



Qualis
LIMS

USER MANUAL

Version 10.0.0.2

CONTENTS

1	Preface	15
1.1	Audience.....	15
1.2	Documentation Accessibility	15
1.3	Conventions	16
1.3.1	Commands	16
1.3.2	Keyboard	16
1.3.3	Notes.....	16
1.3.4	Warning.....	17
1.3.5	Callout.....	17
1.3.6	Description	17
1.3.7	Hyperlink.....	17
2	Getting Started	18
2.1	Login.....	18
2.2	Profile Menu	19
2.2.1	Change Role	19
2.2.2	Change Password.....	20
2.2.3	Logout	21
3	Masters	22
3.1	Common Features	22
3.1.1	List of Common Controls in LIMS	23
3.1.2	Add Records to the Master.....	24
3.1.3	Pagination.....	24
3.1.4	Download Master Records to PDF.....	25
3.1.5	Download Master Records to Excel	27
3.2	Base Masters	28
3.2.1	Unit of Measurement	29
3.2.2	Storage Condition.....	30
3.2.3	Storage Location.....	33
3.2.4	Container Type	35
3.2.5	Barcode.....	36
3.3	Configuration.....	39
3.3.1	Registration Type	39

3.3.2	Registration Sub Type	41
3.3.3	Dynamic Template Design	51
3.3.4	Design Template Mapping	59
3.3.5	User Role Template	62
3.3.6	Approval Configuration.....	65
3.3.7	User Mapping	69
3.3.8	FTP Configuration.....	75
3.4	User Management	78
3.4.1	User role Master	78
3.4.2	Designation Master.....	80
3.4.3	Holiday Planner	81
3.4.4	Password Policy.....	88
3.4.5	Users	92
3.4.6	MIS Rights	98
3.4.7	Screen Rights.....	100
3.4.8	User Role Configuration.....	105
3.4.9	Audit Trail	107
3.5	Organisation	109
3.5.1	Division Master	109
3.5.2	Section Master.....	111
3.5.3	Lab Master.....	112
3.5.4	Organisation Master	114
3.6	Contacts.....	124
3.6.1	Supplier Category Master	124
3.6.2	Supplier Master	126
3.6.3	Courier Master.....	131
3.6.4	Client Master	133
3.6.5	Manufacturer Master	135
3.6.6	Country Master.....	141
3.7	Product.....	143
3.7.1	Product Category Master	143
3.7.2	Product Master.....	145
3.7.3	Component Master	161
3.8	Test Management	164

3.8.1	Method Category Master	164
3.8.2	Method Master.....	166
3.8.3	Test Category Master	168
3.8.4	Test Master	169
3.9	Instrument Management	185
3.9.1	Instrument Category	185
3.9.2	Instrument Master.....	188
3.10	Material Management.....	190
3.10.1	Material Category Master	190
3.11	Checklist.....	193
3.11.1	QB Category	193
3.11.2	QB Master	194
3.11.3	Checklist.....	196
3.12	Competence Management	202
3.12.1	Technique	202
4	Transactions	204
4.1.1	Goods In	204
4.1.2	Receiving Goods	206
4.1.3	Chain Custody	208
4.1.4	Registration	212
4.2	Result Entry.....	223
4.2.1	Adding Instruments	227
4.2.2	Result Entry	228
4.2.3	Result Entry Screen Tabs	230
4.3	Test approval	236
4.3.1	User Role Configuration.....	236
4.3.2	Approval Configuration.....	236
4.3.3	User Mapping	237
4.3.4	Organization Mapping.....	239
4.4	Reviewing Test Results	239
4.4.1	Changing Decision Status.....	242
4.4.2	Recommend Recalculation.....	243
4.4.3	Recommend ReTest.....	245
4.4.4	Review.....	246

4.5 Approving Tests	247
---------------------------	-----

TABLE OF FIGURES

FIGURE: Qualis LIMS – Log in Screen.....	18
FIGURE: Qualis LIMS Home Page	19
FIGURE: Profile Menu.....	19
FIGURE: Profile Menu-Change Role Option.....	20
FIGURE: Profile Menu-Change Password Screen	20
FIGURE: Masters – Screen Layout	22
FIGURE: Set Number of Records for View.....	25
FIGURE: Downloading Master Records to PDF.....	26
FIGURE: Downloaded Master Records in PDF	26
FIGURE: Downloading UOM Master Records to Excel	27
FIGURE: Downloaded Master Records in Excel	28
FIGURE: Unit of Measurement Master Screen	29
FIGURE: Add Unit of Measurement screen.....	30
FIGURE: Storage Condition Master Screen.....	31
FIGURE: Add Storage Condition Screen	32
FIGURE: Storage Location Master Screen.....	33
FIGURE: Add Storage Location Screen	34
FIGURE: Container Type Master Screen	35
FIGURE: Add Container Type Screen	36
FIGURE: Barcode Master Screen.....	37
FIGURE: Add Barcode Screen.....	38
FIGURE: Registration Type Master Screen	40
FIGURE: Add Registration Type Dialog	40
FIGURE: Registration Sub Type Master Screen	42
FIGURE: Selecting Registration Type to add Registration Sub Type.....	43
FIGURE: Registration Sub Type Screen for the selected Registration Type	43
FIGURE: Add Registration Sub Type Dialog	43
FIGURE: Registration Sub Type Created.....	44
FIGURE: Add Version	45
FIGURE: Design Registration No Format.....	46
FIGURE: Registration Sub Type Added	47

FIGURE: View Transaction Flow	48
FIGURE: Registration Sub Type Version Approved	50
FIGURE: Dynamic Template Design Master Screen	51
FIGURE: Selecting Sample Type to add Template Design	52
FIGURE: Dynamic Template Design Screen for the selected Sample Type	52
FIGURE: Add Design Template Dialog	53
FIGURE: Adding Custom Fields 1	54
FIGURE: Adding Custom Fields 2	54
FIGURE: Saving the Template	55
FIGURE: Template Design Added	55
FIGURE: Dynamic Template Design Preview	56
FIGURE: Edit Design Template Dialog	57
FIGURE: Delete Design Template Dialog	57
FIGURE: Template Design Approved	58
FIGURE: Copy Template Dialog	58
FIGURE: Template Design Copied	59
FIGURE: Design Template Mapping Master Screen	60
FIGURE: Selecting Registration sub Type to add Template Design	61
FIGURE: Template mapping for the selected Registration Sub Type	61
FIGURE: Add Design Template Mapping Dialog	61
FIGURE: Design Template Mapped	62
FIGURE: User Role Template Screen Showing Filter	63
FIGURE: User Role Template Screen Showing List of Templates	63
FIGURE: Add User Role Template Screen	64
FIGURE: Approval Configuration Screen	65
FIGURE: Approval Configuration Screen - Add	66
FIGURE: Add Approval Configuration Screen	67
FIGURE: Copy Approval Configuration Screen	69
FIGURE: User Mapping Screen	70
FIGURE: User Mapping Screen	71
FIGURE: User Mapping – Add User Screen	72
FIGURE: Mapping User to the Next Level	72

FIGURE: Graphical View of User Mapping - 1	73
FIGURE: Graphical view of User Mapping – 2	74
FIGURE: Graphical View - Search User.....	74
FIGURE: Graphical View of User Mapping – Enable Expand View.....	74
FIGURE: Graphical View of a Selected User	75
FIGURE: FTP Configuration Screen.....	76
FIGURE: Add FTP Configuration Screen.....	77
FIGURE: User role Master Screen	79
FIGURE: Add User Role Screen	79
FIGURE: Designation Master Screen.....	80
FIGURE: Add Designation Screen.....	81
FIGURE: Holiday Planner Screen	82
FIGURE: Add Holiday Planner Screen	82
FIGURE: New Holiday Planner Added.....	83
FIGURE: Adding New Version to the Holiday Plan	84
FIGURE: Defining Common Holidays	85
FIGURE: Public Holiday Tab.....	86
FIGURE: Add Public Holidays	86
FIGURE: Public Holidays Added.....	87
FIGURE: Approving a Version	88
FIGURE: Password Policy Screen	89
FIGURE: Add Password Policy Screen.....	90
FIGURE: Copy Password Policy Dialog.....	91
FIGURE: Users Screen.....	93
FIGURE: Add Users Screen	93
FIGURE: Users Screen Showing New User Added	94
FIGURE: User Role Tab	95
FIGURE: Add Role Screen	96
FIGURE: Role Tab Showing Roles Mapped to the User	96
FIGURE: Deputy User Tab	97
FIGURE: Add Deputy User Role Screen	97
FIGURE: Deputy User Tab Showing Added Deputy Users	98

FIGURE: MIS Rights Screen	99
FIGURE: Report Rights Tab	99
FIGURE: Add Report Rights Dialog.....	100
FIGURE: Screen Rights Screen.....	101
FIGURE: Selecting User Role to Define Screen Rights.....	101
FIGURE: Add Screens to the User Role.....	102
FIGURE: Add Screen Rights Screen	102
FIGURE: List of Screens, Controls and E-Sign Options.....	103
FIGURE: Screen Rights – Pagination	104
FIGURE: Copy User Role Screen Rights Screen	105
FIGURE: User Role Configuration Screen.....	106
FIGURE: Filter User Role Name.....	107
FIGURE: Audit Trail Screen	108
FIGURE: Filter audit Trail Records	108
FIGURE: Filter audit Records Based on Fields.....	109
FIGURE: Division Master Screen	110
FIGURE: Add Division Screen	110
FIGURE: Section Master Screen	111
FIGURE: Add Section Screen	112
FIGURE: Lab Master Screen.....	113
FIGURE: Add Lab Screen	114
FIGURE: Organisation Master	115
FIGURE: Adding Division to Site.....	116
FIGURE: Add Division Dialog	116
FIGURE: Adding Section to Division	117
FIGURE: Add Section Dialog	118
FIGURE: Adding Labs to Section.....	119
FIGURE: Add Lab Dialog	120
FIGURE: Adding Users to Lab	121
FIGURE: Add Users Dialog.....	122
FIGURE: Users Added to the Lab	123
FIGURE: Graphical View of Organisation Setup.....	124

FIGURE: Supplier Category Master Screen.....	125
FIGURE: Add Supplier Category Dialog	125
FIGURE: Supplier Master Screen	126
FIGURE: Add Supplier Screen.....	127
FIGURE: Adding Supplier Category to Supplier	128
FIGURE: Add Supplier Category Dialog	128
FIGURE: Supplier Categories Added to the Supplier	129
FIGURE: Adding Material Category to Supplier	130
FIGURE: Add Material Category Dialog	130
FIGURE: Courier Master Screen.....	131
FIGURE: Add Courier Screen	132
FIGURE: Client Master Screen	133
FIGURE: Add Client Screen	134
FIGURE: Manufacturer Master Screen	135
FIGURE: Add Manufacturer Screen	136
FIGURE: Adding Sites to the Manufacturer	137
FIGURE: Add Site Details Dialog.....	138
FIGURE: Adding Contact Details to the Selected Site.....	139
FIGURE: Adding Contact Details to the Site	139
FIGURE: Add Contact Details Dialog	140
FIGURE: Added Contact Details	141
FIGURE: Country Master Screen.....	142
FIGURE: Add Country Screen	143
FIGURE: Product Category Master Screen.....	144
FIGURE: Add Product Category Dialog	144
FIGURE: Product Master Screen	146
FIGURE: Add Product Screen.....	147
FIGURE: Changing the Status of the Product Record to COMPLETED	148
FIGURE: Esignature Dialog.....	149
FIGURE: Product Record in the COMPLETED State	150
FIGURE: Approving Product Record.....	151
FIGURE: Product in the APPROVED State	151

FIGURE: Correcting Product Details	152
FIGURE: Esignature Dialog	153
FIGURE: Product Record in the CORRECTION State	154
FIGURE: Edit Product Dialog	155
FIGURE: Adding Product Manufacturer to the Product	156
FIGURE: Add Product Manufacturer Dialog	156
FIGURE: Added Manufacturer to the Selected Product	157
FIGURE: Viewing Approval History of the Product	158
FIGURE: Adding Product MA Holder	159
FIGURE: Add Product MA Holder Dialog	159
FIGURE: Added MA Holder for the Product	161
FIGURE: Component Master Screen	162
FIGURE: Add Component Dialog	163
FIGURE: Method Category Master Screen	165
FIGURE: Add Method Category Dialog	165
FIGURE: Method Master Screen	166
FIGURE: Add Method Dialog	167
FIGURE: Test Category Master Screen	168
FIGURE: Add Test Category Dialog	169
FIGURE: Test Master Screen	170
FIGURE: Test Master Showing Tests in the Selected Test Category	171
FIGURE: Add Test Dialog	172
FIGURE: Parameter Tab	174
FIGURE: Add Parameter Dialog	175
FIGURE: Add Formula Screen	176
FIGURE: Validate Formula	177
FIGURE: Result Calculated	178
FIGURE: Add Specification Dialog	179
FIGURE: Test master – Lab Tab	180
FIGURE: Test master – Add Lab Dialog	180
FIGURE: Labs Added to the Selected Test	181
FIGURE: Test master – Add Method Screen	181

FIGURE: Test master – List of Add Methods Added to the Test.....	182
FIGURE: Test master – Add Test File Screen.....	183
FIGURE: Test master – Add Test File – Link Option.....	183
FIGURE: Test Master – Instrument Category Tab	184
FIGURE: Add Instrument Category Dialog	185
FIGURE: Instrument Category Master Screen	186
FIGURE: Add Instrument Category Dialog	187
FIGURE: Instrument Master Screen.....	188
FIGURE: Add Instrument Dialog.....	189
FIGURE: Material Category Master Screen	191
FIGURE: Add Material Category Screen	192
FIGURE: QB Category Master Screen.....	193
FIGURE: Add QB Category Screen	194
FIGURE: QB Master Screen	195
FIGURE: Add Question Screen.....	196
FIGURE: Checklist Master Screen.....	197
FIGURE: Add Checklist Dialog	198
FIGURE: Adding Version to the Checklist	198
FIGURE: Add Checklist Version Dialog	199
FIGURE: Checklist version in Draft State.....	199
FIGURE: Add Question to Checklist Screen.....	200
FIGURE: Questions Added to the Checklist Version.....	201
FIGURE: View Checklist Items	202
FIGURE: Technique Master Screen	202
FIGURE: Add Technique Dialog	203
FIGURE: Goods In Screen	204
FIGURE: Add Goods In Screen	205
FIGURE: Goods Showing Status as Goods In	206
FIGURE: Receiving Goods	207
FIGURE: Record in GOODS RECEIVED State.....	208
FIGURE: Chain custody Option.....	209
FIGURE: Chain Custody Dialog	210

FIGURE: Goods in Chain Custody	211
FIGURE: Edit and Delete Options for Chain Custody Records	211
FIGURE: Sample Registration Screen.....	212
FIGURE: Using Filter in Registration Screen	213
FIGURE: Registration Add Screen.....	214
FIGURE: Edit Component Dialog.....	216
FIGURE: Registered Sample	217
FIGURE: Registered Sample Showing Edit, Print Barcode and Add Source Options	218
FIGURE: Viewing Tests Added to the Sample	219
FIGURE: Viewing Sample Details.....	220
FIGURE: Accepting Sample	221
FIGURE: Cancel / Reject Sample	222
FIGURE: Quarantine Sample	223
FIGURE: User Role Configuration Screen Showing Result Entry Flow	224
FIGURE: Organisation Screen Showing User Mapped to the Test Lab	224
FIGURE: Result Entry Screen	225
FIGURE: Using Filter in Result Entry Screen.....	226
FIGURE: Result Entry Screen Showing Registered Sample and the List of Tests.....	227
FIGURE: Add Instrument Dialog.....	228
FIGURE: Result Entry for Multiple Tests	229
FIGURE: Attaching files to tests.....	231
FIGURE: Add Test Attachment Dialog.....	232
FIGURE: Attachment Added to the selected Test(s).....	232
FIGURE: Adding Test Comments.....	233
FIGURE: Add Test Comments Dialog	233
FIGURE: Result Change History Tab	234
FIGURE: Filling Default Results to Selected Test(s)	234
FIGURE: Completing Tests	235
FIGURE: Sample with Completed and Partial Status	235
FIGURE: User Role Configuration Screen Showing Approval Flow	236
FIGURE: Approval Configuration Screen Showing User in the Approval Flow.....	237
FIGURE: User Mapping Screen Showing User Level Mapping in the Approval Flow	238

FIGURE: Organisation Screen Showing User Mapped to a Selected Lab	239
FIGURE: Test Approval Screen	240
FIGURE: Using Filter.....	241
FIGURE: Test Approval Screen Showing Filtered Records.....	242
FIGURE: Changing Decision Status	243
FIGURE: Recommend Recalculation.....	244
FIGURE: Sample in the ReCalc State	244
FIGURE: Recommend ReTest	245
FIGURE: Add Retest Count Dialog	246
FIGURE: Result Entry Screen Showing Sample Registered for Retest	246
FIGURE: Tests in Reviewed State	247
FIGURE: Using Filter.....	248
FIGURE: Test Approval Screen Showing Filtered Records.....	248
FIGURE: Generating Report	249
FIGURE: Report Generated	250

1 Preface

This manual provides instructions about configuring and using Qualis LIMS.

This preface contains these topics:

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

1.1 Audience

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

To use this document, you need the following:

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

1.2 Documentation Accessibility

Qualis LIMS documentation set consists of the following:

- Qualis LIMS User Manual
- Qualis LIMS Online Help System

1.3 Conventions

The following text conventions are used in this document:

1.3.1 Commands

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

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

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

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

1.3.2 Keyboard

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

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

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

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

1.3.3 Notes

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

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

1.3.4 Warning

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

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

1.3.5 Callout

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



1.3.6 Description

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

1.3.7 Hyperlink

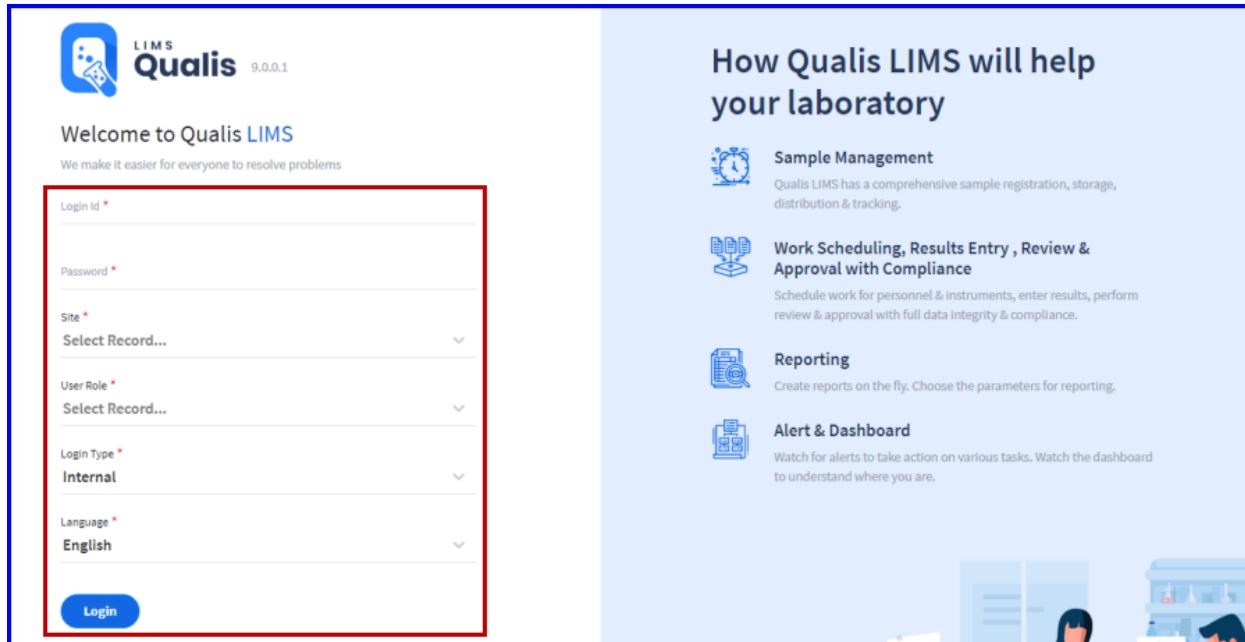
Clicking on hyperlinks will help the user to go to the topic directly in the same document.

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

2 Getting Started

2.1 Login

Qualis LIMS login screen appears as shown in the figure:



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

FIGURE: Qualis LIMS – Log in Screen

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

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

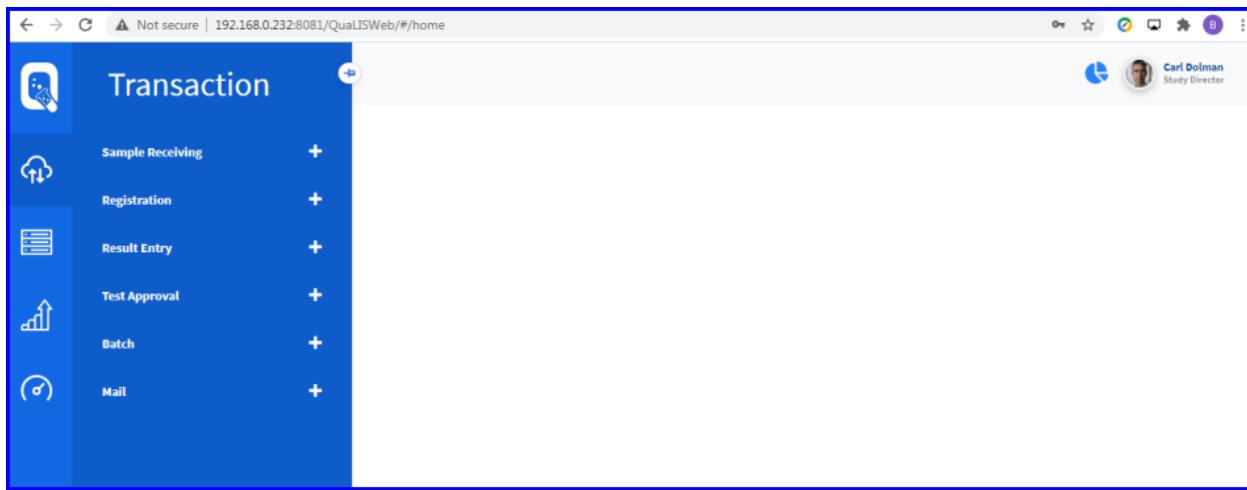


FIGURE: Qualis LIMS Home Page

2.2 Profile Menu

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

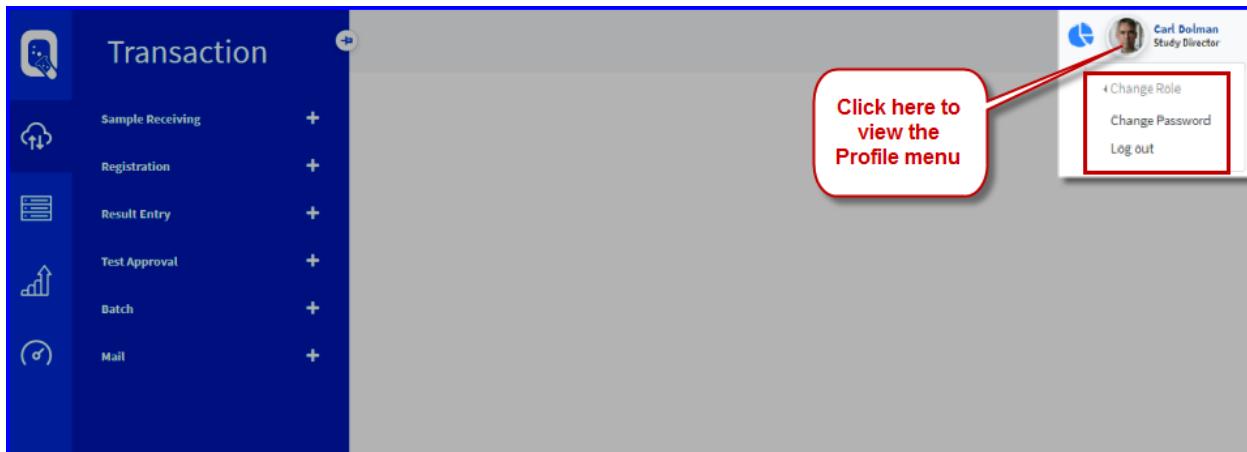


FIGURE: Profile Menu

2.2.1 Change Role

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

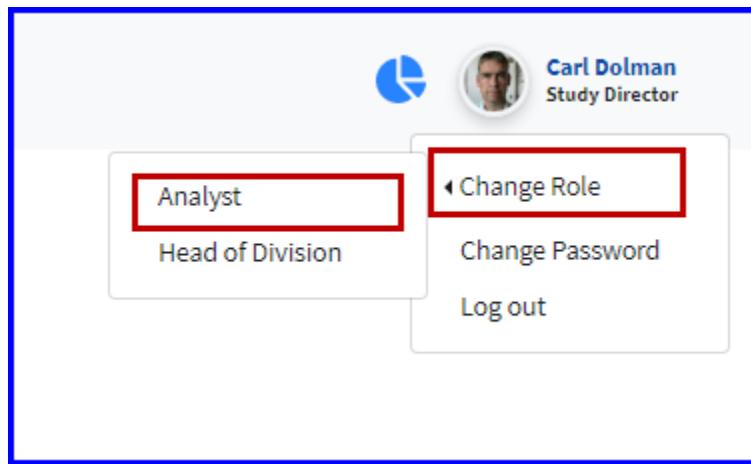


FIGURE: Profile Menu-Change Role Option

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

2.2.2 Change Password

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

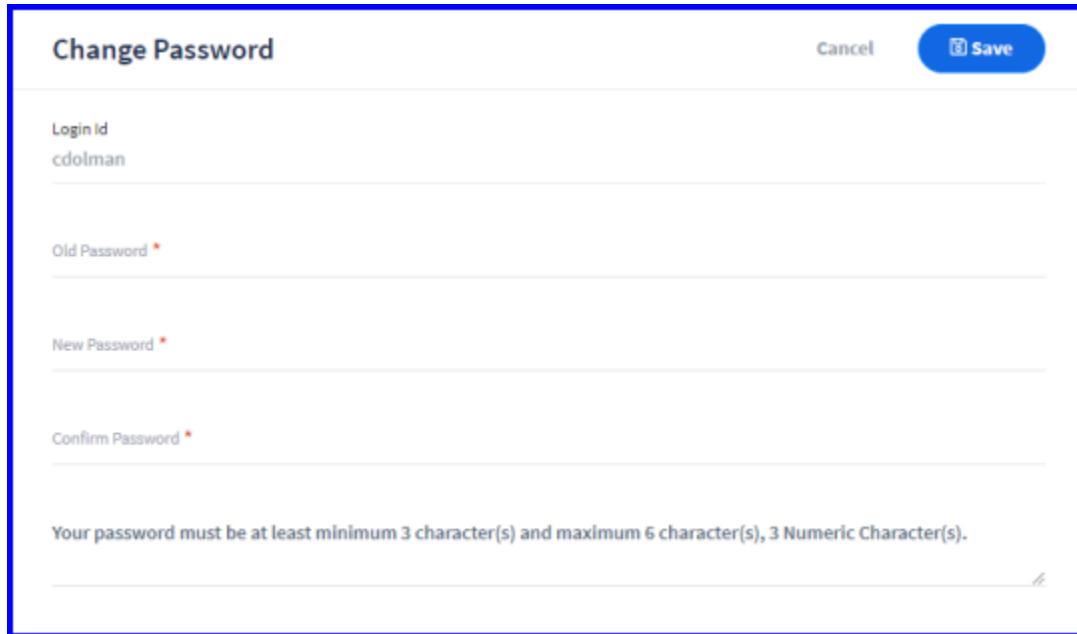
A screenshot of the 'Change Password' screen. The title bar says 'Change Password' with 'Cancel' and 'Save' buttons. The form contains four text input fields: 'Login Id' (cdolman), 'Old Password *', 'New Password *', and 'Confirm Password *'. Below the fields is a note: 'Your password must be at least minimum 3 character(s) and maximum 6 character(s), 3 Numeric Character(s.)'. The 'Save' button is highlighted with a blue box.

FIGURE: Profile Menu-Change Password Screen

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

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

2.2.3 Logout

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

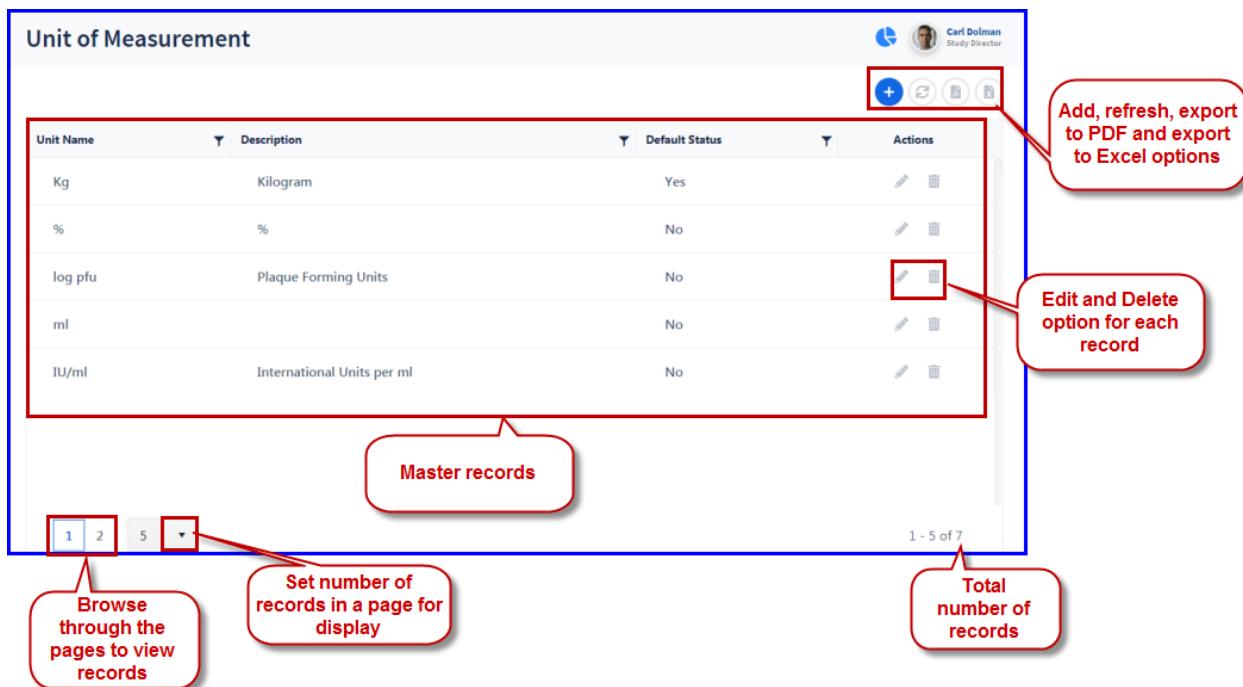
3 Masters

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

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

3.1 Common Features

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



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

FIGURE: Masters – Screen Layout

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

3.1.1 List of Common Controls in LIMS

The descriptions of common controls in LIMS are listed below:

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

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

3.1.2 Add Records to the Master

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

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

3.1.3 Pagination

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

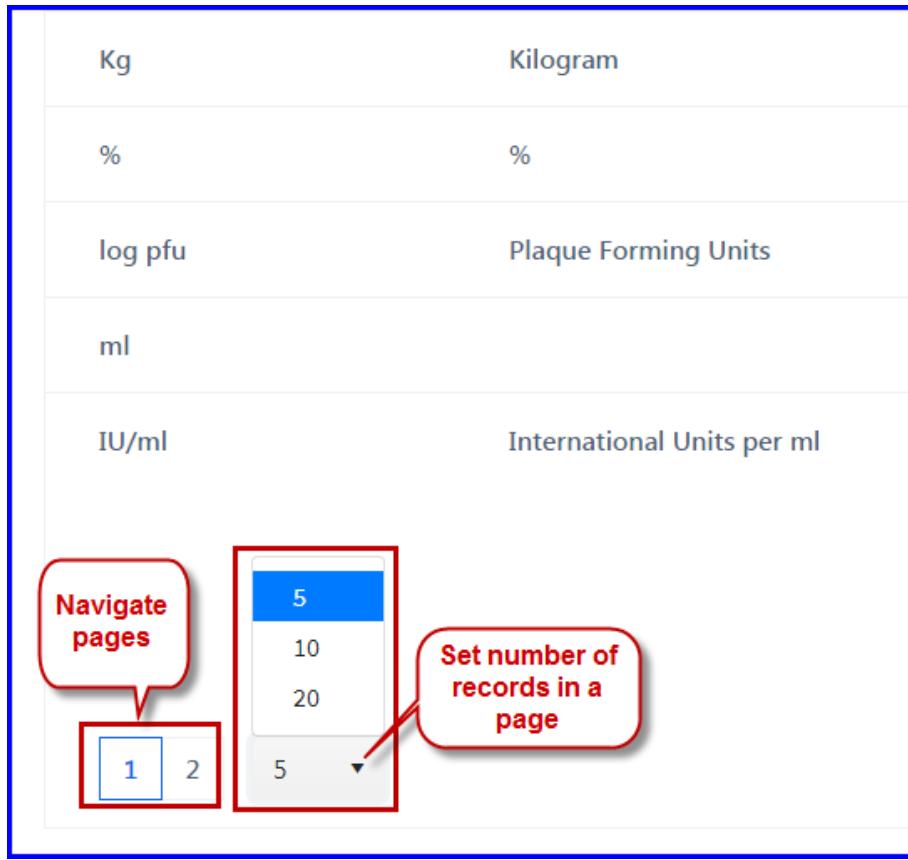


FIGURE: Set Number of Records for View

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

3.1.4 Download Master Records to PDF

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

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

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

FIGURE: Downloading Master Records to PDF

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

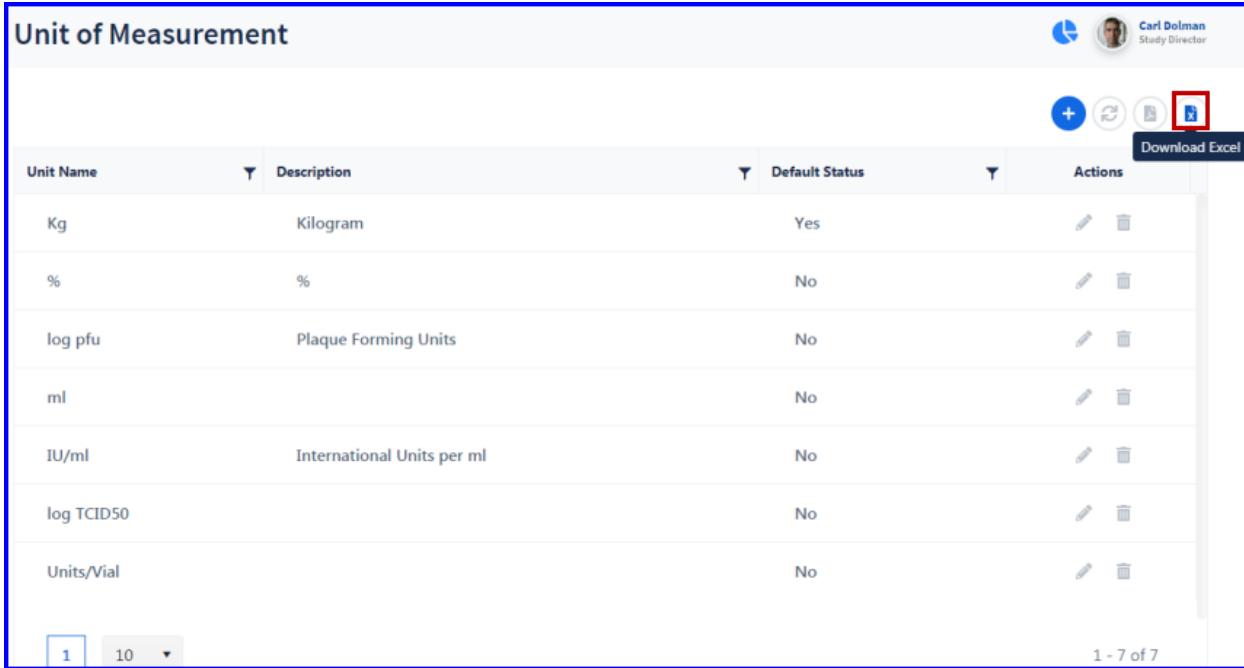
Unit Name	Description	Default Status
Kg	Kilogram	Yes
%	%	No
log pfu	Plaque Forming Units	No
ml		No
IU/ml	International Units per ml	No
log TCID50		No
Units/Vial		No

FIGURE: Downloaded Master Records in PDF

3.1.5 Download Master Records to Excel

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

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

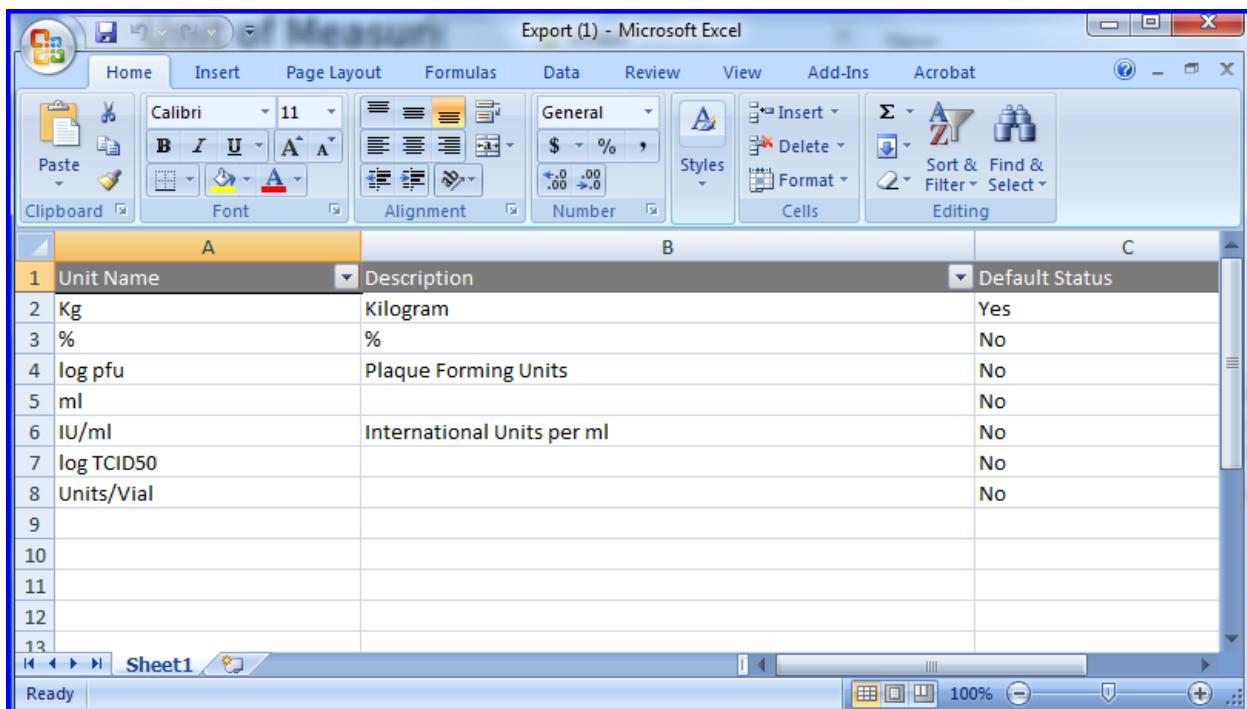


Unit of Measurement					
Unit Name	Description	Default Status	Actions		
Kg	Kilogram	Yes			
%	%	No			
log pfu	Plaque Forming Units	No			
ml		No			
IU/ml	International Units per ml	No			
log TCID50		No			
Units/Vial		No			

1 10 ▾ 1 - 7 of 7

FIGURE: Downloading UOM Master Records to Excel

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



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

FIGURE: Downloaded Master Records in Excel

3.2 Base Masters

Qualis LIMS allows you to create and manage following masters:

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

- Certificate Type

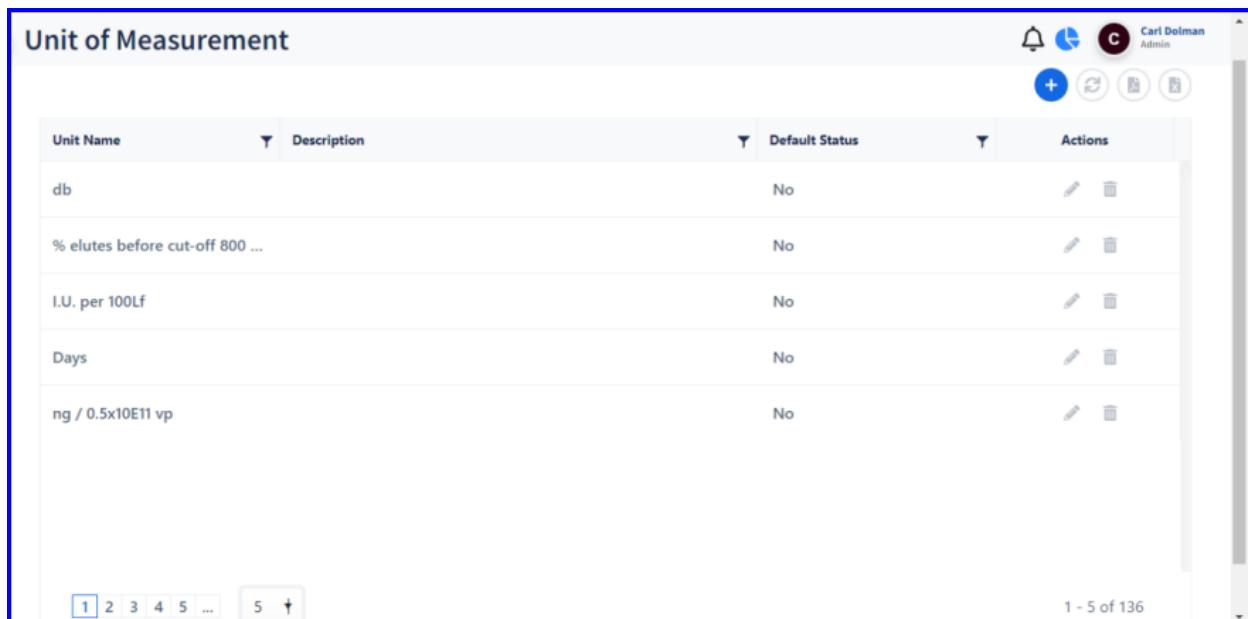
3.2.1 Unit of Measurement

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

3.2.1.1 Creating a New Unit of Measurement

To create a UOM, follow these steps:

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



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

FIGURE: Unit of Measurement Master Screen

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

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



FIGURE: Add Unit of Measurement screen

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

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

3.2.1.2 Editing Unit of Measurement Record

To edit UOM record, follow these steps:

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

3.2.1.3 Deleting Unit of Measurement Record

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

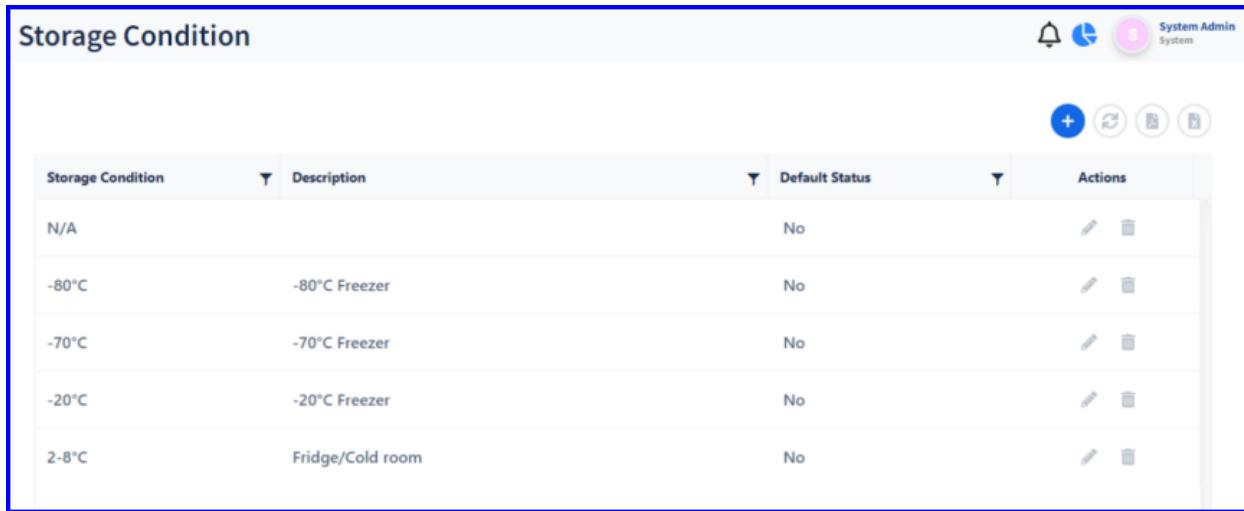
3.2.2 Storage Condition

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

3.2.2.1 Creating a New Storage Condition

To create a new Storage Condition, follow these steps:

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



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

FIGURE: Storage Condition Master Screen

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

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

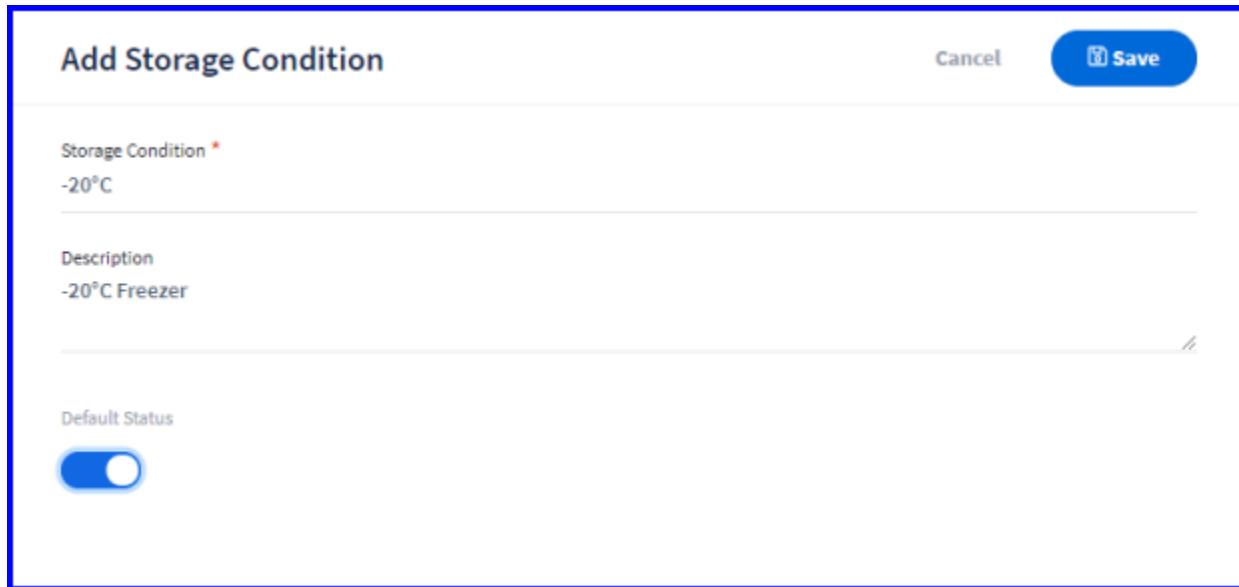


FIGURE: Add Storage Condition Screen

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

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

3.2.2.2 Editing Storage Condition Record

To edit storage condition record, follow these steps:

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

3.2.2.3 Deleting Storage Condition Record

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

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

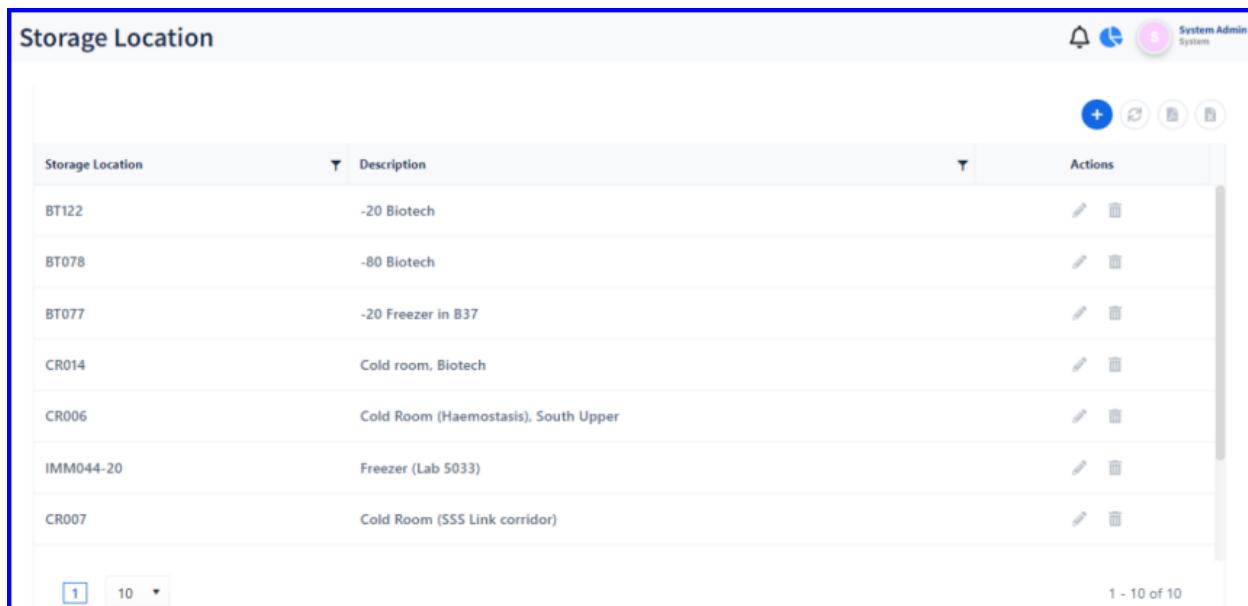
3.2.3 Storage Location

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

3.2.3.1 Creating a New Storage Location

To create a new storage location, follow these steps:

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



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

FIGURE: Storage Location Master Screen

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

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



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

FIGURE: Add Storage Location Screen

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

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

3.2.3.2 Editing Storage Location Record

To edit a storage location record, follow these steps:

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

3.2.3.3 Deleting Storage Location Record

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

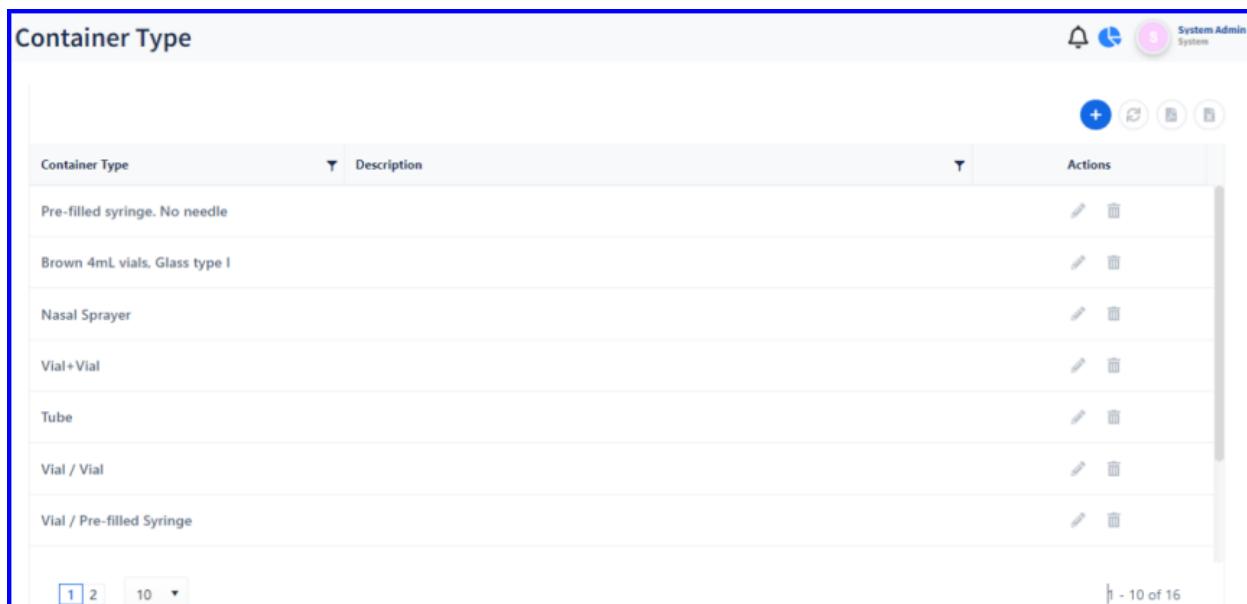
3.2.4 Container Type

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

3.2.4.1 Creating a New Container Type

To create a new Container Type, follow these steps:

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



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

FIGURE: Container Type Master Screen

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

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



FIGURE: Add Container Type Screen

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

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

3.2.4.2 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**.

