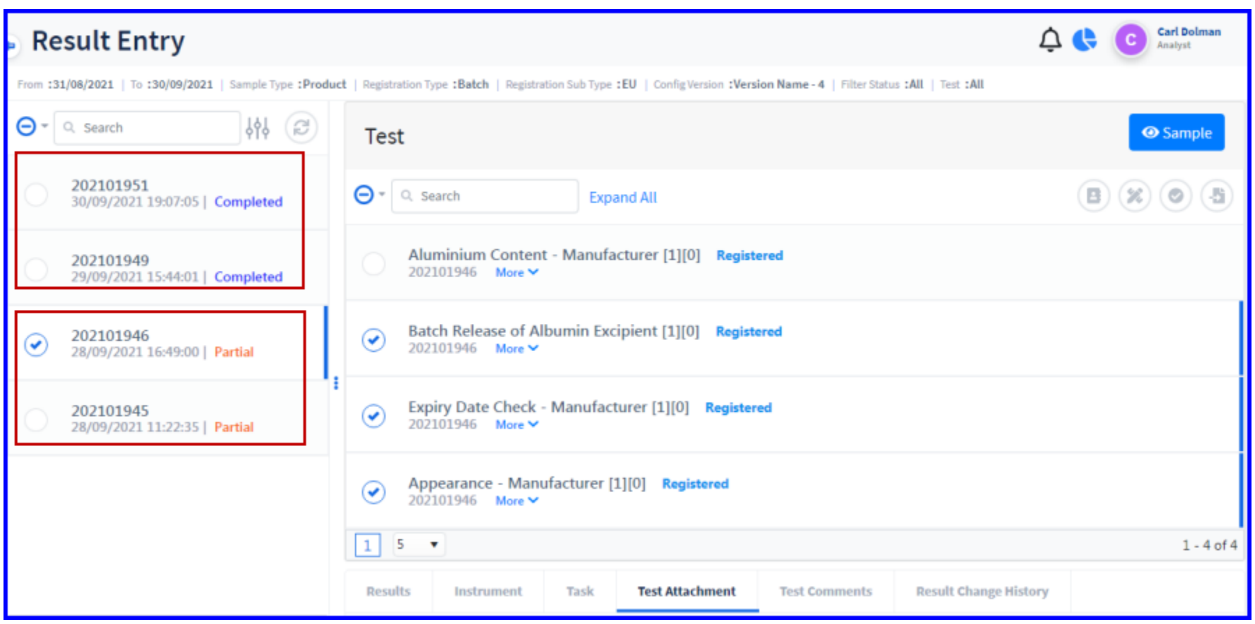


FIGURE: Sample with Completed and Partial Status

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:

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:

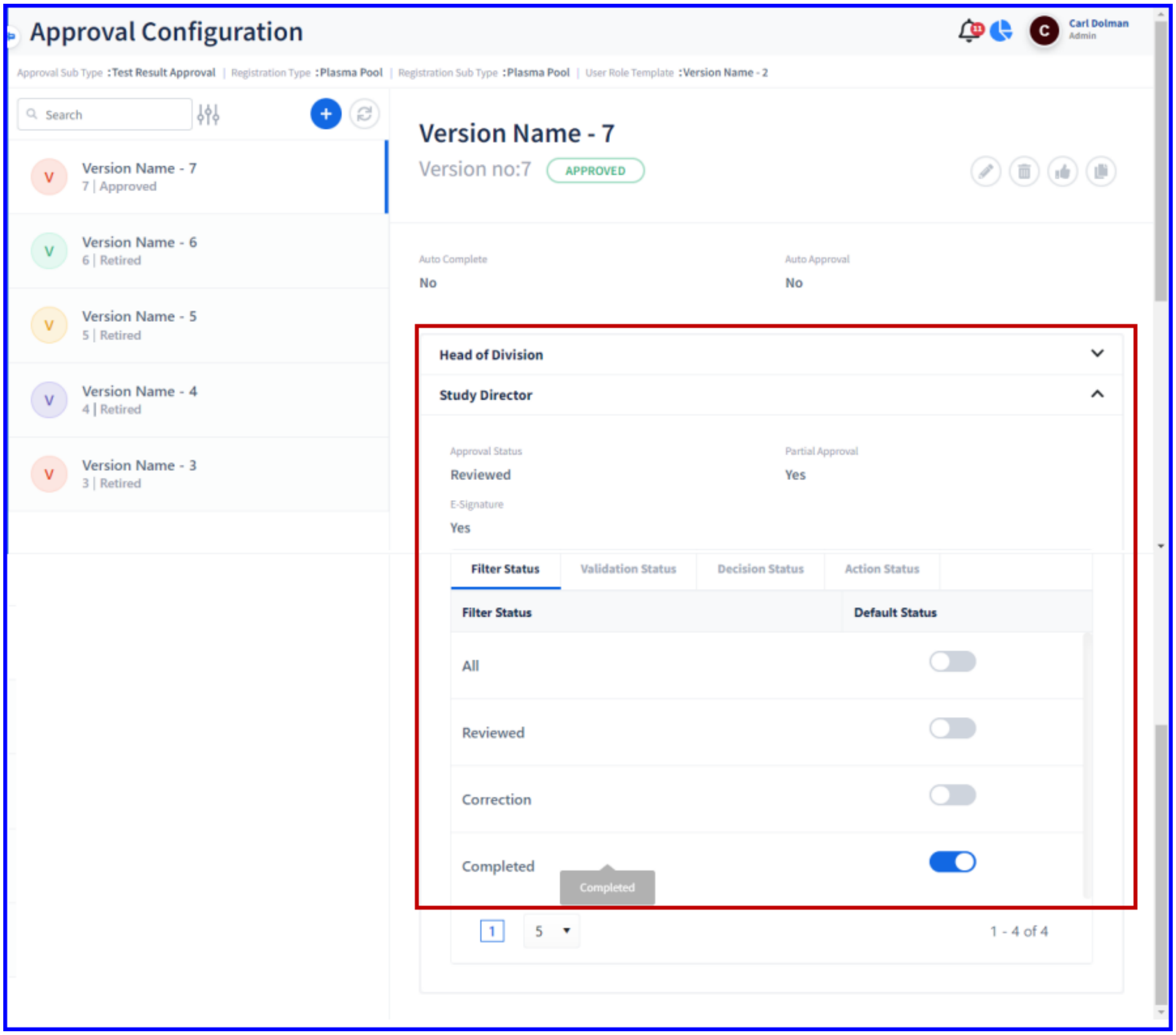


FIGURE: Approval Configuration Screen Showing User in the Approval Flow

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:

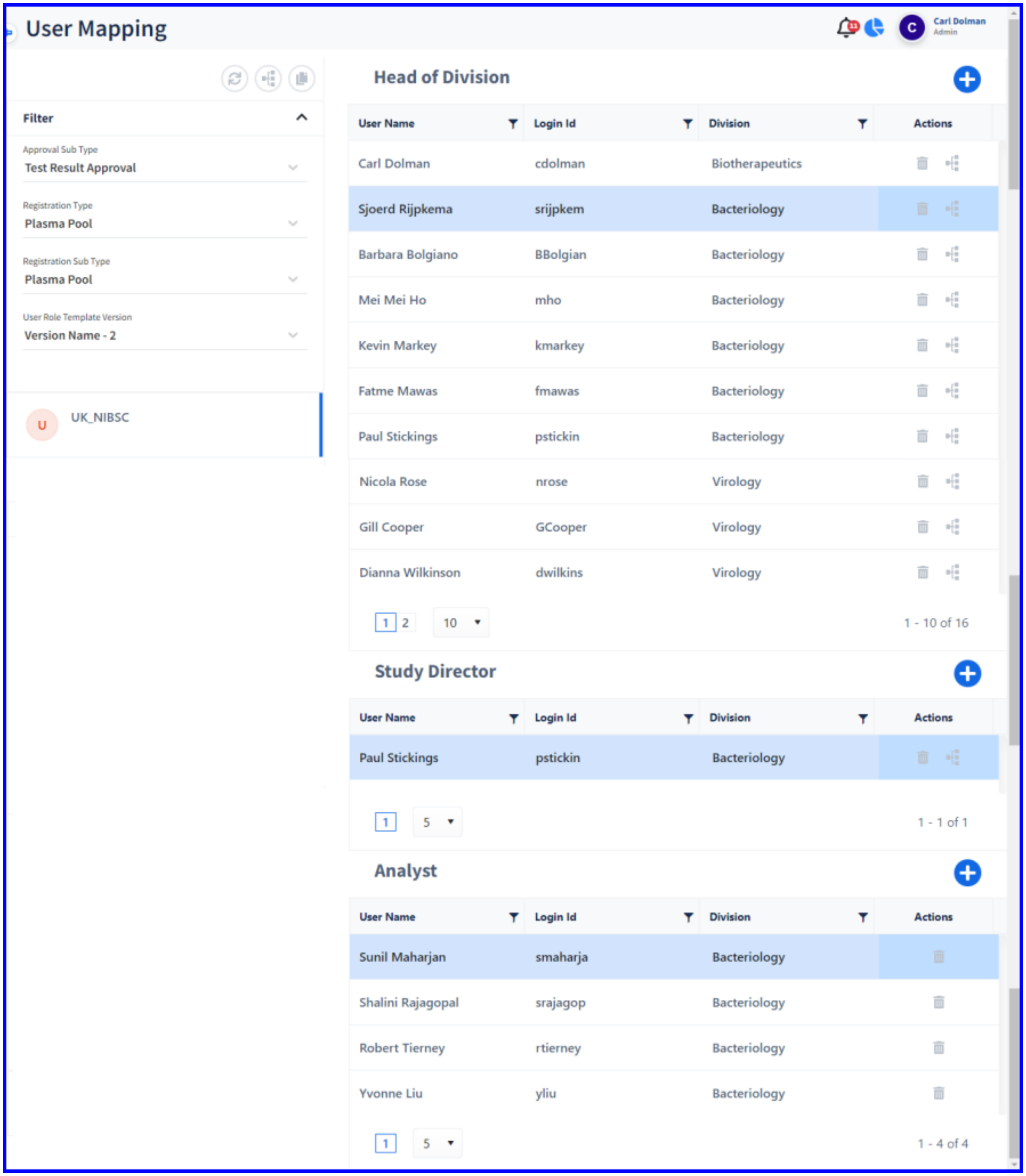


FIGURE: User Mapping Screen Showing User Level Mapping in the Approval Flow

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:

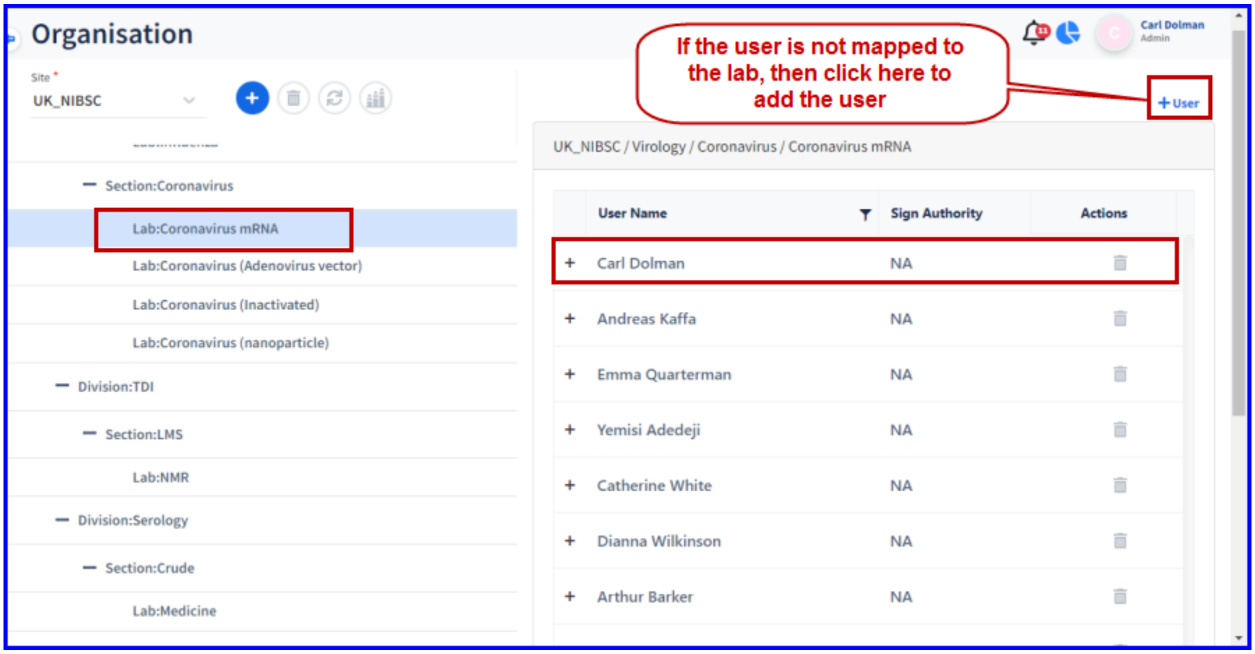


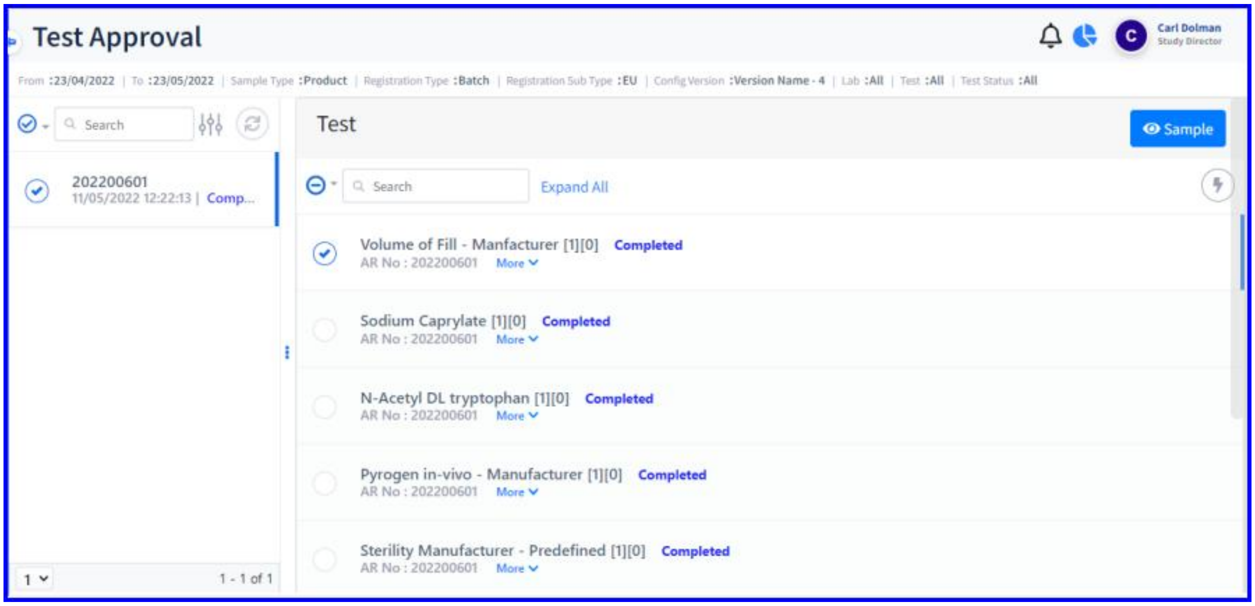
FIGURE: Organisation Screen Showing User Mapped to a Selected Lab

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:



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:

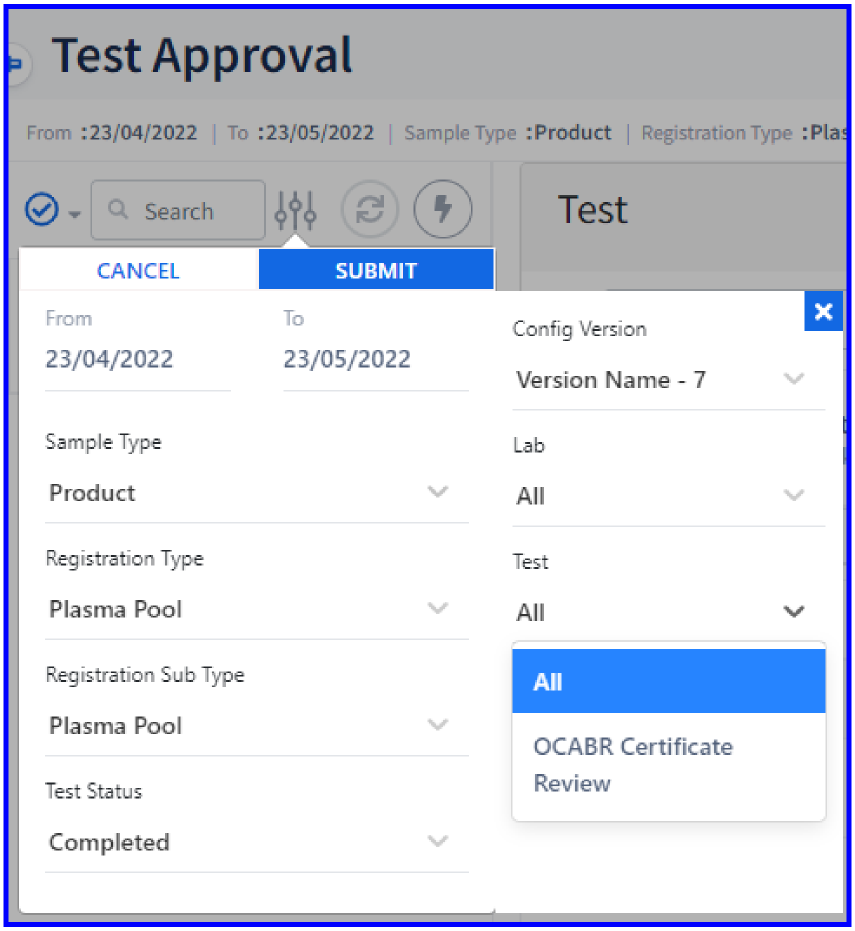


FIGURE: Using Filter

Samples for the given search criteria appears as shown in the figure:

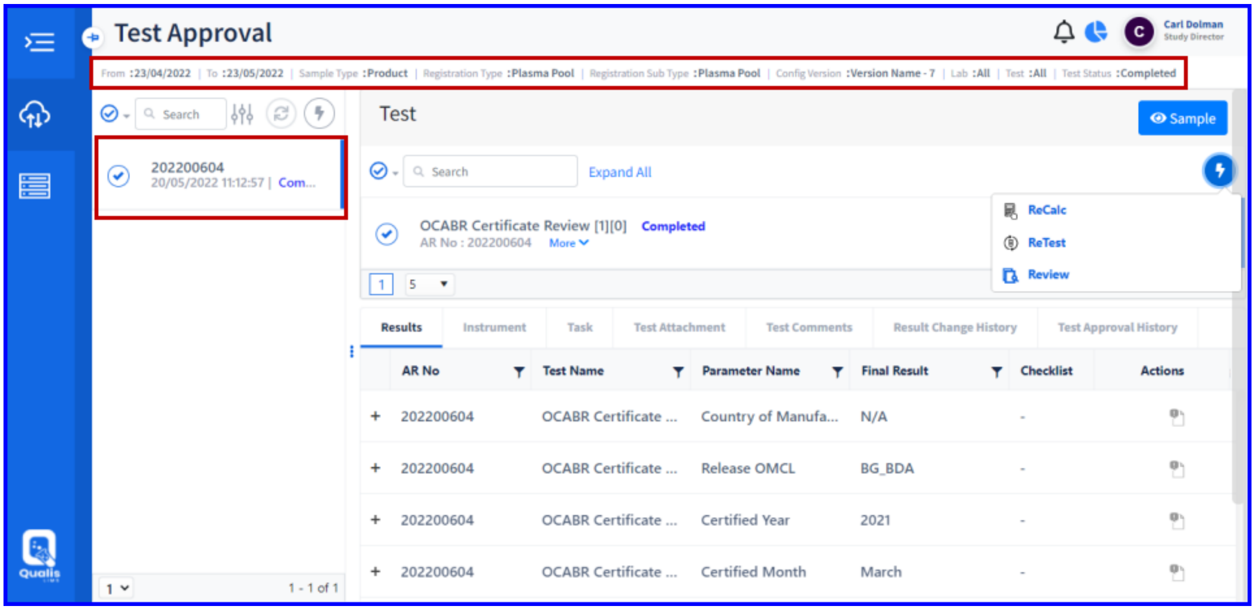


FIGURE: Test Approval Screen Showing Filtered Records

You can review the tests and then do any one of the following:

- Recommend recalculation: The tests go to the 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:

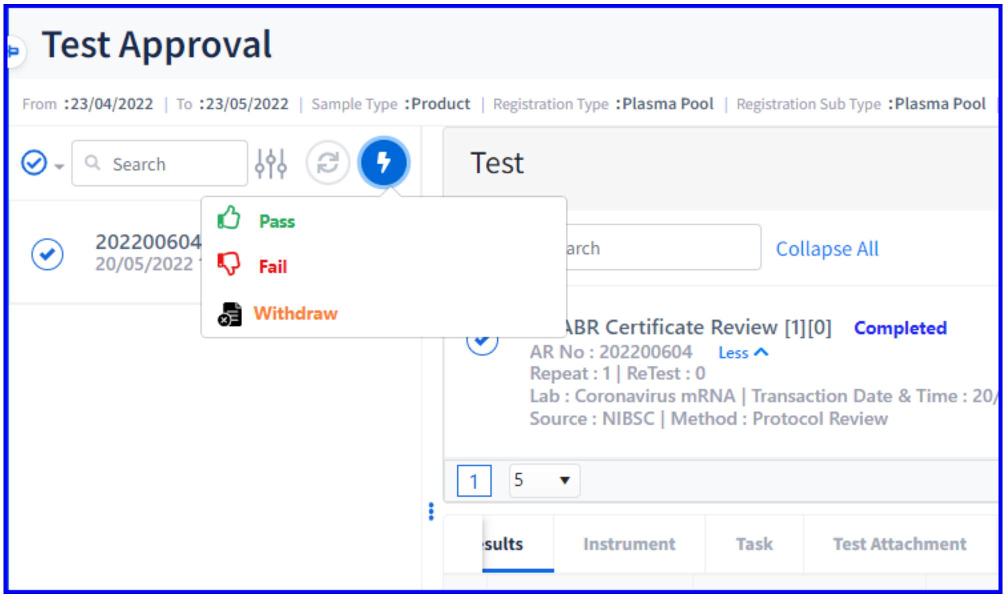


FIGURE: Changing Decision Status

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:

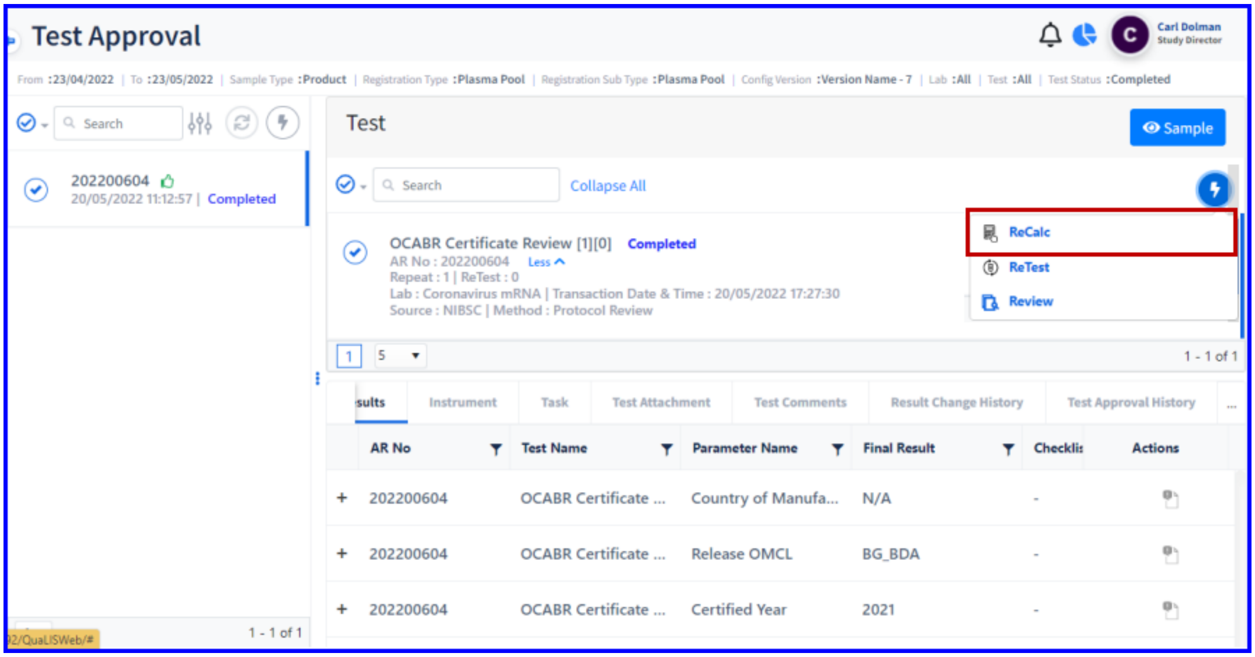


FIGURE: Recommend Recalculation

The sample goes to the **ReCalc** state as shown in the figure:

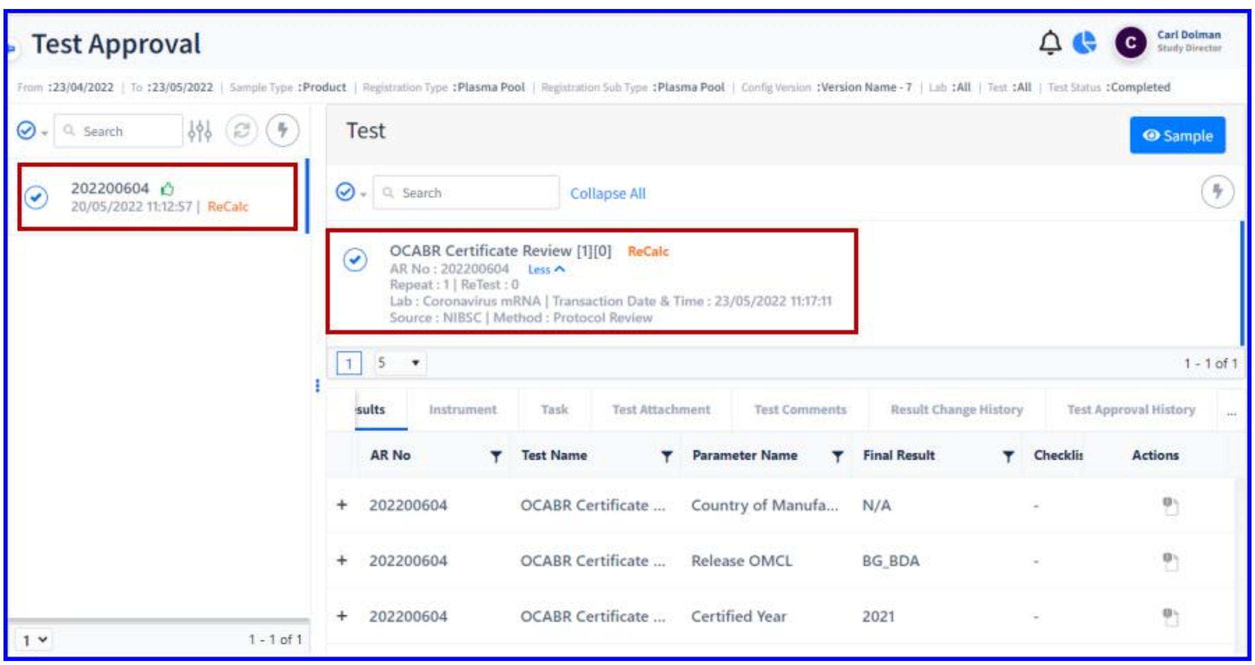


FIGURE: Sample in the ReCalc State

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:

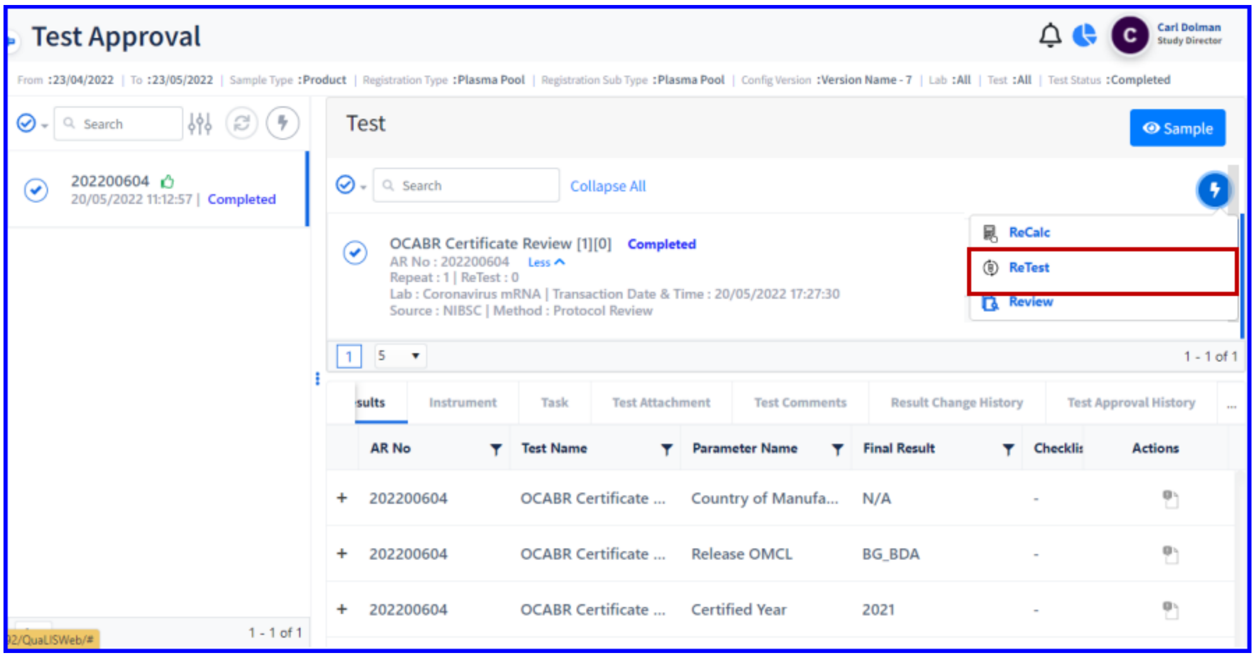


FIGURE: Recommend ReTest

The **Add Retest Count** dialog appears as shown in the figure:

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:

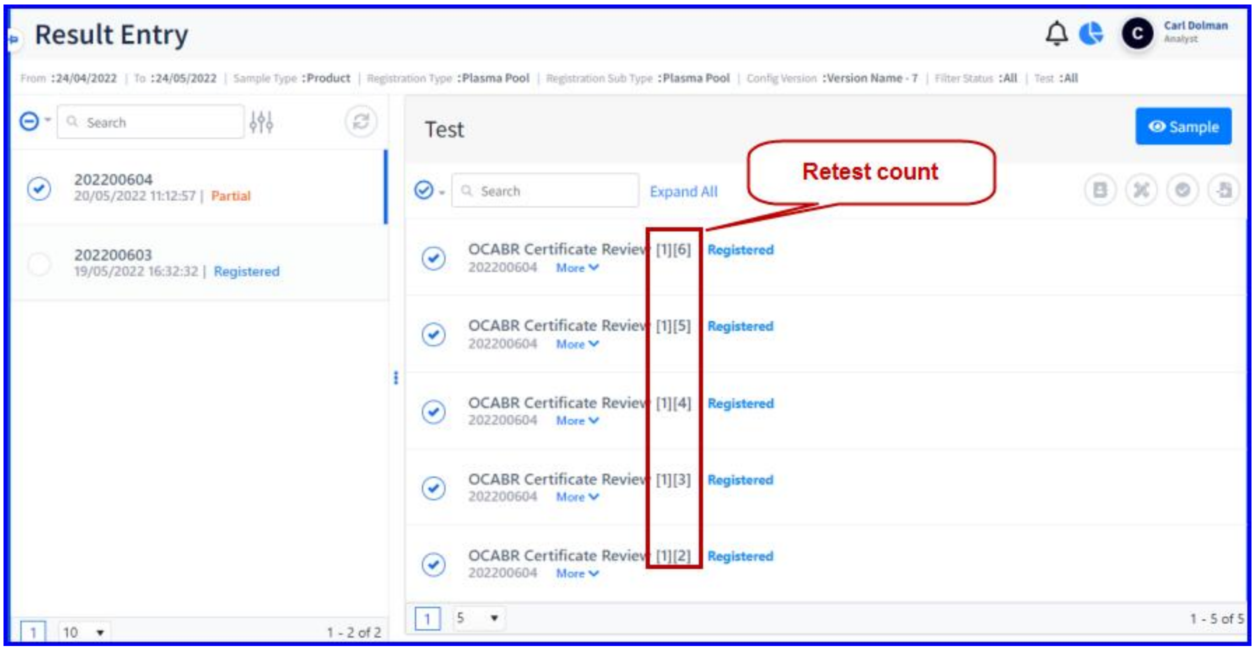


FIGURE: Result Entry Screen Showing Sample Registered for Retest

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:

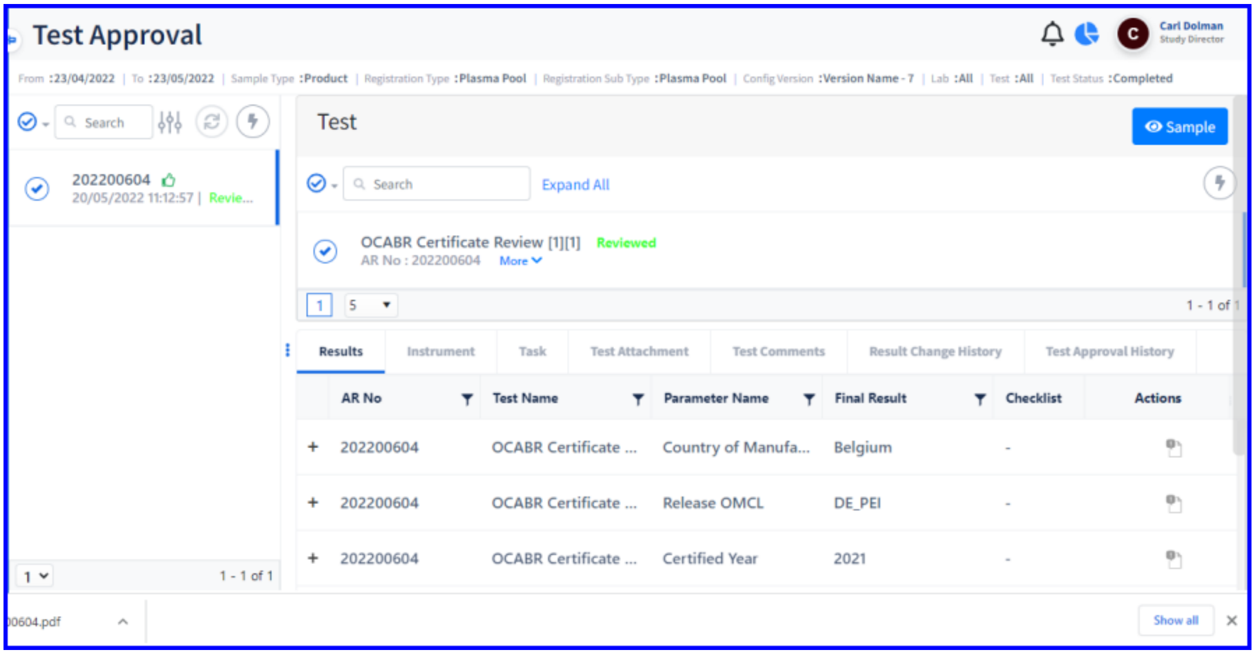


FIGURE: Tests in Reviewed State

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:

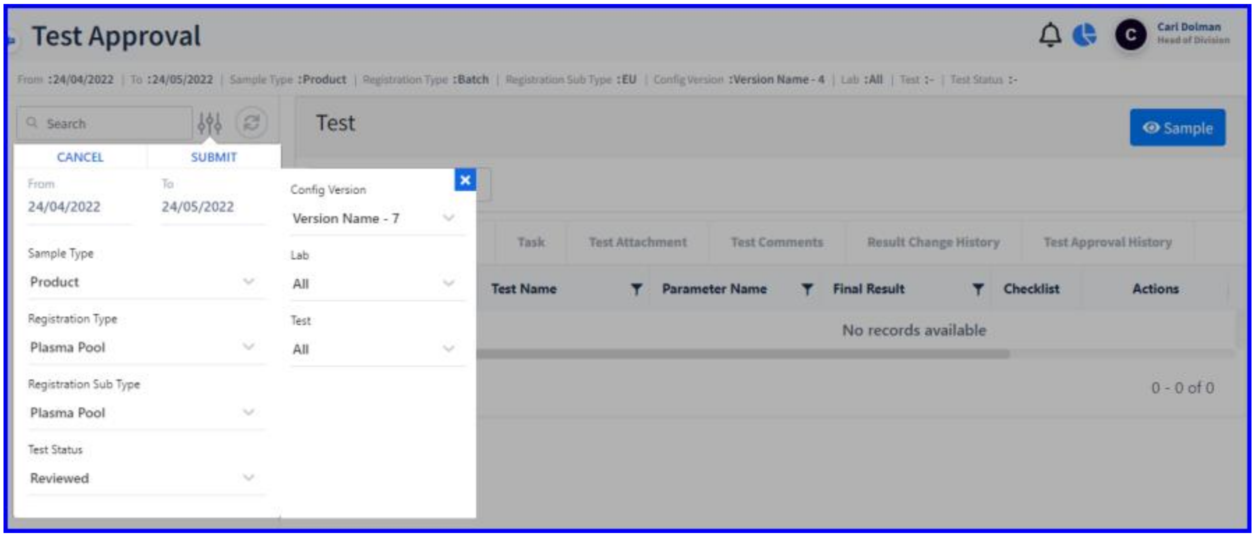


FIGURE: Using Filter

Samples for the given search criteria appears as shown in the figure:

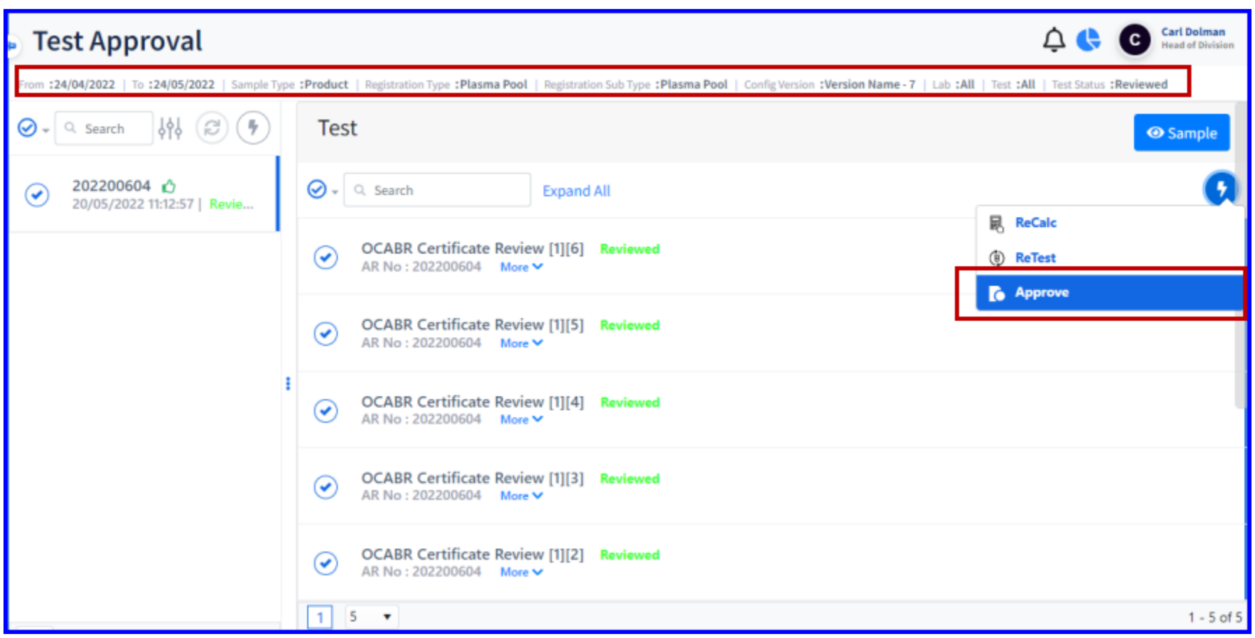


FIGURE: Test Approval Screen Showing Filtered Records

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:

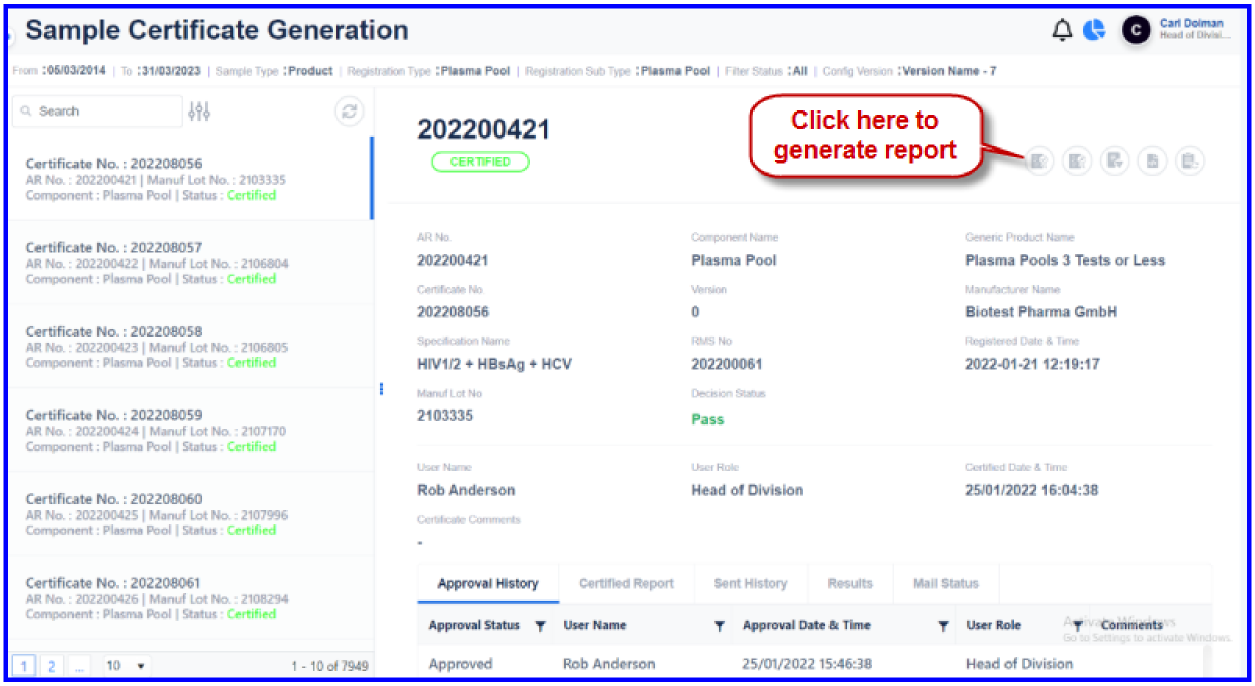


FIGURE: Generating Report

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

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:	27th May 2022
Date of expiry:	26th May 2026
Marketing Authorisation Number (member state / EU): Issued by:	PL 10085/0039 MHRA, United Kingdom
Name and address of Manufacturer:	ALK-Abelló A/S Boge Alle 6-8, P O Box 408, DK - 2970 Horsholm, Denmark
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:

- 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	Signed:	
Function of Signatory:	Head of Division		
Date of Issue:	30th May 2022		

(Form: NI Version: 1) Page 1 of 1

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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FIGURE: Report Generated