3.2.4.3 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.

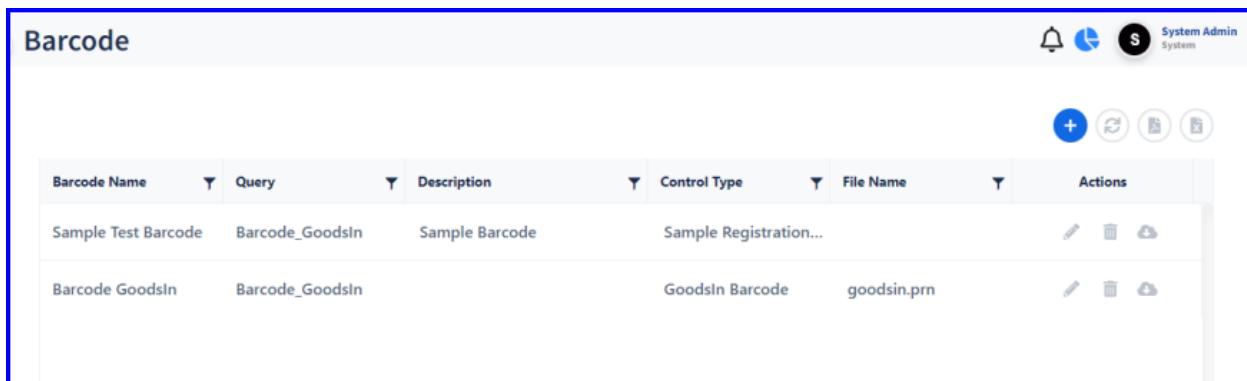
3.2.5 Barcode

Barcode master is used to create and manage Barcodes.

3.2.5.1 Creating a New Barcode

To create a new Barcode, follow these steps:

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



The screenshot shows the 'Barcode' master screen. At the top, there are navigation icons for a bell, a blue circle, and a user profile labeled 'System Admin'. Below the header is a toolbar with a blue plus sign, a magnifying glass, a refresh icon, and other system-related icons. The main area is a table with the following data:

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

FIGURE: Barcode Master Screen

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

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

Add Barcode

Barcode *
Lipid & Serum Barcode

Query *
Barcode_GoodsIn

Control Type *
GoodsIn Barcode

Description
Test Barcode

Barcode

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

 [goodsin.prn](#)
386 Bytes 

Cancel  Save

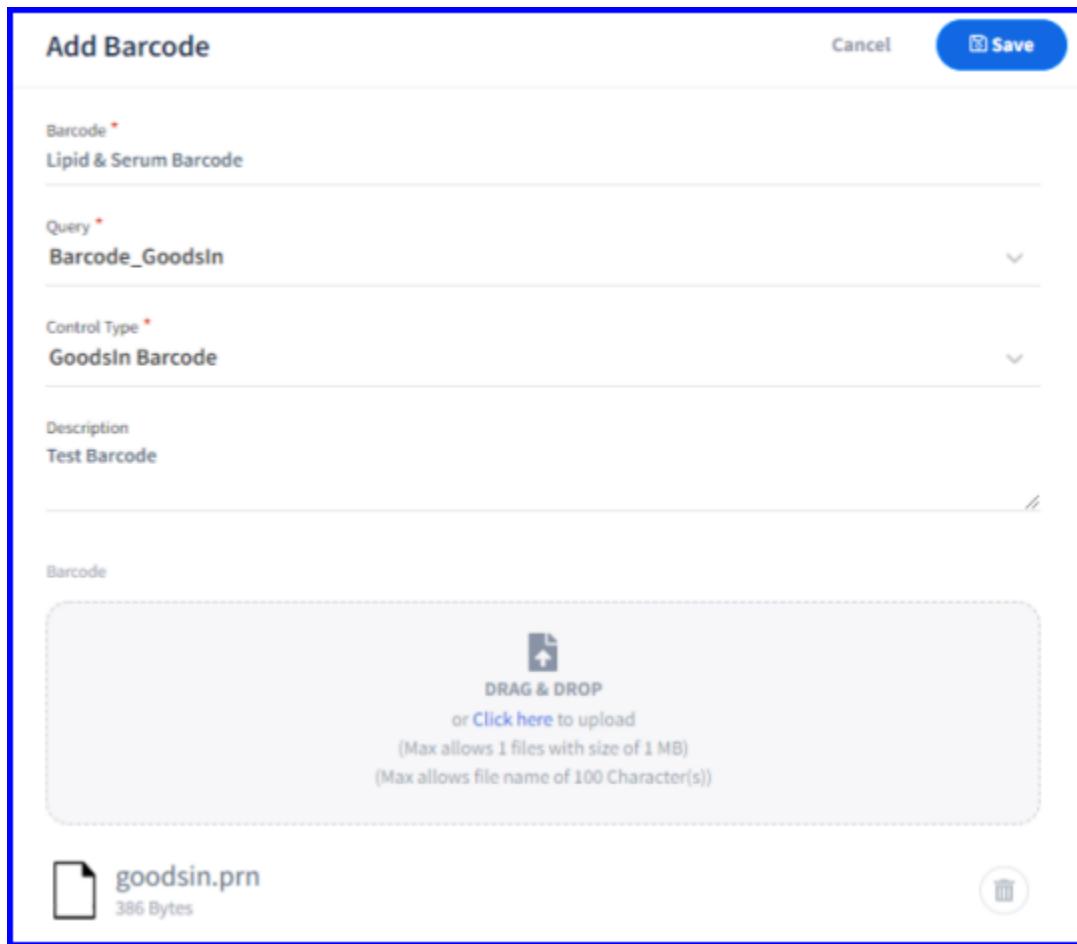


FIGURE: Add Barcode Screen

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

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

3.2.5.2 Editing Barcode Record

To edit a Barcode 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 Barcode Record

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

3.2.5.4 Downloading PRN File

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

3.3 Configuration

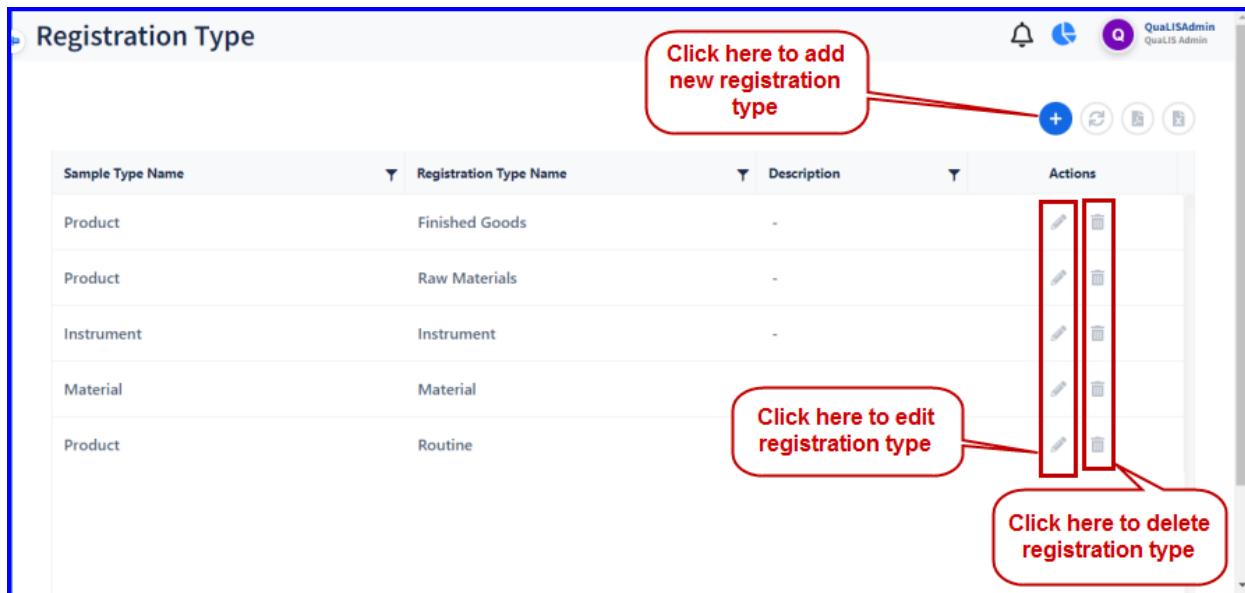
3.3.1 Registration Type

Registration Type master is used to add and manage registration types. Registration type is created for a selected sample type.

3.3.1.1 Adding a New Registration Type

To create a new Registration type, follow these steps:

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



The screenshot shows a table titled 'Registration Type' with the following data:

Sample Type Name	Registration Type Name	Description	Actions
Product	Finished Goods	-	 
Product	Raw Materials	-	 
Instrument	Instrument	-	 
Material	Material	-	 
Product	Routine	-	 

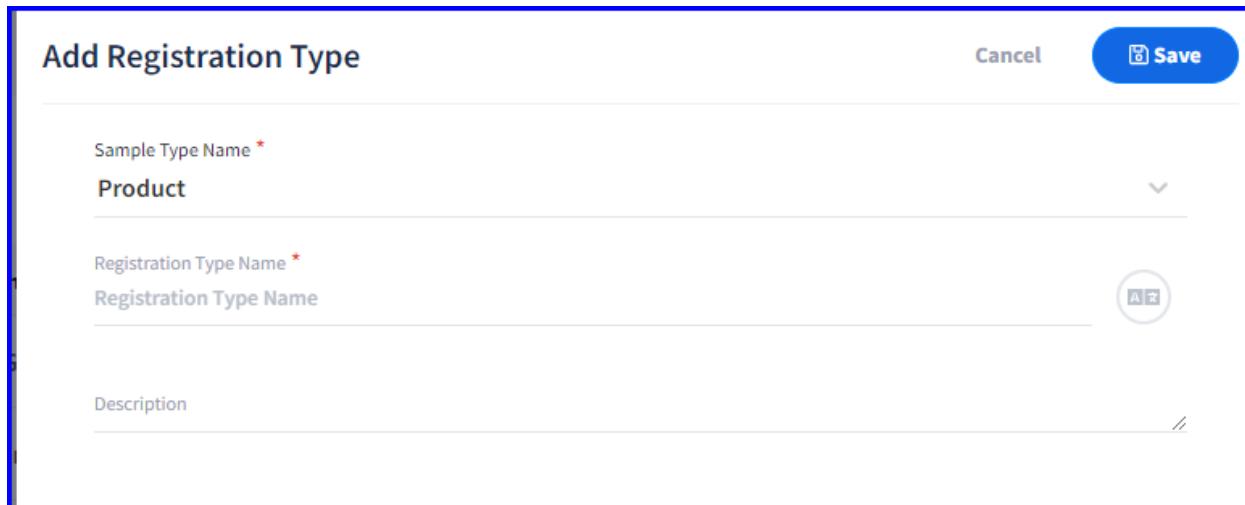
Annotations on the screen:

- A red callout box with a blue border and a red arrow points to the blue '+' icon in the top right corner of the table header. The text inside the box is 'Click here to add new registration type'.
- A red callout box with a blue border and a red arrow points to the first 'Edit' icon (pencil) in the 'Actions' column. The text inside the box is 'Click here to edit registration type'.
- A red callout box with a blue border and a red arrow points to the first 'Delete' icon (trash bin) in the 'Actions' column. The text inside the box is 'Click here to delete registration type'.

FIGURE: Registration Type Master Screen

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

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



The screenshot shows the 'Add Registration Type' dialog box with the following fields:

- Sample Type Name ***: A dropdown menu showing 'Product'.
- Registration Type Name ***: A text input field containing 'Registration Type Name'.
- Description**: A text input field.

Buttons at the top right of the dialog are 'Cancel' and 'Save' (with a blue icon).

FIGURE: Add Registration Type Dialog

3. In the **Sample Type Name** field, select the sample type name to which you want to add the registration type.

4. In the **Registration Type Name** field, type the registration type name.
5. In the **Description** field, type the description.
6. Click **Save**.

You can see the registration type you just created listed in the Registration Type master.

3.3.1.2 Editing and Deleting Registration Type

Options to edit and delete registration type appear in each record in the Registration Type master.

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

3.3.2 Registration Sub Type

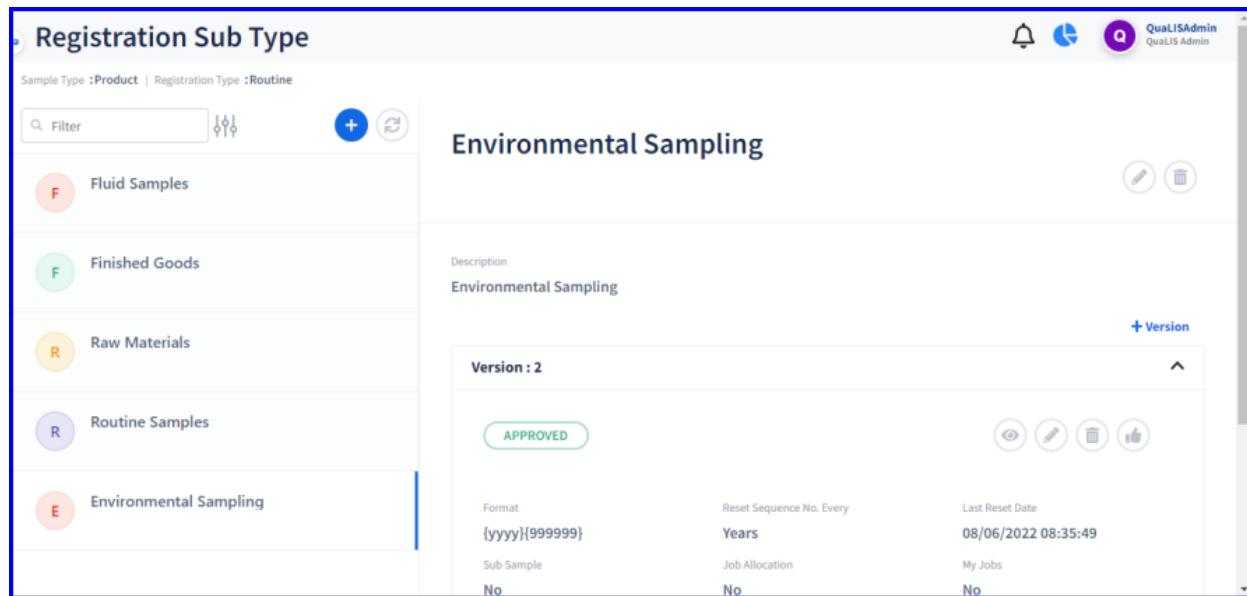
Registration sub Type master is used to add and manage registration sub types. Registration sub type is created for a selected registration type. You can create versions for registration sub type. You can edit the details until the registration sub type is in the Draft state. Once approved you cannot edit the details.

The previous one will expire once you approve an new registration sub type

3.3.2.1 Adding a New Registration Sub Type

To create a new registration sub type, follow these steps:

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



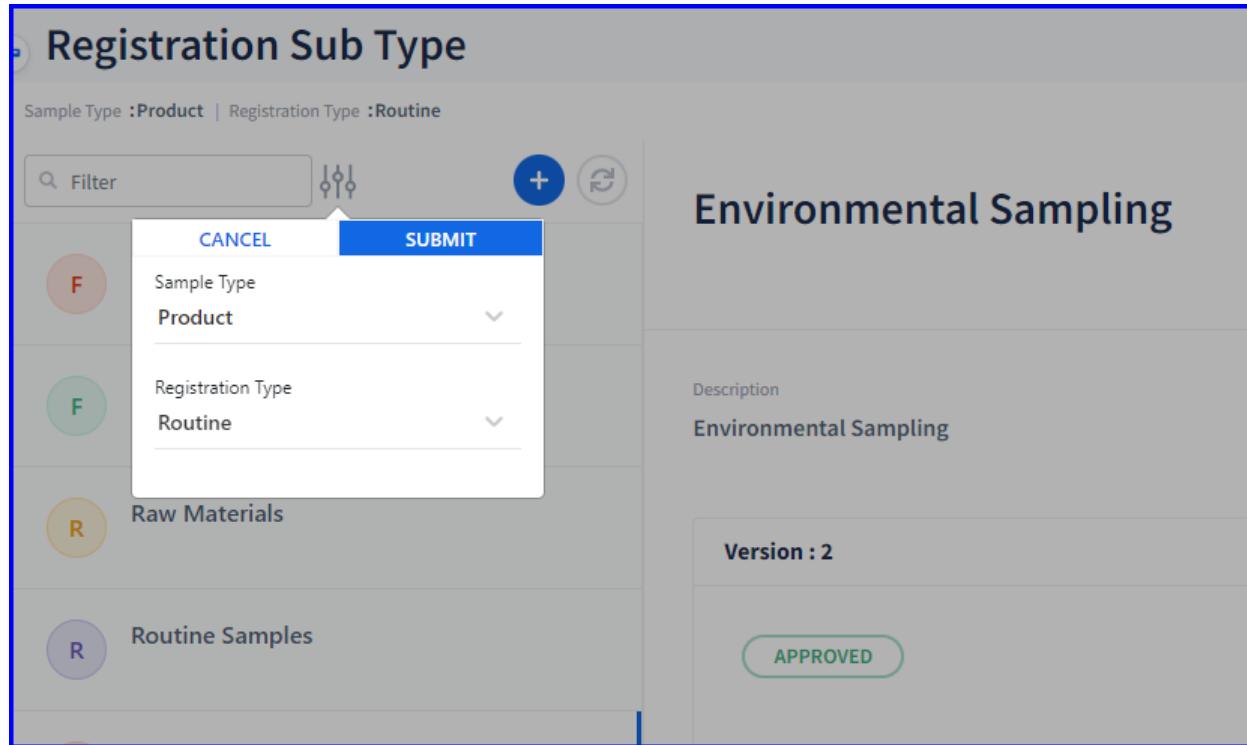
The screenshot shows the 'Registration Sub Type' master screen. On the left, a list of sub types is displayed: Fluid Samples (F), Finished Goods (F), Raw Materials (R), Routine Samples (R), and Environmental Sampling (E). The 'Environmental Sampling' record is selected. The main panel shows the 'Environmental Sampling' record with the following details:

- Description:** Environmental Sampling
- Version:** 2
- APPROVED** (Status)
- Format:** {yyyy}{999999}
- Reset Sequence No. Every:** Years
- Last Reset Date:** 08/06/2022 08:35:49
- Sub Sample No:** No
- Job Allocation:** No
- My Jobs:** No

FIGURE: Registration Sub Type Master Screen

In the Registration Sub Type master screen, you can see the list of registration sub types created. Options to edit and delete registration sub types appear in each record.

2. click . The filter dialog appears as shown in the figure:



The screenshot shows the 'Registration Sub Type' master screen with a filter dialog open. The filter dialog has the following fields:

- Sample Type:** Product
- Registration Type:** Routine

The 'SUBMIT' button is highlighted. The main panel shows the 'Environmental Sampling' record with the following details:

- Description:** Environmental Sampling
- Version:** 2
- APPROVED** (Status)

FIGURE: Selecting Registration Type to add Registration Sub Type

3. Select the **Sample Type** and **Registration Type** to add the registration sub type and then click **SUBMIT**. The screen appears as shown in the figure:



FIGURE: Registration Sub Type Screen for the selected Registration Type

If there is a registration sub type already added, the details appears.

4. Click  . The **Add Registration Type** screen appears as shown in the figure:

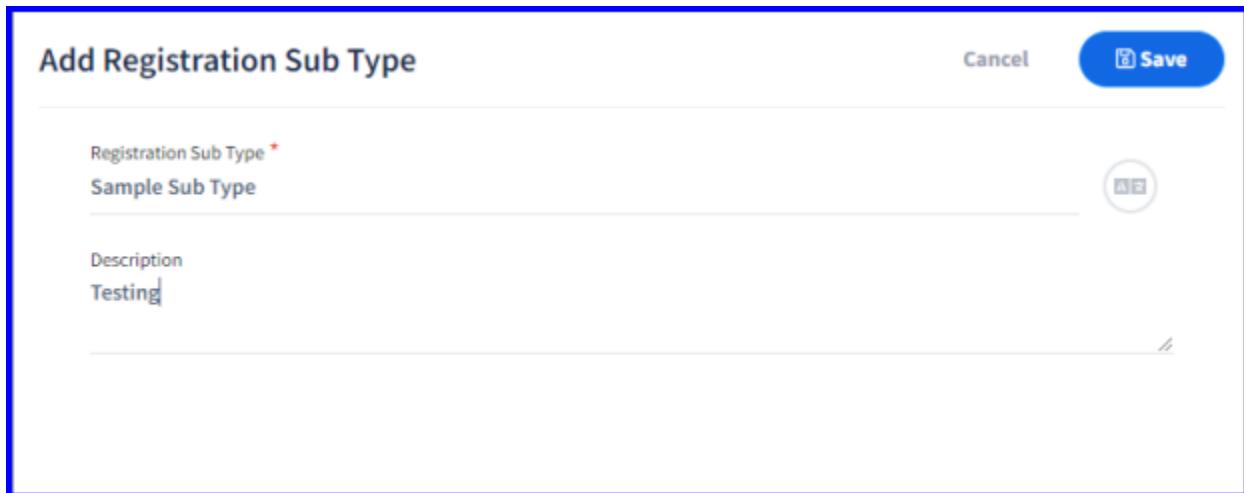


FIGURE: Add Registration Sub Type Dialog

5. In the **Registration Sub Type Name** field, type the registration type name.
6. In the **Description** field, type the description.

7. Click Save.

You can see the registration sub type you just created listed in the Registration Sub Type master as shown in the figure:

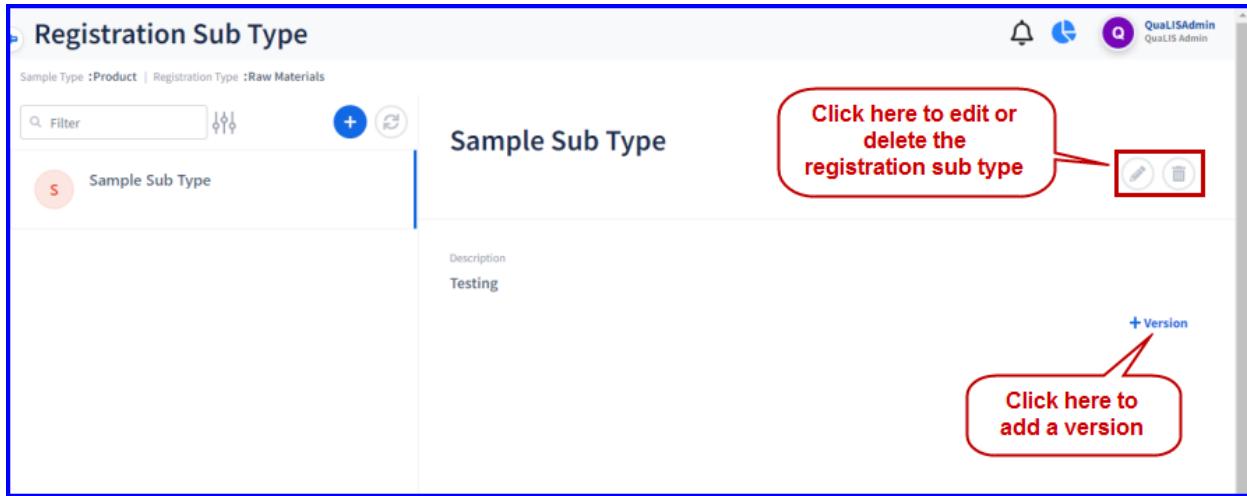


FIGURE: Registration Sub Type Created

3.3.2.2 Adding a Version to the Registration Sub Type

1. In the Registration Sub Type screen, click **+ Version** to add a version. The **Add Version** dialog appears as shown in the figure:

Add Version

Click here to enable Sequence No Length

Sub Sample Sampled By Job Allocation My Jobs

Test Initiate Scheduler Design Template Version Based Flow New Sequence Format

Reset Sequence No. Every * Text Value Sequence No.length *

Reset Duration 4

Format Fields

- Year (2022)
- Year (22)
- Month (08)
- Month (Aug)
- Month (Aug)
- Date (29)
- Character ()
- Sequence Number ({9999})
- /
-

Backspace Clear All

Input Format * 0/30

Output Format * 0/30

FIGURE: Add Version

2. Click to enable options to add to the workflow.
3. You can define the registration number format by enabling the Sequence No. length option. Once you enable this option, the dialog appears as shown in the figure:

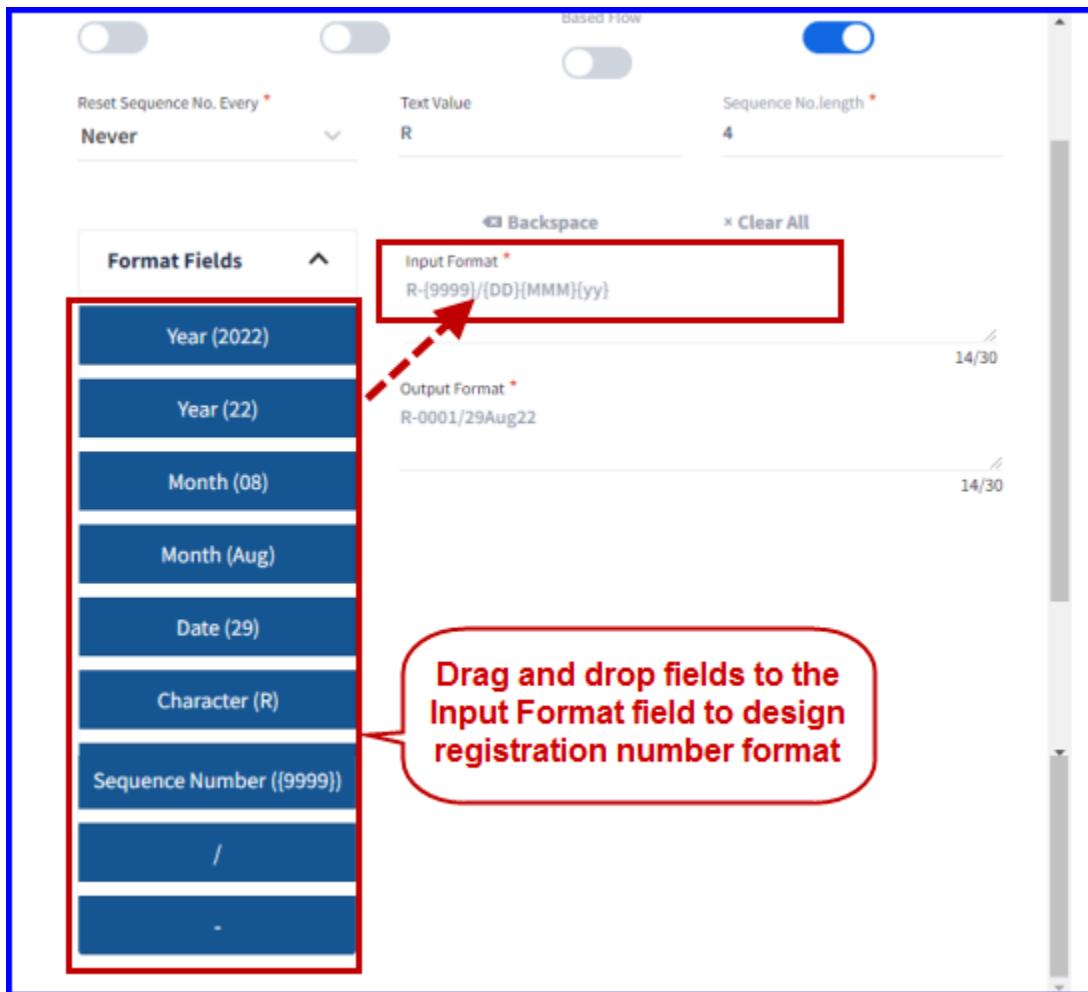


FIGURE: Design Registration No Format

4. In the **Reset Sequence No. Every** field, select the period to reset the sequence number.
5. In the **Text Value** field, type the text to add to the registration number. This text appears in the Character box **Character (R)**. you can drag and drop this character box to the **Input Format** field to add the character to the registration number format.
6. In the **Sequence No. length** field, type the length for the sequence number. This number appears in the Sequence Number box **Sequence Number ({9999})**. you can drag and drop this box to the **Input Format** field to add the length of sequence number to the registration number format
7. Add other boxes to the **Input Format** field as required.

8. Click **Save**. The registration sub type is saved and appears in the DRAFT as shown in the figure:

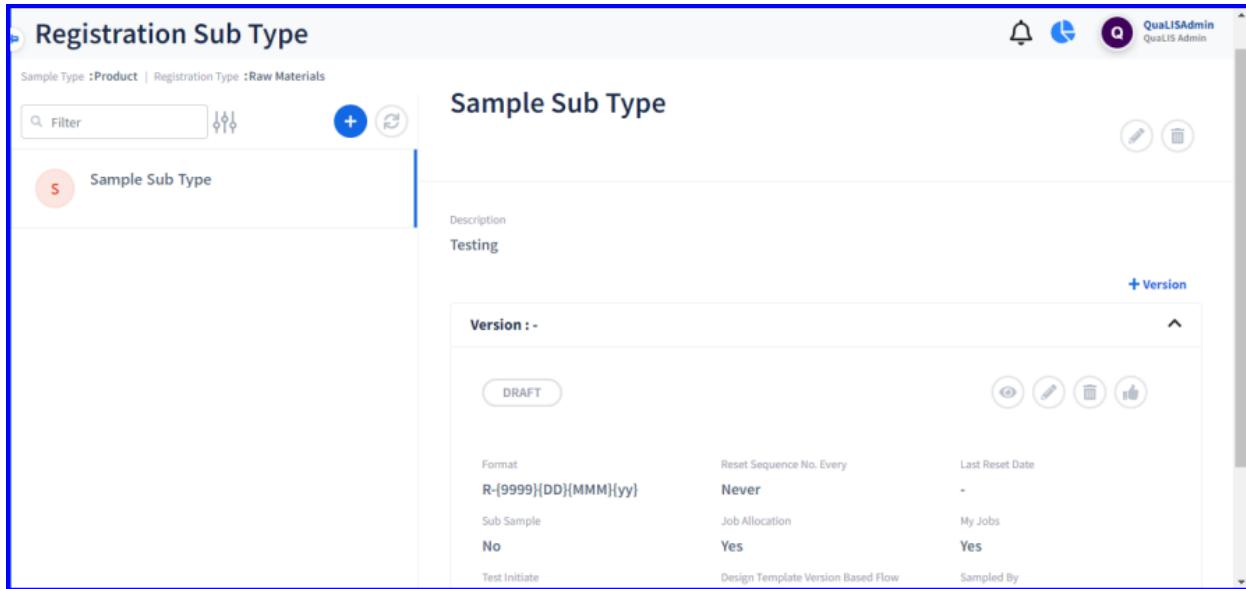


FIGURE: Registration Sub Type Added

3.3.2.3 View Transaction Flow

1. Click  to see the transaction flow as shown in the figure:

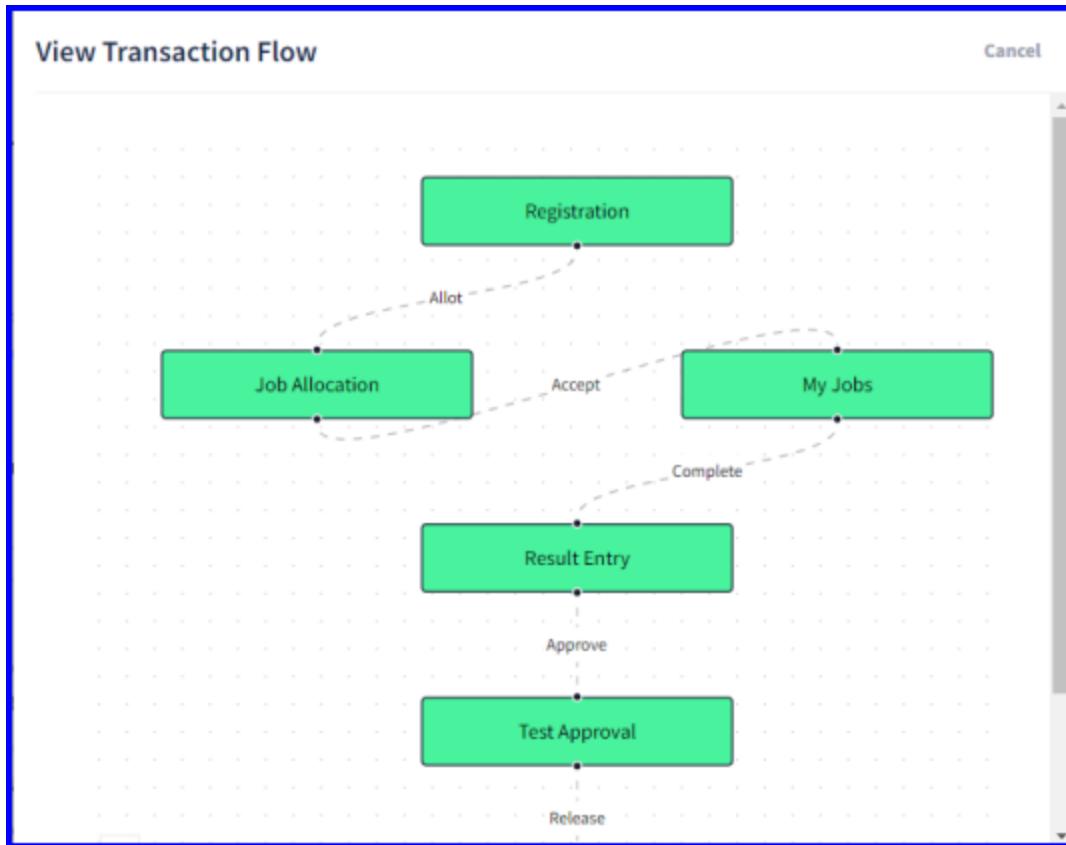
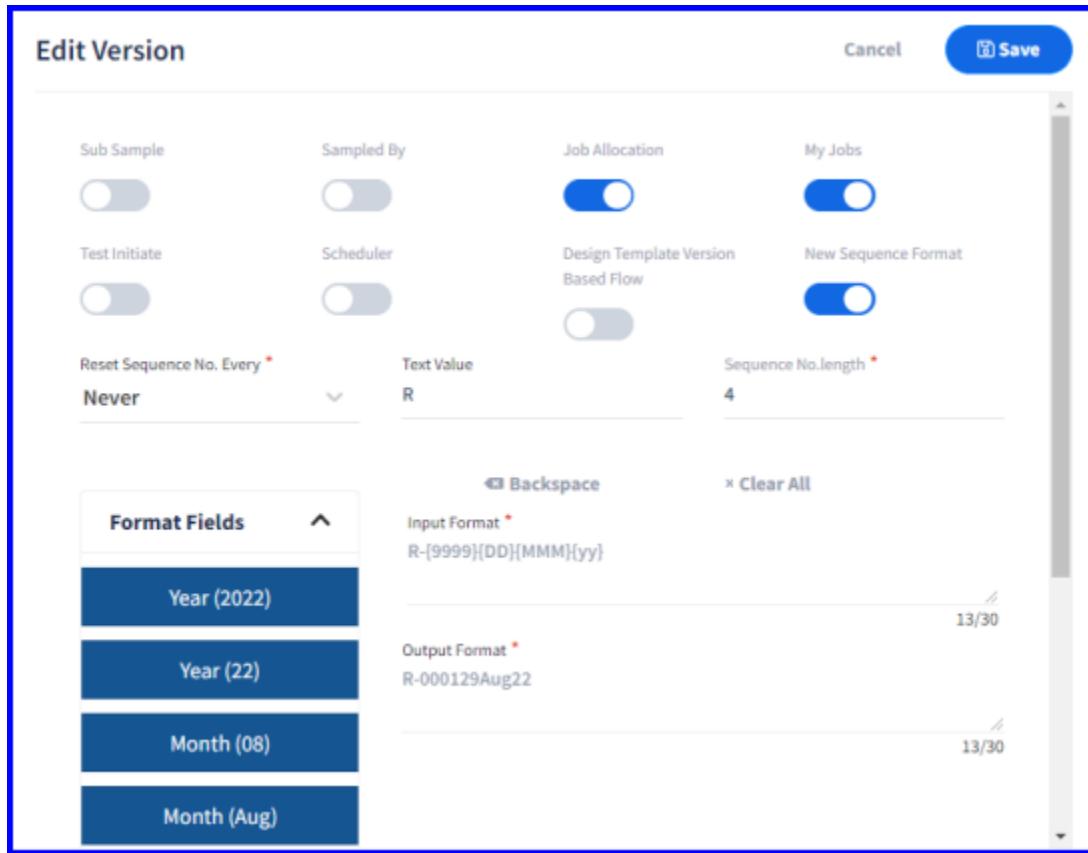


FIGURE: View Transaction Flow

3.3.2.4 Edit Registration Sub Type Version

1. Click to edit the record. The **Edit Version** dialog appears as shown in the figure:



Edit Version

Sub Sample

Sampled By

Job Allocation

My Jobs

Test Initiate

Scheduler

Design Template Version Based Flow

New Sequence Format

Reset Sequence No. Every *

Text Value

Sequence No.length *

Format Fields

Input Format *

Output Format *

Year (2022)

Year (22)

Month (08)

Month (Aug)

Figure: Edit Version Dialog

1. Do required changes and then click **Save**.

3.3.2.5 Delete Registration Sub Type Version

1. Click  to delete the Registration Sub Type Version.

3.3.2.6 Approve Registration Sub Type Version

1. Click  to approve the Registration Sub Type Version. The version is approved and appears as shown in the figure:

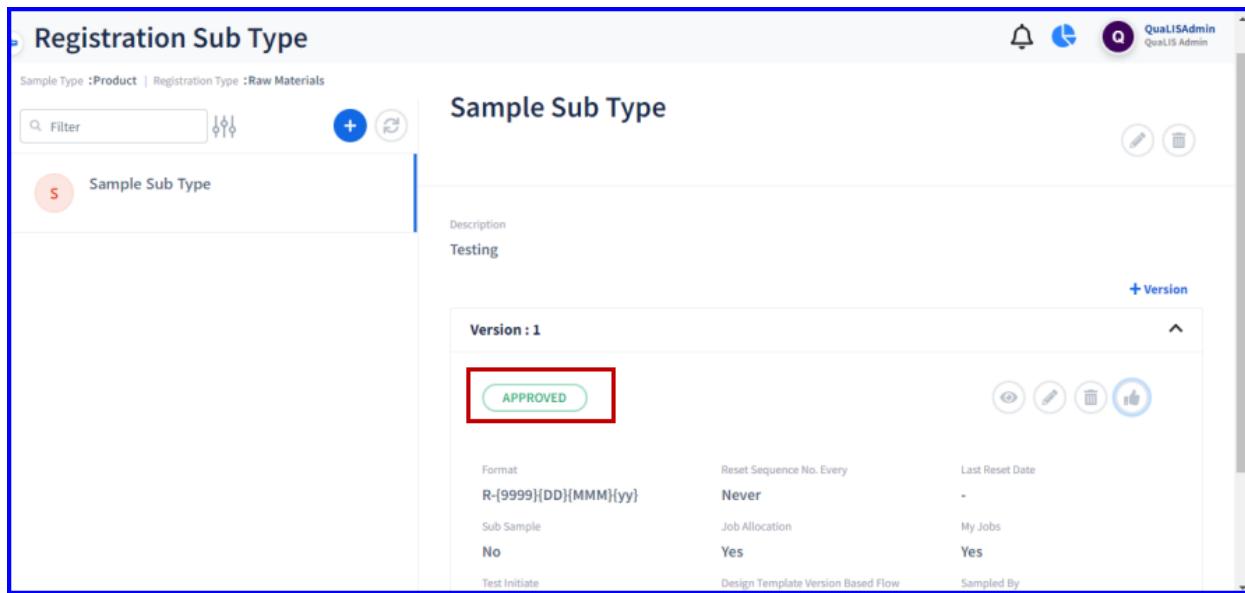


FIGURE: Registration Sub Type Version Approved

3.3.2.7 Editing and Deleting Registration Sub Type

Options to edit and delete registration sub type appear in each record in the Registration Sub Type master. You can edit or delete a registration sub type until it is in the Draft state. You cannot edit or delete a record in the Approved state.

1. To edit registration sub type details, in the Registration Sub Type master screen, select the registration sub type and then click  to edit the registration sub type record. In the **Edit Registration Sub Type** screen, do required changes and then click **Save**.
2. To delete a registration sub type, in the Registration Type master screen, select the registration sub type and then click  to delete the registration sub type record.

3.3.3 Dynamic Template Design

Dynamic Template Design screen is used to design registration form that is used to register a sample in the Registration screen. Template design is created for a selected sample type. You can create versions for templates. You can edit the details until the template is in the DRAFT state. Once approved you cannot edit the details.

The previous one will expire once you approve a new template.

3.3.3.1 Adding a Template

To create a new template, follow these steps:

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

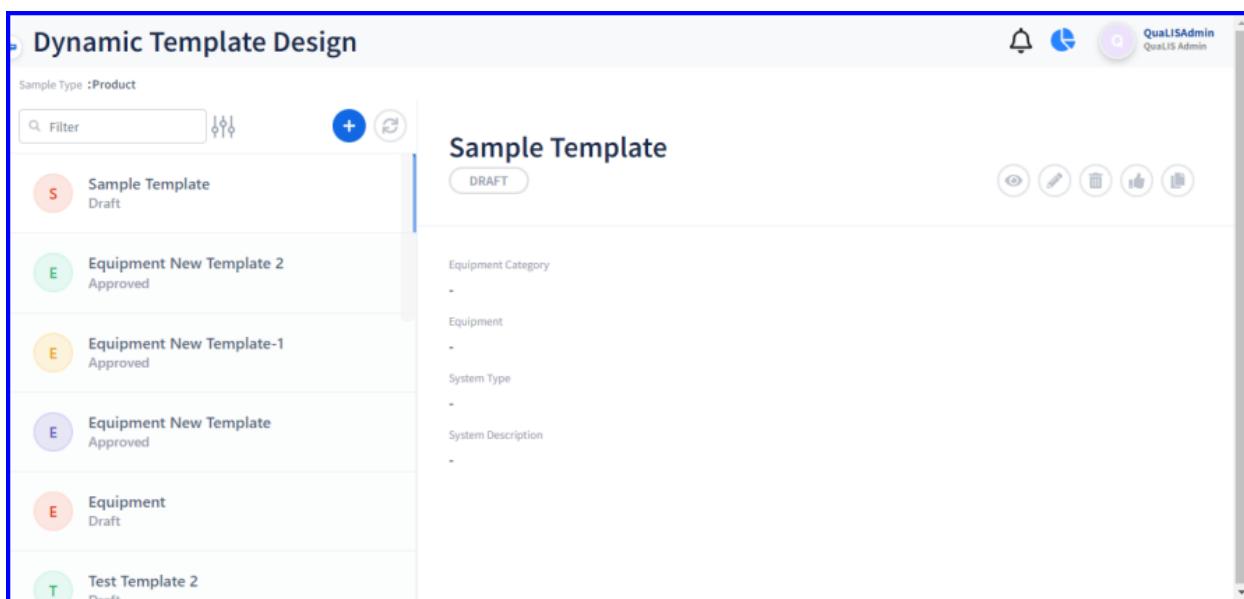


FIGURE: Dynamic Template Design Master Screen

In the Dynamic Template Design master screen, you can see the list of templates created. Options to edit and delete templates appear in each record.

2. Click . The filter dialog appears as shown in the figure:

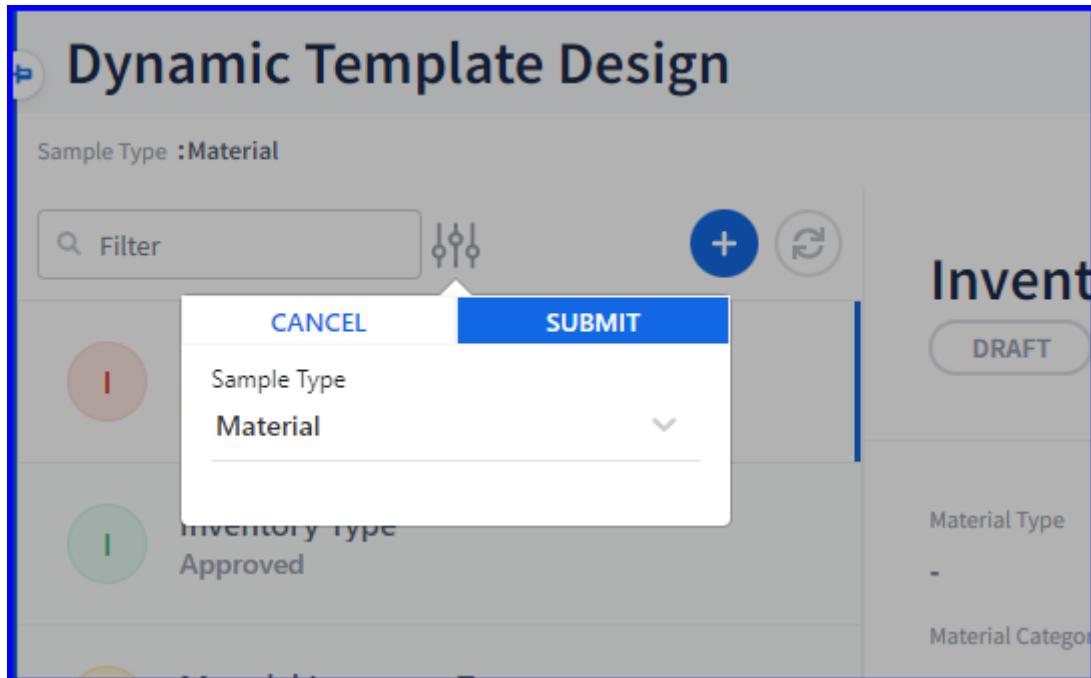


FIGURE: Selecting Sample Type to add Template Design

3. Select the **Sample Type** and then click **SUBMIT**. The screen appears as shown in the figure:

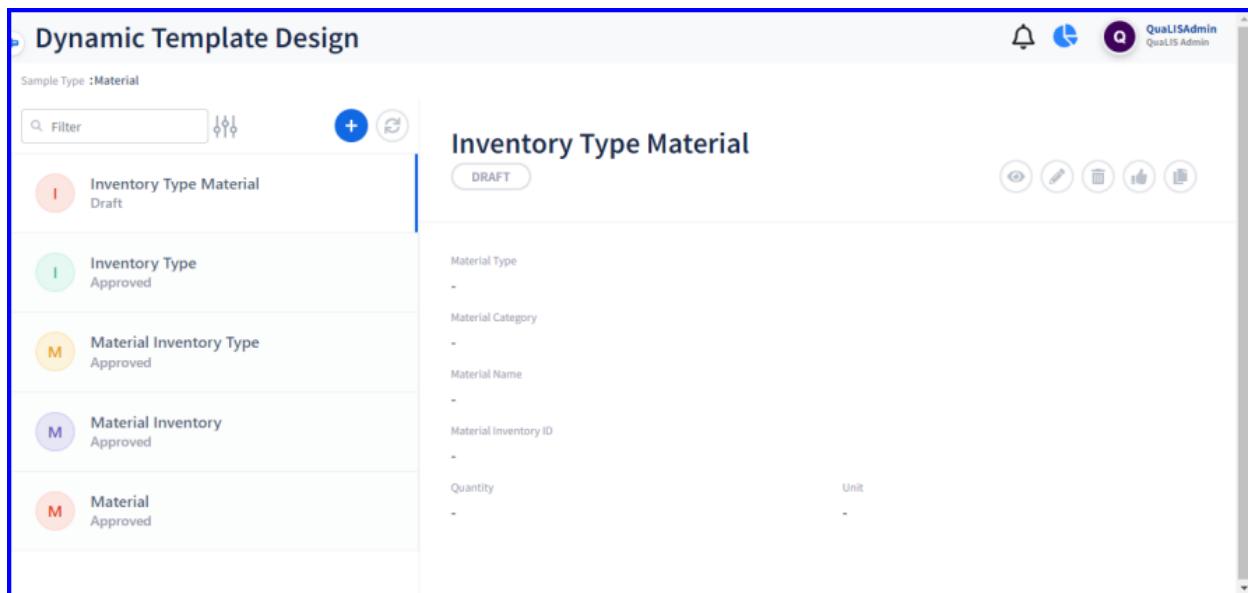


FIGURE: Dynamic Template Design Screen for the selected Sample Type

If there are templates already added, the list of templates appears.

4. Click . The **Add Design Template** screen appears as shown in the figure:

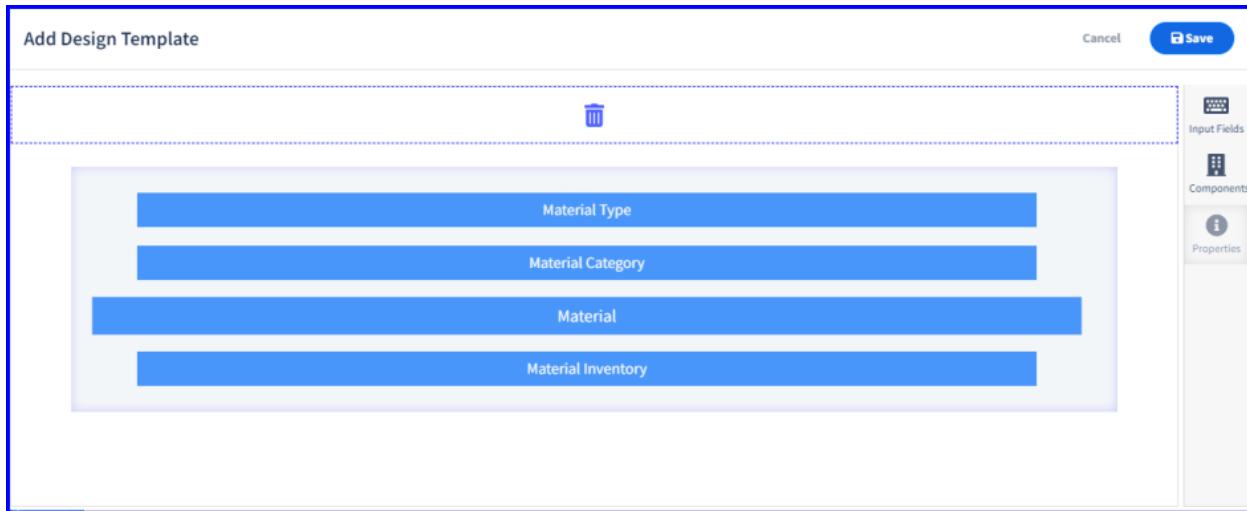


FIGURE: Add Design Template Dialog

The Add Design Template screen enables you to do the following:

- Add custom fields to the template.
- Add predefined fields to the template.

3.3.3.2 Adding Custom Fields to the Template

To add custom fields, follow these steps:

1. In the Add Design Template screen, click . The screen appears as shown in the figure:

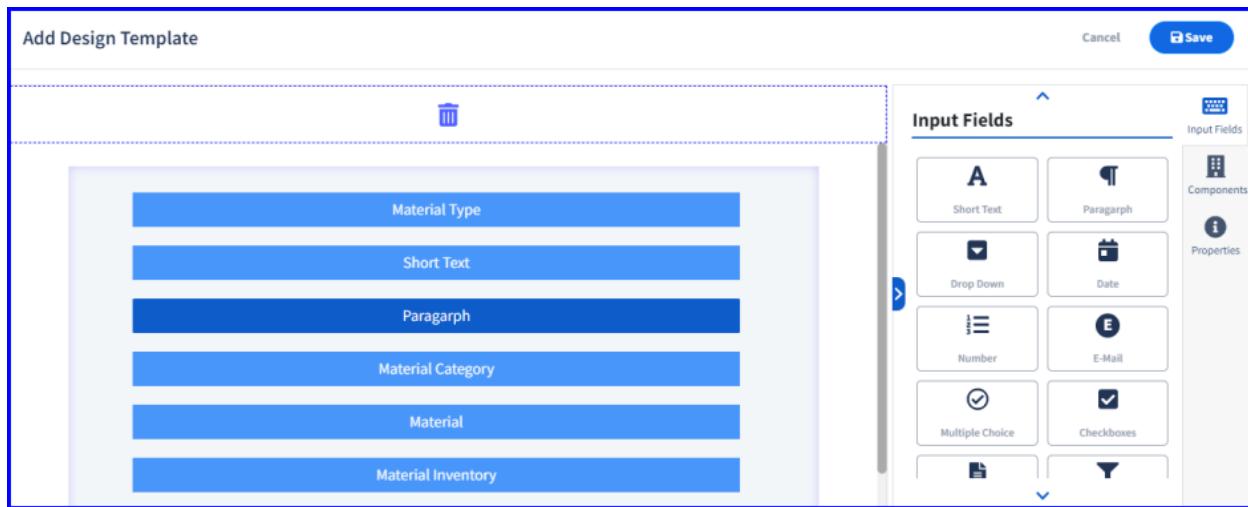


FIGURE: Adding Custom Fields 1

2. Under **Input Fields**, drag and drop the required fields.
3. And then click the dropped field. The **Properties** dialog for the selected field appears as shown in the figure:

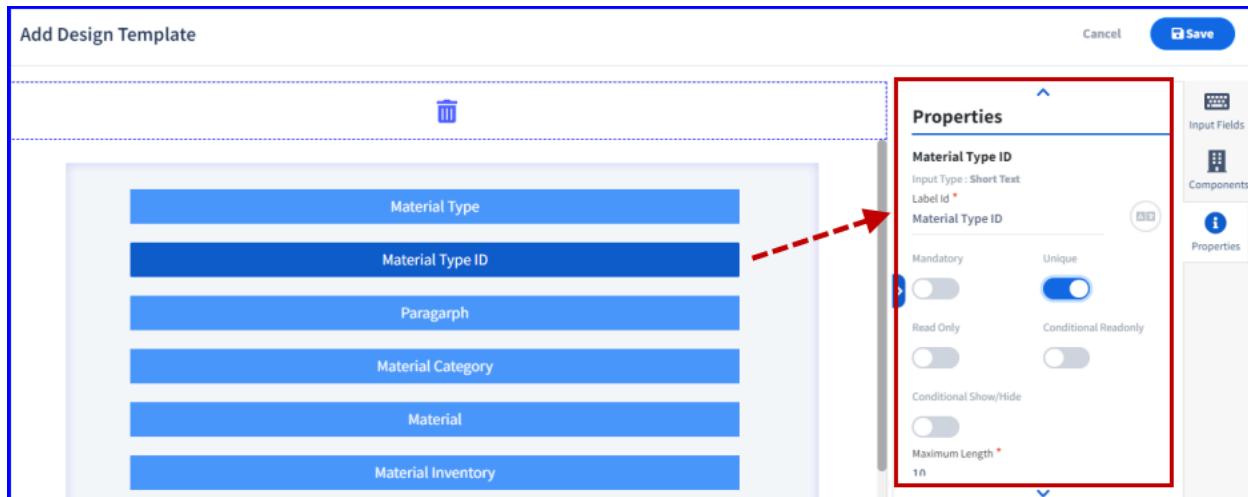


FIGURE: Adding Custom Fields 2

4. In the **Label ID** field, type the label for the field.
5. Click to enable other options like **Mandatory** / **Unique** / **ReadOnly** / **Conditional ReadOnly** / **Conditional Show/Hide** etc.
6. In the **Maximum Length** field, type the maximum number of characters the field shall hold.

7. Add details for all the custom fields added and then click **Save**. The **Template** dialog prompts for the template name as shown in the figure:

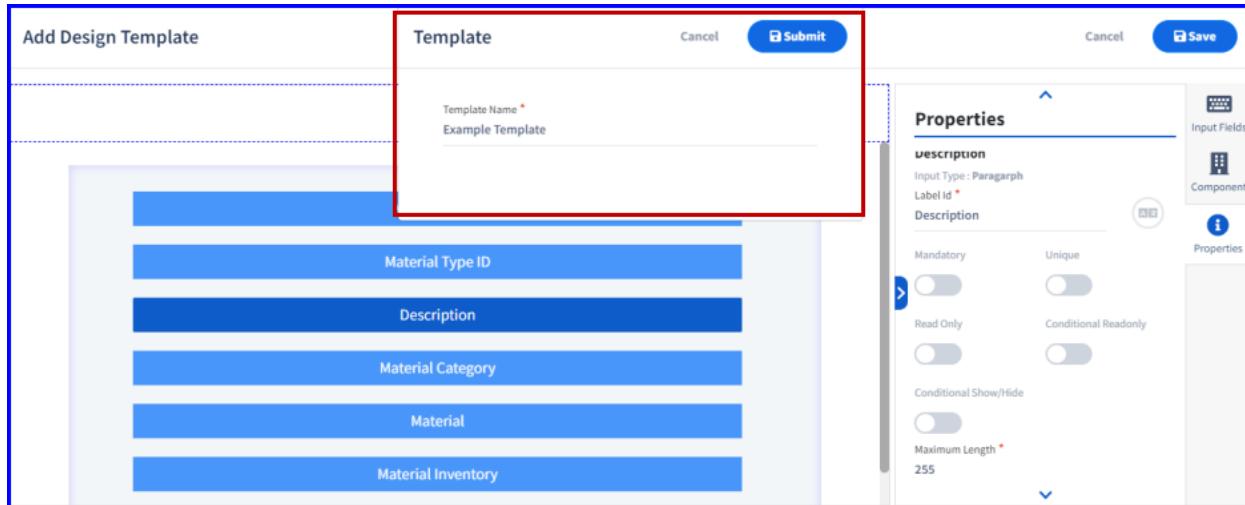


FIGURE: Saving the Template

8. In the **Template Name** field, type a name for the template and then click **Submit**. The template is saved and appears in the Dynamic Template Design screen in the DRAFT state as shown in the figure:

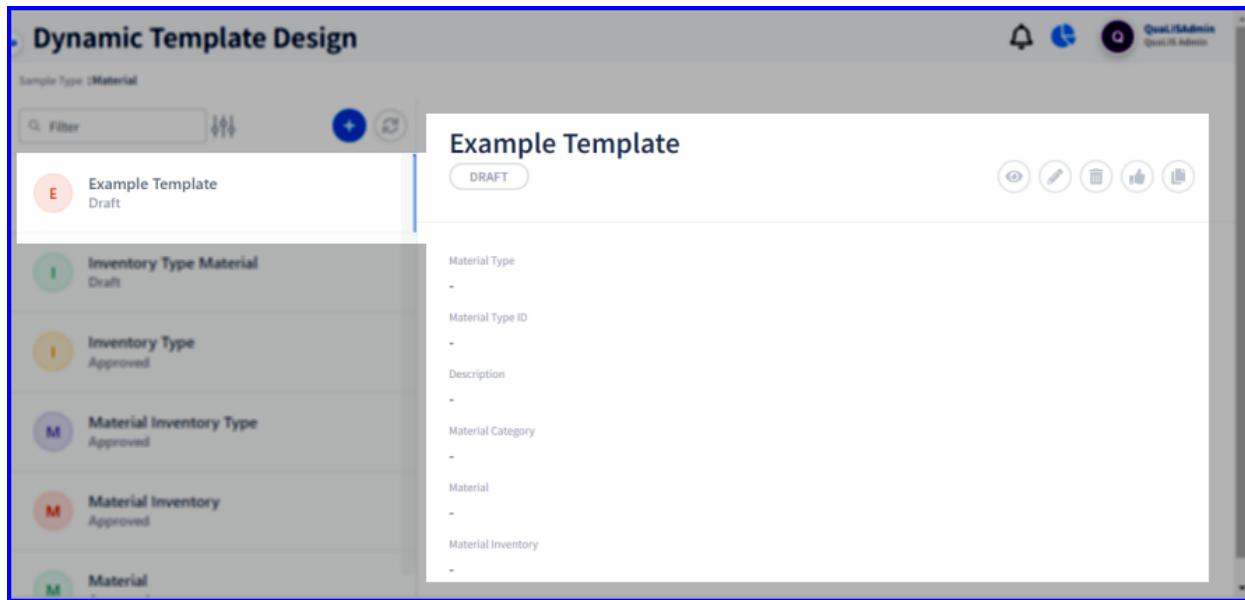
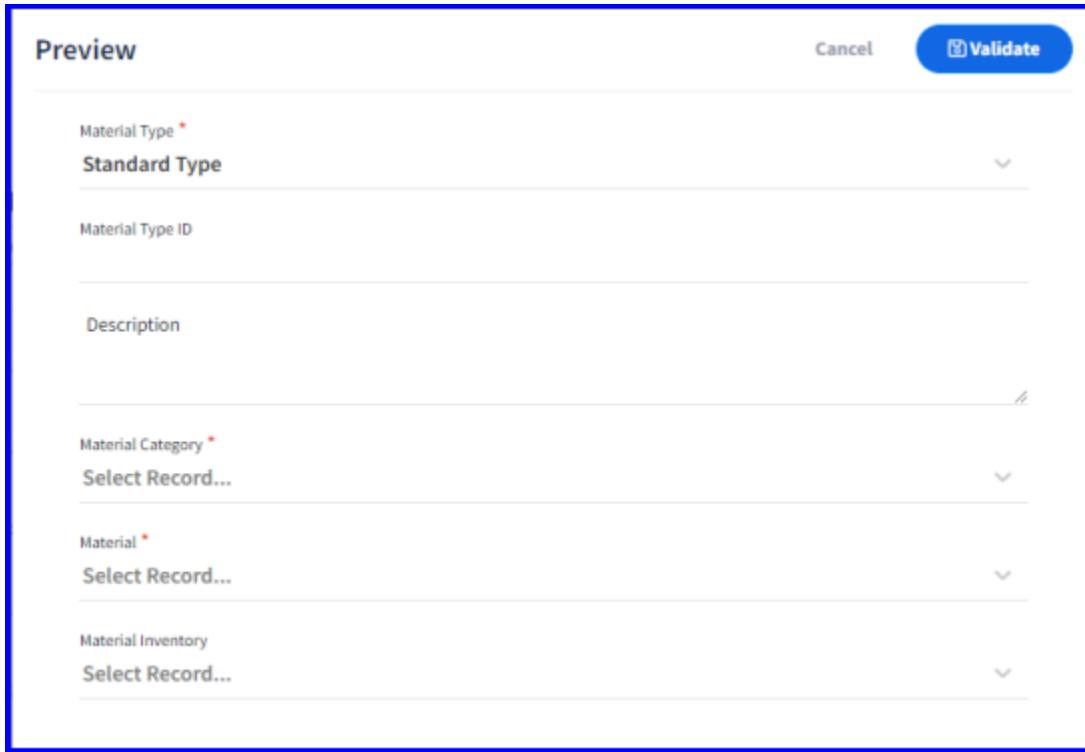


FIGURE: Template Design Added

3.3.3.3 Preview Dynamic Template Design

1. Click  to preview the template design as shown in the figure:



Preview

Material Type *

Standard Type

Material Type ID

Description

Material Category *

Select Record...

Material *

Select Record...

Material Inventory

Select Record...

Cancel

Validate

FIGURE: Dynamic Template Design Preview

3.3.3.4 Edit Design Template

1. Click to edit the record. The **Edit Design Template** dialog appears as shown in the figure:

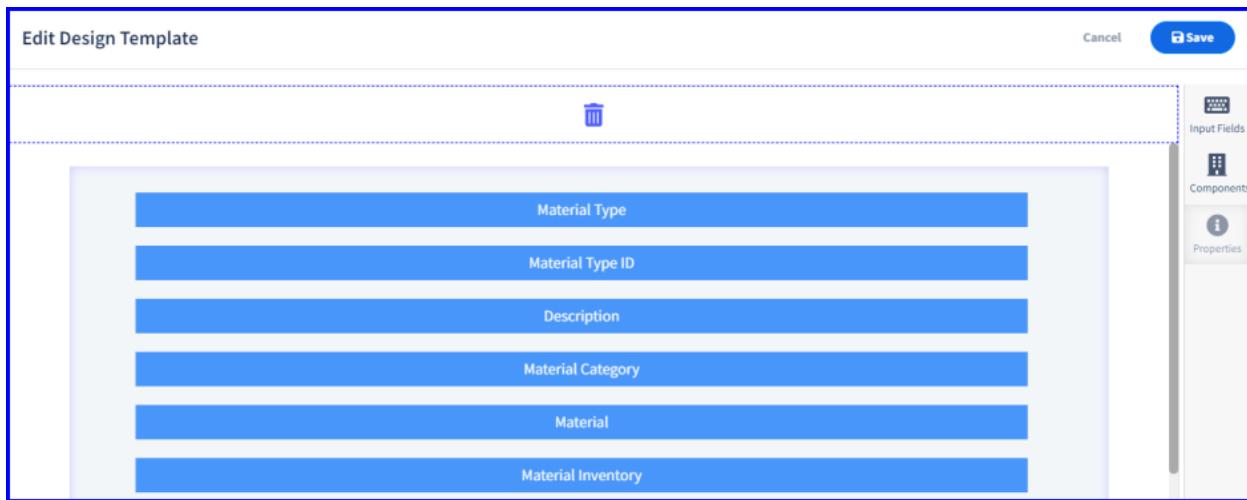


FIGURE: Edit Design Template Dialog

2. Do required changes and then click **Save**.

3.3.3.5 Delete Registration Sub Type Version

1. Click  to delete the Design Template that is in the DRAFT state. The confirmation dialog appears as shown in the figure:

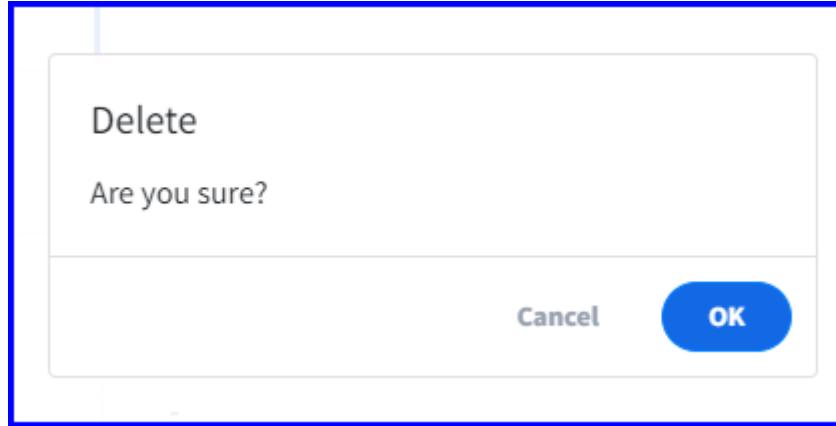


FIGURE: Delete Design Template Dialog

2. Click **Ok** to delete the template.

3.3.3.6 Approve Template Design

1. Click  to approve the template. The template is approved and appears as shown in the figure:

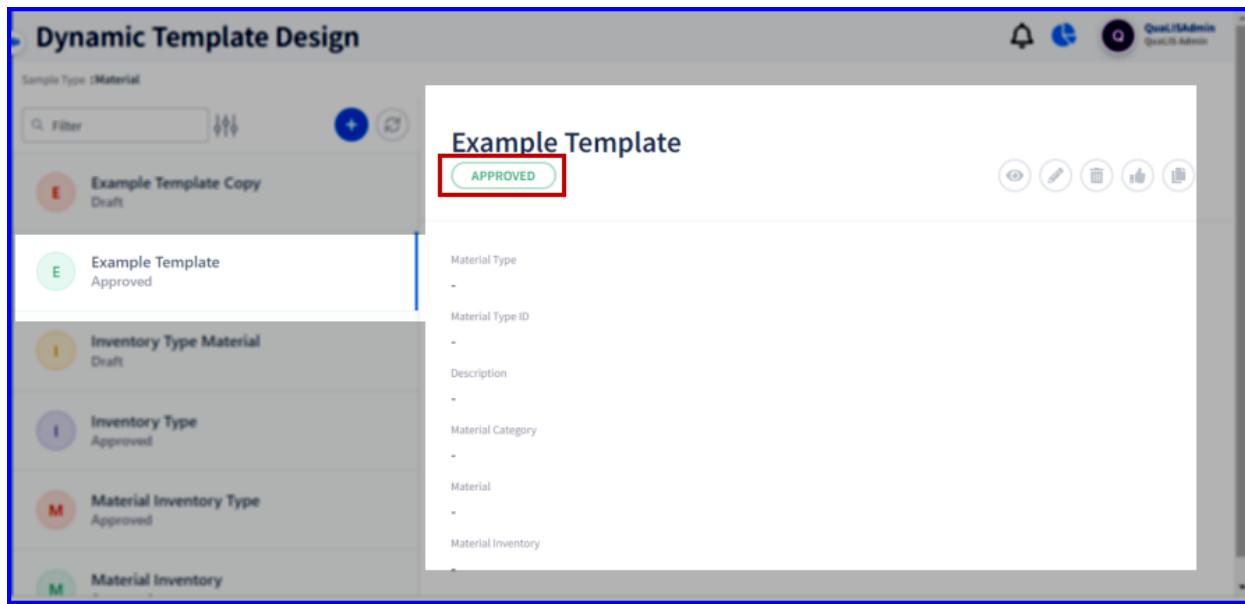


FIGURE: Template Design Approved

3.3.3.7 Copy Template Design

1. Click  to approve copy the template. The **Copy Template** dialog appears as shown in the figure:

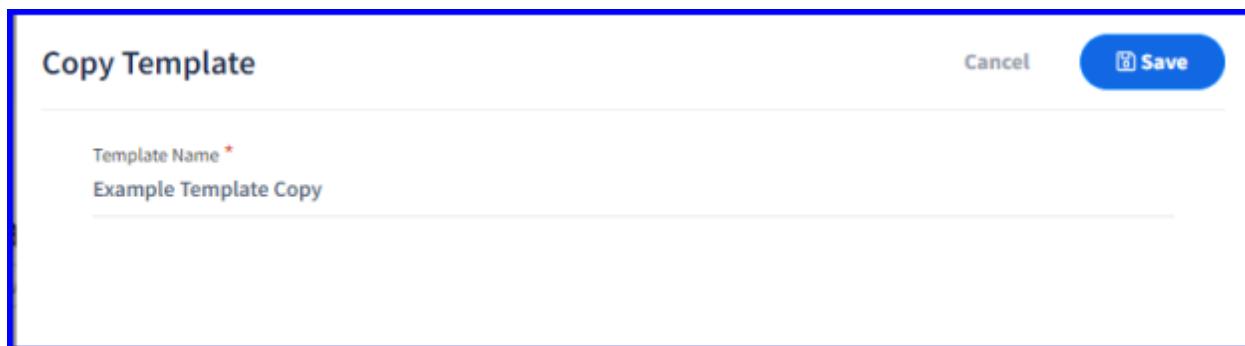


FIGURE: Copy Template Dialog

2. In the **Template Name** field, type name for the template and then click **Save**. The copied template appears as shown in the figure:

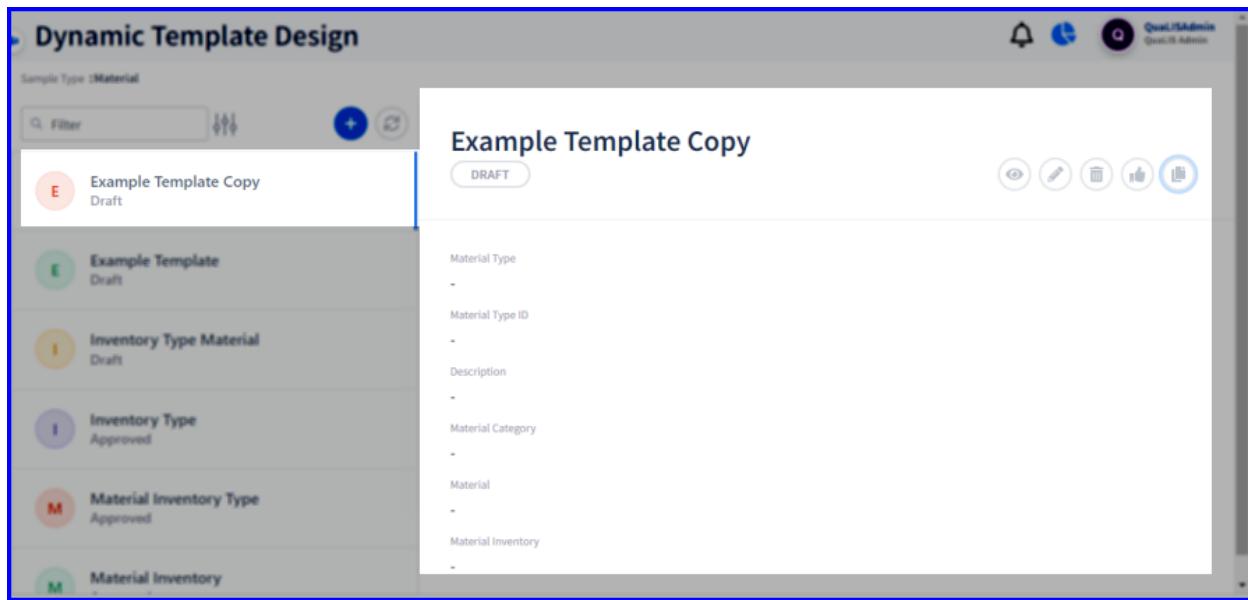


FIGURE: Template Design Copied

You can do required changes and then save the template.

3.3.4 Design Template Mapping

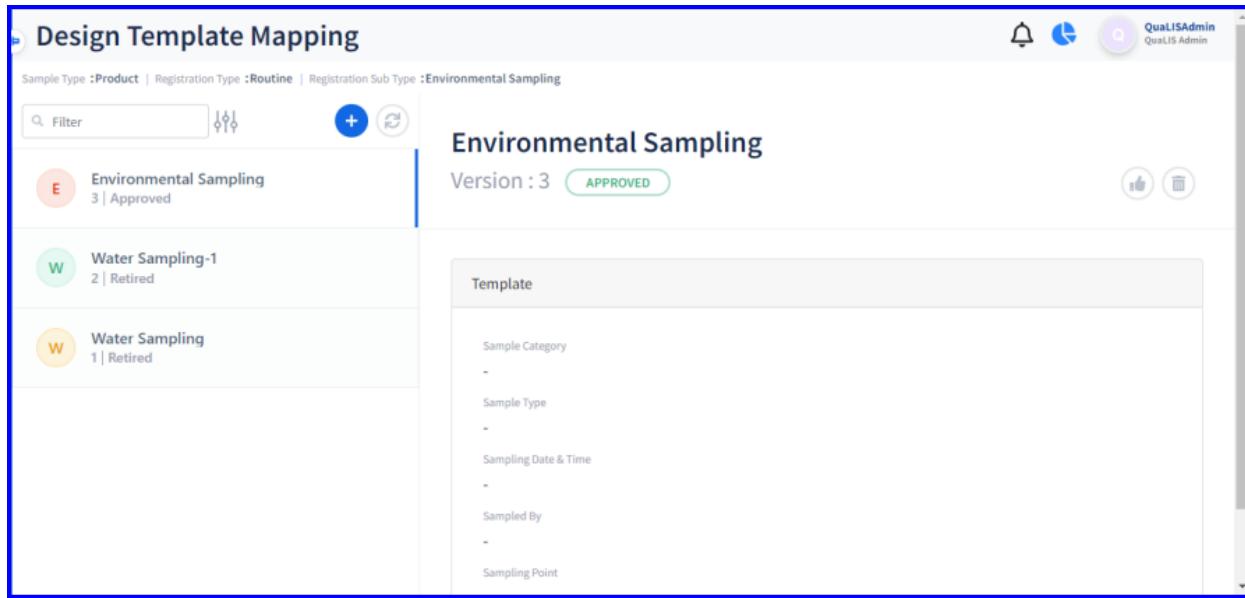
Design Template Mapping screen is used to map design templates to the selected Registration Sub Type. You must map a template to the selected Registration Sub Type and approve it to use the template for the sub type. You can edit the details until the template mapping is in the Draft state. Once approved you cannot edit the details.

The previous one will expire once you approve a new template mapping.

3.3.4.1 Mapping Template

To map a template, follow these steps:

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



The screenshot shows the 'Design Template Mapping' master screen. At the top, there are filter and search icons, a '+' button for creating new templates, and a 'Filter' button. The top right shows a user profile for 'QualisAdmin'.

The main area displays a list of templates:

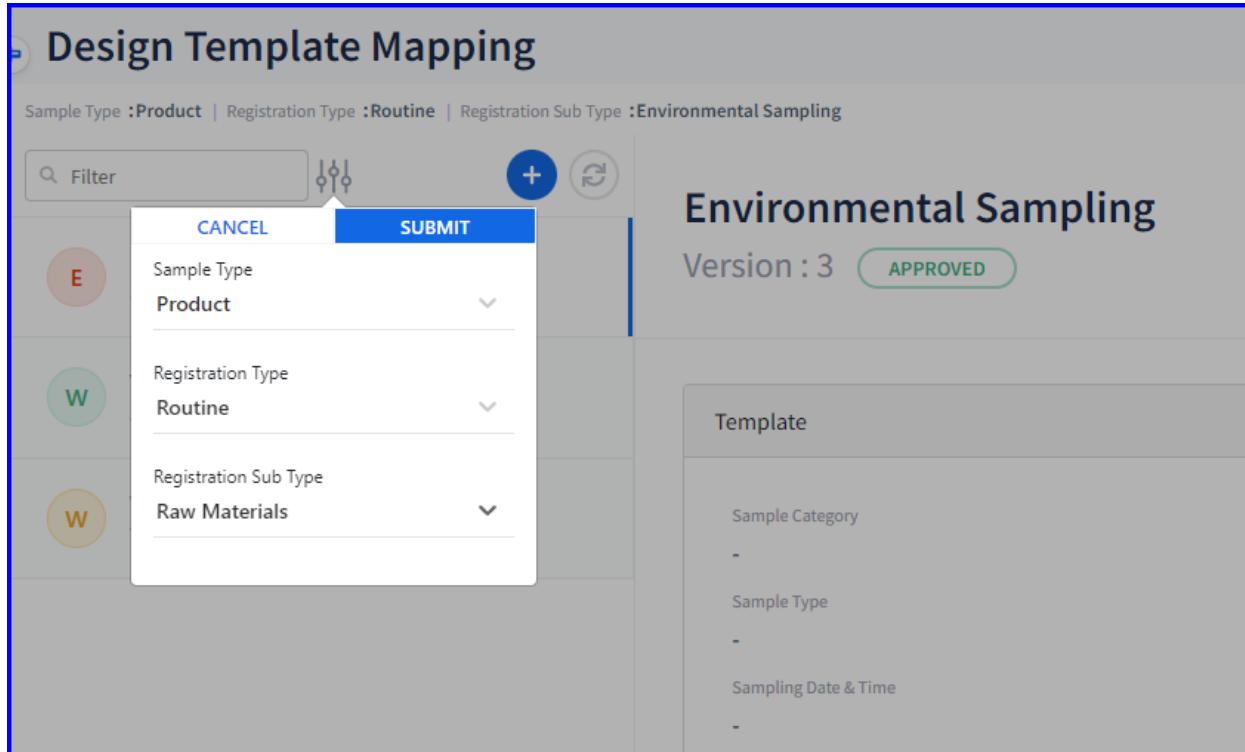
- Environmental Sampling** (Version 3, APPROVED): Status icons: thumbs up, trash, and a blue circular icon.
- Water Sampling-1** (2, Retired): Status icons: thumbs up, trash, and a blue circular icon.
- Water Sampling** (1, Retired): Status icons: thumbs up, trash, and a blue circular icon.

On the right, a detailed view of the 'Environmental Sampling' template is shown, listing its fields: Sample Category, Sample Type, Sampling Date & Time, Sampled By, and Sampling Point.

FIGURE: Design Template Mapping Master Screen

In the **Design Template Mapping** master screen, you can see the list of templates created. Options to edit and delete templates appear in each record.

2. Click . The filter dialog appears as shown in the figure:



The screenshot shows the 'Design Template Mapping' master screen with a filter dialog open over the list of templates.

The filter dialog has three dropdown fields:

- Sample Type**: Product (selected)
- Registration Type**: Routine (selected)
- Registration Sub Type**: Raw Materials (selected)

Below the dialog, the list of templates is shown, with the 'Environmental Sampling' template selected and its details visible on the right.

FIGURE: Selecting Registration sub Type to add Template Design

3. Select the **Sample Type, Registration Type and Registration Sub Type** and then click **SUBMIT**. The screen appears as shown in the figure:

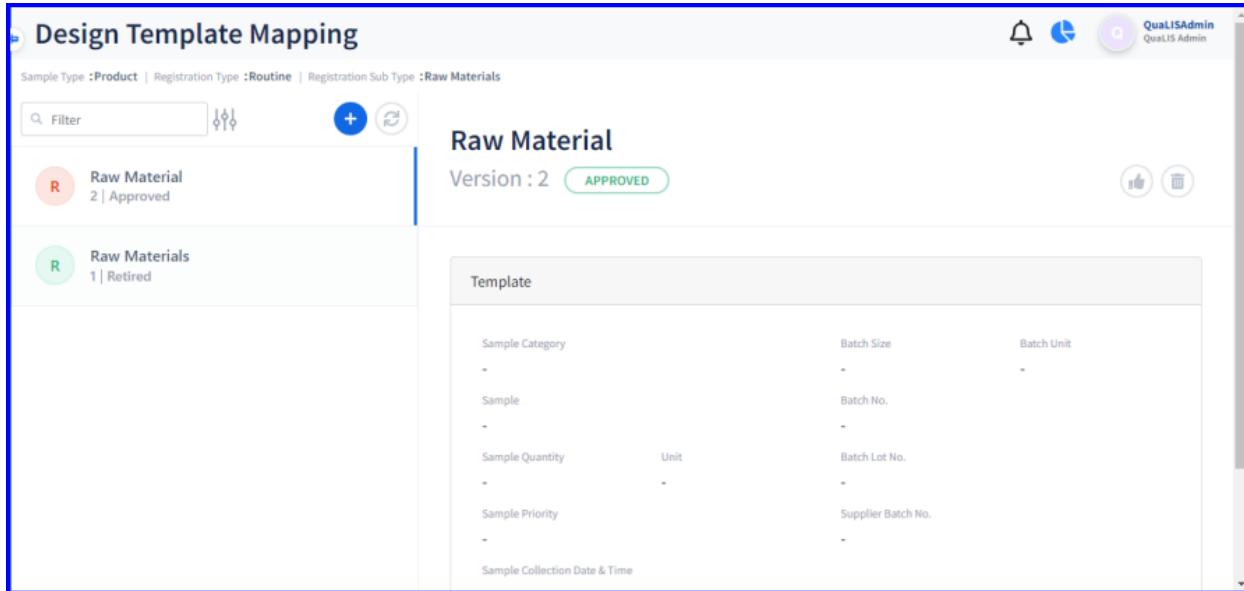


FIGURE: Template mapping for the selected Registration Sub Type

If there are templates already mapped, the list of mapping appears. The approved template mapping will be in use.

4. Click  . The **Add Design Template Mapping** screen appears as shown in the figure:

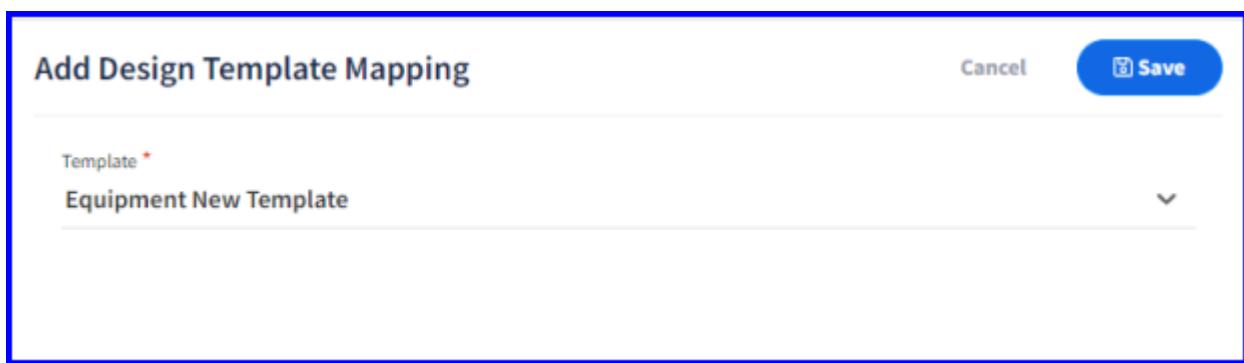


FIGURE: Add Design Template Mapping Dialog

5. In the **Template** field, select a template to map to the selected registration sub type.
6. Click **Save**. The template is mapped and the record appears in DRAFT state as shown in the figure:

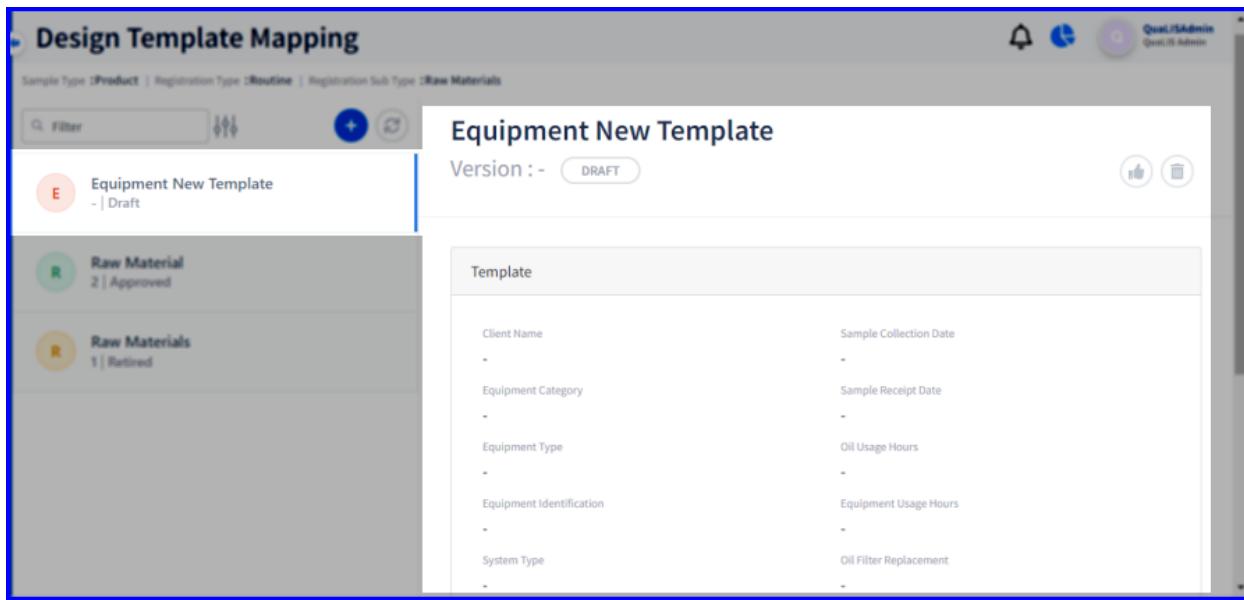


FIGURE: Design Template Mapped

You can delete the mapping in the DRAFT state. Once approved, the previous mapping will retire.

3.3.5 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.

3.3.5.1 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:

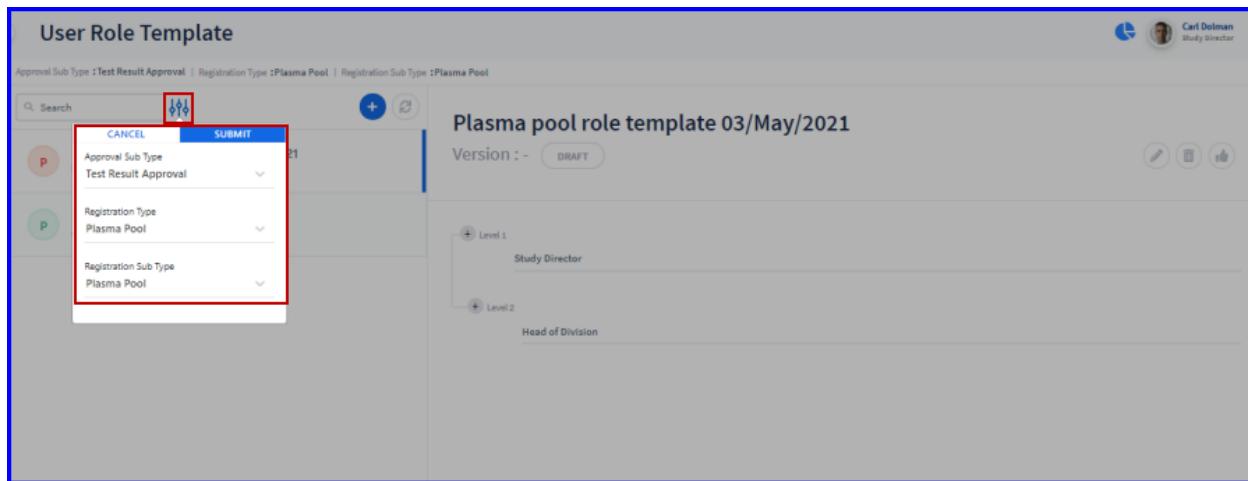


FIGURE: User Role Template Screen Showing Filter

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**.

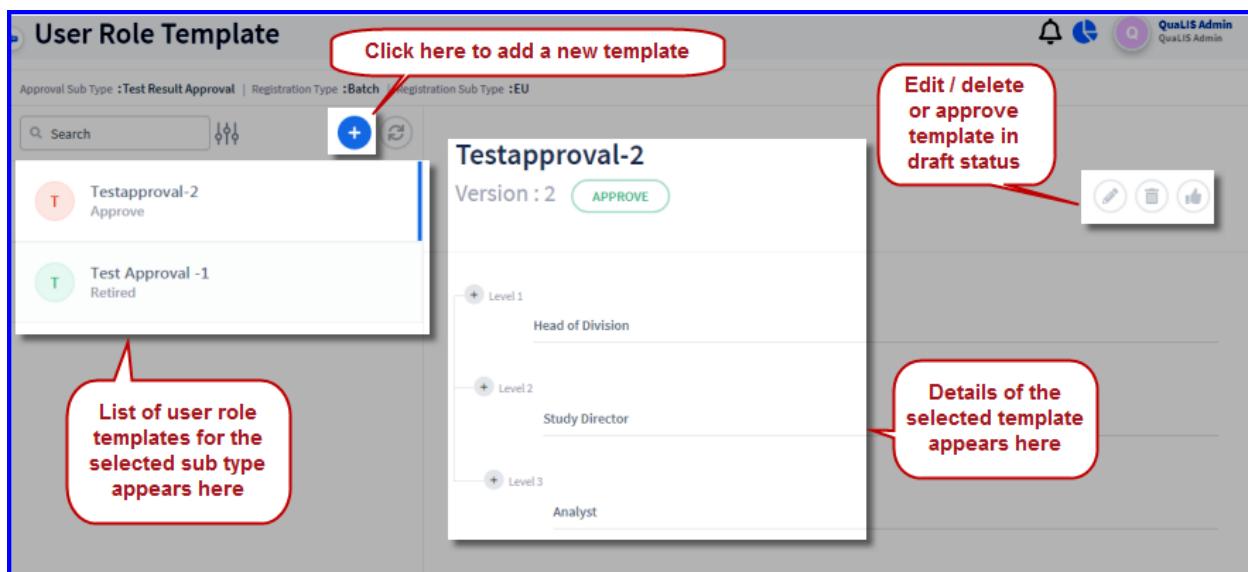


FIGURE: User Role Template Screen Showing List of Templates

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:

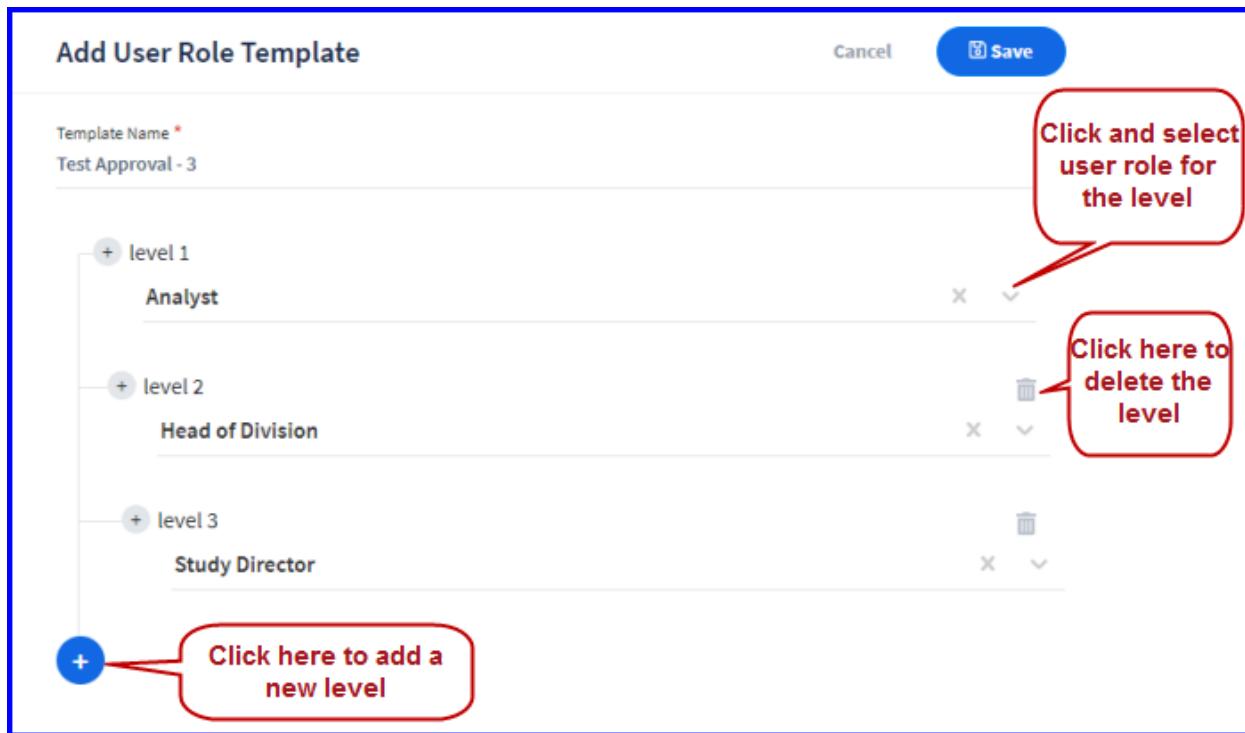


FIGURE: Add User Role Template Screen

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:

3.3.5.2 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 **edit**. 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 .

3.3.5.3 Approving User Role Template

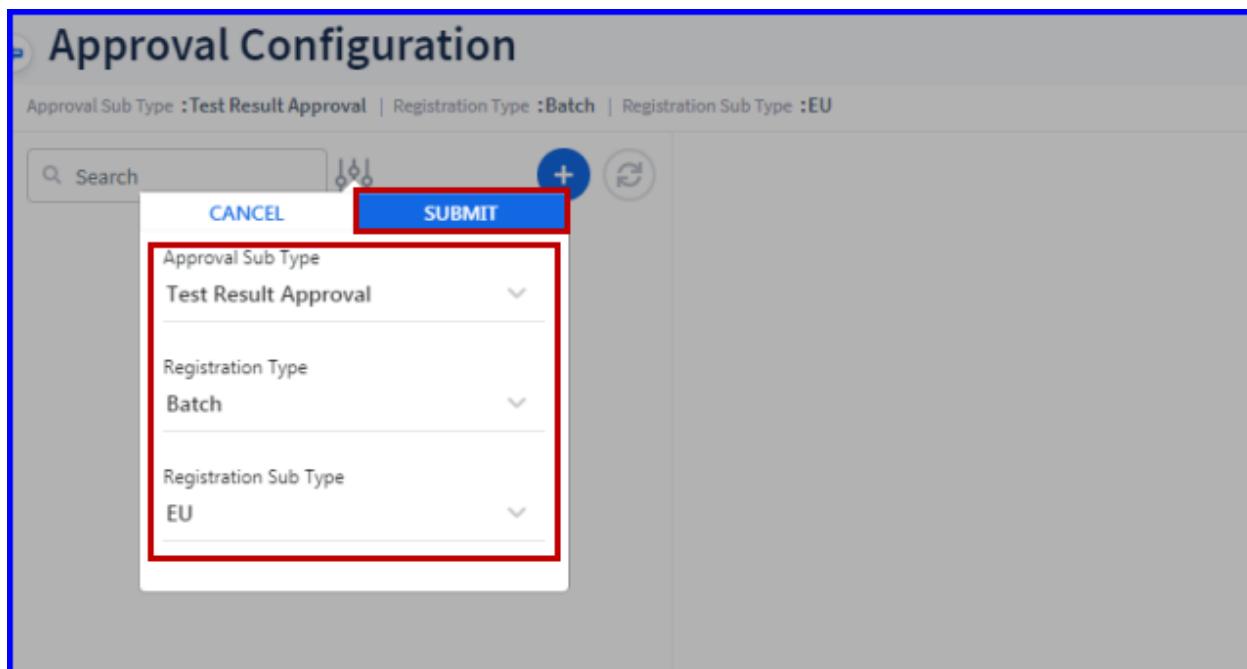
You can approve a template in the draft state.

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**.

3.3.6 Approval Configuration

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

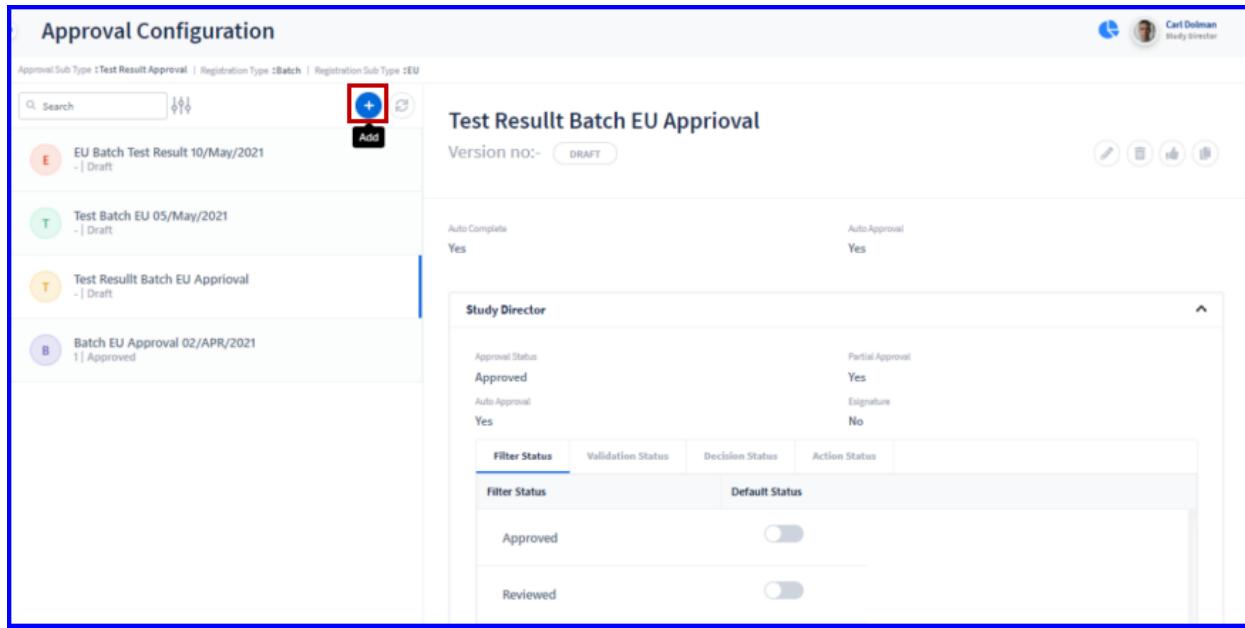
1. On the main menu, click , **User Management**, and then click **Approval Configuration**. The **Approval Configuration** screen appears as shown in the figure:



The screenshot shows the 'Approval Configuration' screen. At the top, there is a header with the text 'Approval Sub Type :Test Result Approval | Registration Type :Batch | Registration Sub Type :EU'. Below the header is a search bar and a toolbar with icons for search, refresh, and add. A modal dialog is open in the center, containing three dropdown menus. The first dropdown is labeled 'Approval Sub Type' with 'Test Result Approval' selected. The second dropdown is labeled 'Registration Type' with 'Batch' selected. The third dropdown is labeled 'Registration Sub Type' with 'EU' selected. At the top of the modal, there are 'CANCEL' and 'SUBMIT' buttons, with 'SUBMIT' being highlighted. The entire modal is enclosed in a red box.

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:



The screenshot shows the 'Approval Configuration' screen. On the left, there is a list of existing approval configurations: 'EU Batch Test Result 10/May/2021' (Draft), 'Test Batch EU 05/May/2021' (Draft), 'Test Result Batch EU Approval' (Draft), and 'Batch EU Approval 02/APR/2021' (Approved). On the right, the 'Test Result Batch EU Approval' configuration is displayed. The 'Add' button is highlighted with a red box. The configuration details for the 'Study Director' role are shown, including 'Approval Status' (Approved), 'Auto Approval' (Yes), 'Partial Approval' (Yes), and 'Signature' (No). The 'Filter Status' section shows two options: 'Approved' and 'Reviewed', each with a toggle switch.

FIGURE: Approval Configuration Screen - Add

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

Add Approval Configuration

Version Name *

Auto Approval Auto Complete

Head of Division Study Director

Partial Approval Auto Approval

Esignature

Recommend Retest Recommend Recalc

ReTest ReCalc

Approval Status *

Approve

Filter Status *

Completed Reviewed Verified

Validation Status *

Reviewed

Decision Status *

Pass Withdrawn

Cancel  Save

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.

3.3.6.1 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.

3.3.6.2 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 .

Approval Sub Type	Registration Type
Test Result Approval	Batch
Registration Sub Type	Version Name
EU	Test Batch EU 05/May/2021
Version no	
3	

Version Name *

Version Name

Registration Type

Batch

Registration Sub Type

EU

FIGURE: Copy Approval Configuration Screen

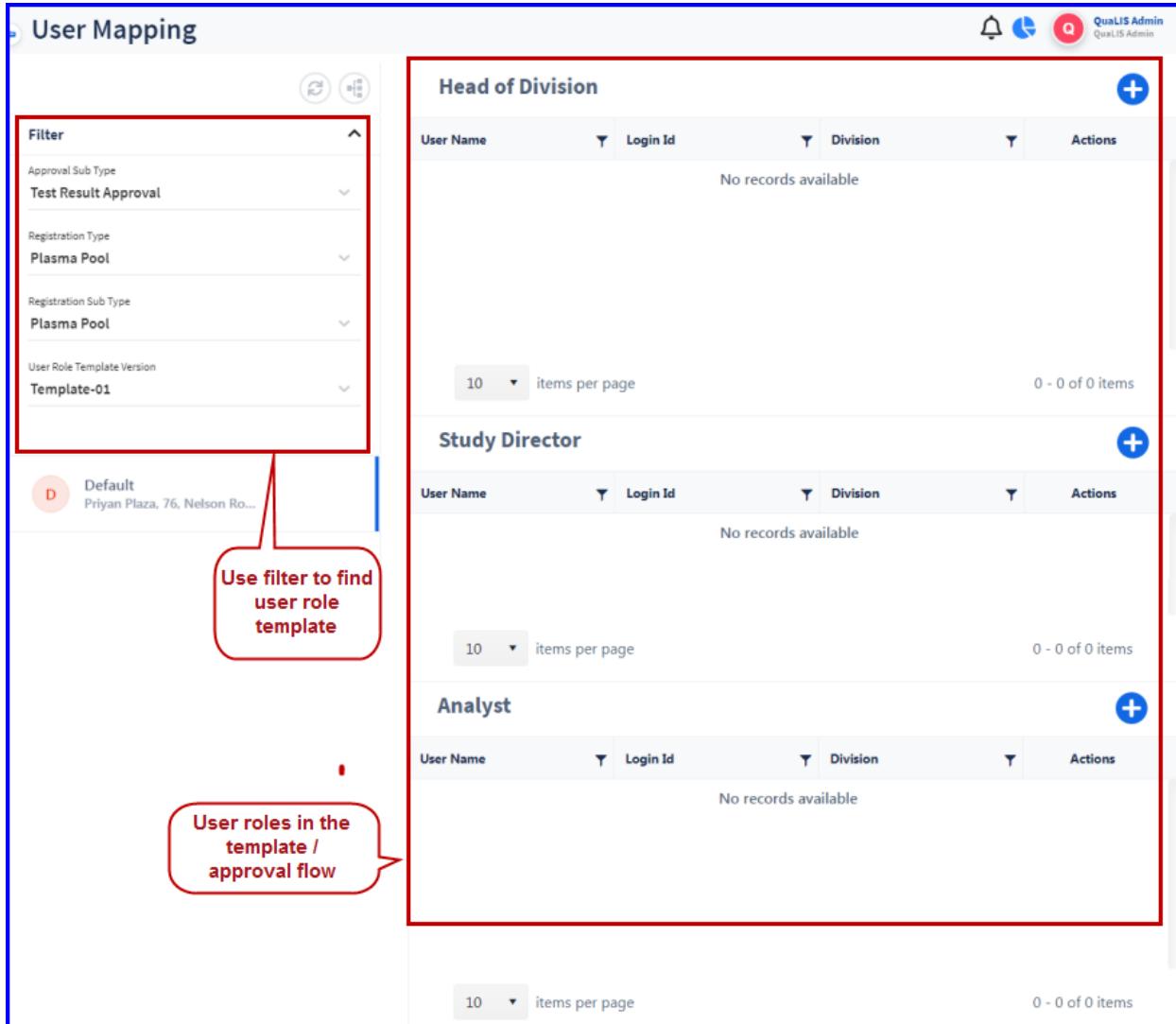
2. In the **Version Name** field, type name for the version you copy.
3. In the **registration Type** field, select the registration type.
4. In the **registration Sub Type** field, select the registration sub type.
5. Click **Save**.
6. Now the configuration is copied to the selected type / sub type

3.3.7 User Mapping

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

To set approval hierarchy, follow these steps:

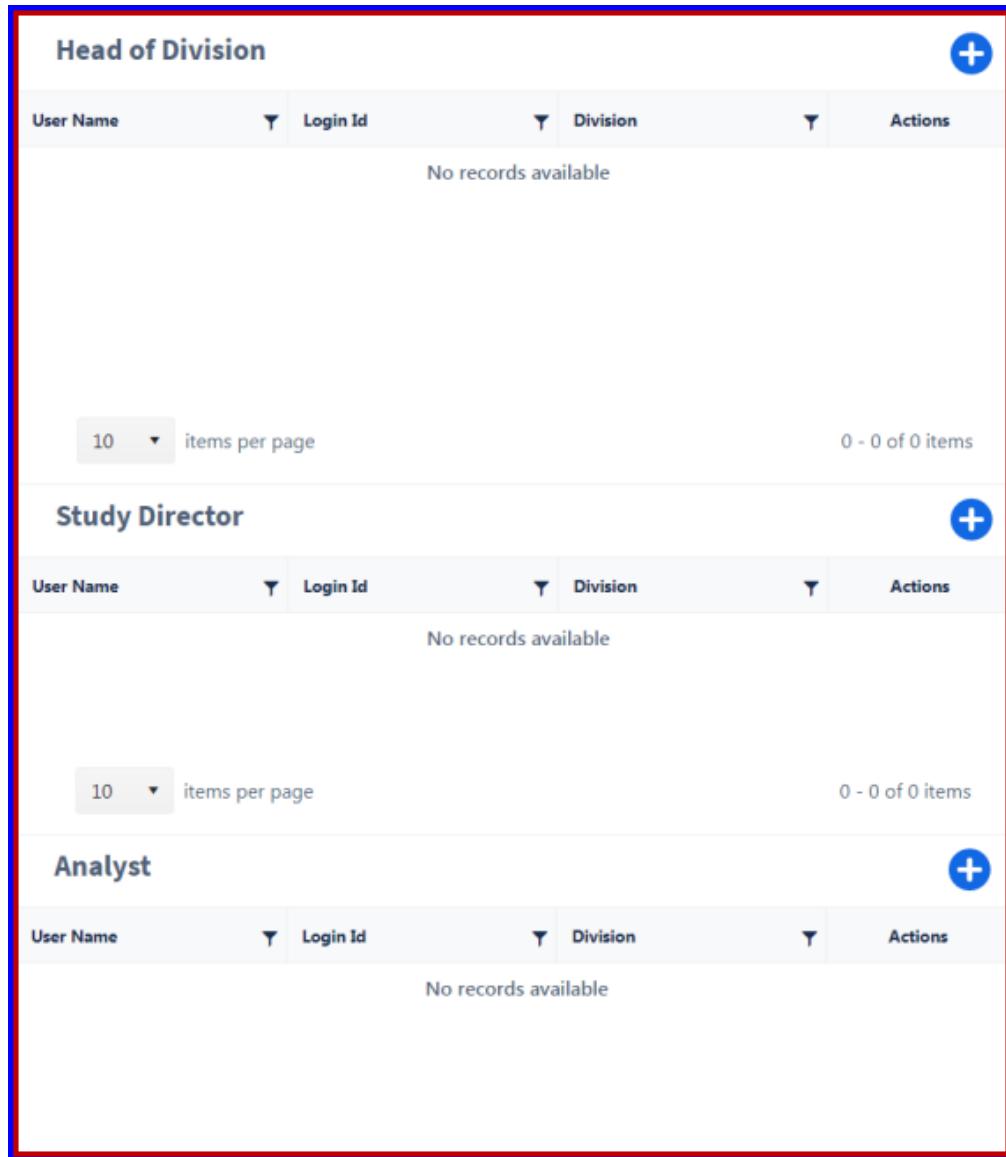
1. On the main menu, click  **Organisation** and then click **User Mapping**. The **User Mapping** screen appears as shown in the figure:



The screenshot shows the 'User Mapping' screen in the Qualis LIMS application. The left side features a 'Filter' panel with dropdown menus for 'Approval Sub Type' (Test Result Approval), 'Registration Type' (Plasma Pool), 'Registration Sub Type' (Plasma Pool), and 'User Role Template Version' (Template-01). A red box highlights this panel, and a callout bubble points to it with the text 'Use filter to find user role template'. Below the filter is a 'Default' button with the address 'Priyan Plaza, 76, Nelson Ro...'. Another callout bubble points to this area with the text 'User roles in the template / approval flow'. The right side of the screen displays three tabs: 'Head of Division', 'Study Director', and 'Analyst', each with a table showing 'No records available'. The top right corner shows the user 'Qualis Admin'.

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:



The image shows a user interface for managing user roles. It is divided into three main sections, each with a title and a table:

- Head of Division**: The table has columns for User Name, Login Id, Division, and Actions. It displays the message "No records available".
- Study Director**: The table has columns for User Name, Login Id, Division, and Actions. It displays the message "No records available".
- Analyst**: The table has columns for User Name, Login Id, Division, and Actions. It displays the message "No records available".

Each section includes a blue circular icon with a white plus sign in the top right corner. At the bottom of the interface, there is a dropdown menu set to "10 items per page" and a status message "0 - 0 of 0 items".

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:

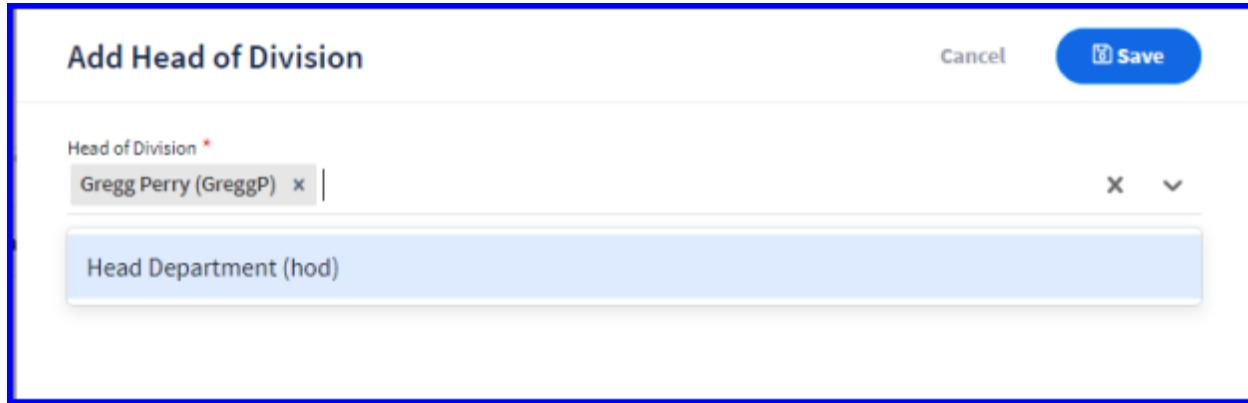
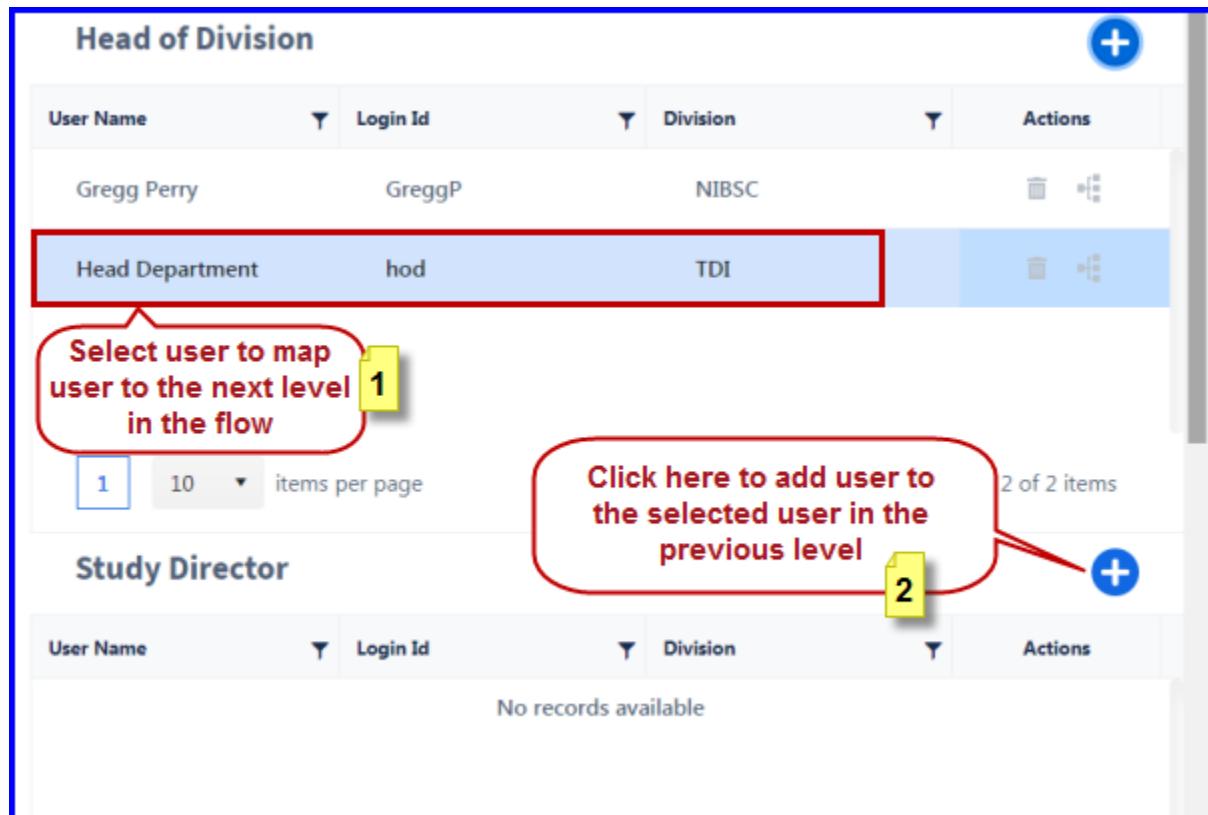


FIGURE: User Mapping – Add User Screen

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:



User Name	Login Id	Division	Actions
Gregg Perry	GreggP	NIBSC	 
Head Department	hod	TDI	 

Study Director			
User Name	Login Id	Division	Actions
No records available			

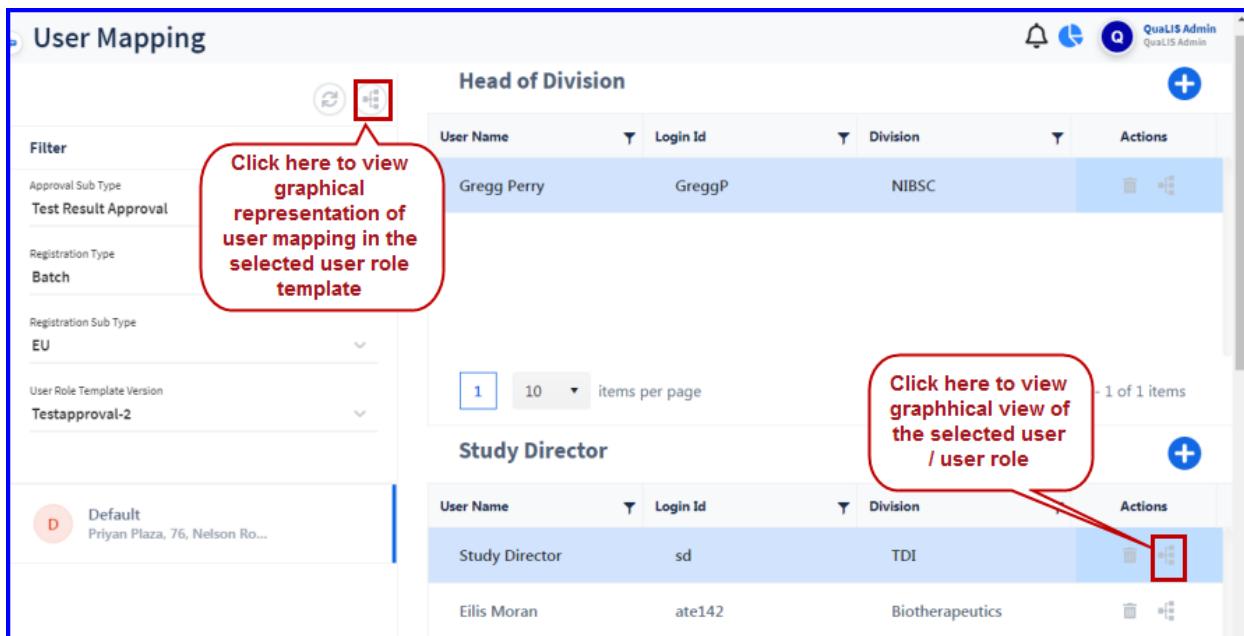
FIGURE: Mapping User to the Next Level

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

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

3.3.7.1 Graphical view of User Mapping

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



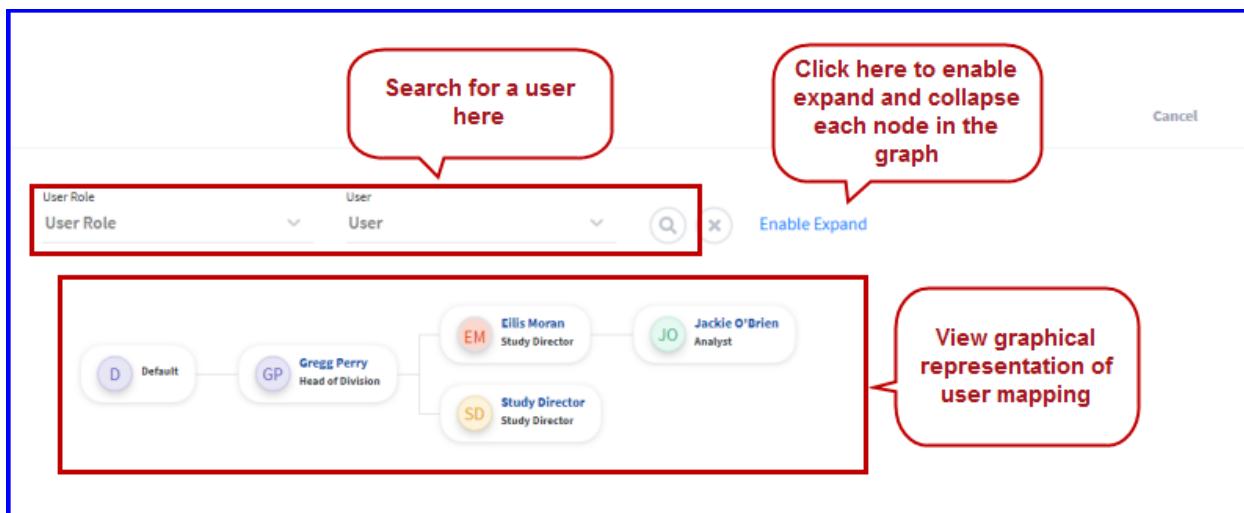
User Mapping

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

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

FIGURE: Graphical View of User Mapping - 1

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



Search for a user here

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

View graphical representation of user mapping

User Role: User Role

User: User

Enable Expand

Graph View:

```

graph LR
    D((D)) --- GP((GP))
    GP --- GP_HD[Gregg Perry Head of Division]
    GP_HD --- SD((SD))
    GP_HD --- EM((EM))
    SD --- SD_SD[Study Director]
    EM --- EM_SD[Study Director]
    EM --- JO((JO))
    JO --- JO_A[Jackie O'Brien Analyst]
  
```

FIGURE: Graphical view of User Mapping – 2

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

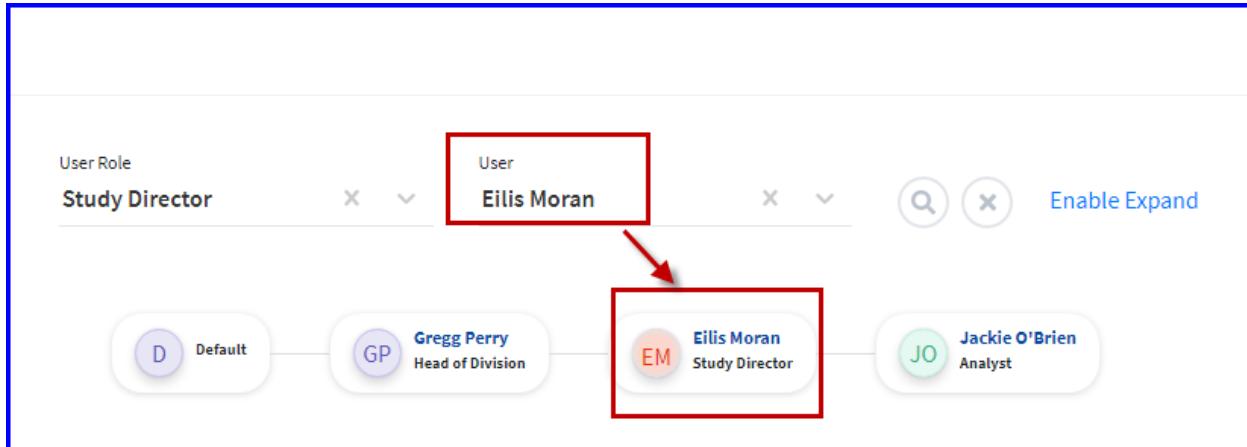


FIGURE: Graphical View - Search User

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

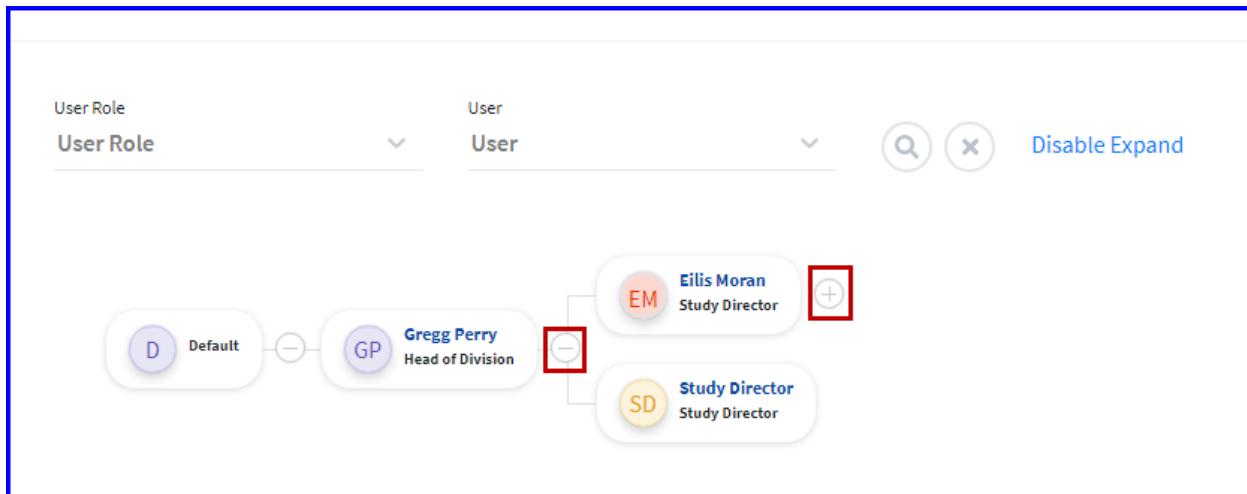


FIGURE: Graphical View of User Mapping – Enable Expand View

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

Head of Division

User Name	Login Id	Division	Actions
Gregg Perry	GreggP	NIBSC	  

1 10 items per page

of 1 items

Study Director

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

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

Enable Expand

```
graph LR; EM((EM  
Eilis Moran  
Study Director)) --- JO((JO  
Jackie O'Brien  
Analyst))
```

FIGURE: Graphical View of a Selected User

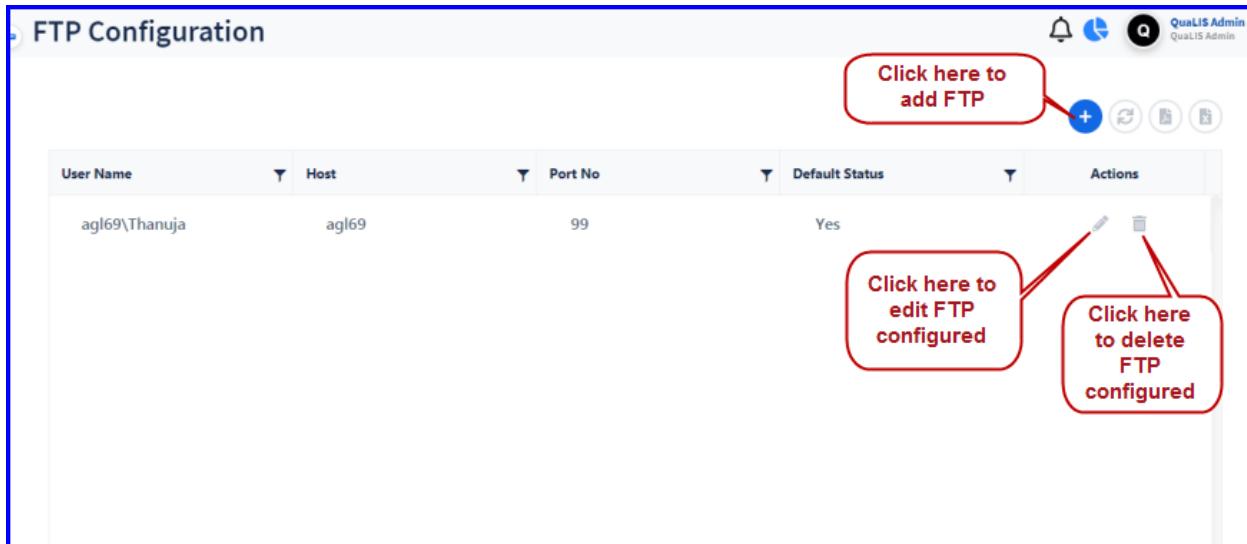
3.3.8 FTP Configuration

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

3.3.8.1 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:



The screenshot shows the 'FTP Configuration' screen. At the top, there is a header with the title 'FTP Configuration' and a user profile for 'QuaLIS Admin'. Below the header is a table with the following data:

User Name	Host	Port No	Default Status	Actions
agl69\Thanuja	agl69	99	Yes	 

Three red callout boxes with arrows point to the following elements:

- 'Click here to add FTP' points to the blue '+' button in the top right corner of the table header.
- 'Click here to edit FTP configured' points to the edit icon in the 'Actions' column for the first row.
- 'Click here to delete FTP configured' points to the delete icon in the 'Actions' column for the first row.

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 Configuration** screen appears as shown in the figure:

Add FTP Configuration

User Name *
FTP1

Password *

Host *
192.168.0.232

Port No *
26

Physical Path *
C:\LIMSFTP\LIMSPATH

Default Status

SSL

Checksum

Save

Cancel

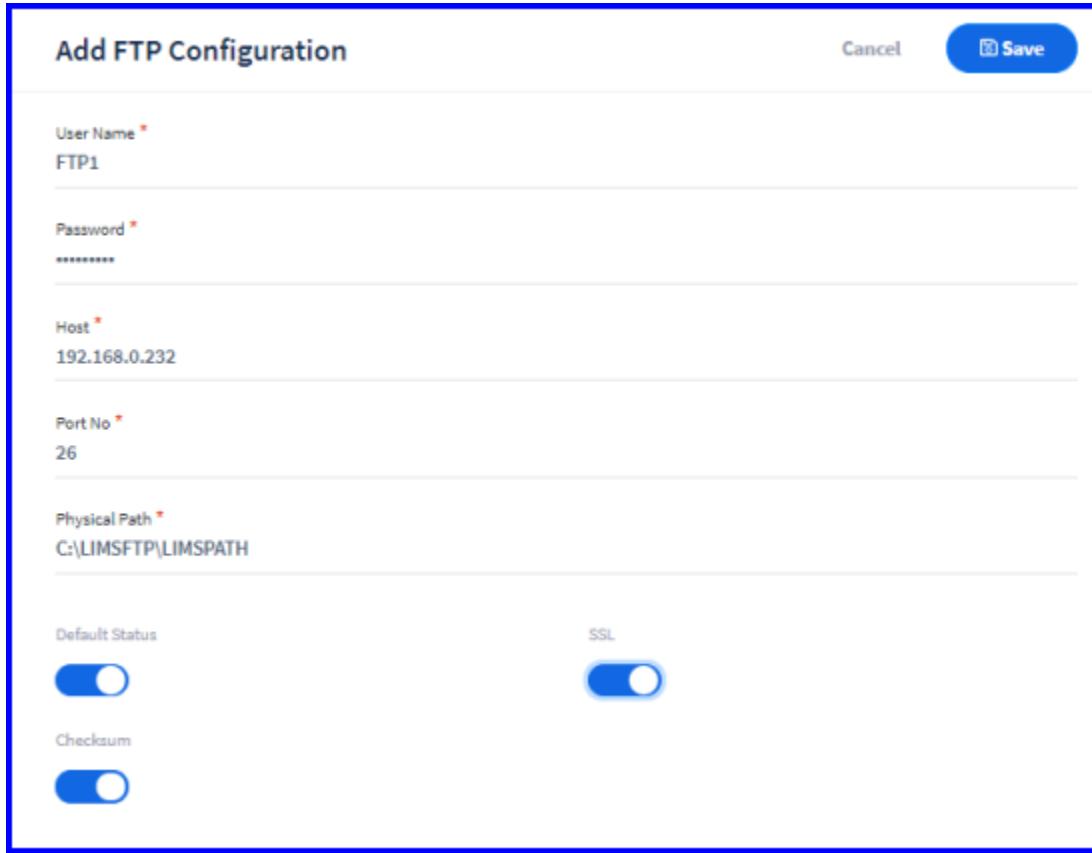


FIGURE: Add FTP Configuration Screen

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

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

3.3.8.2 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 User Management

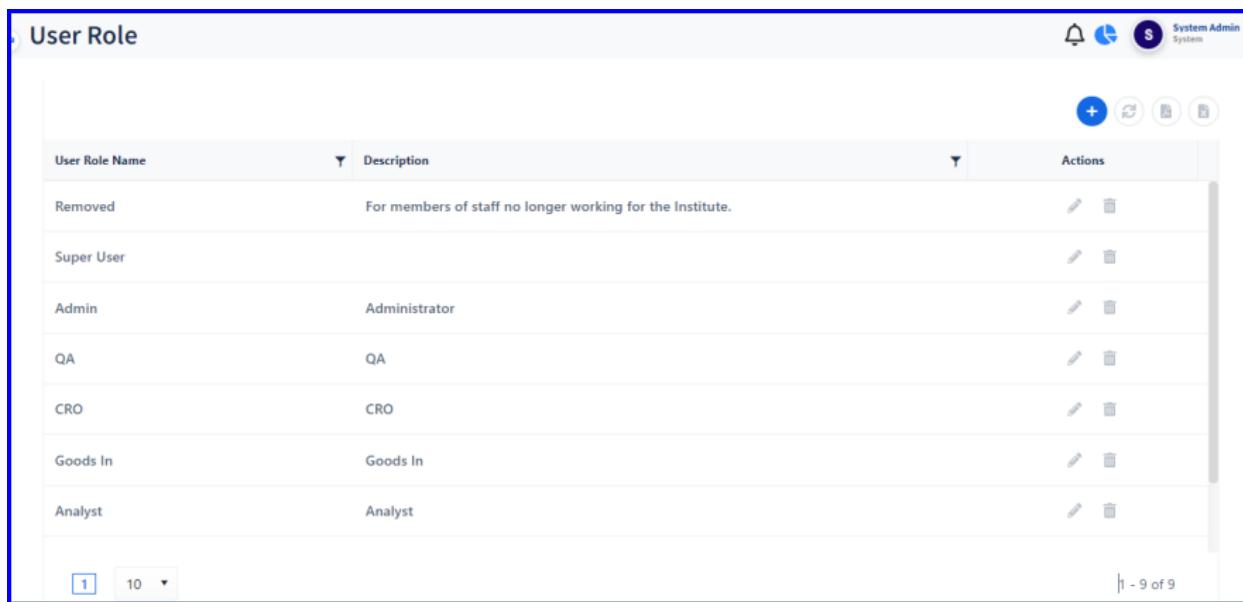
3.4.1 User role Master

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

3.4.1.1 Adding a New User role

To create a new User role, follow these steps:

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



The screenshot shows the 'User Role' master screen. The table lists the following user roles:

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

At the bottom left, there is a page number '1' and a dropdown '10'. At the bottom right, it says '1 - 9 of 9'.

FIGURE: User role Master Screen

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

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



The screenshot shows the 'Add User Role' form. At the top left is the title 'Add User Role'. On the right are 'Cancel' and 'Save' buttons. The 'Save' button is highlighted with a blue border. Below the title are two input fields: 'User Role Name' with a red asterisk and 'Description'. Both fields contain the text 'QA'. The 'Save' button has a blue background and white text.

FIGURE: Add User Role Screen

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

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

3.4.1.2 Editing User Role

To edit user role, follow these steps:

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

3.4.1.3 Deleting User Role

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

3.4.2 Designation Master

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

3.4.2.1 Adding a New Designation

To create a new Designation, follow these steps:

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



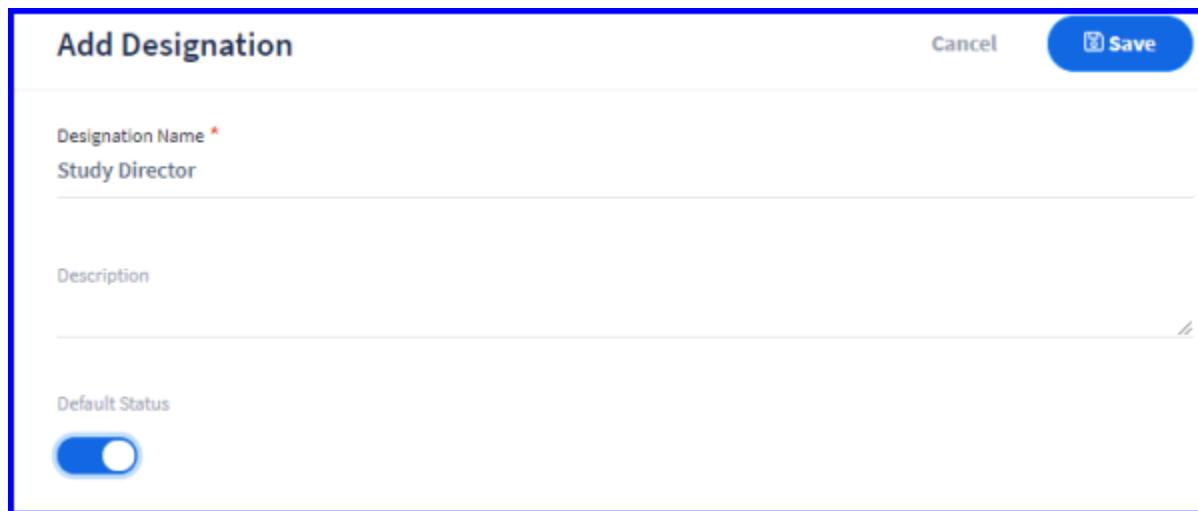
The screenshot shows the 'Designation' master screen. At the top, there is a header with the title 'Designation' and a user profile for 'Carl Dolman, Study Director'. Below the header is a table with two rows of data. The columns are 'Designation Name', 'Description', 'Default Status', and 'Actions'. The first row contains 'Study Director' and 'Yes' in the 'Actions' column. The second row contains 'HeadOfDivision' and 'No' in the 'Actions' column. Each row has edit and delete icons in the 'Actions' column. A blue 'Add' button is located in the top right corner of the table area.

Designation Name	Description	Default Status	Actions
Study Director		Yes	 
HeadOfDivision		No	 

FIGURE: Designation Master Screen

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

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



The screenshot shows the 'Add Designation' screen. At the top, there is a header with the title 'Add Designation' and buttons for 'Cancel' and 'Save'. Below the header is a form with three fields: 'Designation Name *' (containing 'Study Director'), 'Description' (containing 'Study Director'), and 'Default Status' (with a toggle switch set to 'On').

Designation Name *

Study Director

Description

Default Status

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:

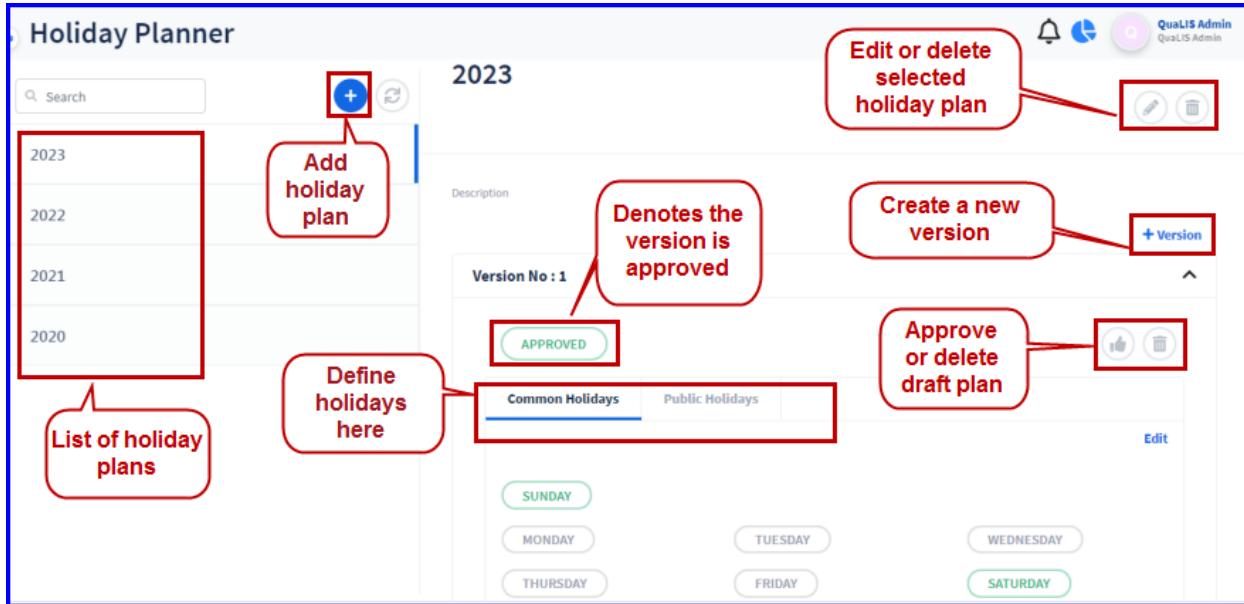


FIGURE: Holiday Planner Screen

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:

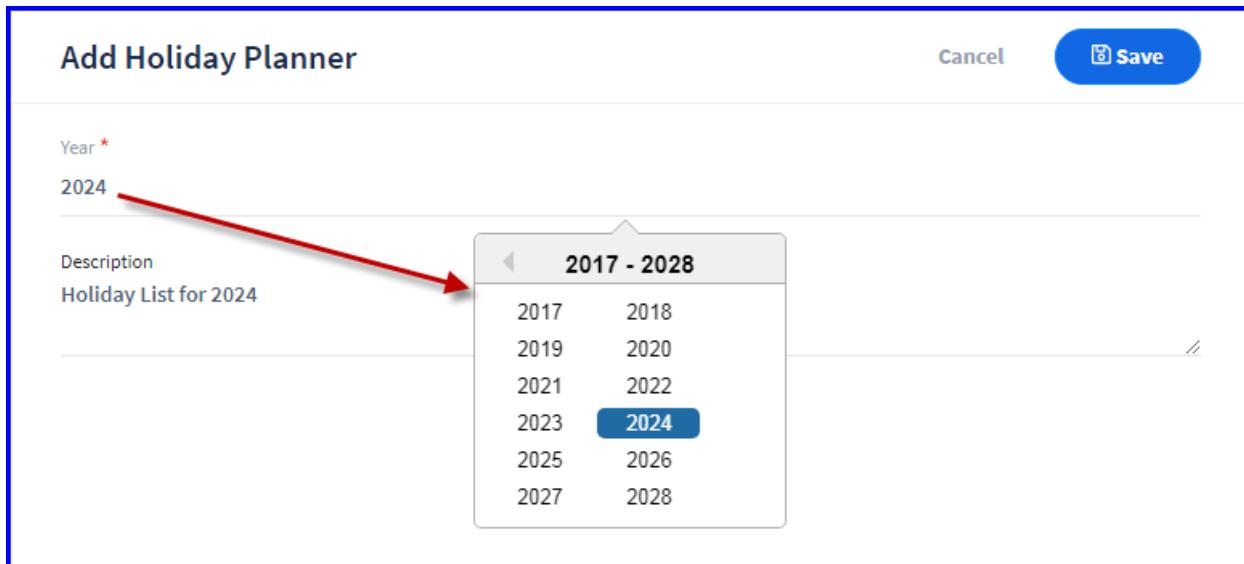


FIGURE: Add Holiday Planner Screen

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:

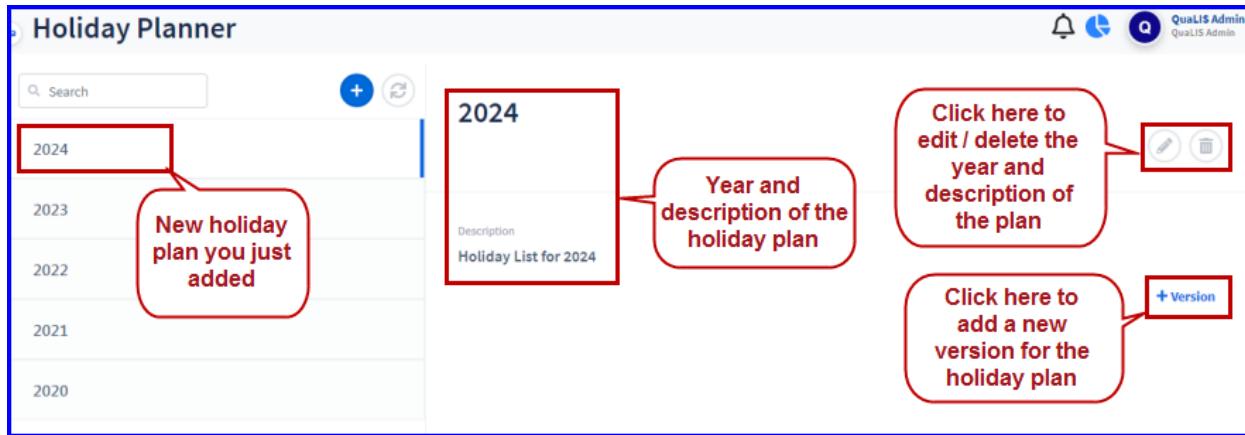


FIGURE: New Holiday Planner Added

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:

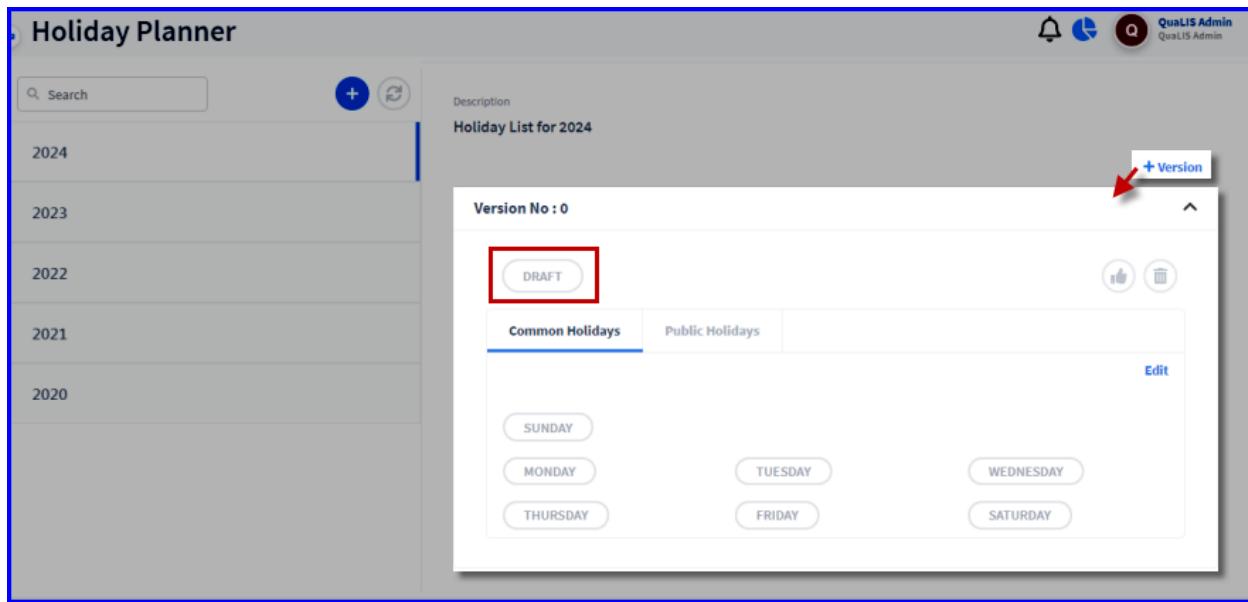


FIGURE: Adding New Version to the Holiday Plan

This section has Common Holidays and Public Holidays tabs.

3.4.3.3 Defining Common Holidays

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

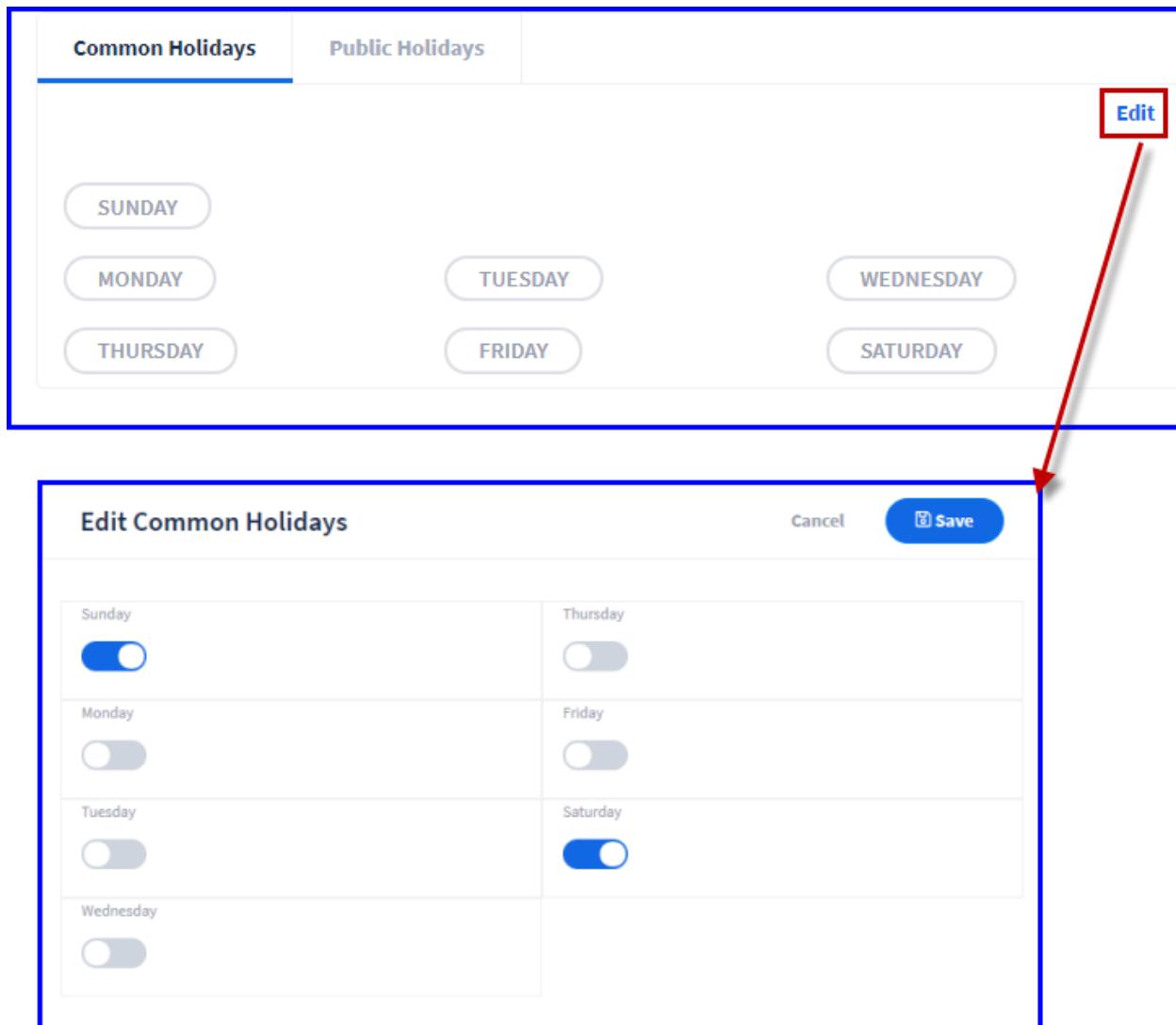


FIGURE: Defining Common Holidays

2. 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:

Common Holidays		Public Holidays
		+ Public Holidays
Date	Description	Actions
No records available		
10		0 - 0 of 0

FIGURE: Public Holiday Tab

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

Add Public Holidays

Date *
2024-01-01

Time Zone *
Europe/London

Description *
New Year

January 2024

31	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31	1	2	3
4	5	6	7	8	9	10

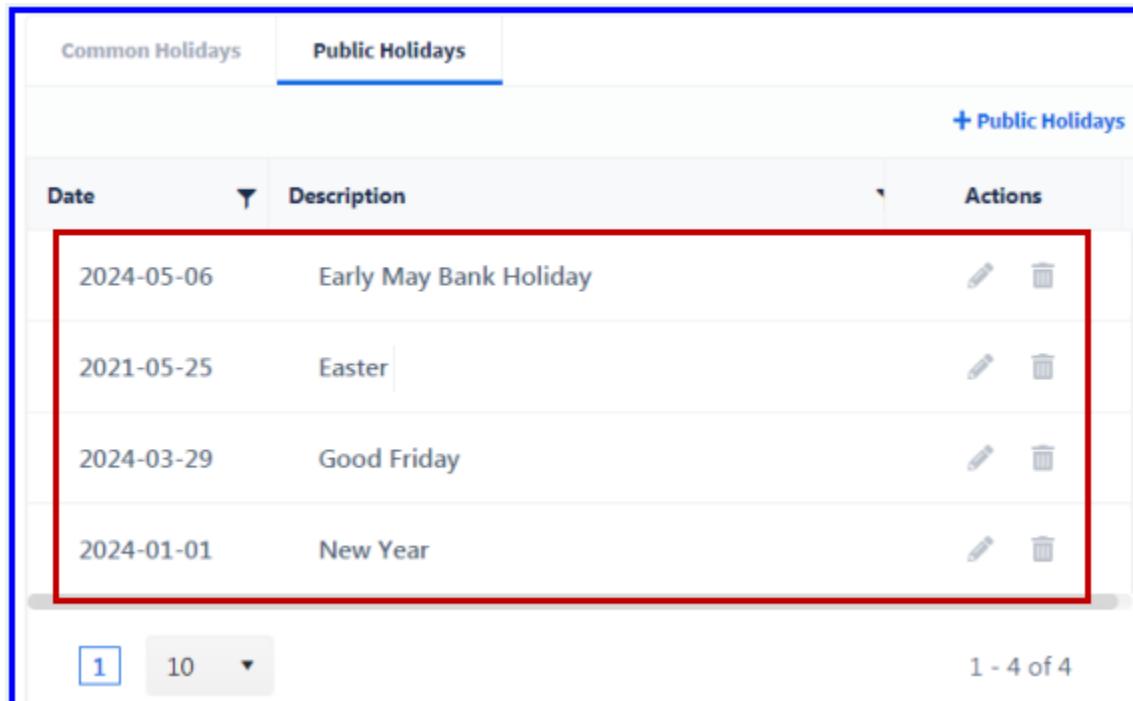
FIGURE: Add Public Holidays

- In the **Date** field, click and select the day to define as holiday as shown in the above figure.
- In the **Time Zone** field, select the time zone as applicable.
- In the **Description** field, type the description for the holiday selected in the **Date** field.

7. Click **Save and Continue** to save and add more holiday(s).

8. Click **Save** to save and exit Add Public Holiday screen.

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



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

1 10 1 - 4 of 4

FIGURE: Public Holidays Added

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

9. Click  to edit the record.

10. Click  to delete the record.

3.4.3.5 Approving Version

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

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

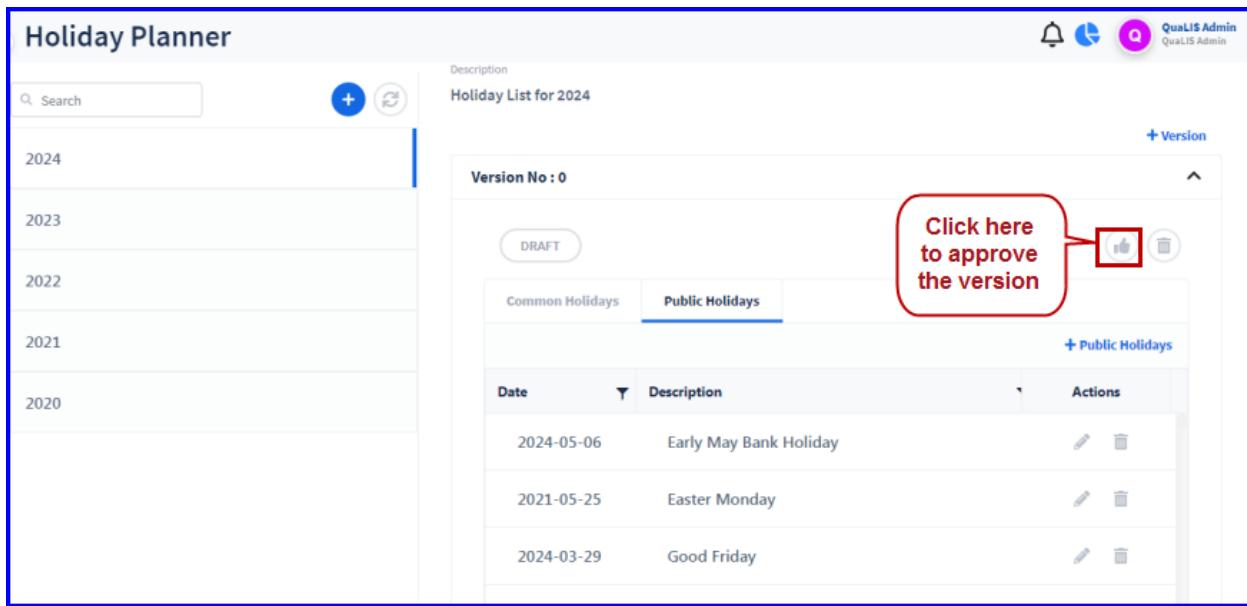


FIGURE: Approving a Version

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

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

You can click  to refresh the Holiday Planner screen.

3.4.4 Password Policy

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

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

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

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

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

3.4.4.1 Creating a New Password Policy

To create a new Password Policy, follow these steps:

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



FIGURE: Password Policy Screen

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

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

Add Password Policy

Policy Name *
CRO policy

Max Password Length *
6

Min No. of Number Char *
3

No. of Failed Attempt *
9

Min No. of Lower Char *
0

Expiry Required

Expiry Policy Days
Expiry Policy Days

Min No. of Upper Char *
0

Remainder Days
Remainder Days

Min No. of Special Char *
0

Comments
CRO

FIGURE: Add Password Policy Screen

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

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

3.4.4.2 Editing and Deleting Password Policy

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

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

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

3.4.4.3 Approving Password Policy

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

3.4.4.4 Copying Password Policies

You can copy password policy to multiple roles.

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

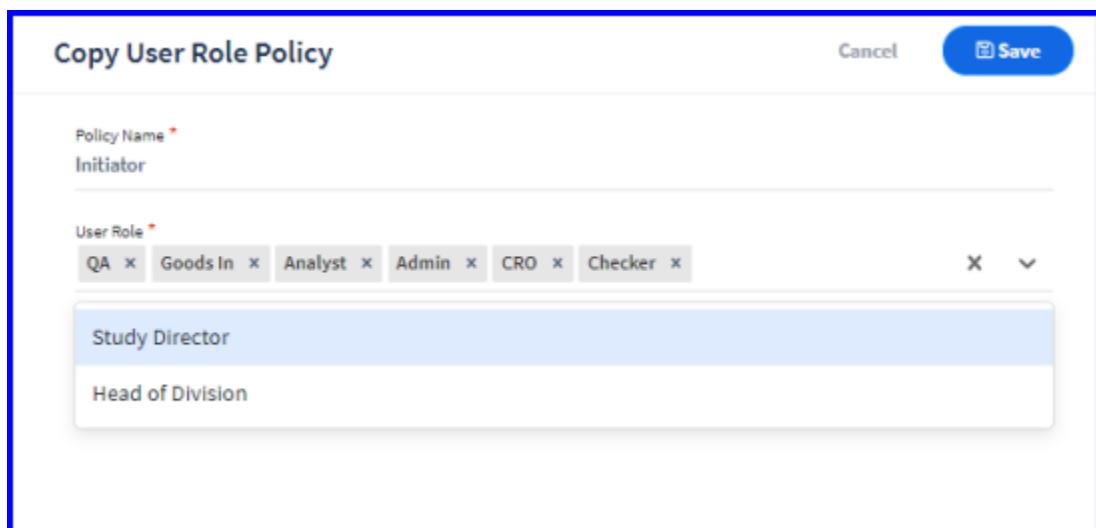


FIGURE: Copy Password Policy Dialog

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

3.4.5 Users

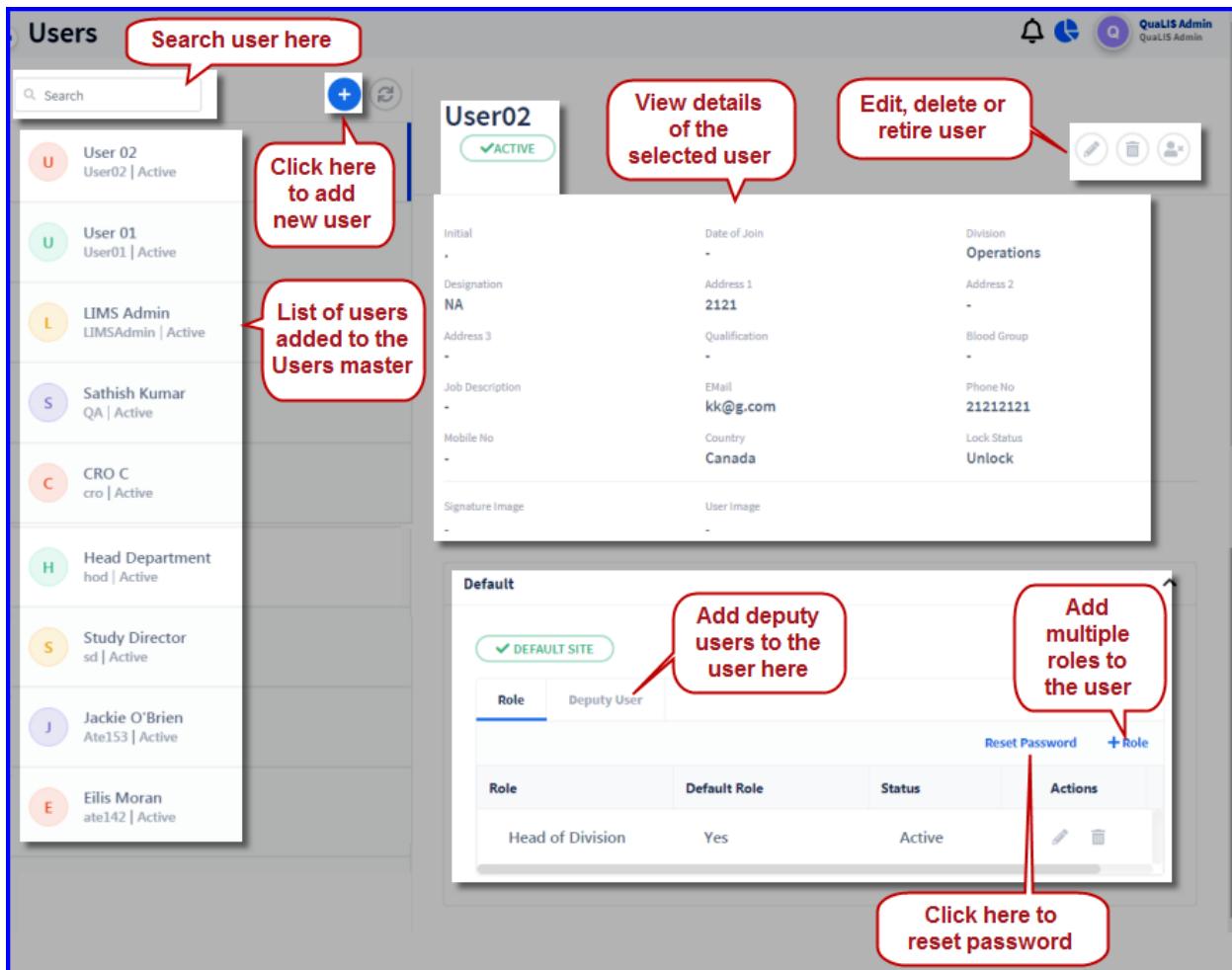
Users screen enables you to do the following in Qualis LIMS:

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

3.4.5.1 Adding a New User / User Account

To create a new user account, follow these steps:

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

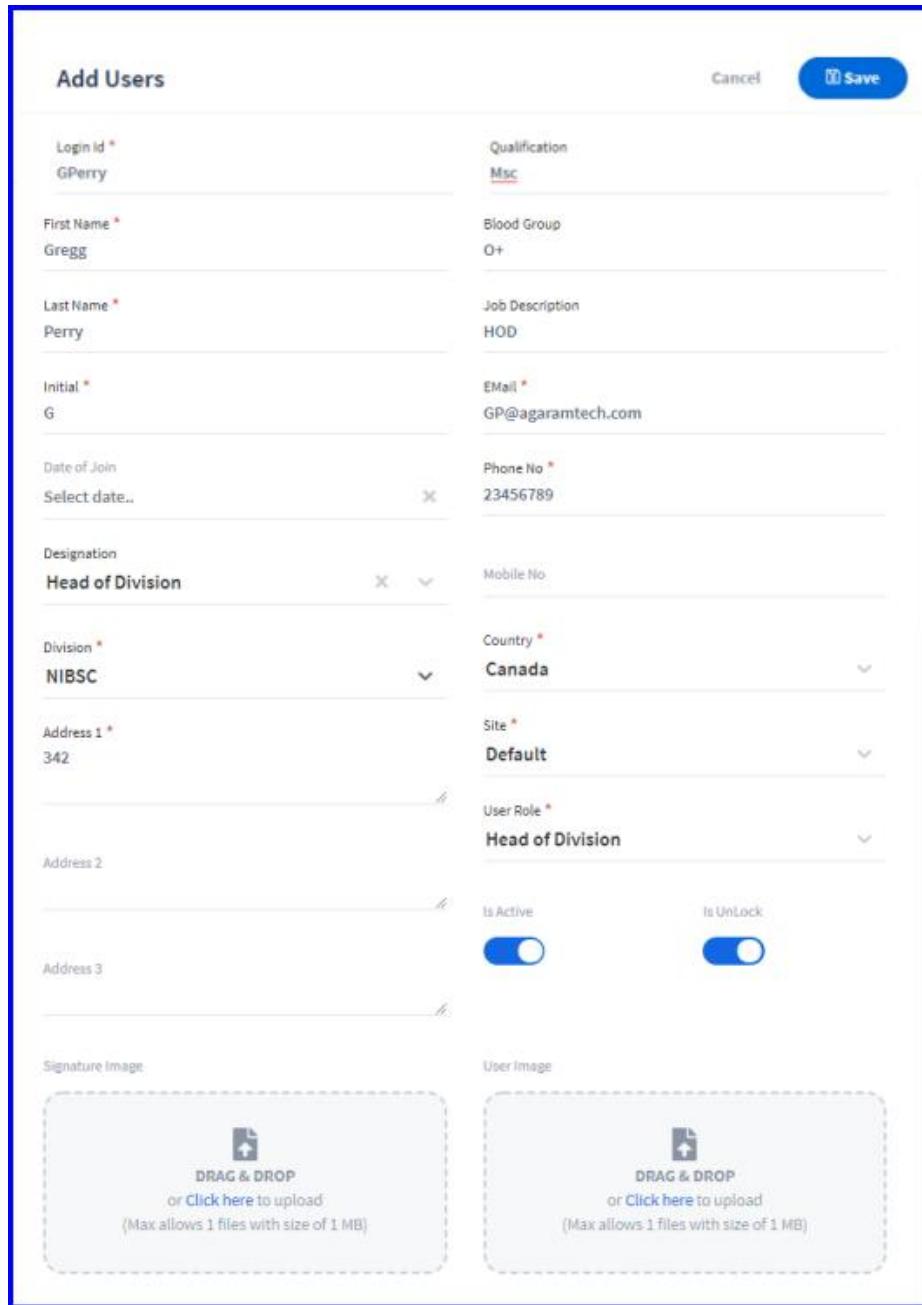


The screenshot shows the 'Users' master screen in Qualis LIMS. The left side displays a list of users with their names, initials, and status (e.g., User 02, User 01, LIMS Admin, Sathish Kumar, CRO C, Head Department, Study Director, Jackie O'Brien, Eilis Moran). A red box highlights the search bar with the placeholder 'Search user here'. A red callout 'Click here to add new user' points to a blue '+' icon. Another red callout 'List of users added to the Users master' points to the user list. The right side shows a detailed view of 'User02' (Initial: NA, Designation: NA, Address 1: 2121, EMail: kk@g.com, Mobile No: -, Job Description: -, Qualification: -, Country: Canada, Division: Operations, Address 2: -, Blood Group: -, Phone No: 21212121, Lock Status: Unlock). A red callout 'View details of the selected user' points to the user card. A red callout 'Edit, delete or retire user' points to the edit, delete, and retire buttons. Below this is a 'Default' section with tabs for 'Role' (selected) and 'Deputy User'. A red callout 'Add deputy users to the user here' points to the 'Deputy User' tab. Another red callout 'Add multiple roles to the user' points to the '+ Role' button. A red callout 'Click here to reset password' points to the 'Reset Password' button. The bottom table lists roles, default roles, and status for users like Head of Division (Role: Head of Division, Default Role: Yes, Status: Active).

FIGURE: Users Screen

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

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



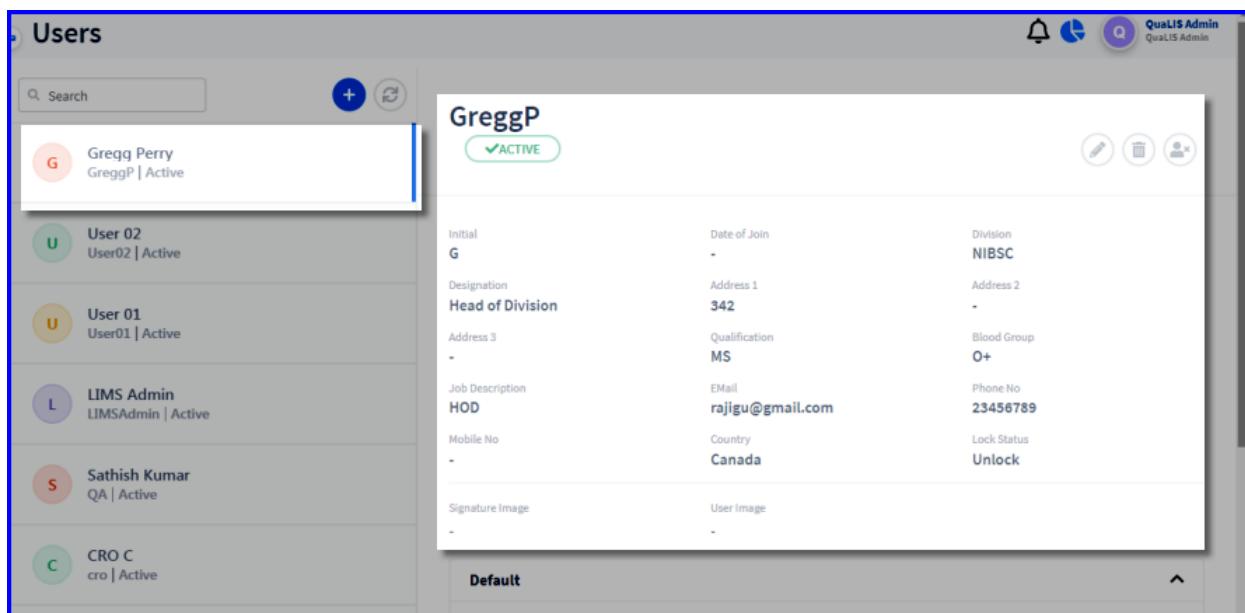
The screenshot shows the 'Add Users' form. The fields and their values are as follows:

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

FIGURE: Add Users Screen

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

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



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

FIGURE: Users Screen Showing New User Added

3.4.5.2 Editing and Deleting User

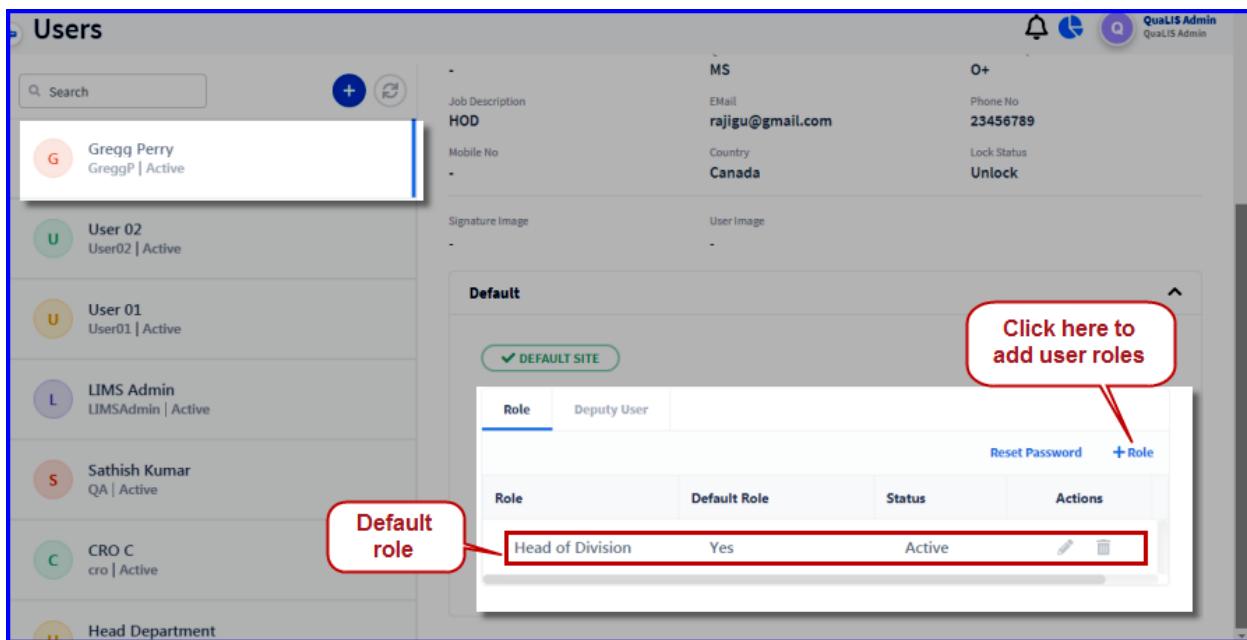
1. To edit user details, in the Users screen, select the user, and then click  . In the **Edit Users** screen, do required changes and then click **Save**.
2. To delete a user, in the Users screen, select the user you want to delete, and then click 

3.4.5.3 Mapping User Role(s) to the User

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

To do so, follow these steps:

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



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

FIGURE: User Role Tab

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

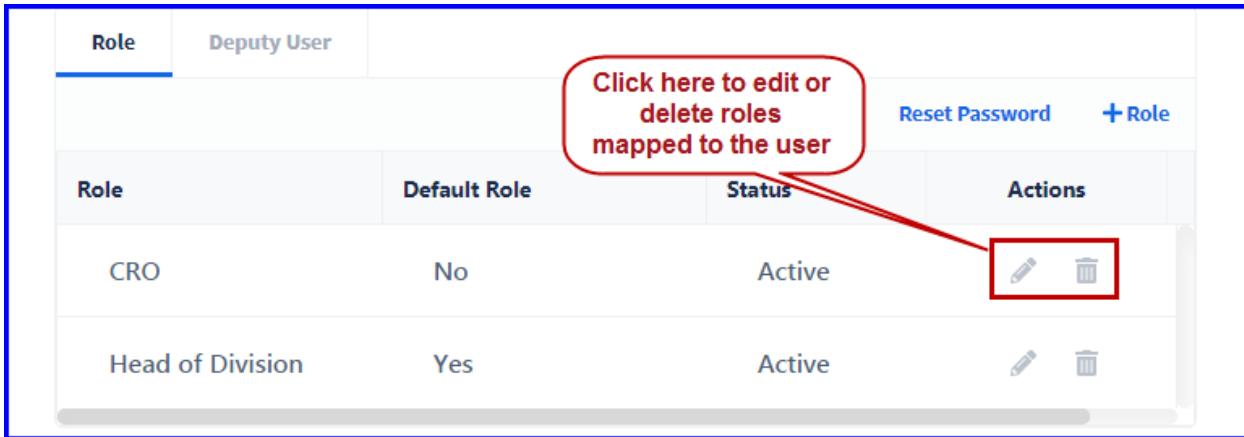
2. To add another role to the selected user, click **+ Role**. The **Add Role** screen appears as shown in the figure:



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

FIGURE: Add Role Screen

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



The screenshot shows the 'Role' tab for a user. It has a header with 'Role' and 'Deputy User' tabs. Below is a table with columns: Role, Default Role, Status, and Actions. Two rows are shown:

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

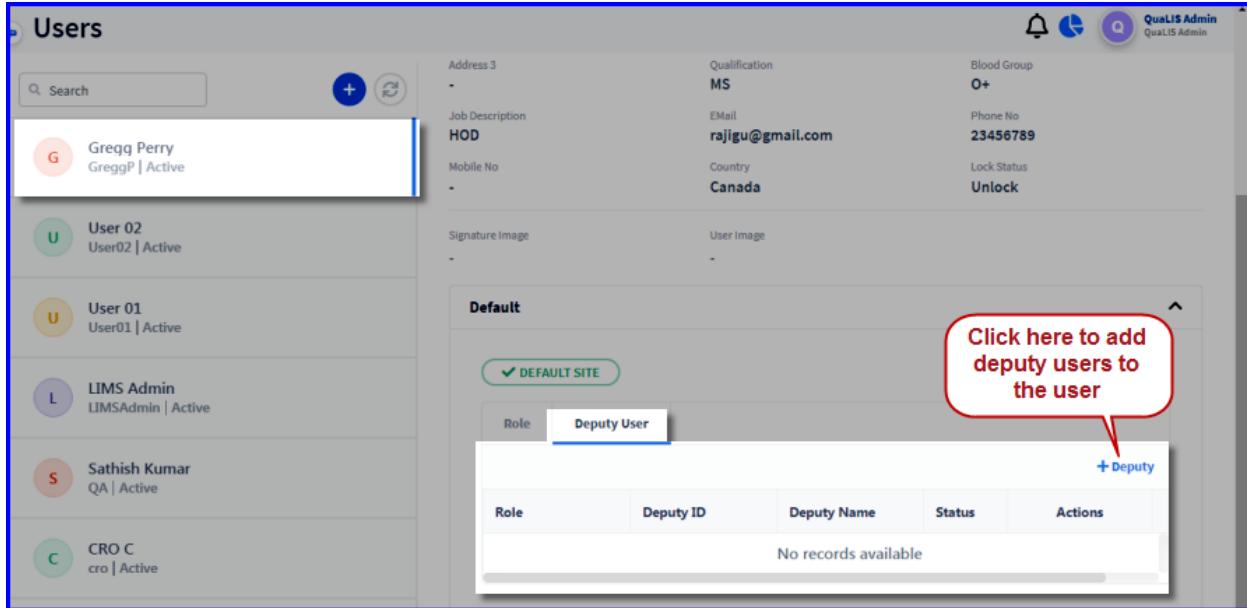
A red callout box with a red border and arrow points to the 'Actions' column of the first row, containing the edit and delete icons. The callout text is: 'Click here to edit or delete roles mapped to the user'.

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



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

FIGURE: Deputy User Tab

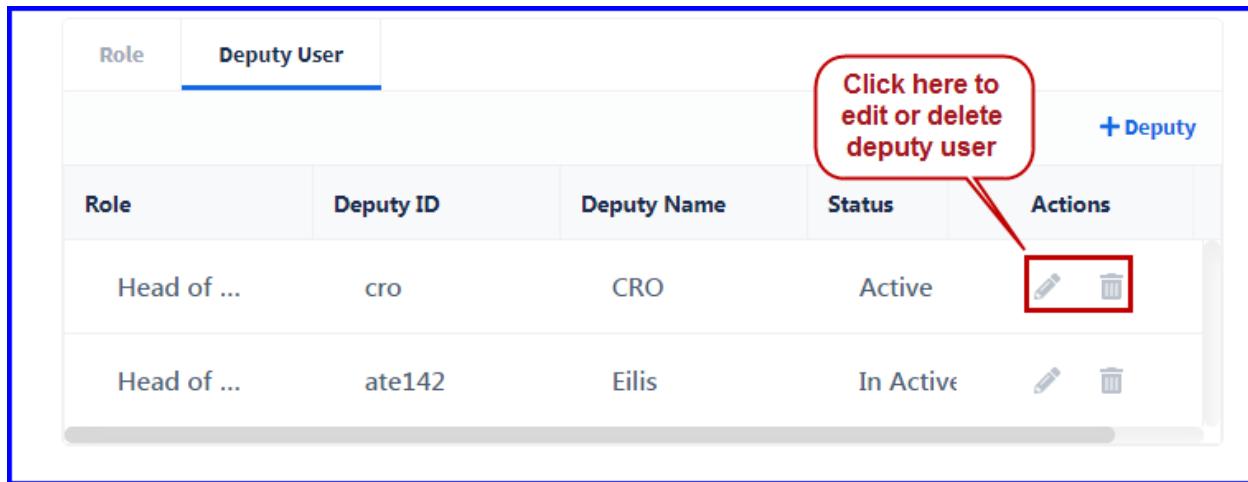
2. Click **+ Deputy**. The **Add Deputy** user screen appears as shown in the figure:



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

FIGURE: Add Deputy User Role Screen

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



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

FIGURE: Deputy User Tab Showing Added Deputy Users

3.4.6 MIS Rights

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

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

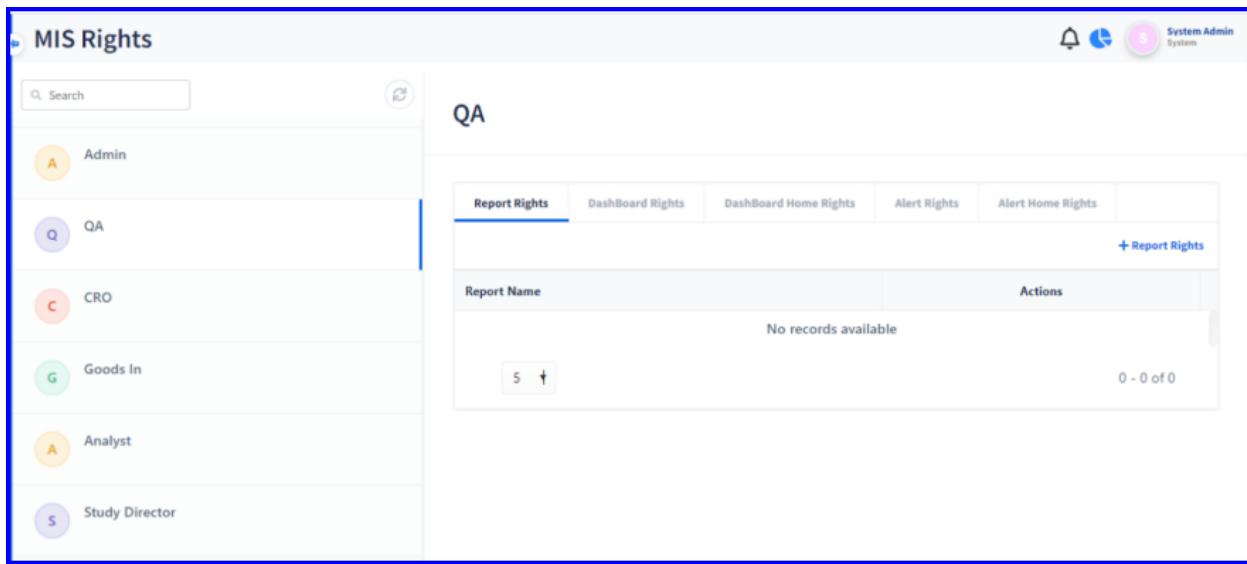


FIGURE: MIS Rights Screen

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

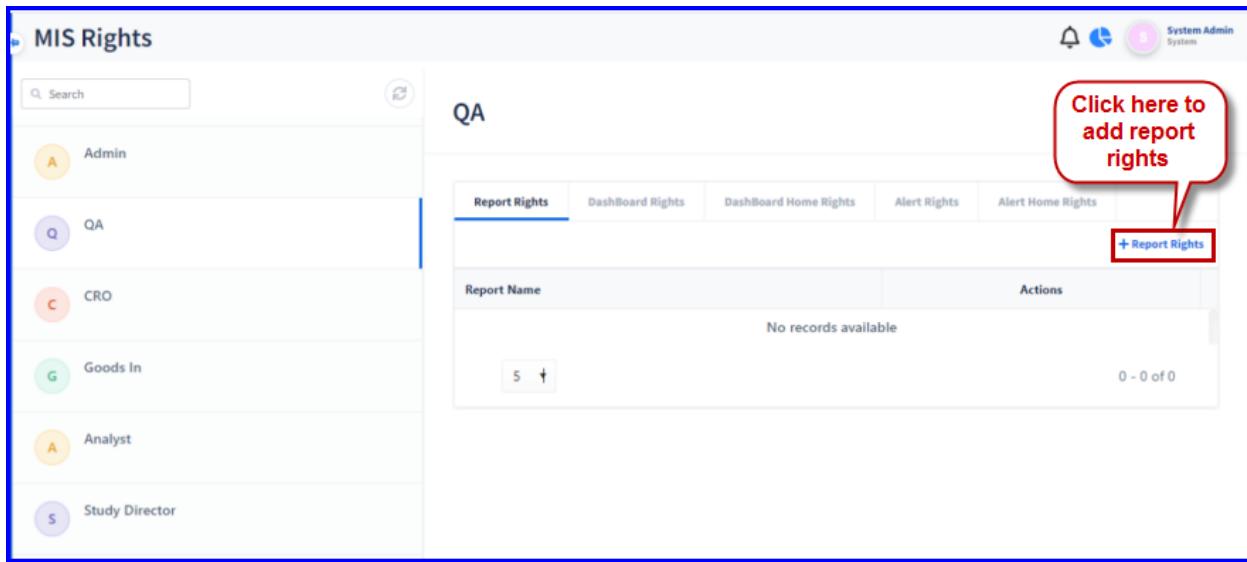


FIGURE: Report Rights Tab

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

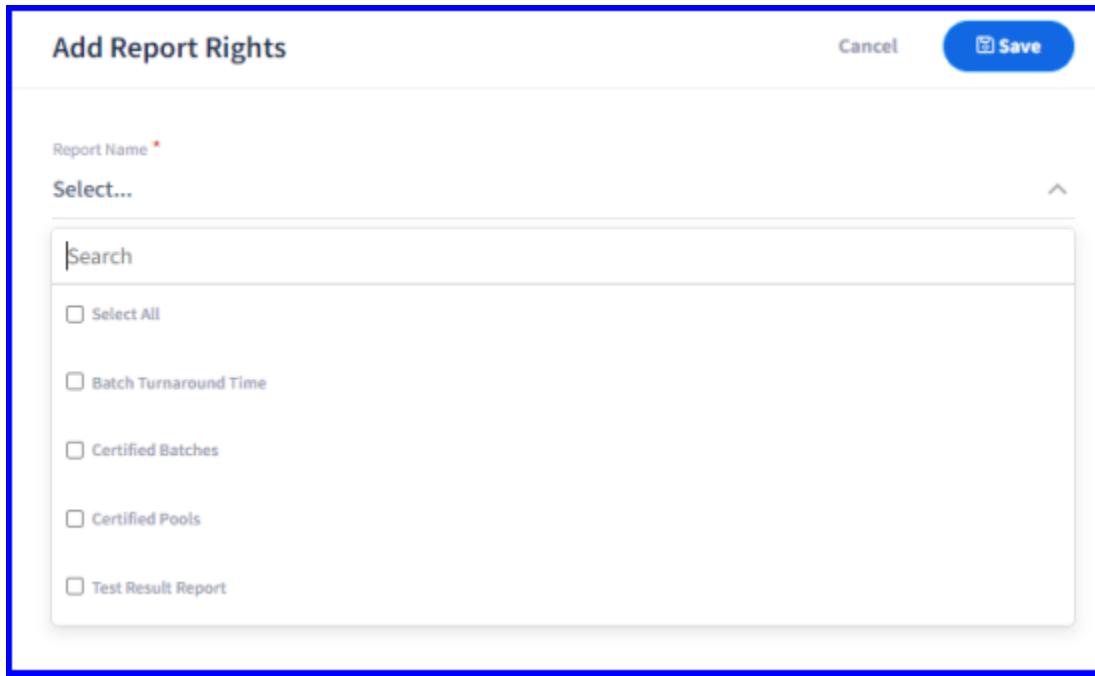


FIGURE: Add Report Rights Dialog

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

3.4.7 Screen Rights

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

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



FIGURE: Screen Rights Screen

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

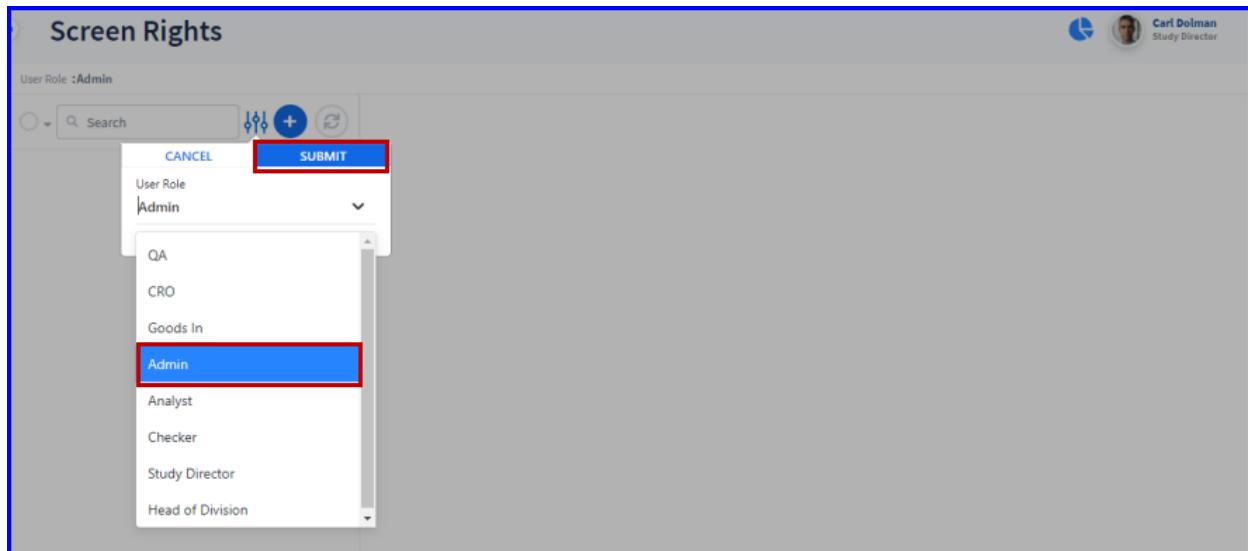


FIGURE: Selecting User Role to Define Screen Rights

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

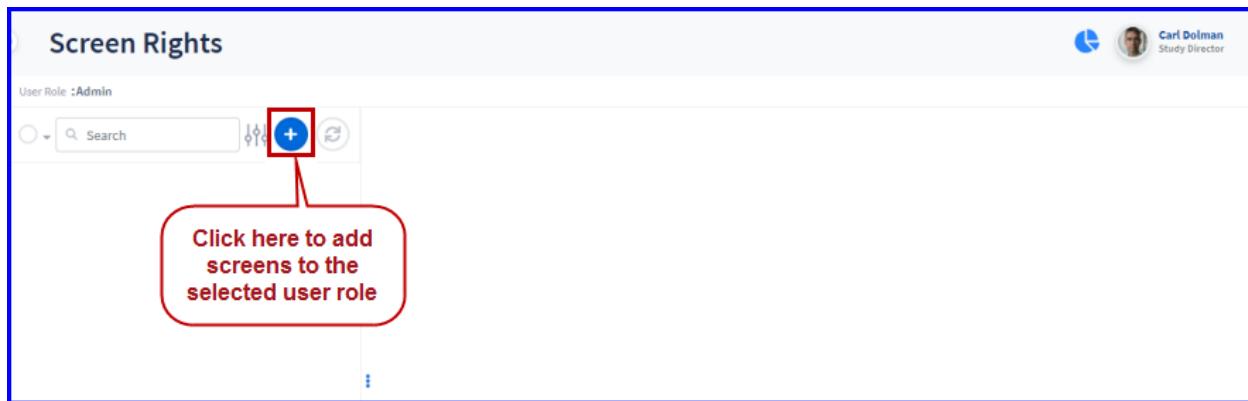


FIGURE: Add Screens to the User Role

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

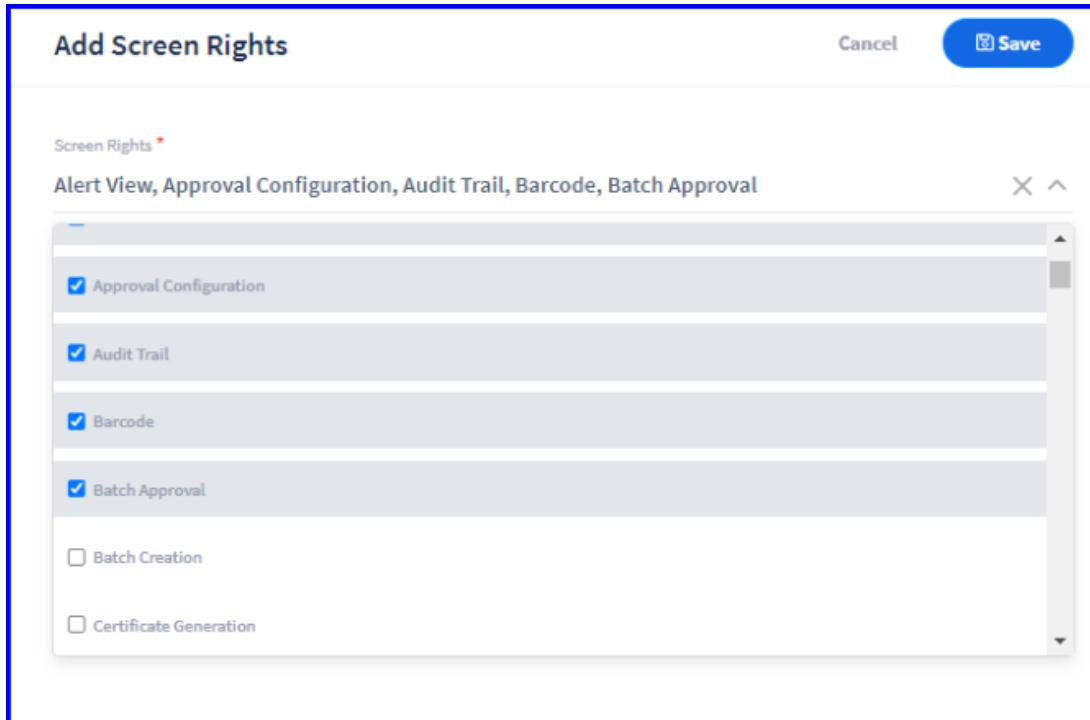


FIGURE: Add Screen Rights Screen

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

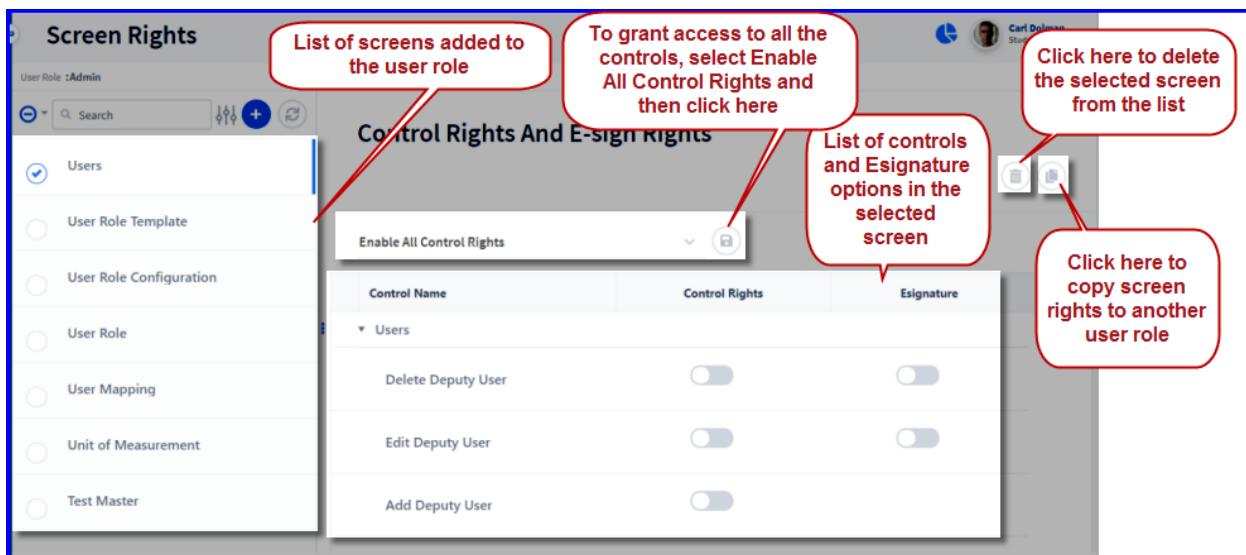


FIGURE: List of Screens, Controls and E-Sign Options

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

3.4.7.1 Pagination

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

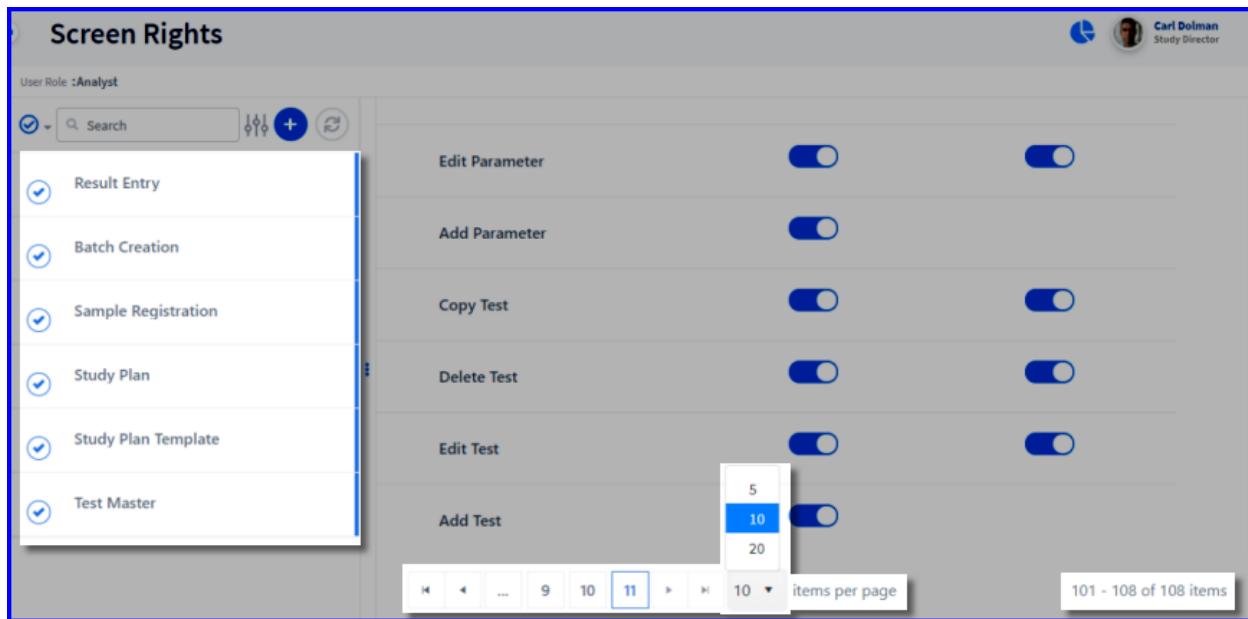
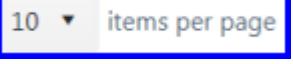
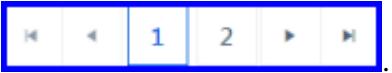


FIGURE: Screen Rights – Pagination

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

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

3.4.7.2 Copying Screen Rights

You can copy screen rights to multiple roles.

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

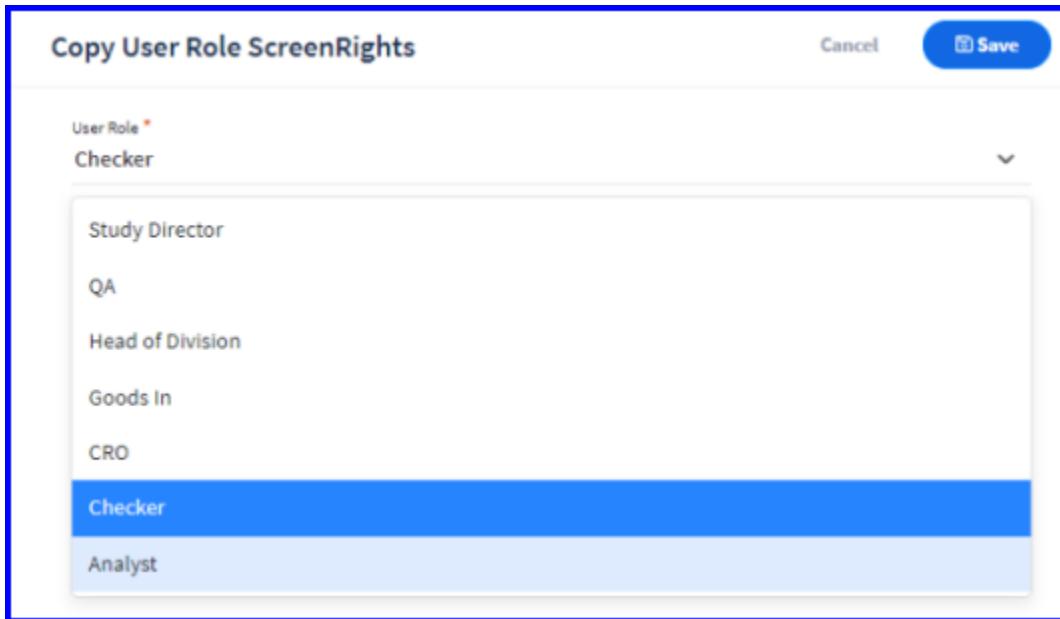


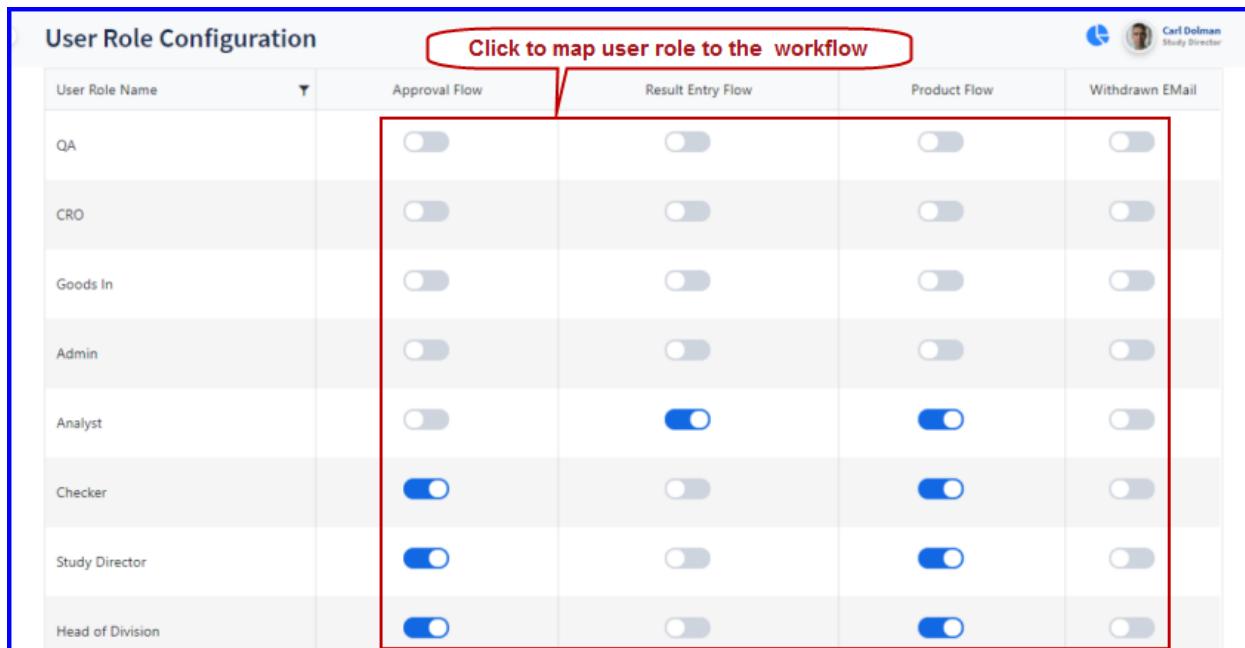
FIGURE: Copy User Role Screen Rights Screen

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

3.4.8 User Role Configuration

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

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



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

FIGURE: User Role Configuration Screen

You can see the list of user role and workflows.

5. 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.

3.4.8.1 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:

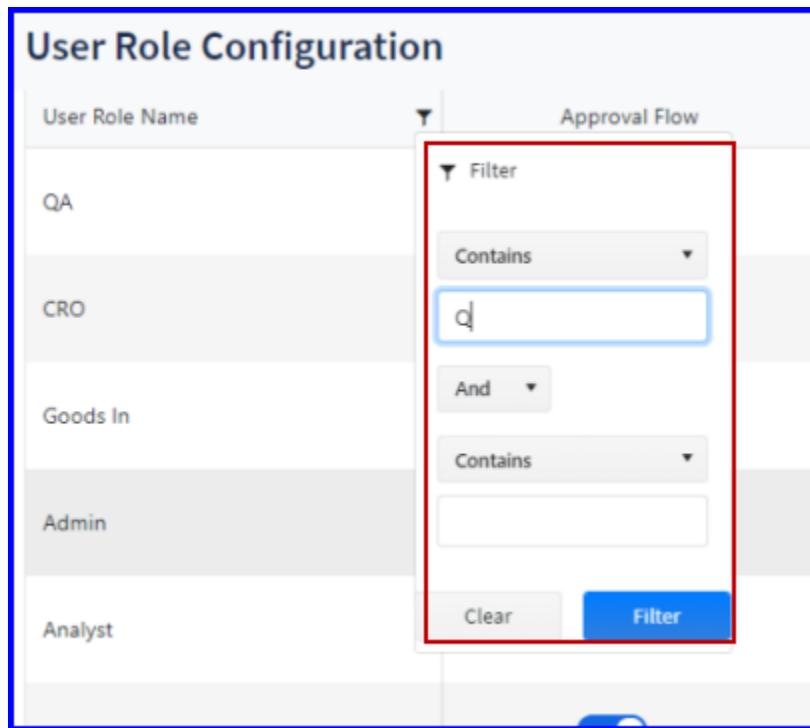


FIGURE: Filter User Role Name

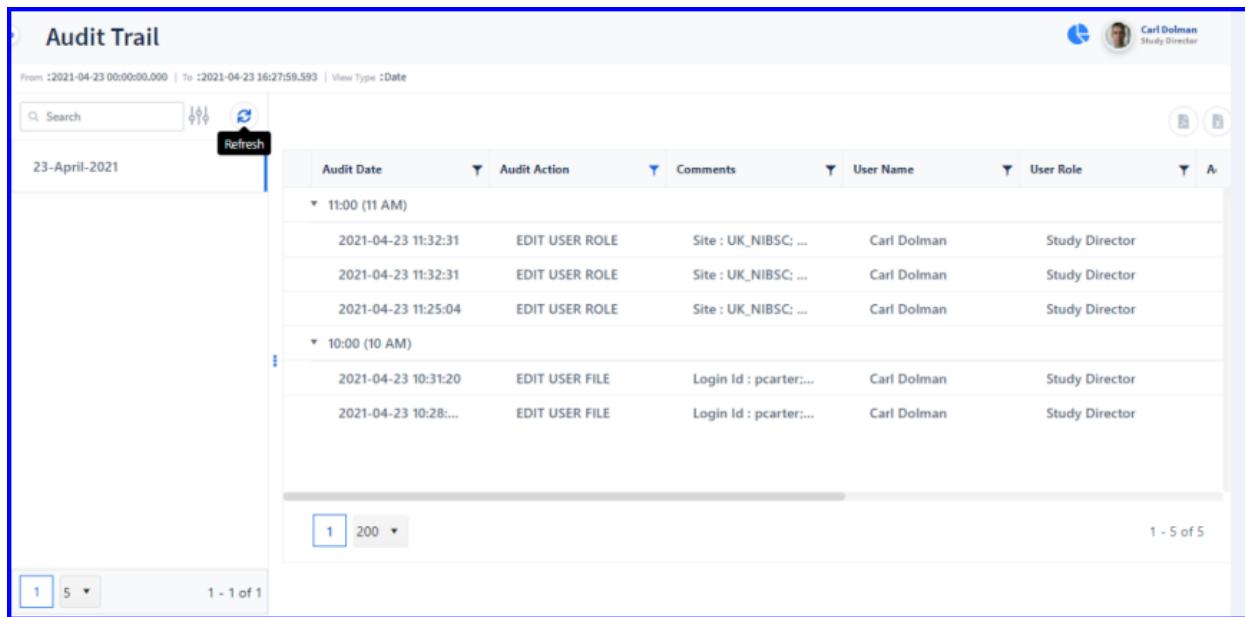
2. Use the filter to search for the user role names and then click **Filter**.

3.4.9 Audit Trail

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

To do so, follow these steps:

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

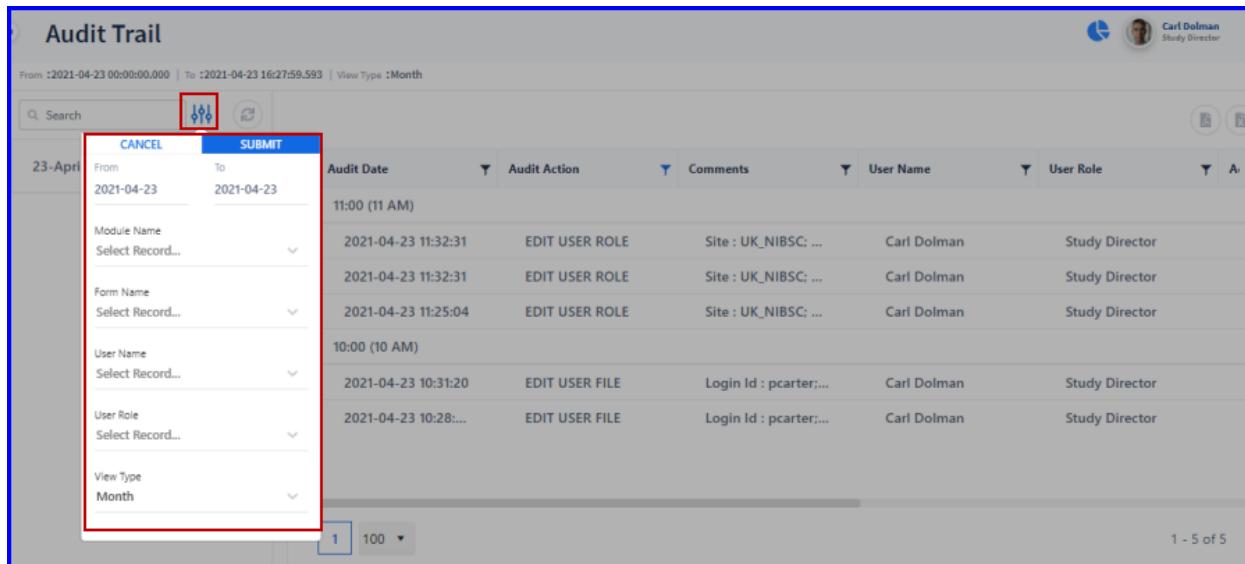


The screenshot shows the Audit Trail screen with a blue border. At the top, there is a search bar, a date range selector (From: 2021-04-23, To: 2021-04-23), and a refresh button. The main area is a table with columns: Audit Date, Audit Action, Comments, User Name, User Role, and Actions. The data is grouped by time: 11:00 (11 AM) and 10:00 (10 AM). Each group contains multiple rows of audit entries. At the bottom, there is a page number (1/200), a page size selector (200), and a total record count (1 - 5 of 5).

Audit Date	Audit Action	Comments	User Name	User Role	A
11:00 (11 AM)					
2021-04-23 11:32:31	EDIT USER ROLE	Site : UK_NIBSC: ...	Carl Dolman	Study Director	
2021-04-23 11:32:31	EDIT USER ROLE	Site : UK_NIBSC: ...	Carl Dolman	Study Director	
2021-04-23 11:25:04	EDIT USER ROLE	Site : UK_NIBSC: ...	Carl Dolman	Study Director	
10:00 (10 AM)					
2021-04-23 10:31:20	EDIT USER FILE	Login Id : pcarter:...	Carl Dolman	Study Director	
2021-04-23 10:28:...	EDIT USER FILE	Login Id : pcarter:...	Carl Dolman	Study Director	

FIGURE: Audit Trail Screen

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

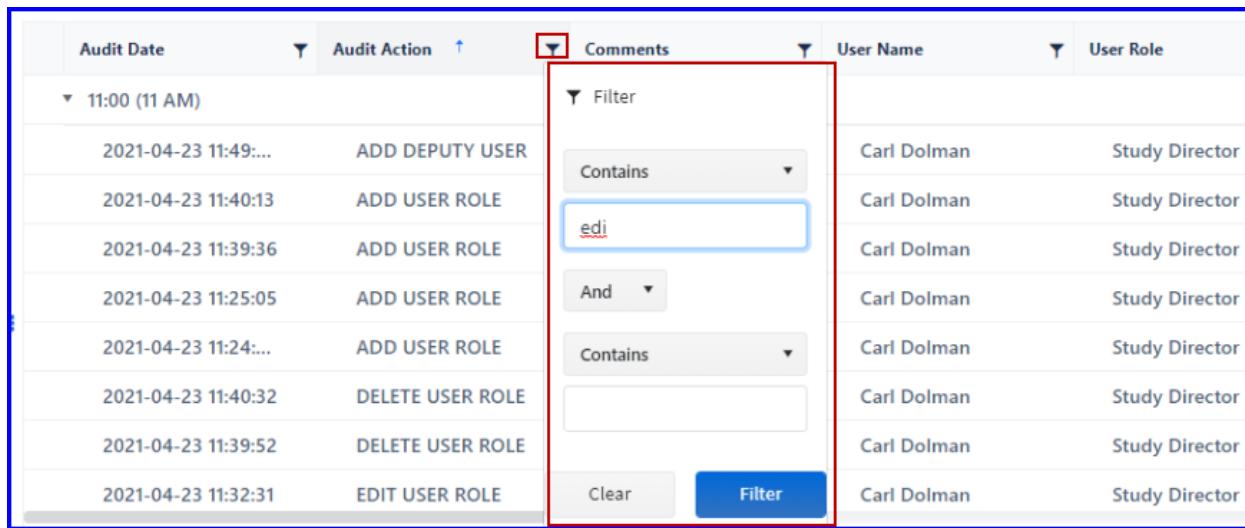


The screenshot shows the Audit Trail screen with a blue border. A red box highlights the filter icon  and the filter dialog box. The filter dialog box contains fields for From (2021-04-23), To (2021-04-23), Module Name (Select Record...), Form Name (Select Record...), User Name (Select Record...), User Role (Select Record...), and View Type (Month). The main table area shows the same audit data as the first screenshot. At the bottom, there is a page number (1/100), a page size selector (100), and a total record count (1 - 5 of 5).

Audit Date	Audit Action	Comments	User Name	User Role	A
11:00 (11 AM)					
2021-04-23 11:32:31	EDIT USER ROLE	Site : UK_NIBSC: ...	Carl Dolman	Study Director	
2021-04-23 11:32:31	EDIT USER ROLE	Site : UK_NIBSC: ...	Carl Dolman	Study Director	
2021-04-23 11:25:04	EDIT USER ROLE	Site : UK_NIBSC: ...	Carl Dolman	Study Director	
10:00 (10 AM)					
2021-04-23 10:31:20	EDIT USER FILE	Login Id : pcarter:...	Carl Dolman	Study Director	
2021-04-23 10:28:...	EDIT USER FILE	Login Id : pcarter:...	Carl Dolman	Study Director	

FIGURE: 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:



Audit Date	Audit Action	Comments	User Name	User Role
11:00 (11 AM)				
2021-04-23 11:49:...	ADD DEPUTY USER		Carl Dolman	Study Director
2021-04-23 11:40:13	ADD USER ROLE		Carl Dolman	Study Director
2021-04-23 11:39:36	ADD USER ROLE		Carl Dolman	Study Director
2021-04-23 11:25:05	ADD USER ROLE		Carl Dolman	Study Director
2021-04-23 11:24:...	ADD USER ROLE		Carl Dolman	Study Director
2021-04-23 11:40:32	DELETE USER ROLE		Carl Dolman	Study Director
2021-04-23 11:39:52	DELETE USER ROLE		Carl Dolman	Study Director
2021-04-23 11:32:31	EDIT USER ROLE		Carl Dolman	Study Director

FIGURE: Filter audit Records Based on Fields

3.5 Organisation

Organisation in Qualis LIMS consists of the following:

Site: Added and managed in the back end.

Division: Consists of sections.

Section: Consists of labs.

Lab: Consists of users

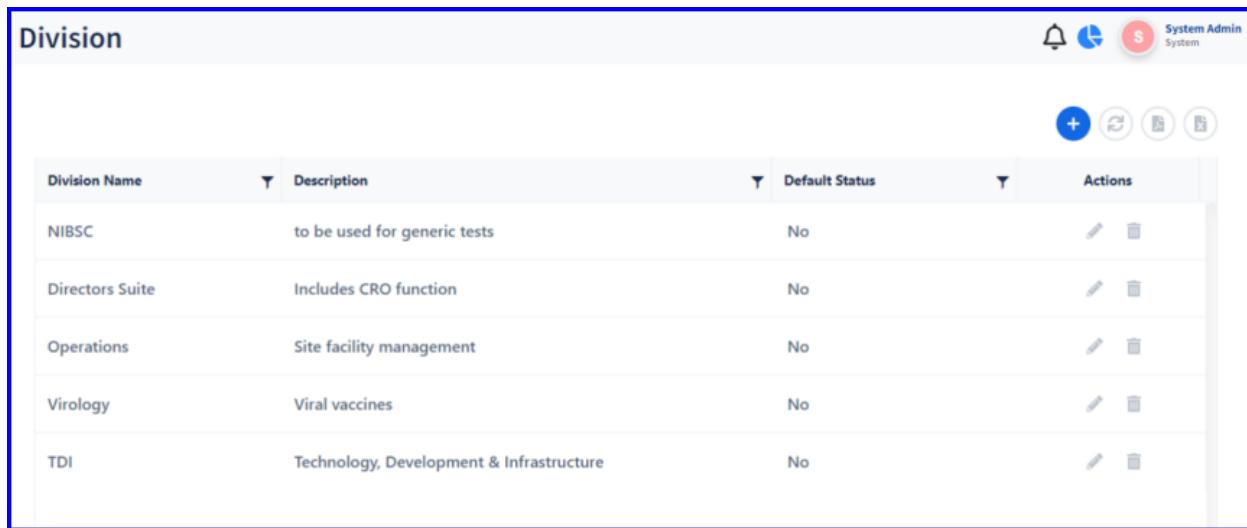
3.5.1 Division Master

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

3.5.1.1 Adding a New Division

To create a new division, follow these steps:

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



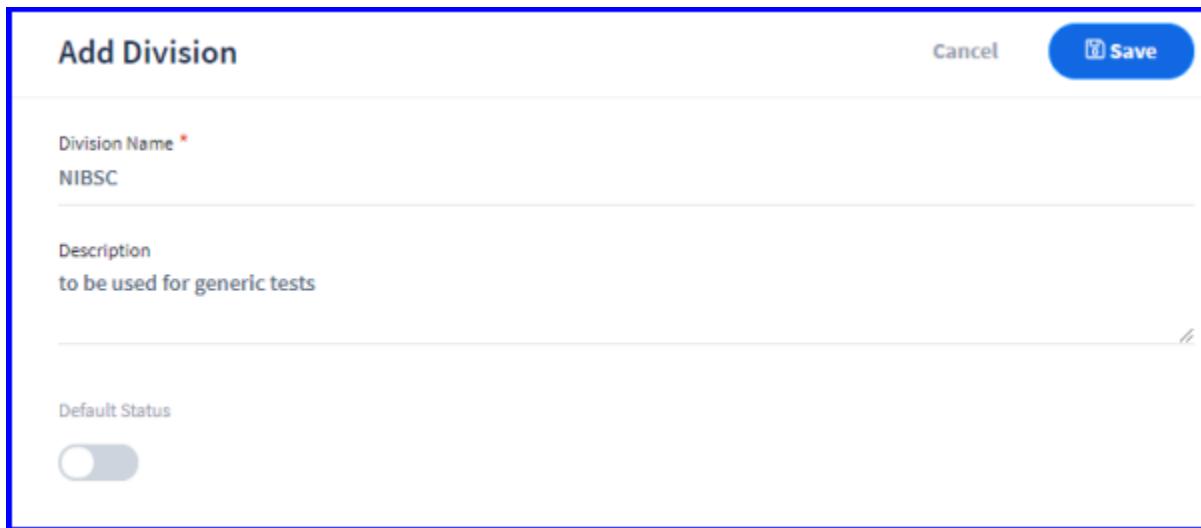
The screenshot shows a table titled 'Division' with a blue border. The table has columns: 'Division Name', 'Description', 'Default Status', and 'Actions'. The 'Actions' column contains edit and delete icons. The data in the table is as follows:

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

FIGURE: Division Master Screen

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

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



The screenshot shows the 'Add Division' form with a blue border. It has fields for 'Division Name *', 'Description', and 'Default Status'. The 'Save' button is highlighted with a blue oval.

Division Name *	<input type="text" value="NIBSC"/>	Save
Description	<input type="text" value="to be used for generic tests"/>	
Default Status	<input type="checkbox"/>	

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 .

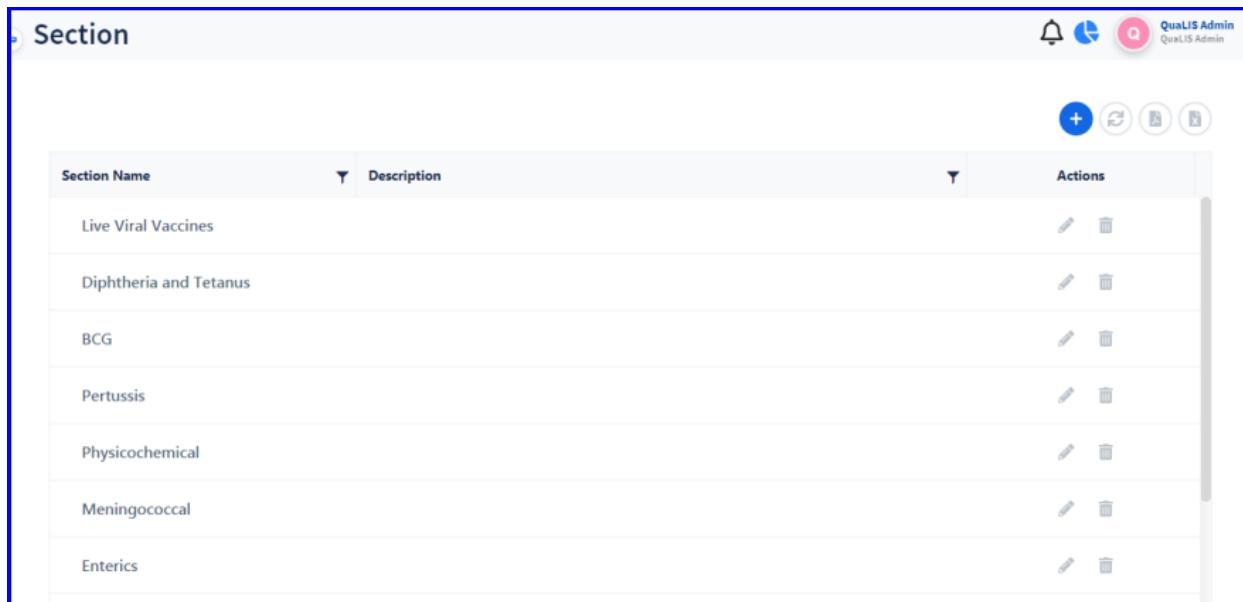
3.5.2 Section Master

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:

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



The screenshot shows the 'Section' master screen. At the top, there is a header with the title 'Section' and a back arrow. On the right, there are user icons for 'Qualis Admin' and 'Qualis Admin'. Below the header is a toolbar with icons for adding (+), refreshing, and deleting. The main area is a table with the following data:

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

FIGURE: Section Master Screen

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

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

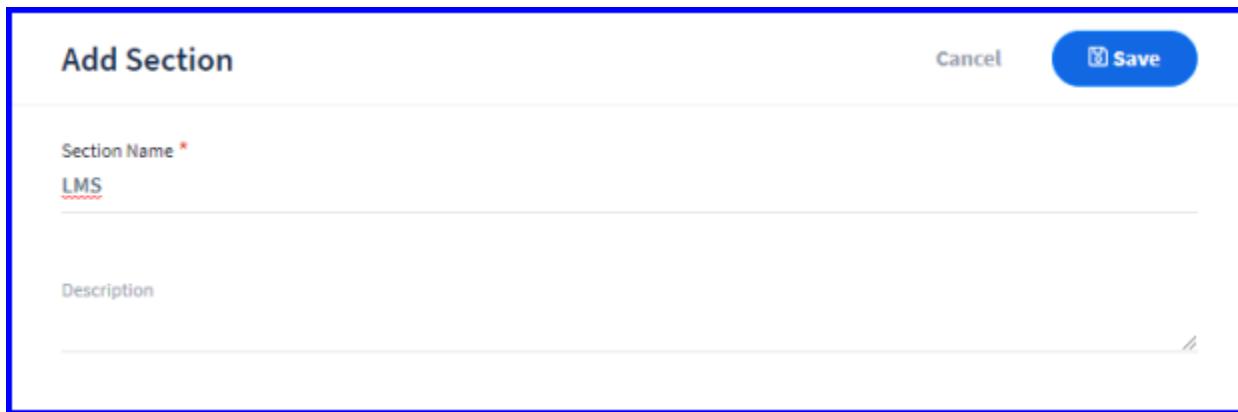


FIGURE: Add Section Screen

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

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

3.5.2.2 Editing and Deleting Section

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

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

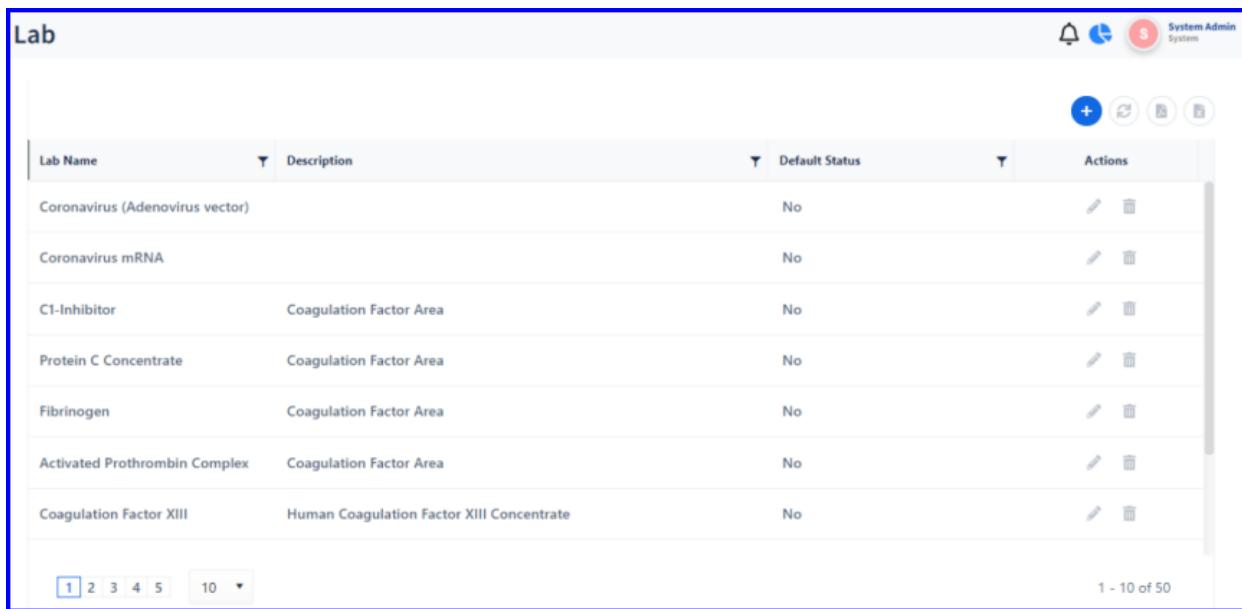
3.5.3 Lab Master

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

3.5.3.1 Adding a New Lab

To create a new lab, follow these steps:

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



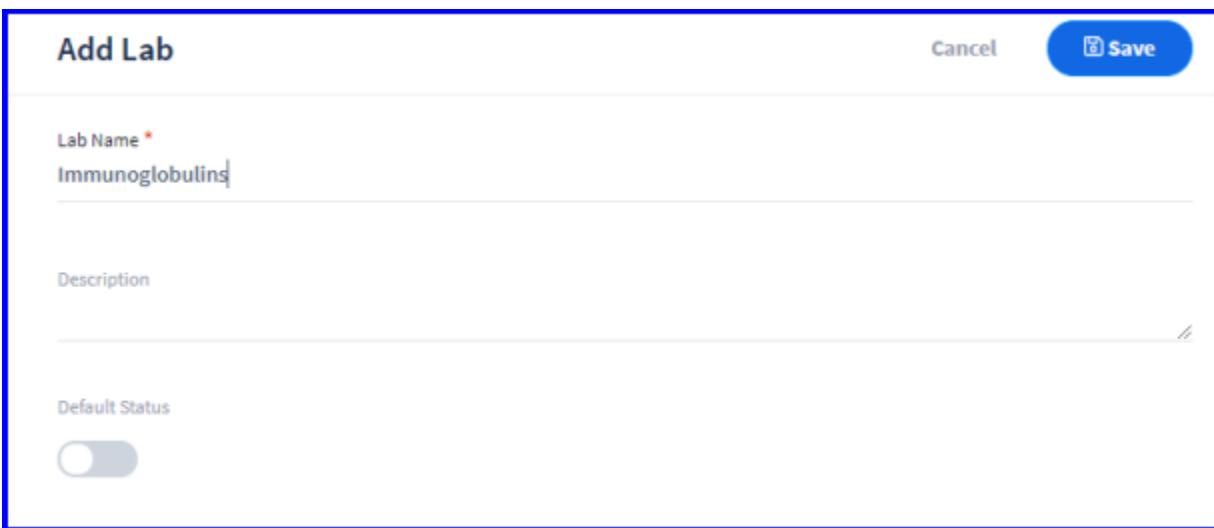
Lab Name	Description	Default Status	Actions
Coronavirus (Adenovirus vector)		No	 
Coronavirus mRNA		No	 
C1-Inhibitor	Coagulation Factor Area	No	 
Protein C Concentrate	Coagulation Factor Area	No	 
Fibrinogen	Coagulation Factor Area	No	 
Activated Prothrombin Complex	Coagulation Factor Area	No	 
Coagulation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

1 - 10 of 50

FIGURE: Lab Master Screen

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

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



Add Lab

Lab Name *

Description

Default Status

Cancel  Save

FIGURE: Add Lab Screen

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

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

3.5.3.2 Editing and Deleting Lab

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

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

3.5.4 Organisation Master

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

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

3.5.4.1 View Organisation Hierarchy

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

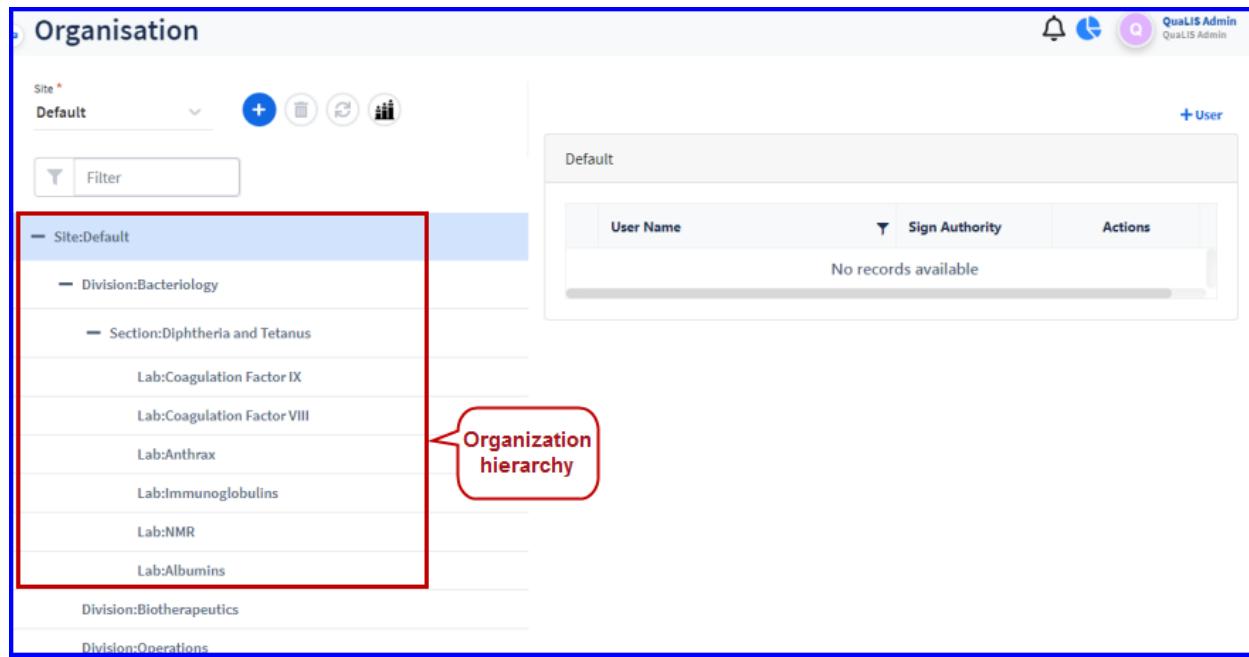


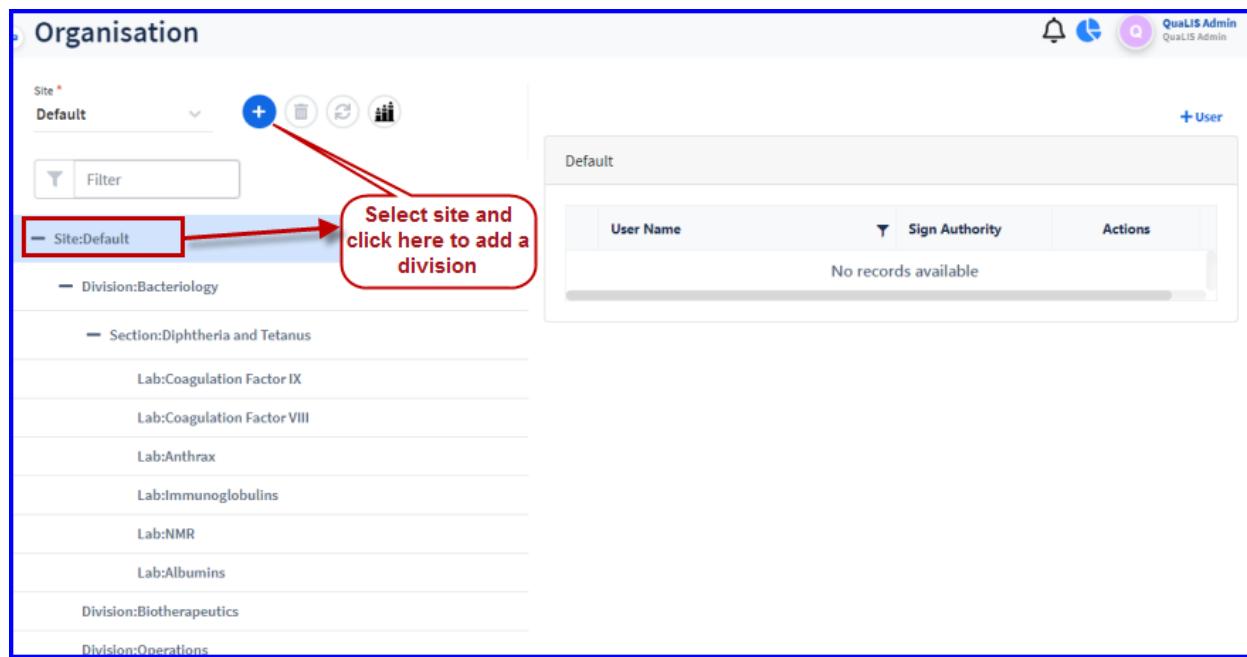
FIGURE: Organisation Master

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

3.5.4.2 Add Division to Site

To add divisions to site, follow these steps:

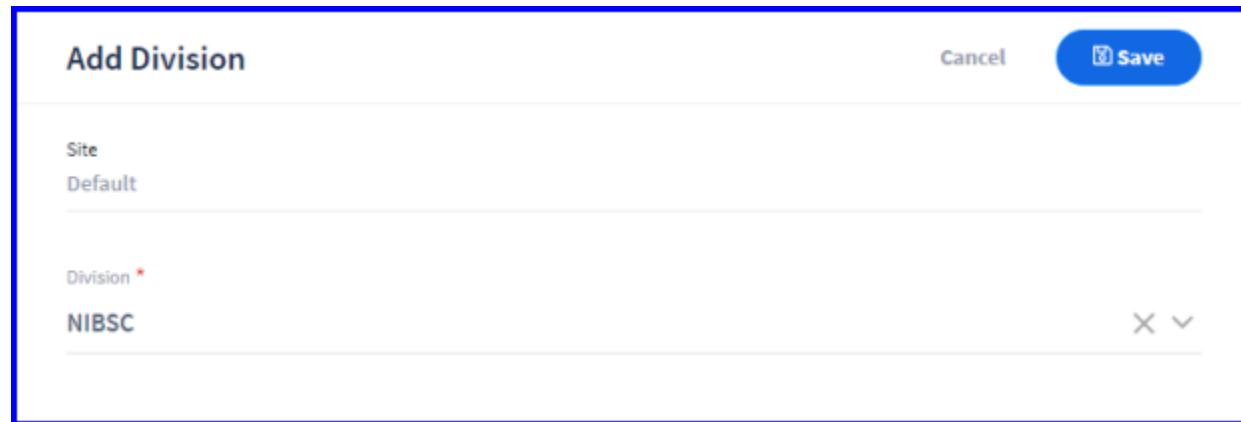
2. In the Organisation master screen, select a site and then click  as shown in the figure:



The screenshot shows the 'Organisation' page in Qualis LIMS. The 'Site' dropdown is set to 'Default'. A red box highlights the 'Site:Default' dropdown. A red callout box with the text 'Select site and click here to add a division' points to the blue '+' button in the toolbar. The right panel shows a table with columns 'User Name', 'Sign Authority', and 'Actions', with a message 'No records available'.

FIGURE: Adding Division to Site

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



The screenshot shows the 'Add Division' dialog. The 'Site' field is set to 'Default'. The 'Division' field contains 'NIBSC'. A blue 'Save' button is visible in the top right corner.

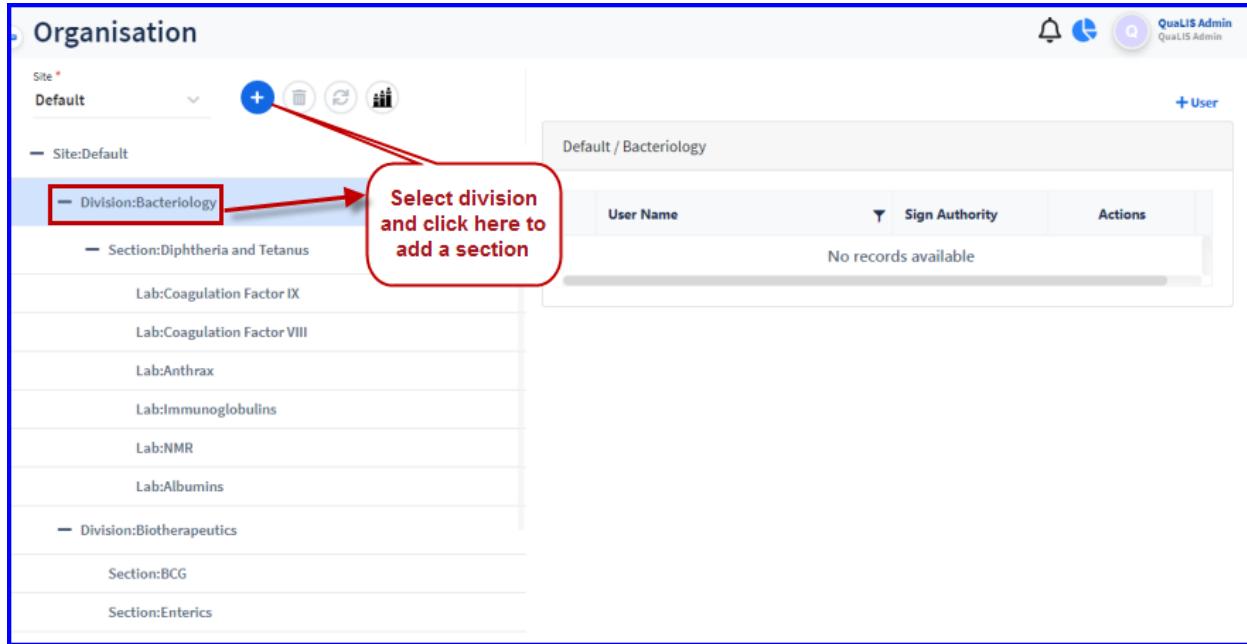
FIGURE: Add Division Dialog

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

3.5.4.3 Add Section to Division

To add section to divisions, follow these steps:

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



Organisation

Site *
Default

Default / Bacteriology

User Name	Sign Authority	Actions
No records available		

Division:Bacteriology

Section:Diphtheria and Tetanus

Lab:Coagulation Factor IX

Lab:Coagulation Factor VIII

Lab:Anthrax

Lab:Immunoglobulins

Lab:NMR

Lab:Albumins

Division:Biotherapeutics

Section:BCG

Section:Enterics

QuaLIS Admin

+ User

FIGURE: Adding Section to Division

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

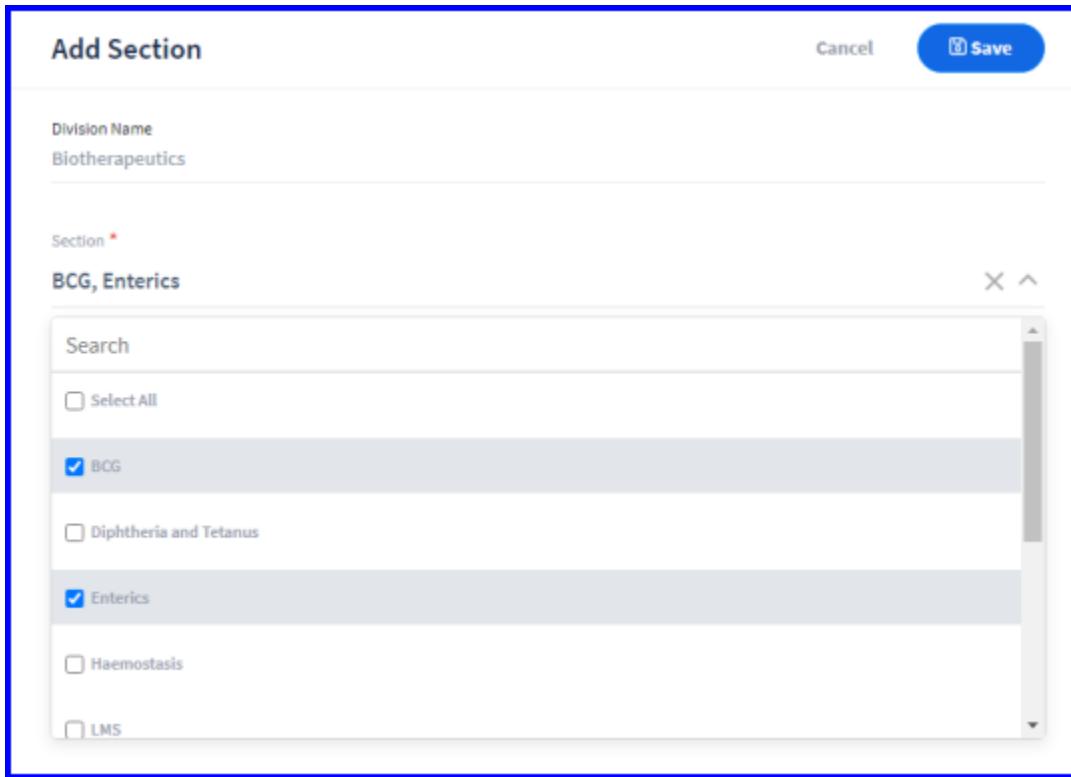


FIGURE: Add Section Dialog

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

3.5.4.4 Add Labs to Sections

To add labs to section, follow these steps:

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

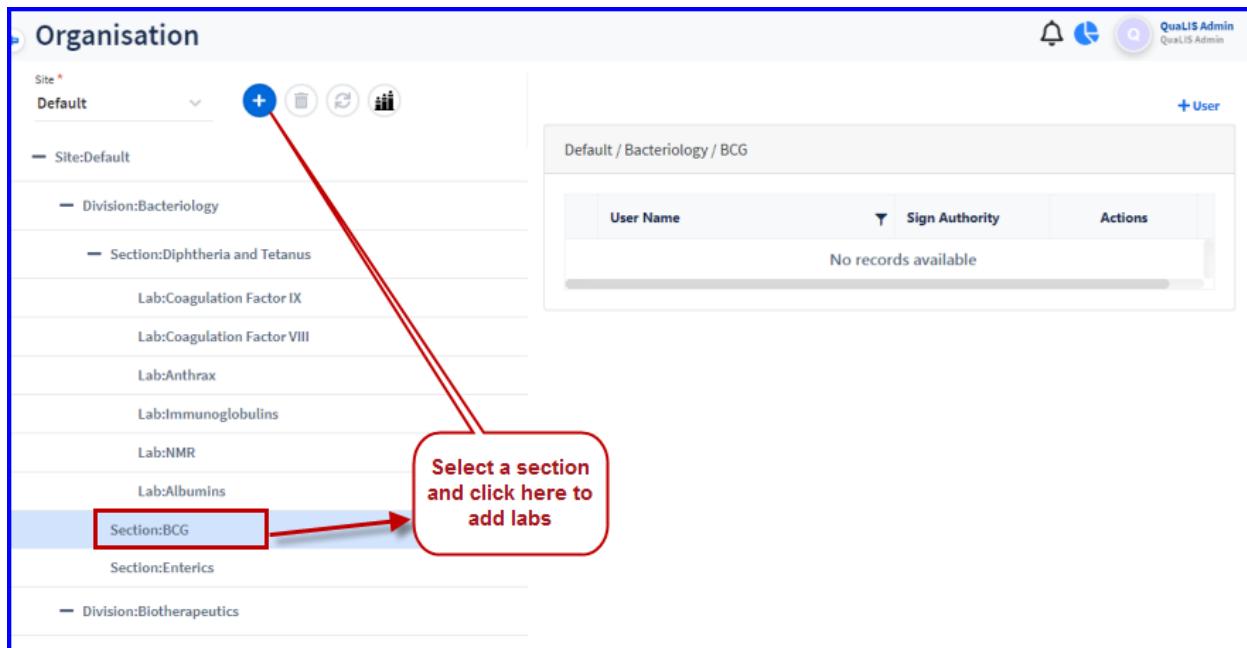


FIGURE: Adding Labs to Section

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

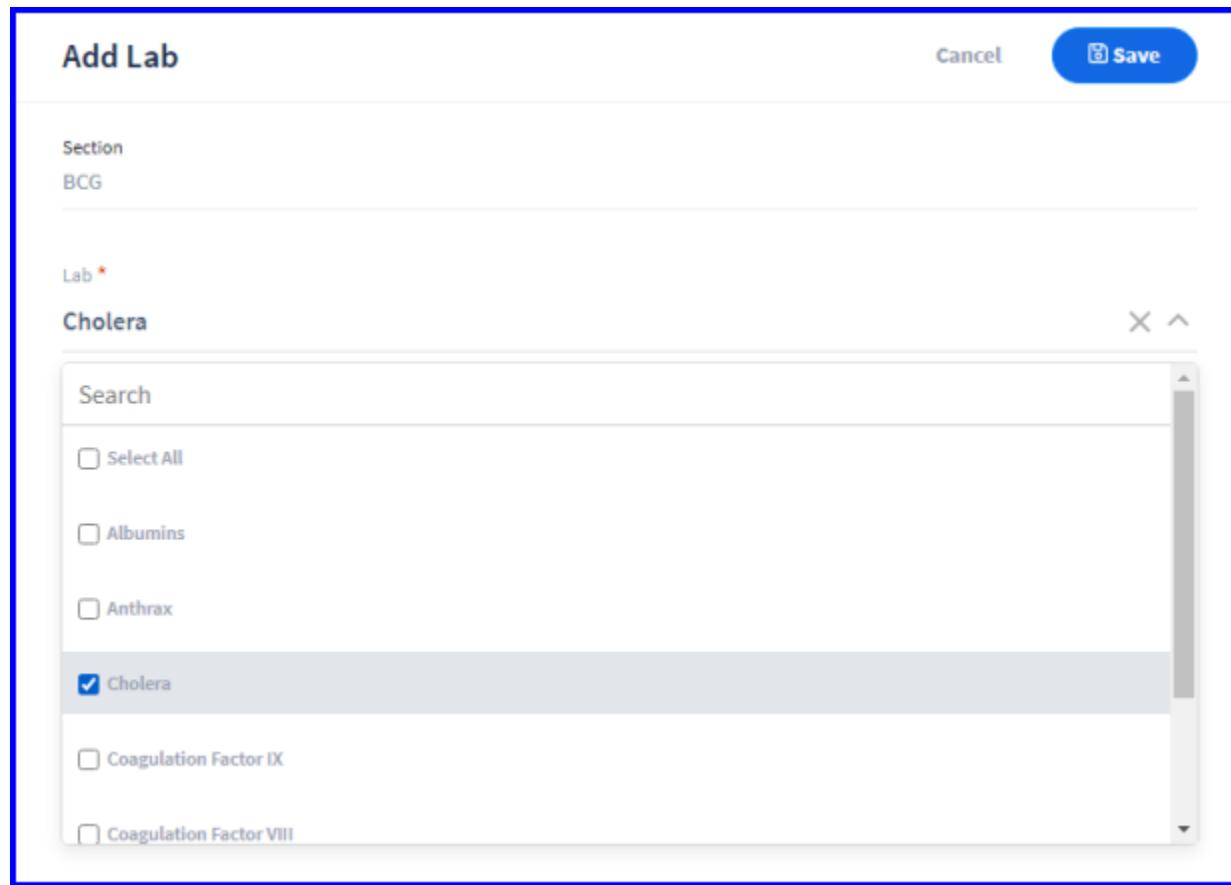


FIGURE: Add Lab Dialog

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

3.5.4.5 Add User

To add users to lab, follow these steps:

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

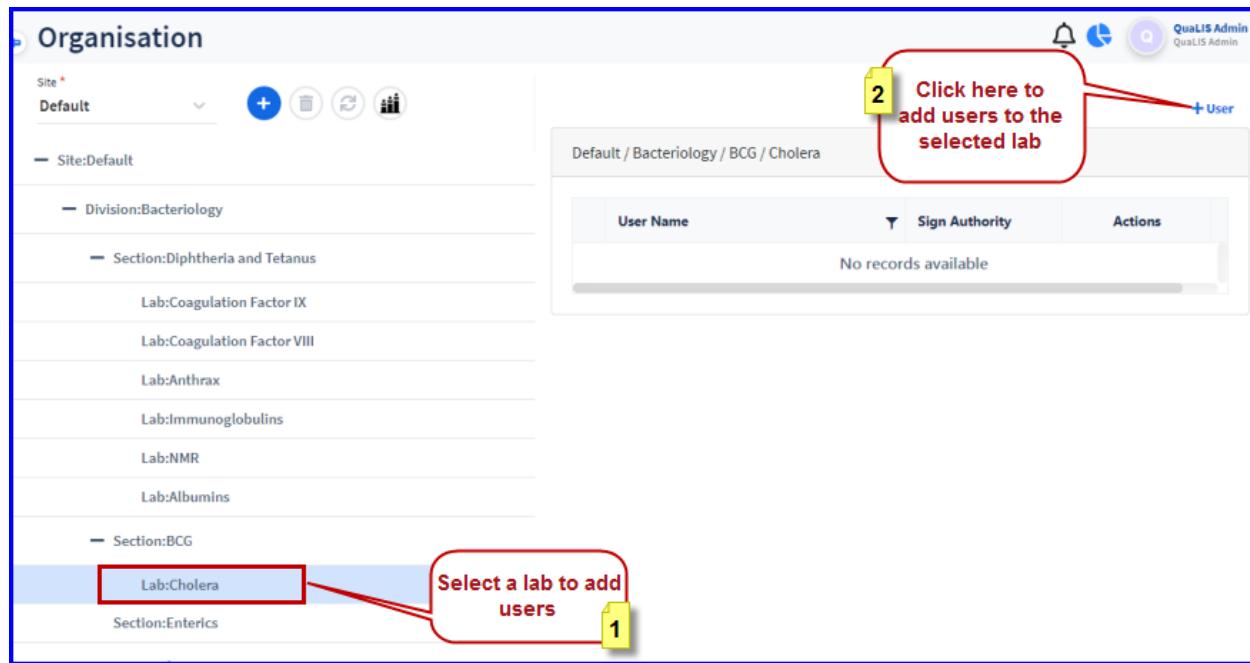
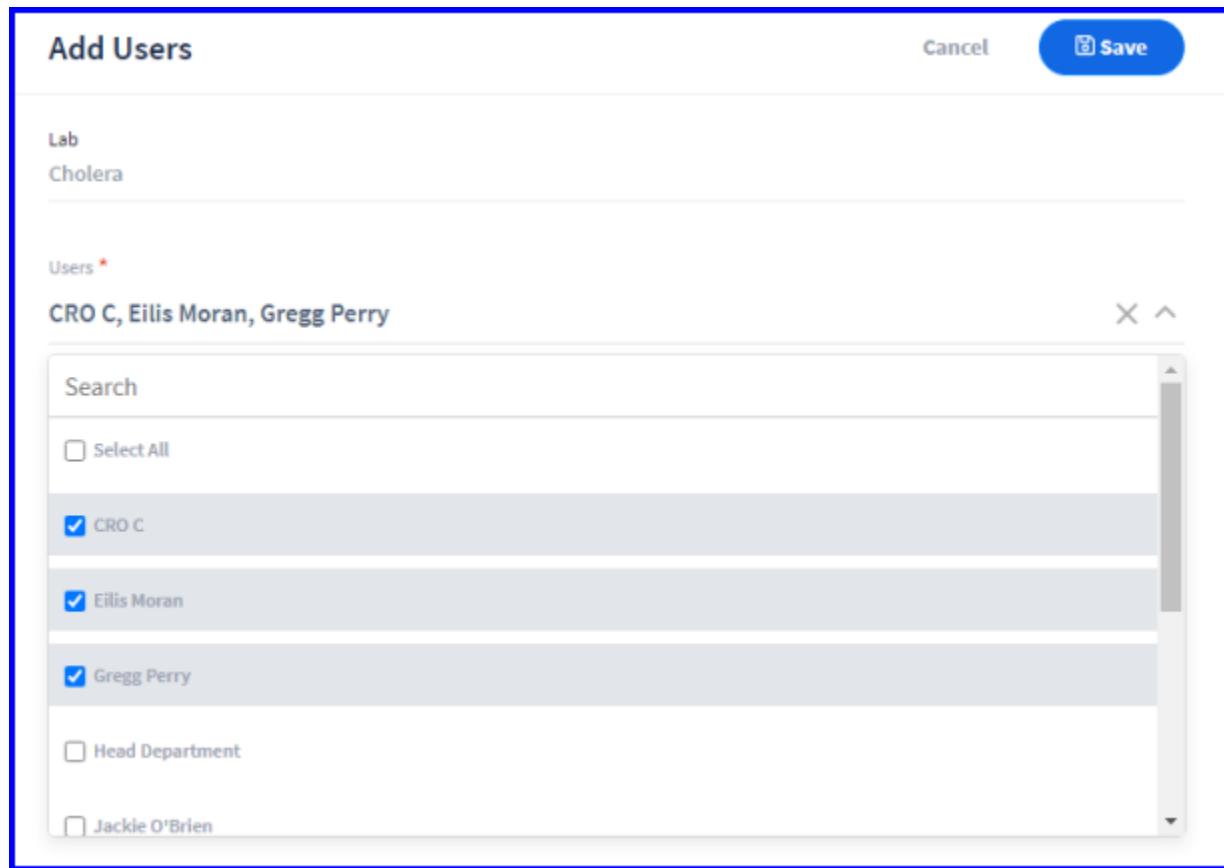


FIGURE: Adding Users to Lab

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



Lab
Cholera

Users *

CRO C, Eilis Moran, Gregg Perry

Search

Select All

CRO C

Eilis Moran

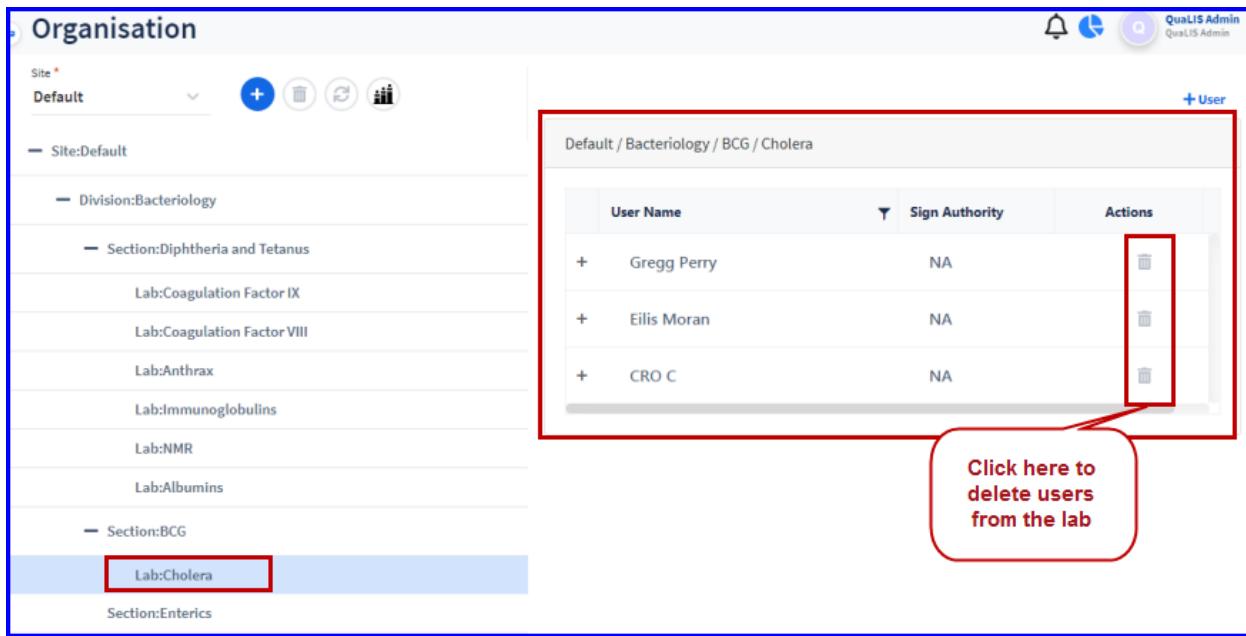
Gregg Perry

Head Department

Jackie O'Brien

FIGURE: Add Users Dialog

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



The screenshot shows the 'Organisation' module in Qualis LIMS. On the left, a tree view shows the site structure: Default > Site:Default > Division:Bacteriology > Section:Diphtheria and Tetanus > Lab:Coagulation Factor IX, Lab:Coagulation Factor VIII, Lab:Anthrax, Lab:Immunoglobulins, Lab:NMR, Lab:Albumins > Section:BCG > Lab:Cholera (highlighted with a red box) > Section:Enterics. On the right, a grid lists users assigned to 'Default / Bacteriology / BCG / Cholera'. The grid has columns for 'User Name', 'Sign Authority' (all NA), and 'Actions' (each with a delete icon). A red box highlights the 'Actions' column, and a callout bubble with the text 'Click here to delete users from the lab' points to the delete icon for the user 'CRO C'.

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

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:

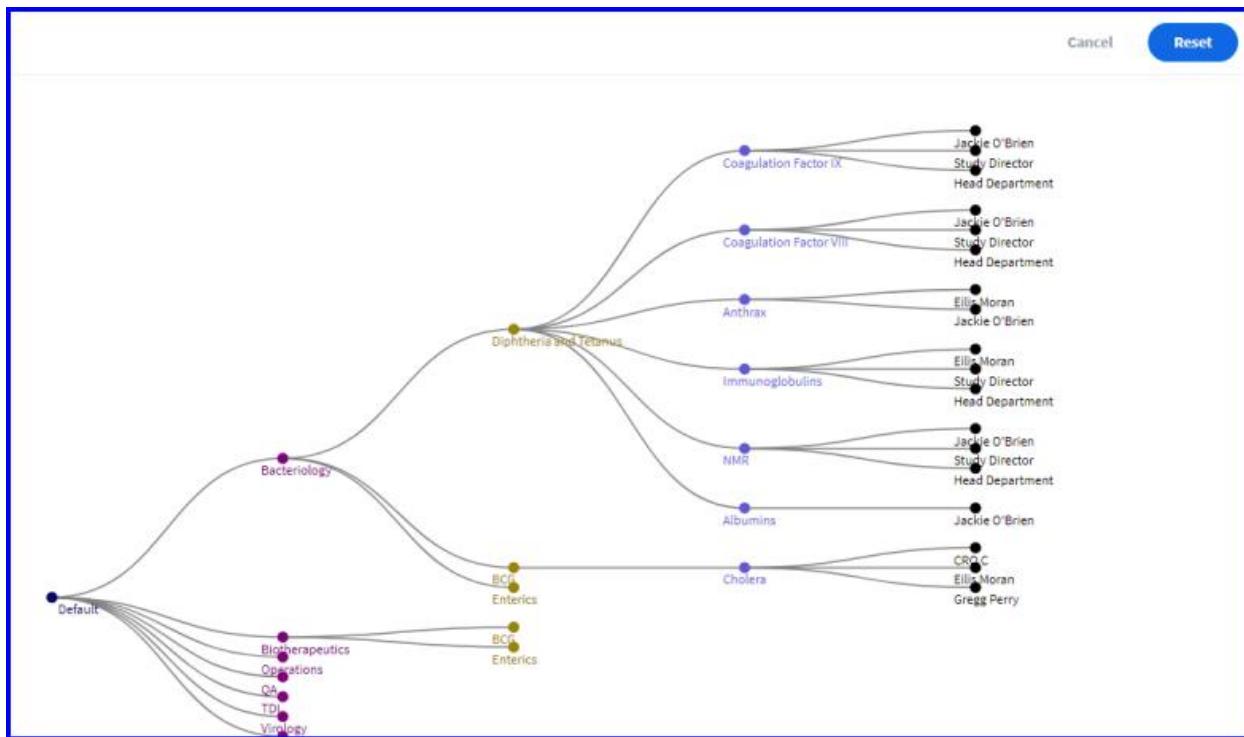


FIGURE: Graphical View of Organisation Setup

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

3.6 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:

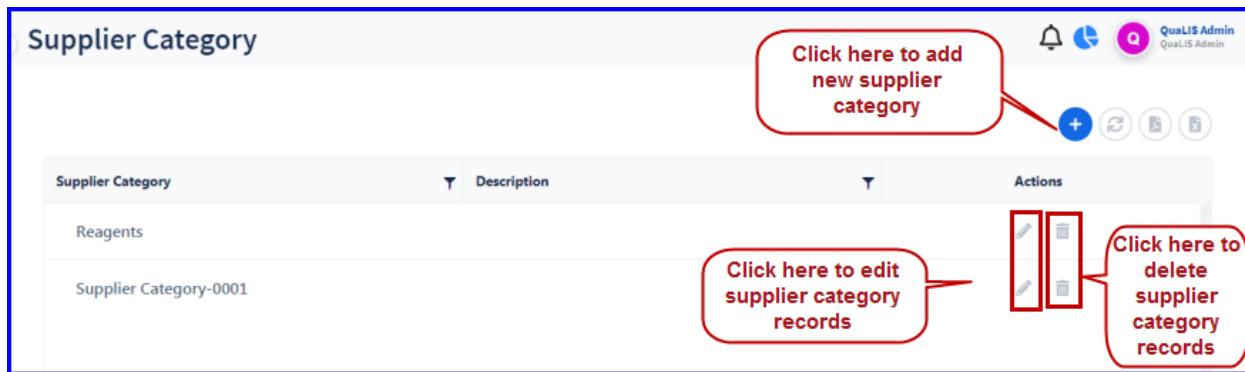


FIGURE: Supplier Category Master Screen

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:

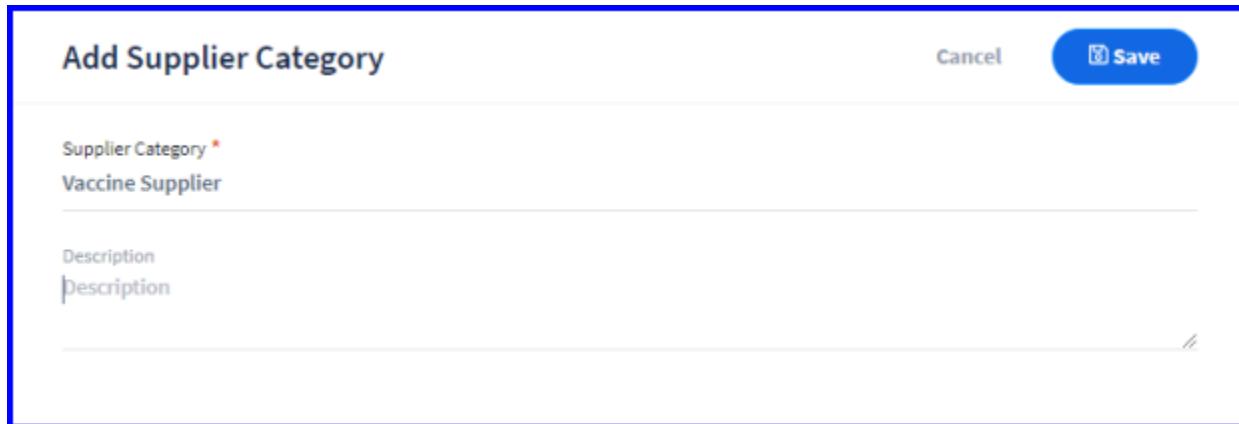


FIGURE: Add Supplier Category Dialog

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:

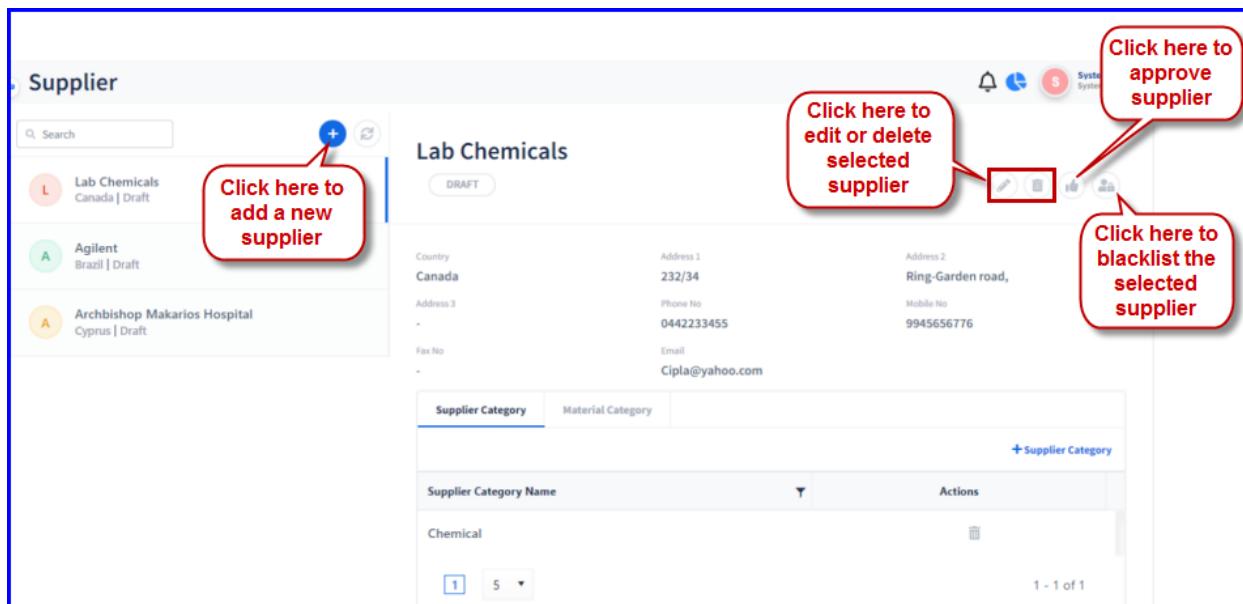
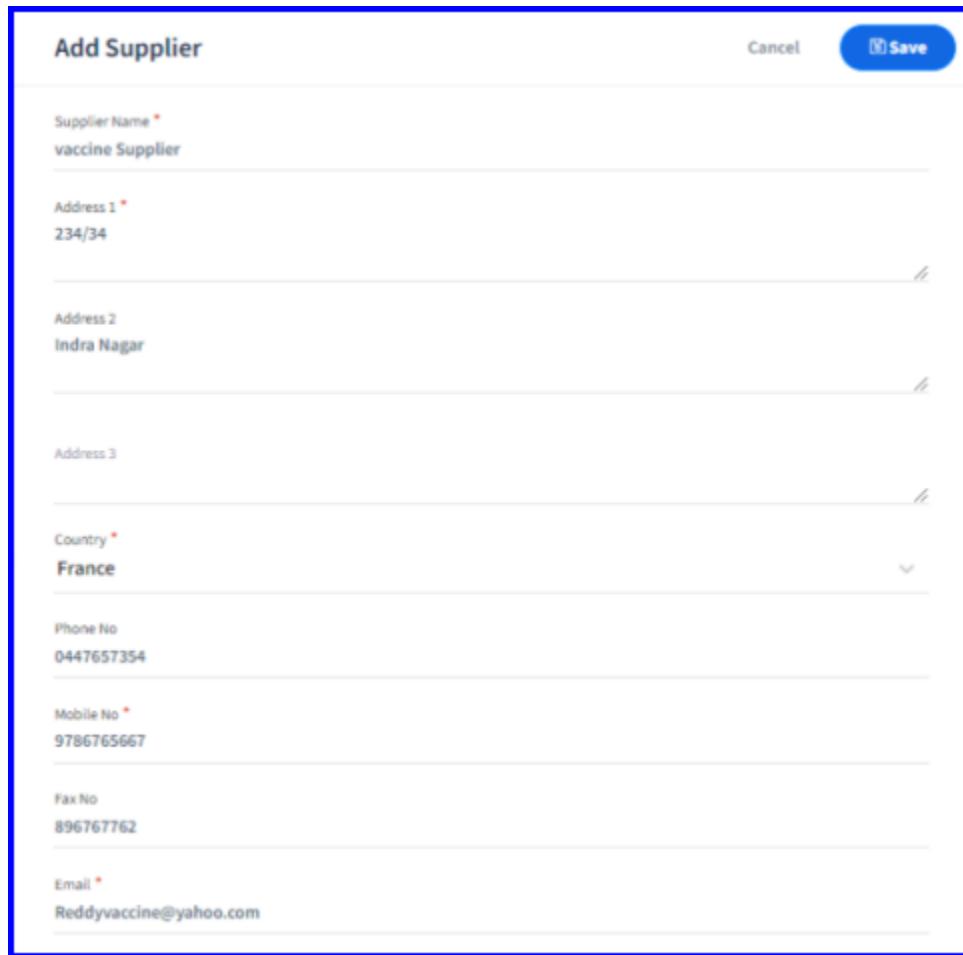


FIGURE: Supplier Master Screen

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:



Add Supplier

Supplier Name *
vaccine Supplier

Address 1 *
234/34

Address 2
Indra Nagar

Address 3

Country *
France

Phone No
0447657354

Mobile No *
9786765667

Fax No
896767762

Email *
Reddyvaccine@yahoo.com

Cancel 

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:

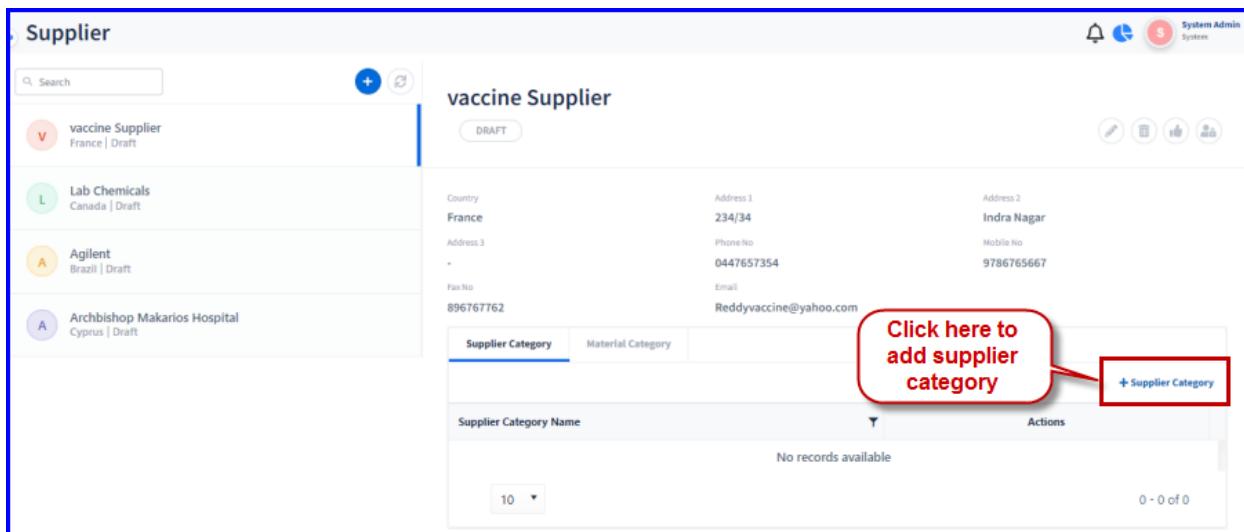


FIGURE: Adding Supplier Category to Supplier

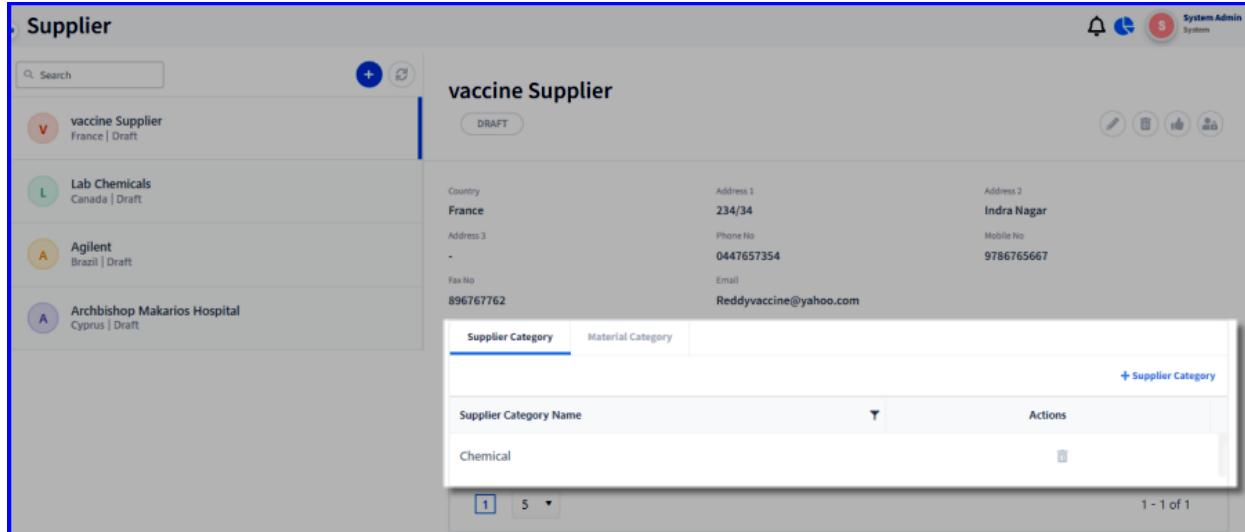
The **Add Supplier Category** dialog appears as shown in the figure:



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:



The screenshot shows the LIMS Qualis Supplier master screen. On the left, a sidebar lists other suppliers: 'vaccine Supplier' (France | Draft), 'Lab Chemicals' (Canada | Draft), 'Agilent' (Brazil | Draft), and 'Archbishop Makarios Hospital' (Cyprus | Draft). The main panel shows the details for 'vaccine Supplier' (France | Draft), including address, phone number, fax number, and email. Below this, the 'Supplier Category' tab is selected in a sub-menu, showing a table with one row: 'Supplier Category Name' is 'Chemical'. The sub-menu also includes a 'Material Category' tab and a 'Supplier Category' button.

FIGURE: Supplier Categories Added to the Supplier

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

3.6.2.4 Adding Material Category to Supplier

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

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

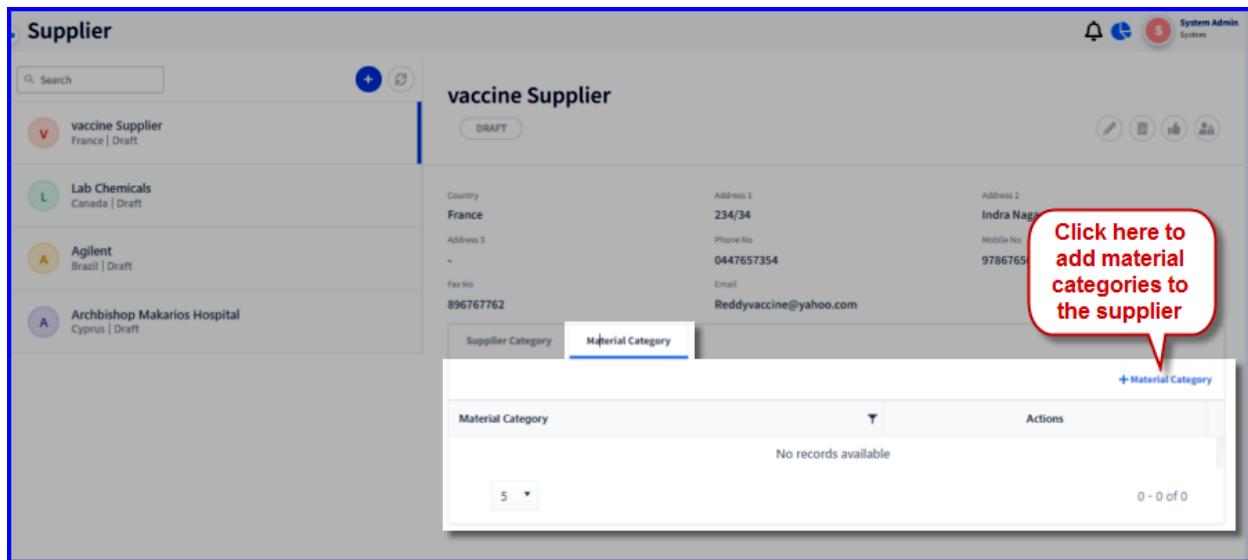


FIGURE: Adding Material Category to Supplier

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



FIGURE: Add Material Category Dialog

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

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

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

3.6.2.5 Approving Selected Supplier

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

3.6.2.6 Blacklist Selected Supplier

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

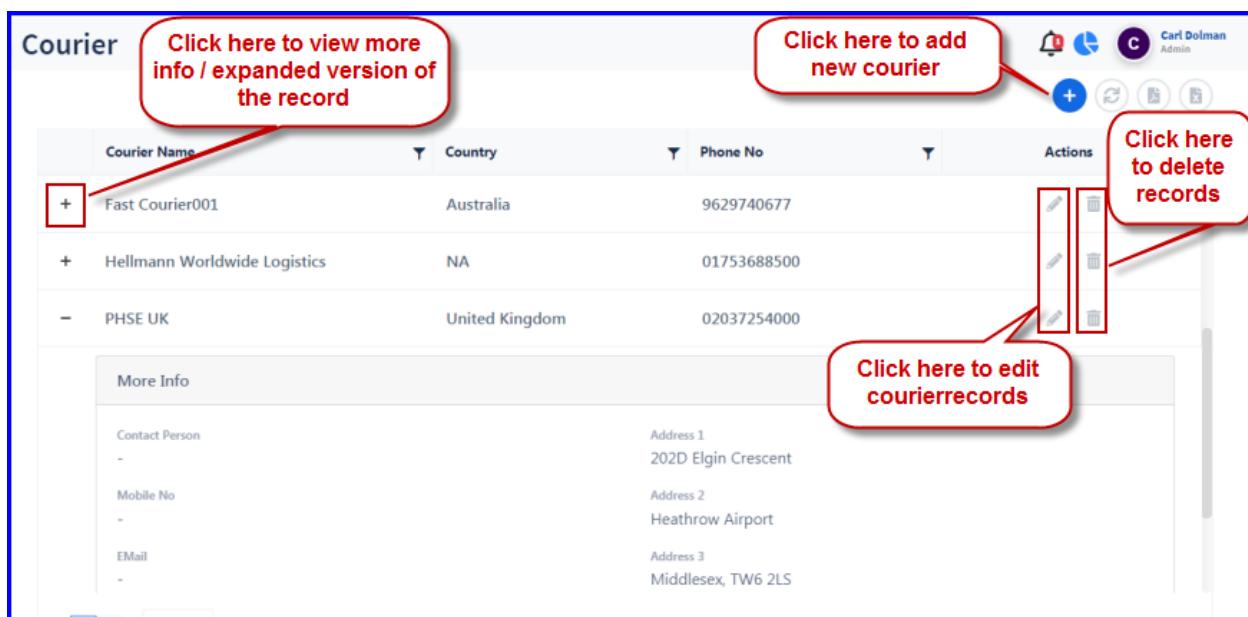
3.6.3 Courier Master

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

3.6.3.1 Adding a New Courier

To create a new courier record, follow these steps:

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



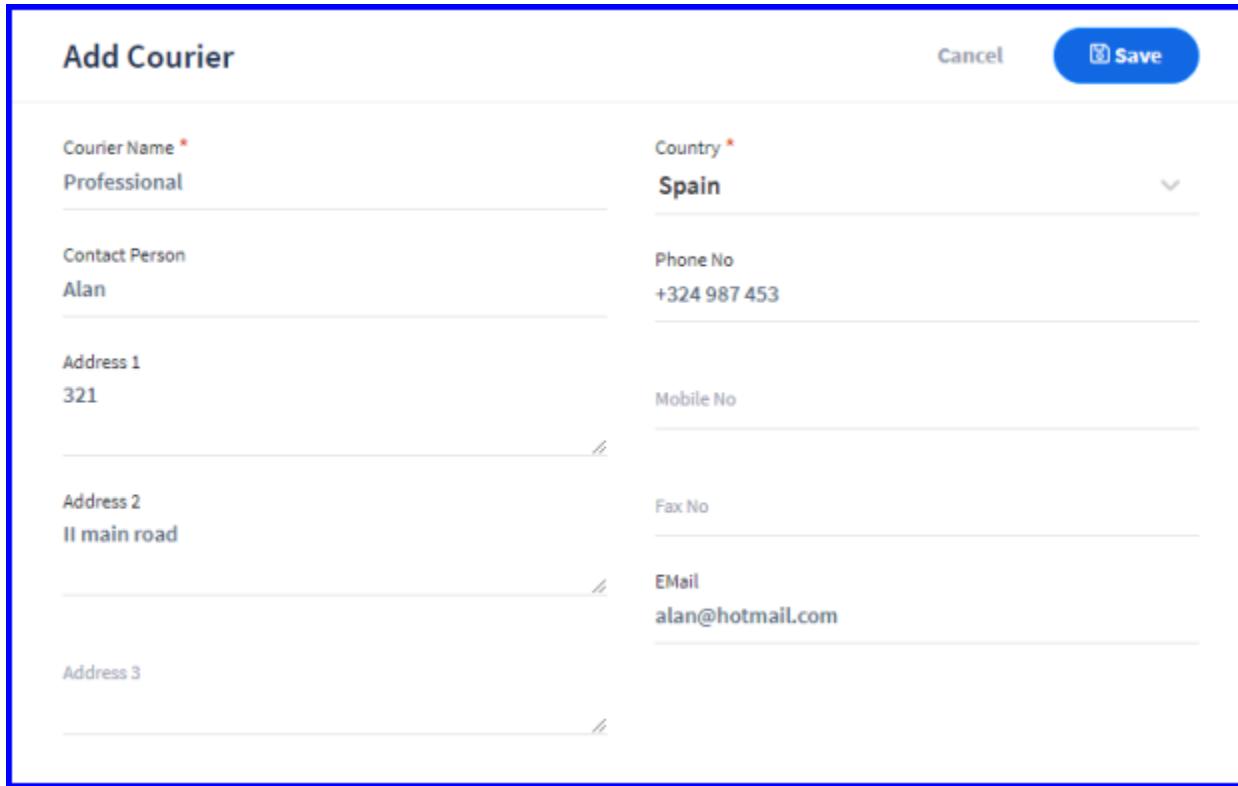
The screenshot shows the Courier master screen with the following details:

- Header:** Shows the title "Courier" and a user profile for "Carl Dolman Admin".
- Table:** A list of couriers with columns for "Courier Name", "Country", "Phone No", and "Actions". The table contains three rows:
 - Fast Courier001 (Australia, 9629740677)
 - Hellmann Worldwide Logistics (NA, 01753688500)
 - PHSE UK (United Kingdom, 02037254000)
- Action Menu:** Located on the right side of the table, with options:
 - "Click here to view more info / expanded version of the record" (points to the "Fast Courier001" row)
 - "Click here to add new courier" (points to the "Actions" column)
 - "Click here to delete records" (points to the "Actions" column)
 - "Click here to edit courierrecords" (points to the "Actions" column)
- More Info:** A sidebar with sections for "Contact Person", "Mobile No", "EMail", "Address 1", "Address 2", and "Address 3".

FIGURE: Courier Master Screen

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

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



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

FIGURE: Add Courier Screen

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

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

3.6.3.2 Editing and Deleting Courier

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

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

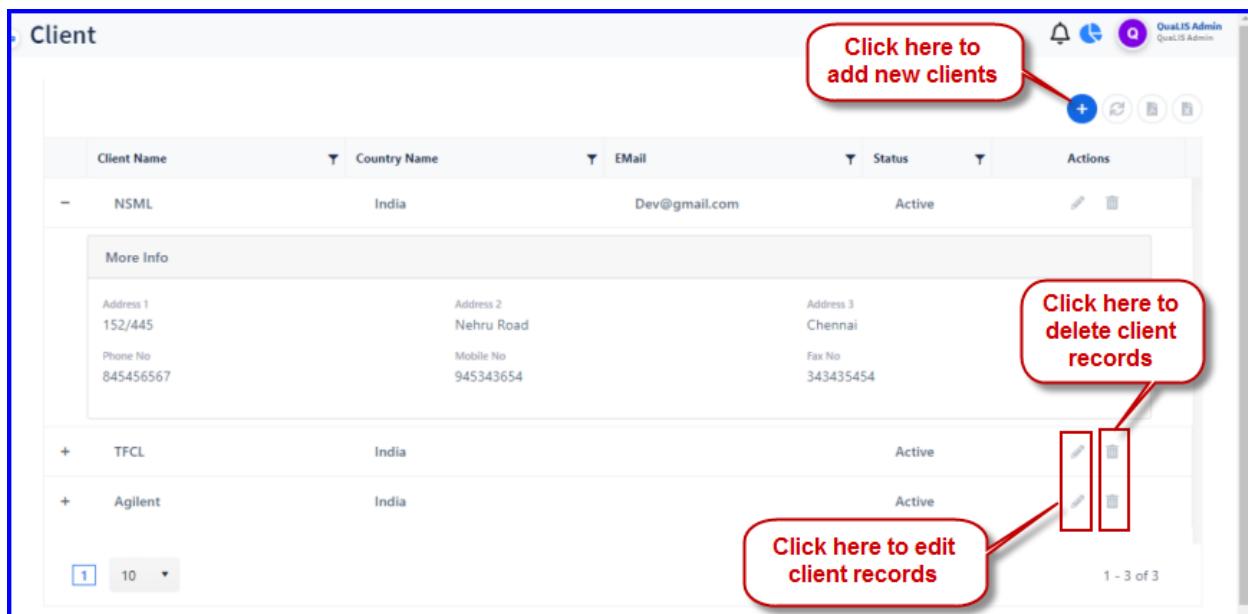
3.6.4 Client Master

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

3.6.4.1 Adding a New Client

To create a new client, follow these steps:

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



The screenshot shows the 'Client' master screen in Qualis LIMS. The top navigation bar includes a bell icon, a blue circular icon, and two user profile icons for 'Qualis Admin' and 'Qualis Admin'. The main title 'Client' is on the left. A red callout box with the text 'Click here to add new clients' points to a blue '+' button in the top right corner of the table header. The table lists three client records:

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

Below the table, a red callout box with the text 'Click here to delete client records' points to the delete icons in the 'Actions' column. Another red callout box with the text 'Click here to edit client records' points to the edit icons in the 'Actions' column. The bottom left of the screen shows a page number '1 10 ▾' and the bottom right shows '1 - 3 of 3'.

FIGURE: Client Master Screen

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

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

Add Client

Client Name *
ABC Pvt Ltd

Address 1 *
456

Address 2
Park

Address 3

Phone No
456 987 234

Mobile No

Fax No

Email
abc@abc.com

Country *
Canada

Is Active

Cancel **Save**

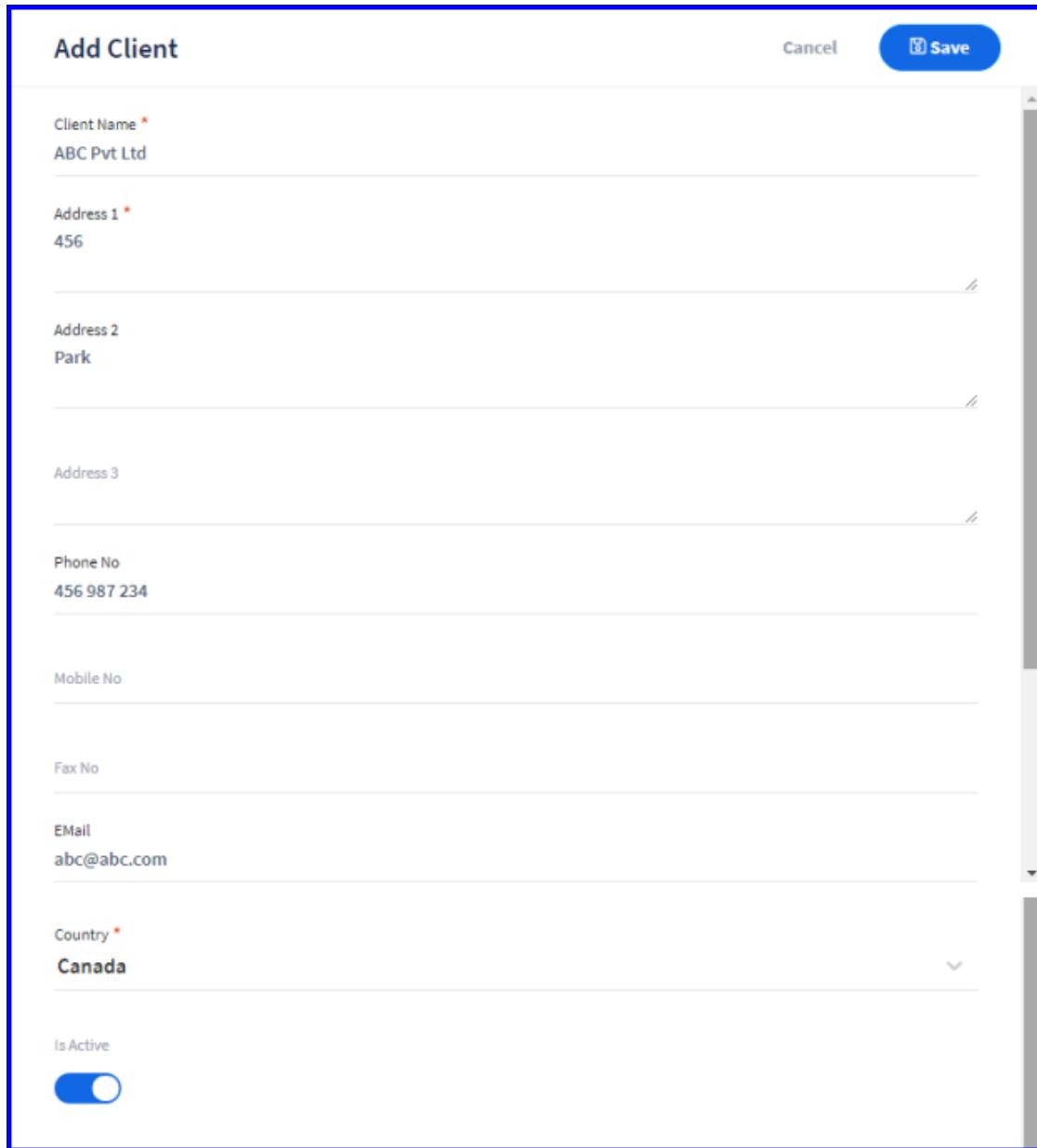


FIGURE: Add Client Screen

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

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

3.6.4.2 Editing and Deleting Client

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

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

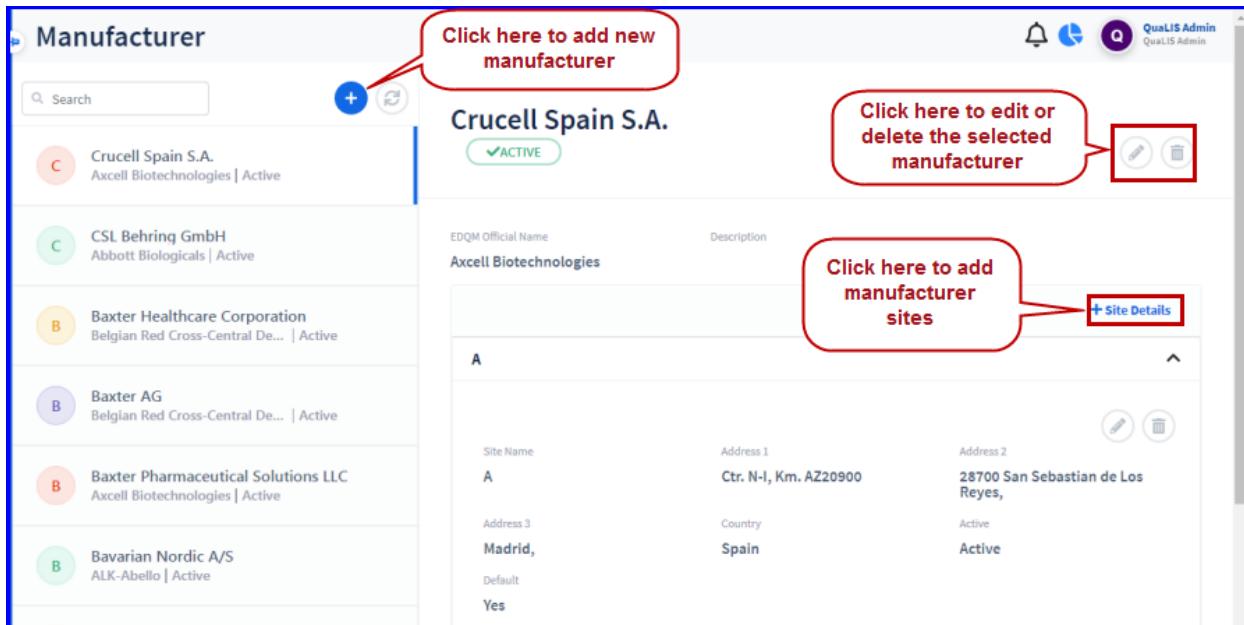
3.6.5 Manufacturer Master

Manufacturer master is used to add and manage manufacturer details.

3.6.5.1 Adding a New Manufacturer

To create a new manufacturer, follow these steps:

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



The screenshot shows the Manufacturer master screen. On the left, a list of manufacturers is displayed with a blue box around it. Each manufacturer entry includes a color-coded circle (C, C, B, B, B, B), the manufacturer name, and a status indicator (Active). A red callout box points to a blue '+' button in the header of this list. On the right, a detailed view of 'Crucell Spain S.A.' is shown with a red box around it. The view includes the manufacturer's name, EDQM Official Name, and description. Below this, a table shows site details for site 'A'. A red callout box points to a '+ Site Details' button. The top right corner shows user information: 'QuaLIS Admin' and 'QuaLIS Admin'.

FIGURE: Manufacturer Master Screen

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

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



Add Manufacturer

Manufacturer Name *

ALK-Abello A/s

EDQM Official Name *

Abbott Biologicals

Description

Is Active

Save

FIGURE: Add Manufacturer Screen

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

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

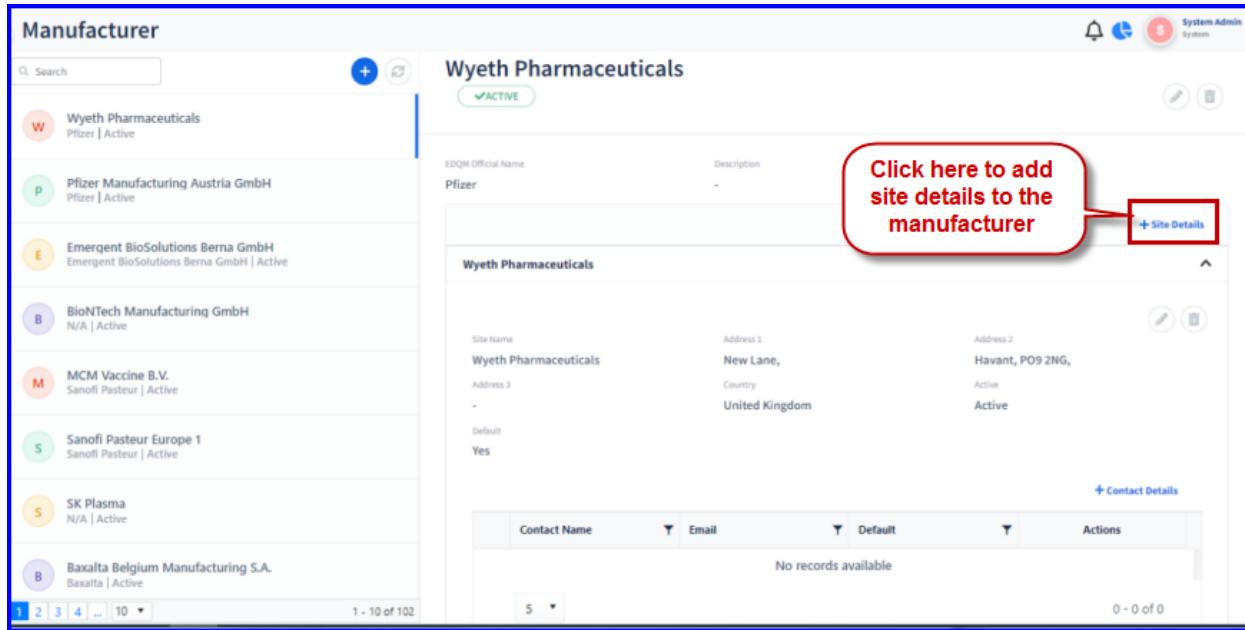
3.6.5.2 Editing and Deleting Manufacturer

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

3.6.5.3 Adding Sites to the Manufacturer

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

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



The screenshot shows the Manufacturer master screen. On the left, a list of manufacturers is displayed with their names, logos, and status (e.g., Wyeth Pharmaceuticals, Pfizer, Emergent BioSolutions, BioNTech, MCM Vaccine, Sanofi Pasteur, SK Plasma, Baxalta). On the right, the details for 'Wyeth Pharmaceuticals' are shown. The 'Status' is marked as 'ACTIVE'. The 'EDQM Official Name' is listed as 'Pfizer'. The 'Description' field is empty. Below this, a sub-panel titled 'Wyeth Pharmaceuticals' shows the site details for 'Wyeth Pharmaceuticals'. The site name is 'Wyeth Pharmaceuticals', the address is 'New Lane, Havant, PO9 2NG, United Kingdom', and the country is 'United Kingdom'. The status is 'Active'. A red callout box with the text 'Click here to add site details to the manufacturer' points to the '+ Site Details' button in the top right corner of this sub-panel. The bottom of the screen shows a table for 'Contact Details' with no records available.

FIGURE: Adding Sites to the Manufacturer

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

Add Site Details

Site Name *
Vancouver

Address 1 *
305

Address 2
ave 34

Address 3

Country Name *
Canada

Active

Default

Cancel  Save

FIGURE: Add Site Details Dialog

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

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

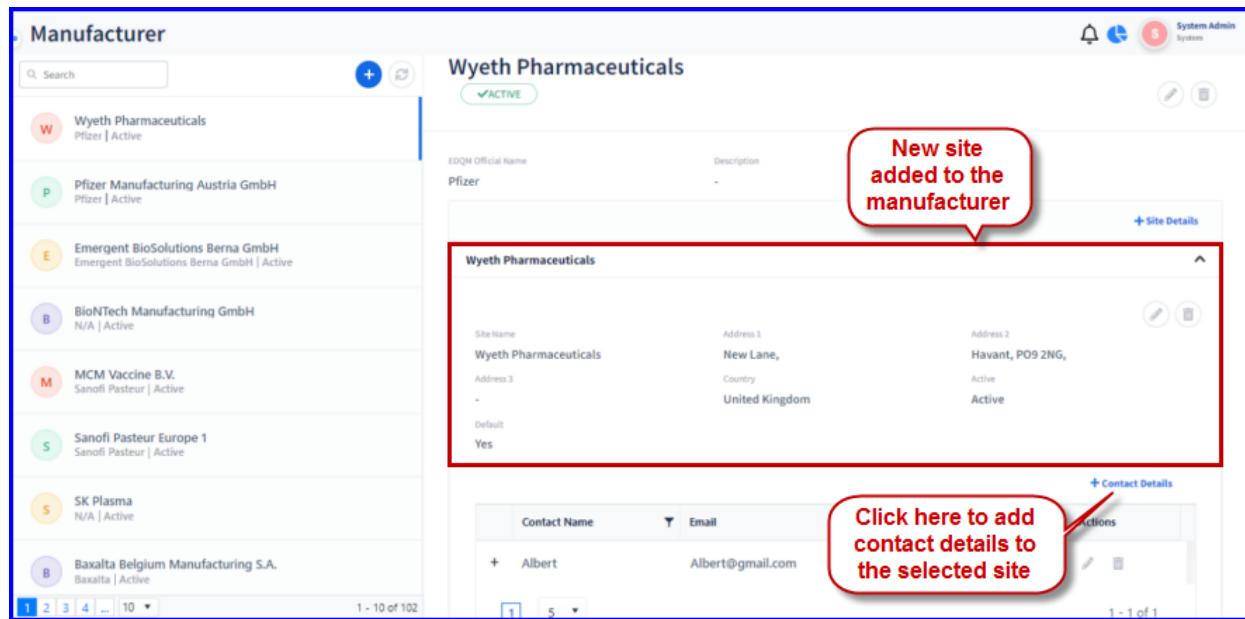


FIGURE: Adding Contact Details to the Selected Site

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

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

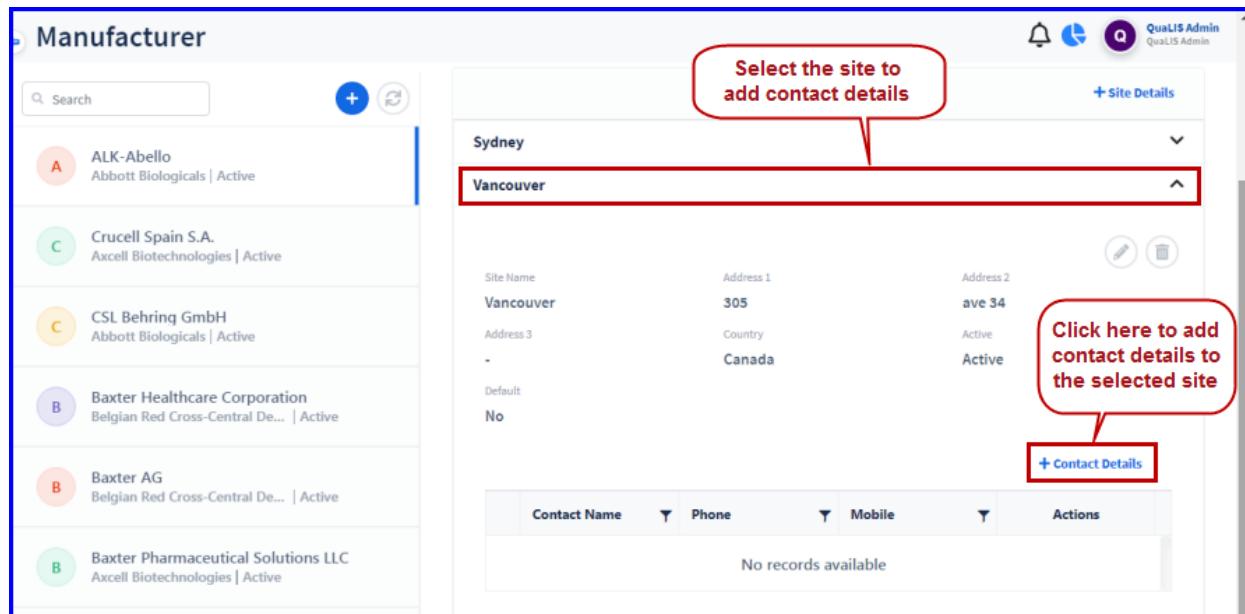
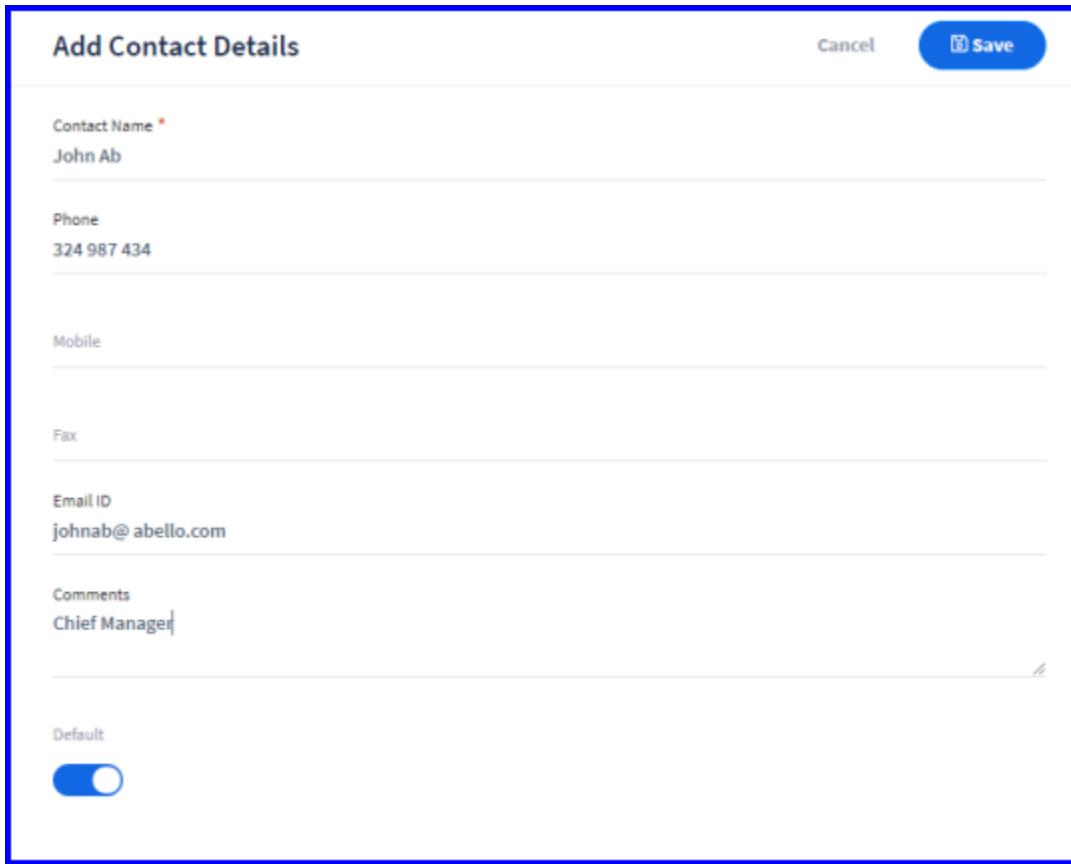


FIGURE: Adding Contact Details to the Site

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



Contact Name *

John Ab

Phone

324 987 434

Mobile

Fax

Email ID

johnab@ abello.com

Comments

Chief Manager

Default

FIGURE: Add Contact Details Dialog

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

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

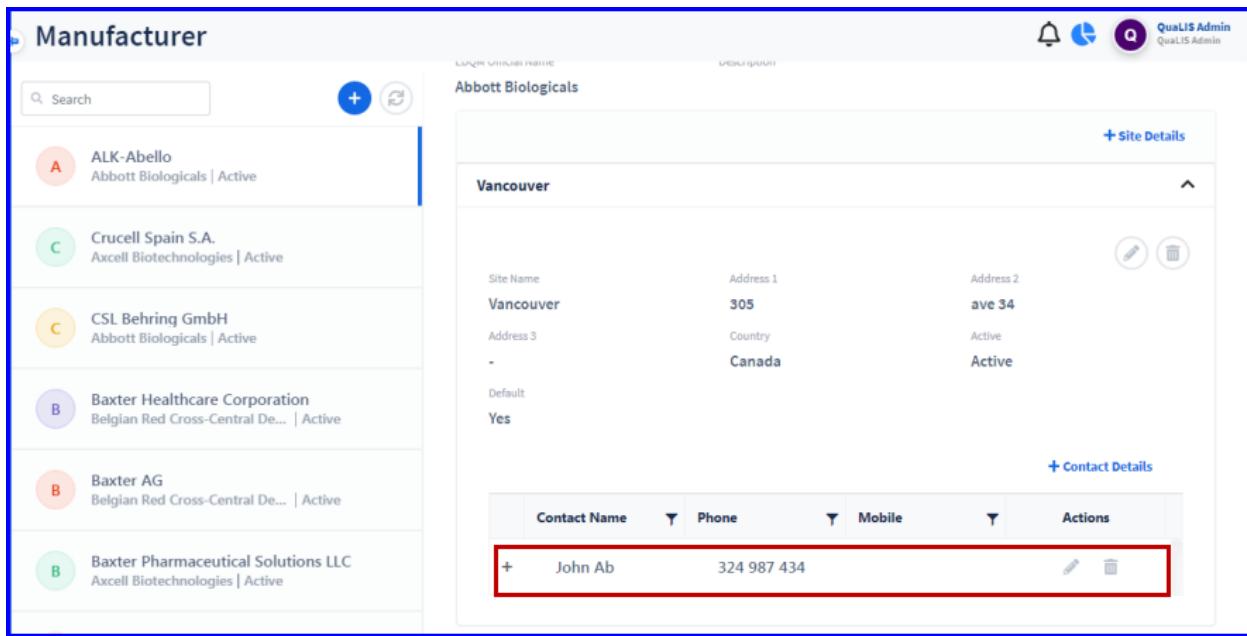


FIGURE: Added Contact Details

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

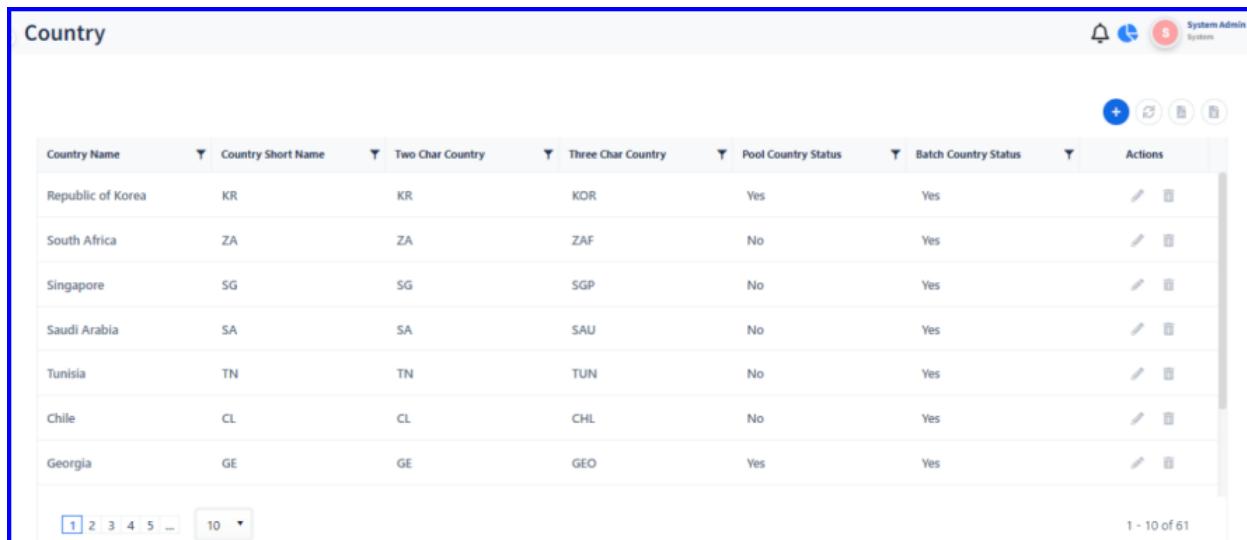
3.6.6 Country Master

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

3.6.6.1 Adding a New Country

To create a new country, follow these steps:

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



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

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

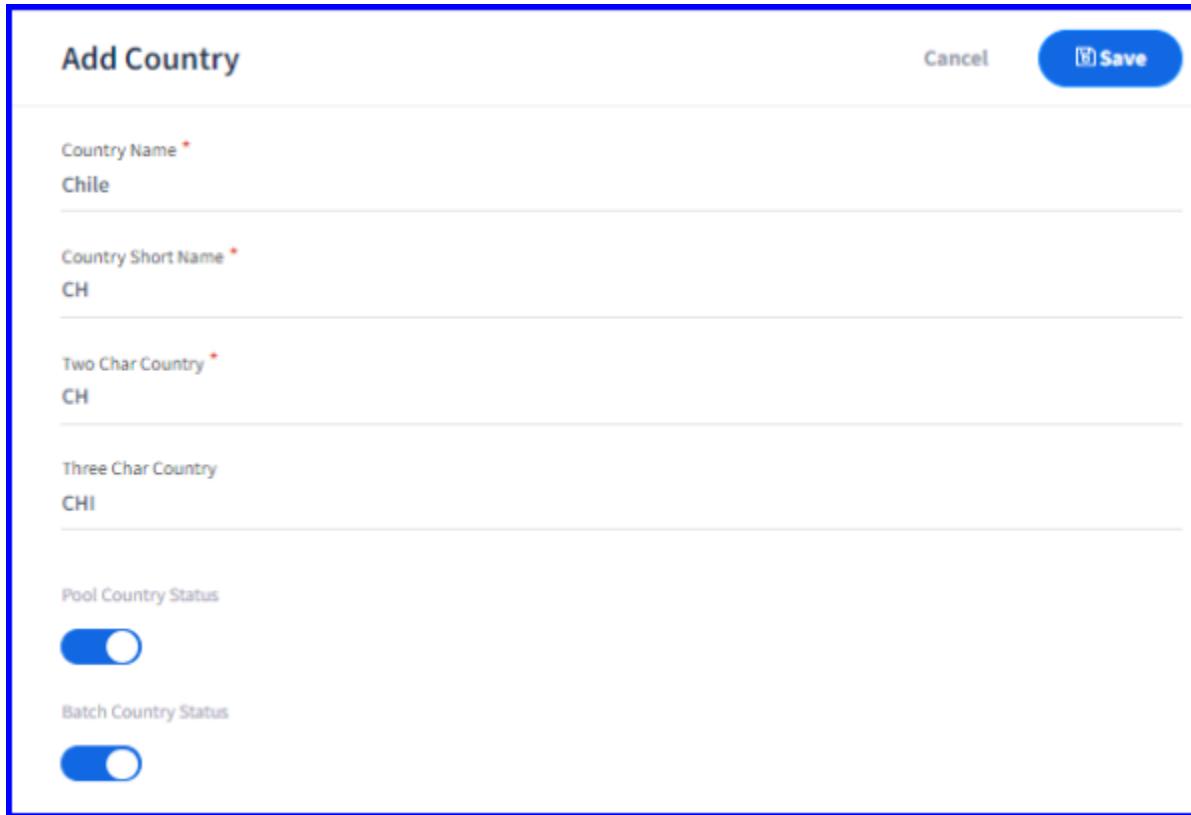
Page navigation: 1 2 3 4 5 ... 10

1 - 10 of 61

FIGURE: Country Master Screen

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

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



The screenshot shows the 'Add Country' form with a blue border. The fields are:

- Country Name *****: Chile
- Country Short Name *****: CH
- Two Char Country *****: CH
- Three Char Country: CHI
- Pool Country Status:
- Batch Country Status:

Buttons: Cancel,

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.

3.7 Product

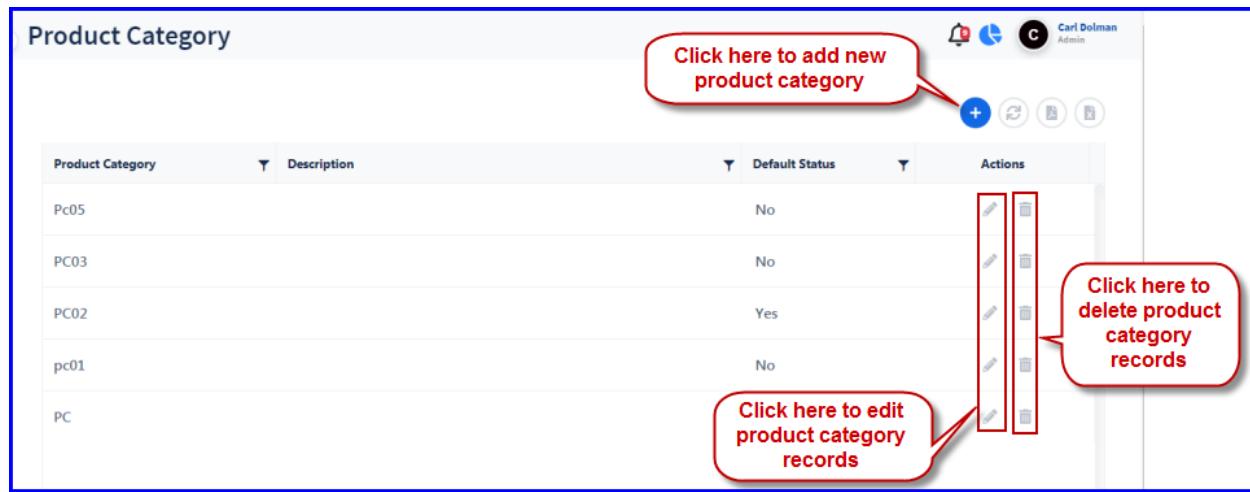
3.7.1 Product Category Master

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

3.7.1.1 Adding a New Product Category

To create a new product category, follow these steps:

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



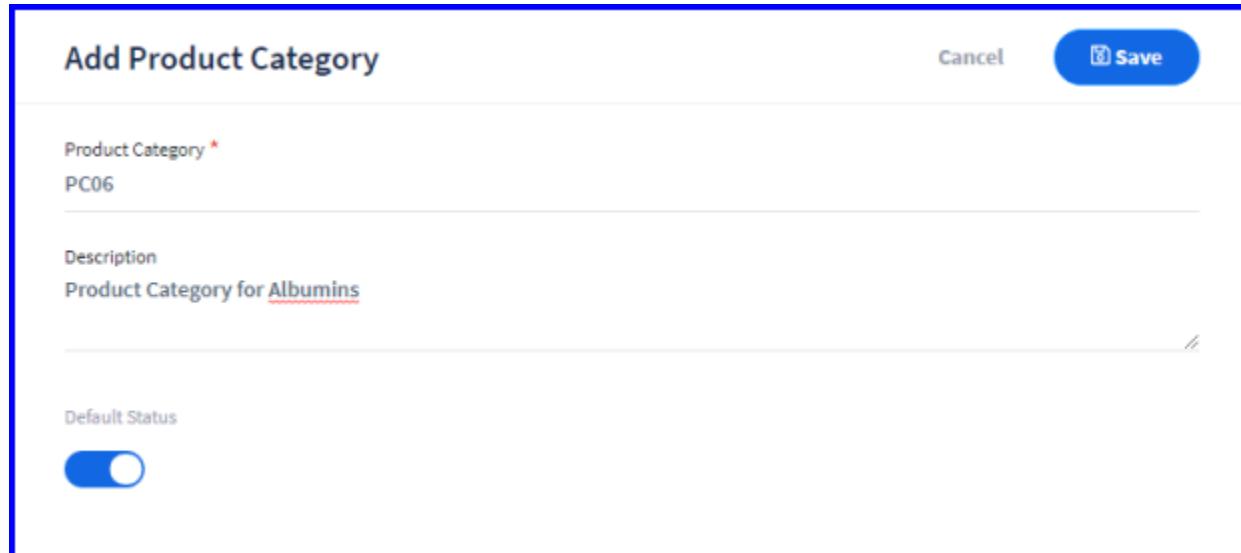
The screenshot shows a table titled 'Product Category' with columns: Product Category, Description, Default Status, and Actions. The table contains five rows with data: 'Pc05' (No), 'PC03' (No), 'PC02' (Yes), 'pc01' (No), and 'PC' (No). The 'Actions' column contains icons for edit and delete. Three callout bubbles provide instructions: 'Click here to add new product category' points to the blue '+' icon in the top right; 'Click here to edit product category records' points to the edit icon in the 'Actions' column; and 'Click here to delete product category records' points to the delete icon in the 'Actions' column.

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

FIGURE: Product Category Master Screen

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

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



The screenshot shows the 'Add Product Category' dialog. It has fields for Product Category (PC06), Description (Product Category for Albumins), and Default Status (a toggle switch set to on). There are 'Cancel' and 'Save' buttons at the top right.

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:

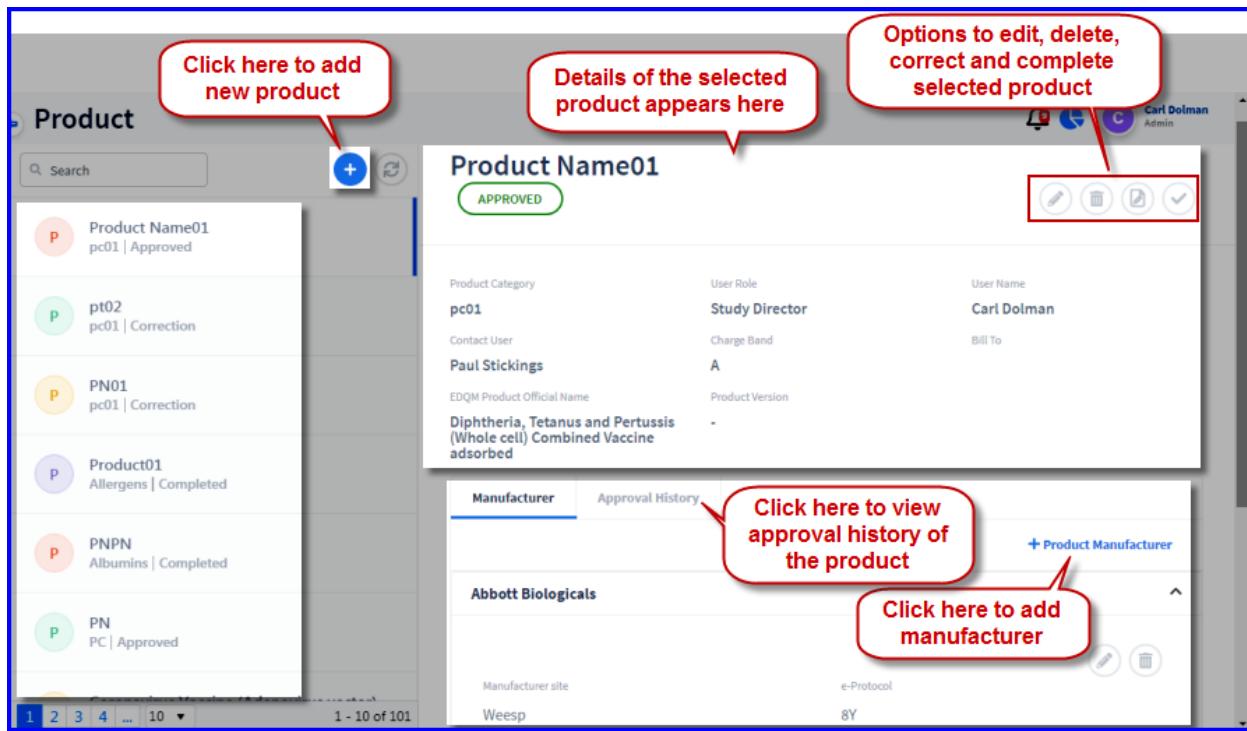


FIGURE: Product Master Screen

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:

Add Product

Cancel  Save

Product Category *****
Albumins

Product Name *****
Albumin 5% - NCPR

User Role *****
Study Director

User Name *****
Bernard Fox

Contact User *****
Graham Roberts

Charge Band *****
NCPR2

Bill To

EDQM Product Official Name *****
Human Albumin

FIGURE: Add Product Screen

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

11. Click **Save**.

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

3.7.2.2 Editing and Deleting Product

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

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

3.7.2.3 Change Product Record Status to **COMPLETED**

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

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

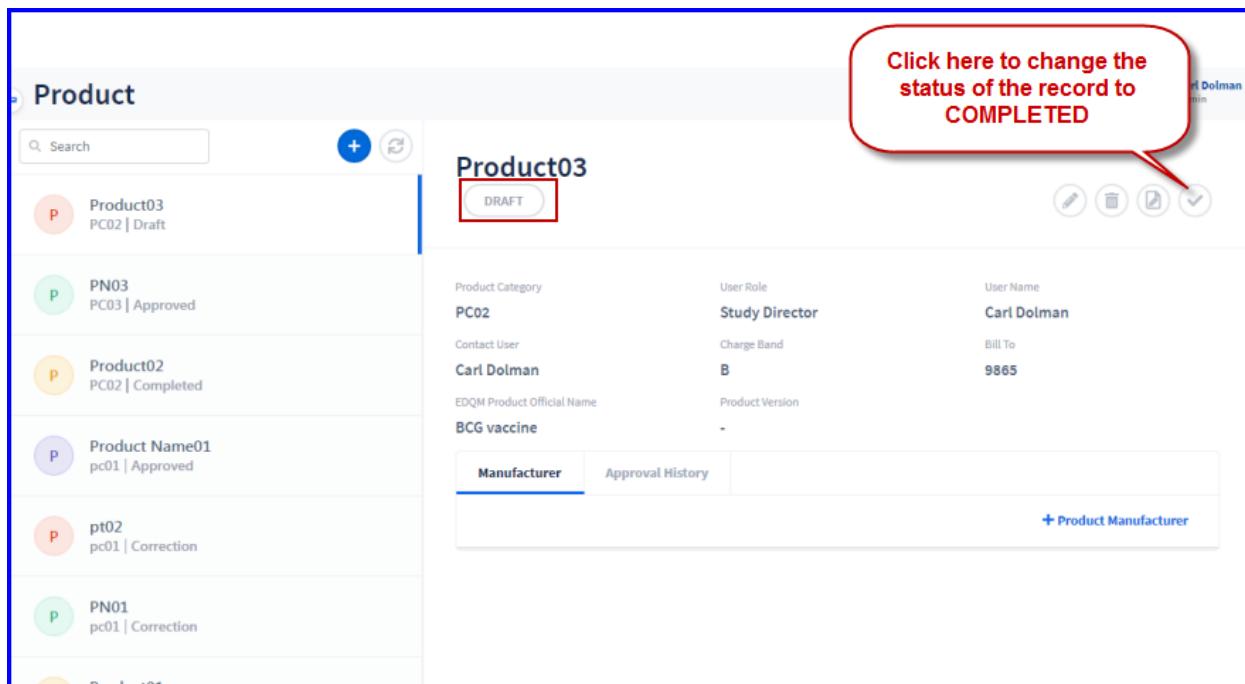
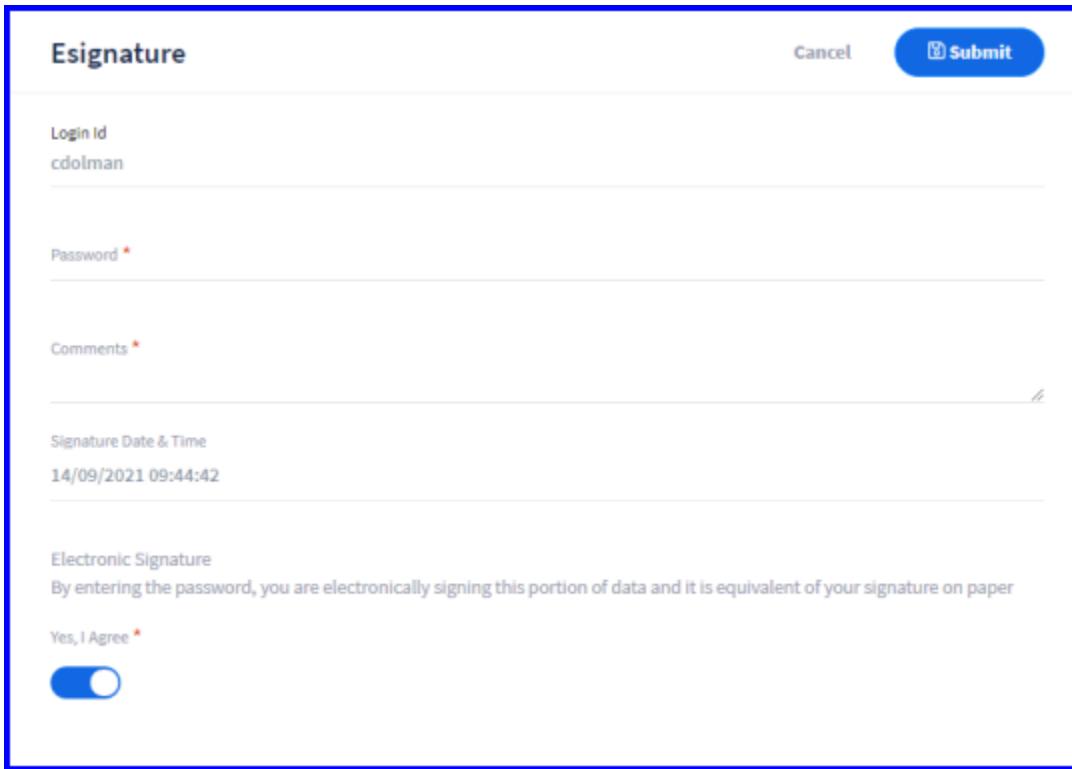


FIGURE: Changing the Status of the Product Record to COMPLETED

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



Esignature

Cancel **Submit**

Login Id
cdolman

Password *

Comments *

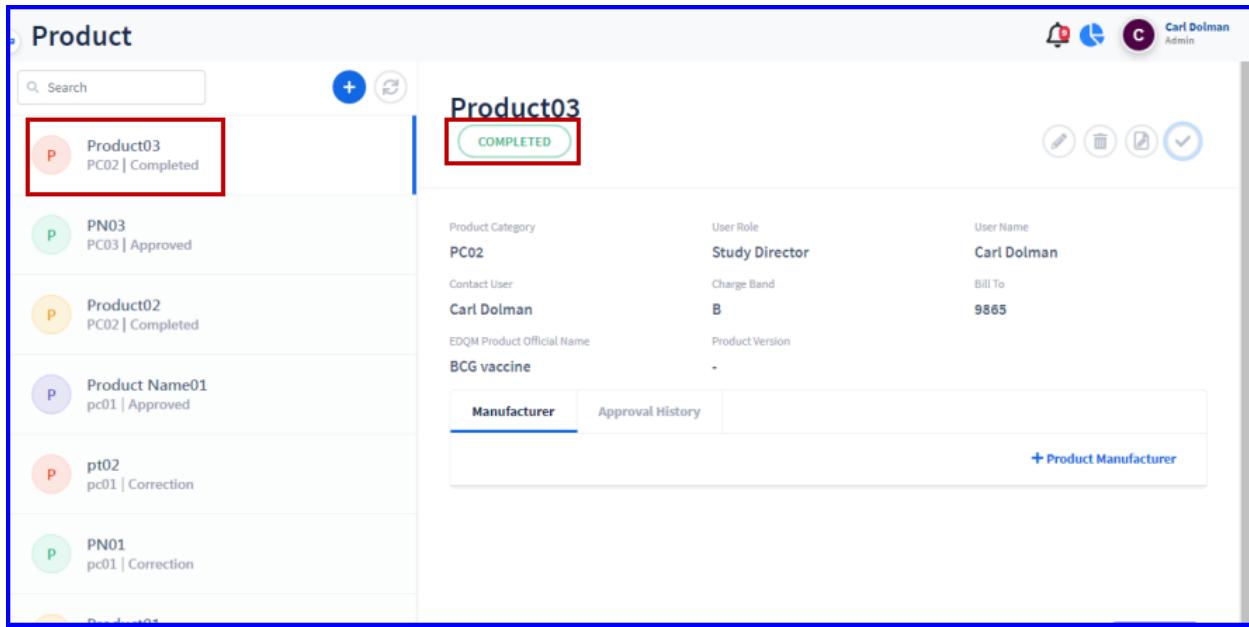
Signature Date & Time
14/09/2021 09:44:42

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

Yes, I Agree *

FIGURE: Esignature Dialog

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



The screenshot shows the Product master screen. On the left, a list of products is displayed, with 'Product03' selected and highlighted with a red box. On the right, the details for 'Product03' are shown in a card format, also with a red box around the 'COMPLETED' status indicator. The product details include:

Product Category: PC02	User Role: Study Director	User Name: Carl Dolman				
Contact User: Carl Dolman	Charge Band: B	Bill To: 9865				
EDQM Product Official Name: BCG vaccine	Product Version: -					
<table border="1"> <tr> <td>Manufacturer</td> <td>Approval History</td> </tr> <tr> <td colspan="2"> + Product Manufacturer </td> </tr> </table>			Manufacturer	Approval History	+ Product Manufacturer	
Manufacturer	Approval History					
+ Product Manufacturer						

FIGURE: Product Record in the COMPLETED State

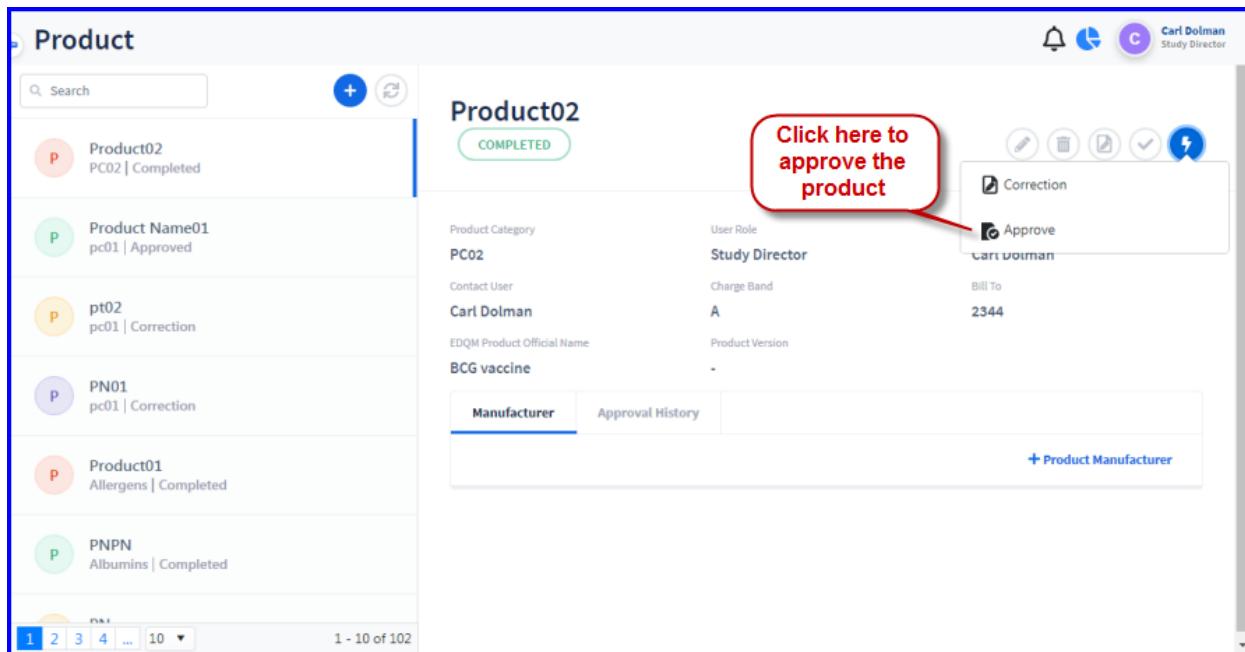
3.7.2.4 Approving Product Record

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

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

To approve a product record, follow these steps:

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



Product

Product02
PC02 | Completed

Product Name01
pc01 | Approved

pt02
pc01 | Correction

PN01
pc01 | Correction

Product01
Allergens | Completed

PNPN
Albumins | Completed

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

Product02
COMPLETED

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

Manufacturer Approval History

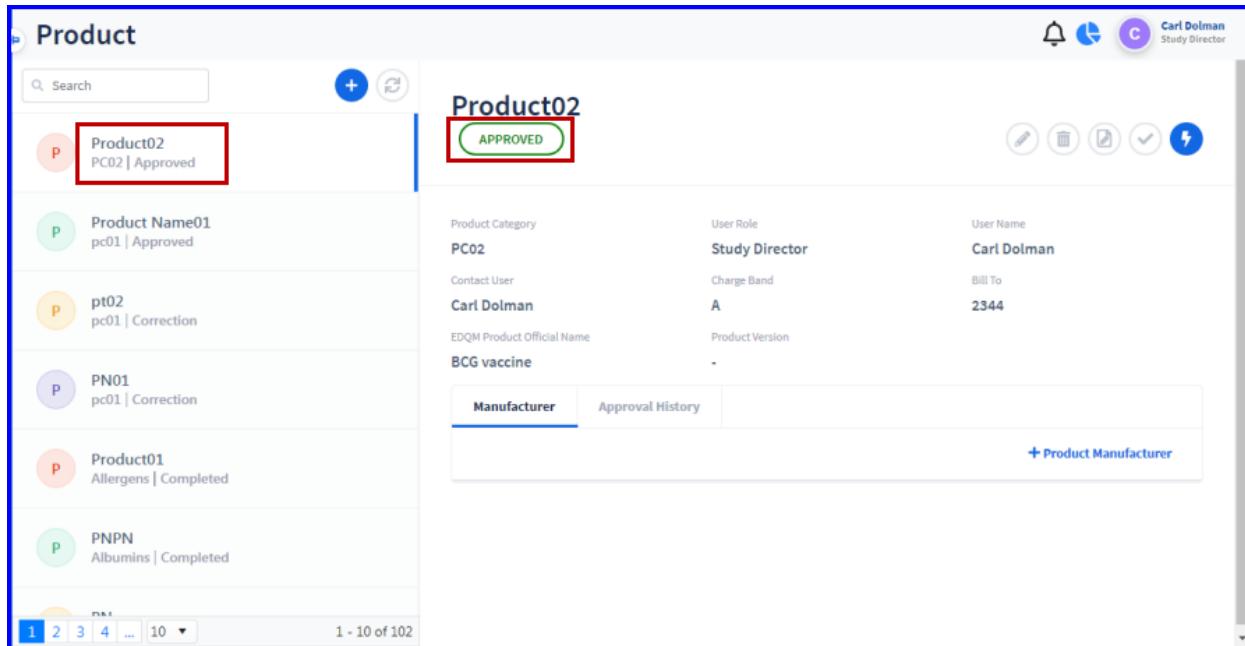
Click here to approve the product

Correction Approve Carl Dolman 2344

+ Product Manufacturer

FIGURE: Approving Product Record

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



Product

Product02
PC02 | Approved

Product Name01
pc01 | Approved

pt02
pc01 | Correction

PN01
pc01 | Correction

Product01
Allergens | Completed

PNPN
Albumins | Completed

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

Product02
APPROVED

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

Manufacturer Approval History

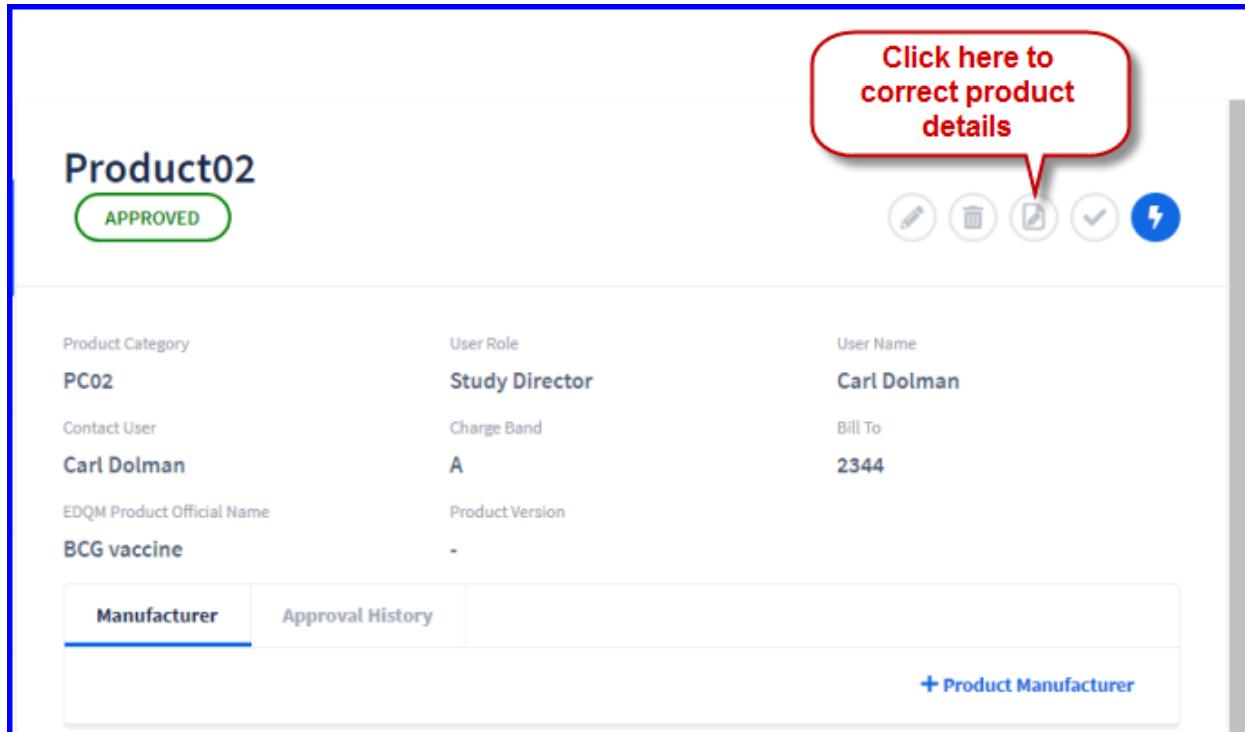
+ Product Manufacturer

FIGURE: Product in the APPROVED State

3.7.2.5 Correcting Product Details

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

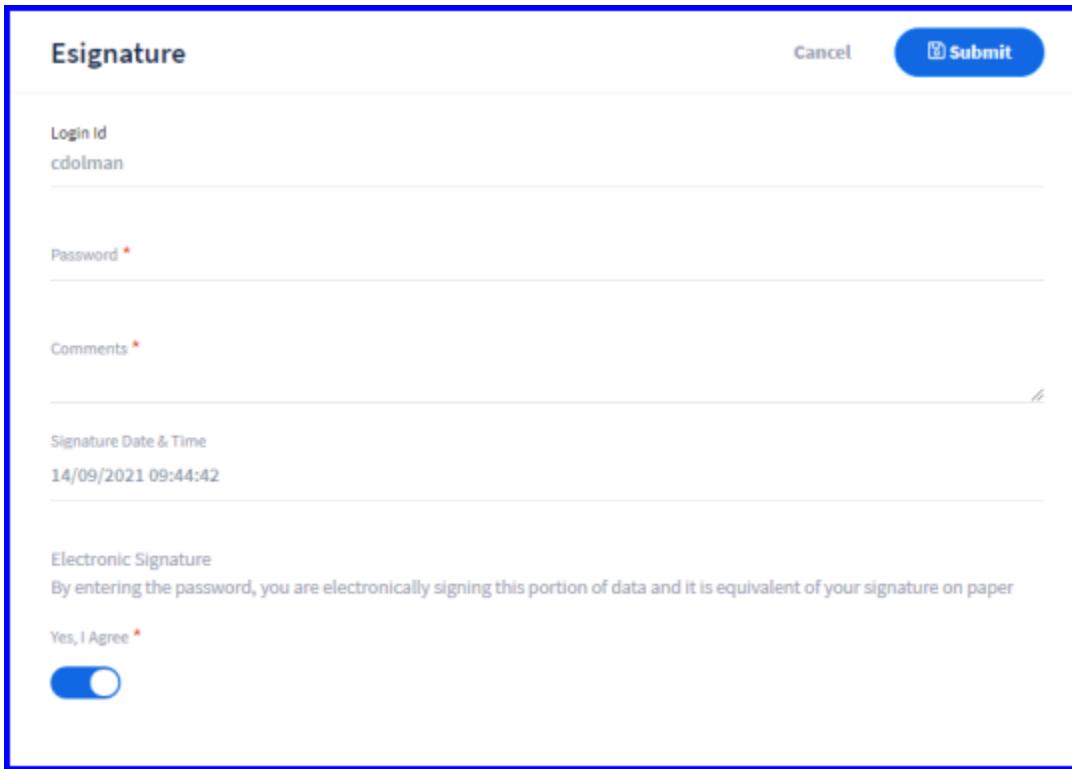
1. In the Product master screen, select the product you want to correct details and then click  as shown in the figure:



Manufacturer	Approval History
+ Product Manufacturer	

FIGURE: Correcting Product Details

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



Esignature

Cancel **Submit**

Login Id
cdolman

Password *

Comments *

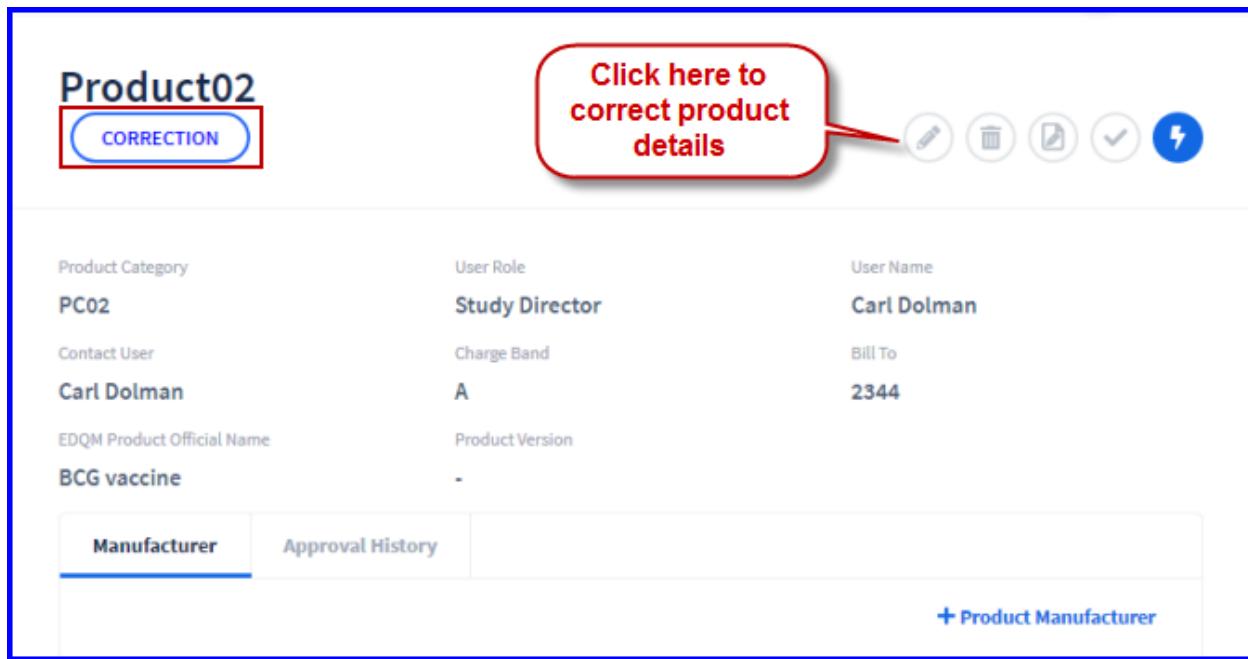
Signature Date & Time
14/09/2021 09:44:42

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

Yes, I Agree *

FIGURE: Esignature Dialog

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



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

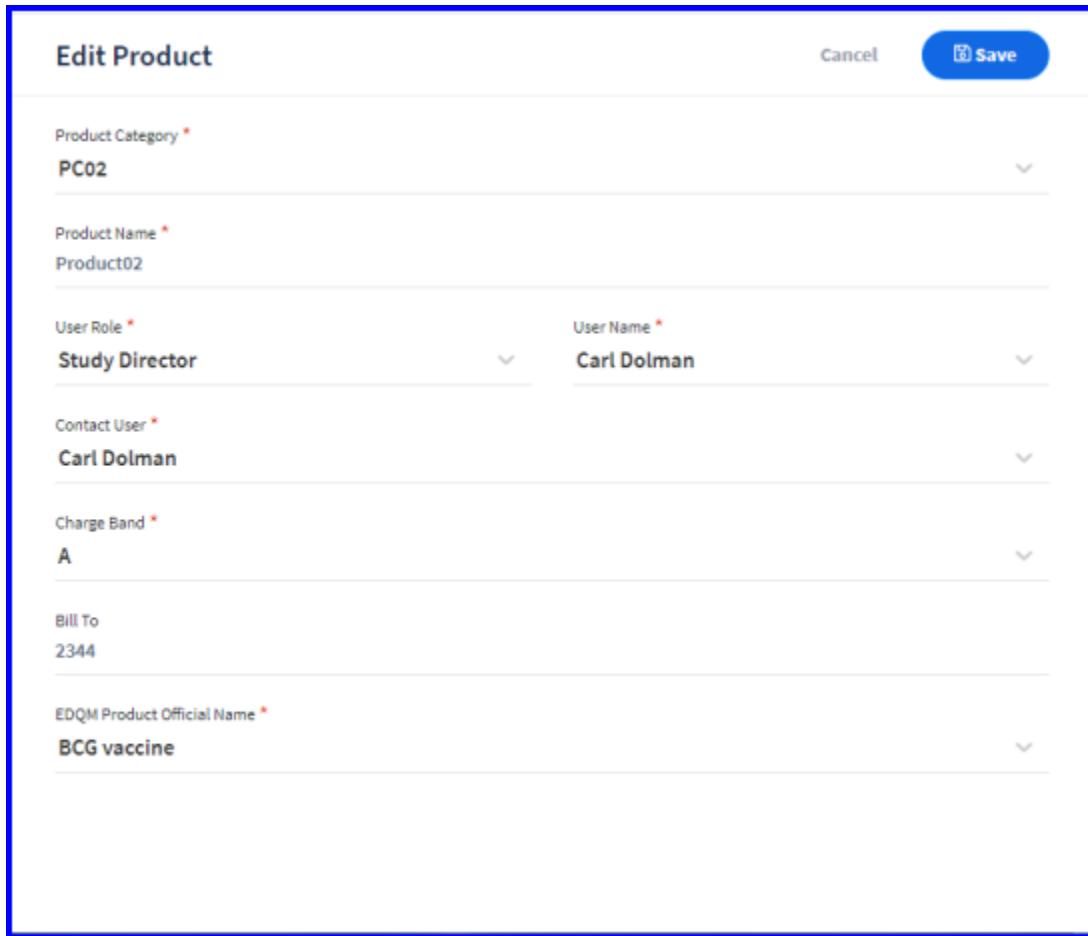
Manufacturer Approval History

[+ Product Manufacturer](#)

FIGURE: Product Record in the CORRECTION State

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

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



Product Category *

PC02

Product Name *

Product02

User Role *

Study Director

User Name *

Carl Dolman

Contact User *

Carl Dolman

Charge Band *

A

Bill To

2344

EDQM Product Official Name *

BCG vaccine

FIGURE: Edit Product Dialog

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

3.7.2.6 Adding Manufacturer to the Product

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

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

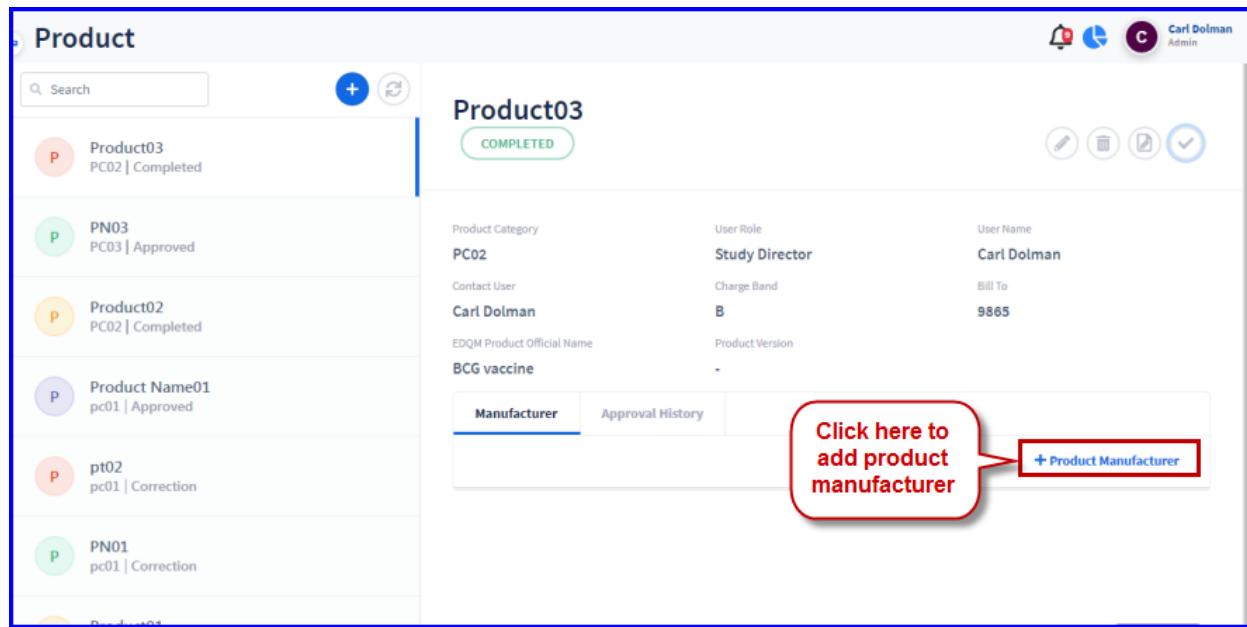


FIGURE: Adding Product Manufacturer to the Product

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

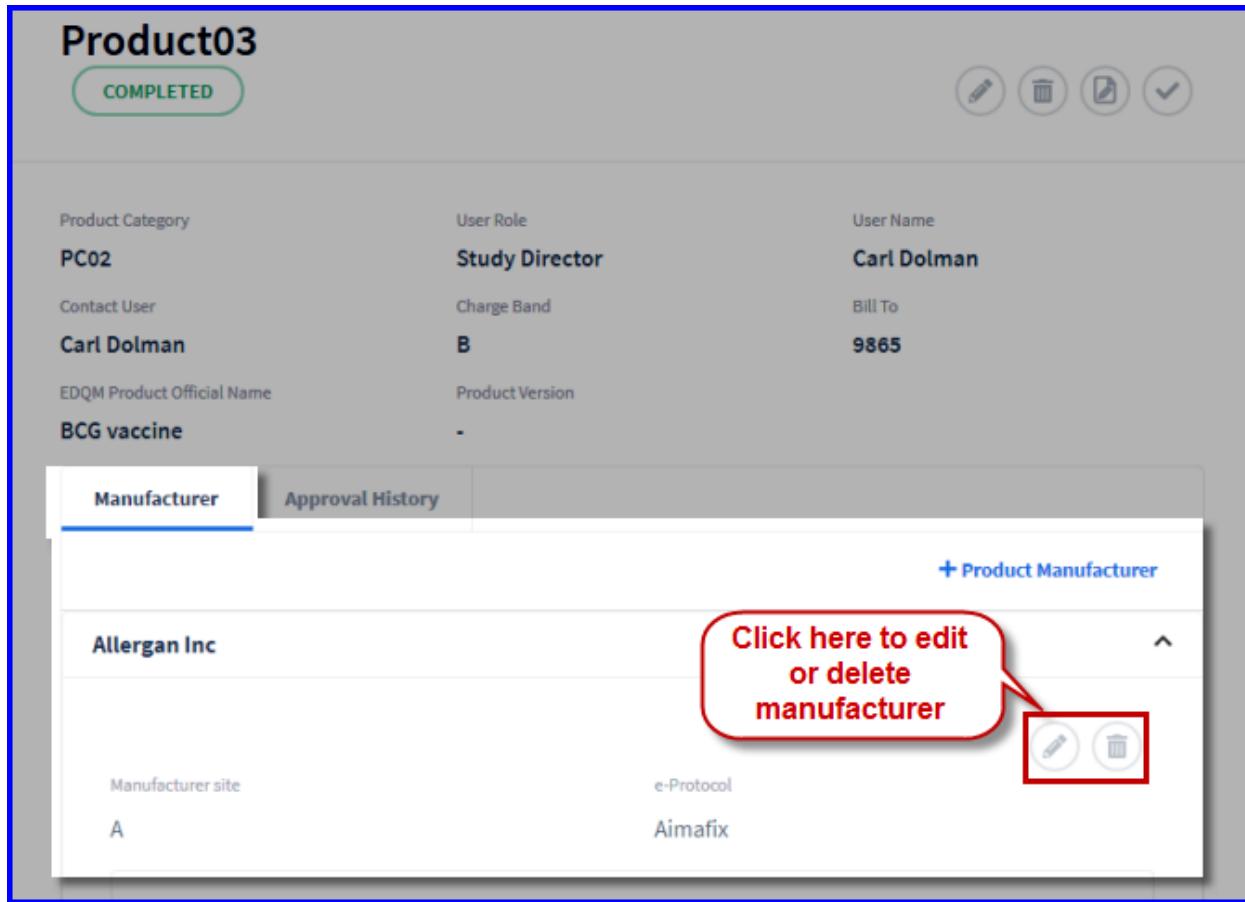


FIGURE: Add Product Manufacturer Dialog

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:



The screenshot shows the 'Product03' page with the following details:

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

Below this, there are two tabs: 'Manufacturer' (selected) and 'Approval History'.

The 'Manufacturer' tab displays the following information for Allergan Inc:

Manufacturer site	e-Protocol
A	Aimafix

A red callout box with the text 'Click here to edit or delete manufacturer' points to the edit and delete icons for Allergan Inc.

FIGURE: Added Manufacturer to the Selected Product

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

3.7.2.7 Viewing Approval History of the Product

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

Product03

APPROVED

✓

Product Category
PC02

Contact User
Carl Dolman

EDQM Product Official Name
BCG vaccine

User Role
Study Director

Charge Band
B

Product
-

User Name
Carl Dolman

Bill To
9865

Manufacturer
Approval History

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

1
5
▼
1 - 2 of 2

Click this tab to view
approval history of
the product

FIGURE: Viewing Approval History of the Product

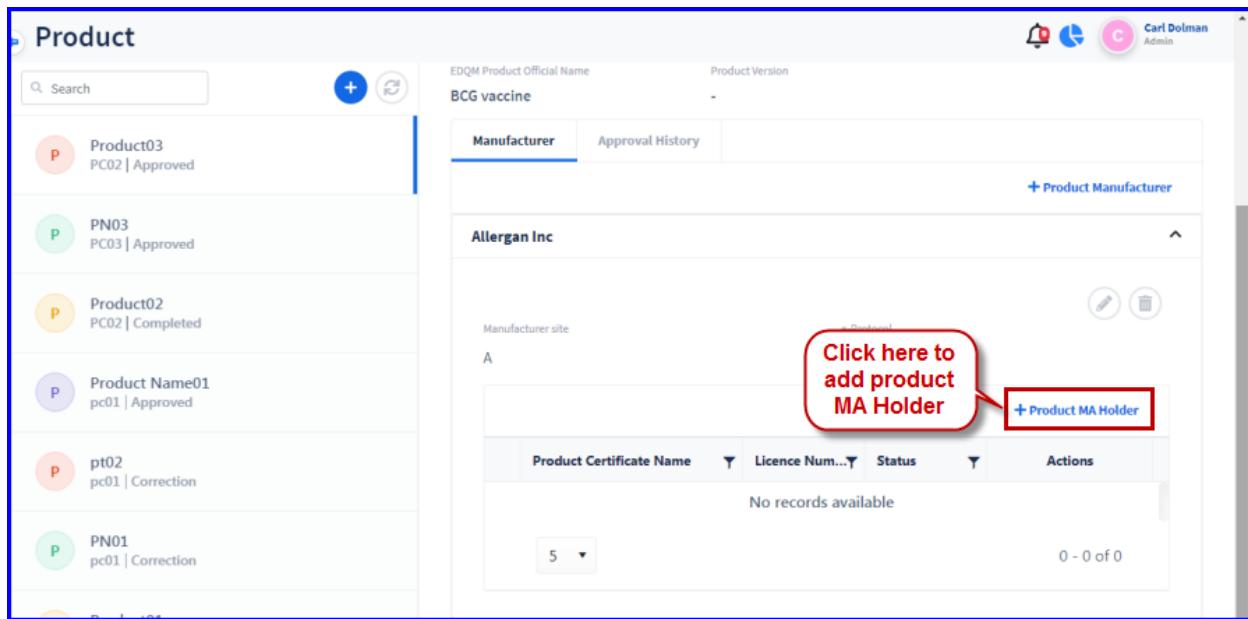
You can see the approval history of the product like approval status, user approved, user role date and time of approval and comments as shown in the above figure.

3.7.2.8 Adding MA Holder to the Product Manufacturer

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

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

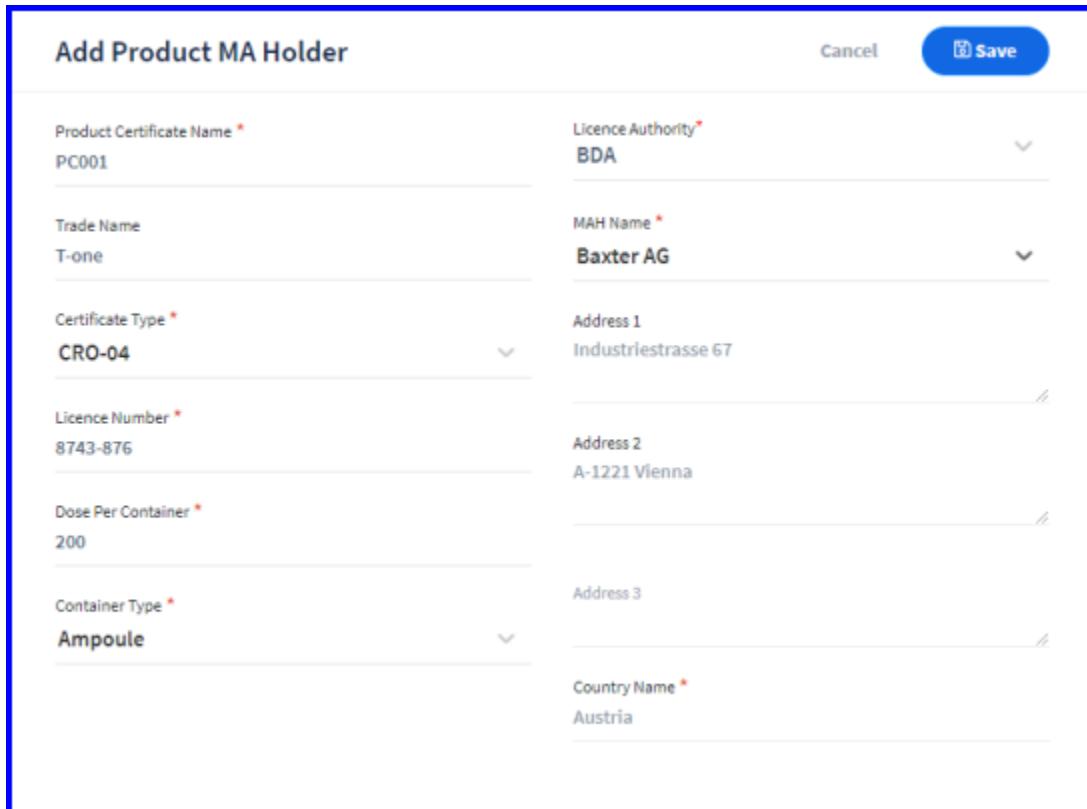
158



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

FIGURE: Adding Product MA Holder

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



The dialog box contains the following fields:

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

FIGURE: Add Product MA Holder Dialog

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

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

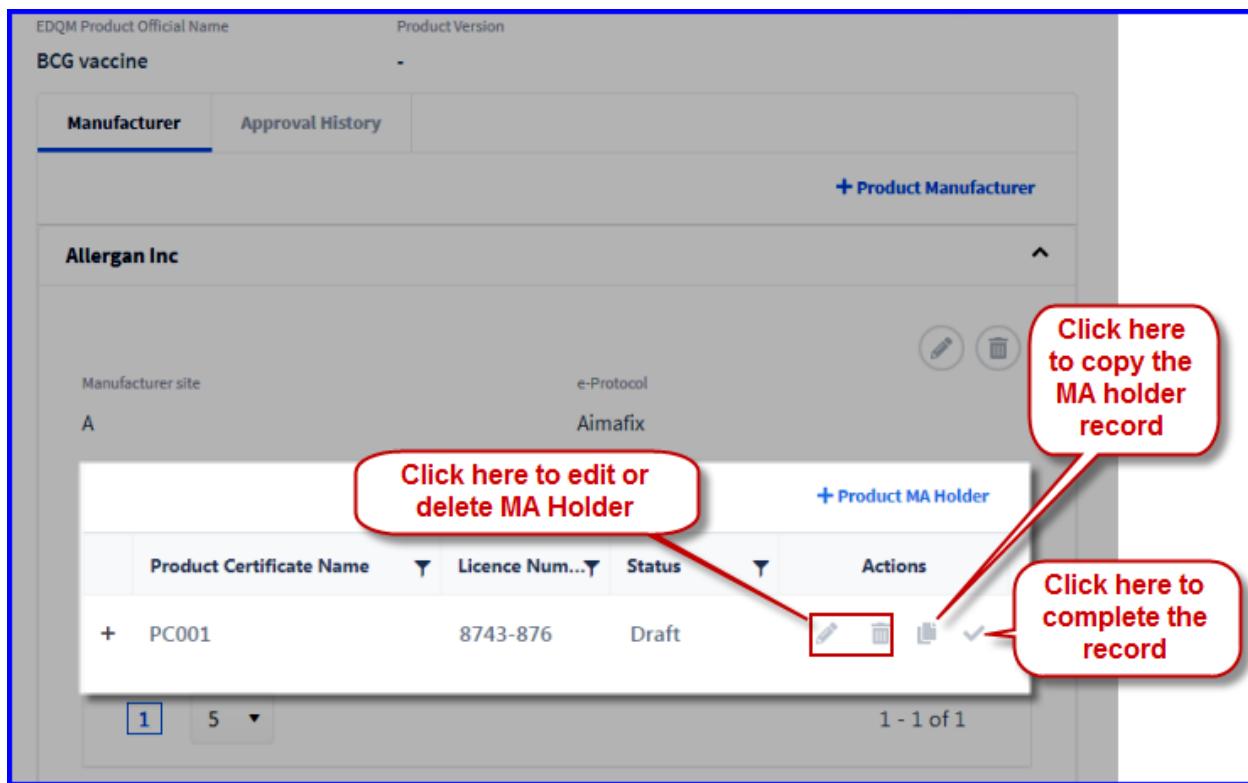


FIGURE: Added MA Holder for the Product

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

Click **+** to expand to view more information of the record.

Click **-** to collapse more information view of the record.

Click  to copy the MA Holder record.

Click  to complete the MA Holder record.

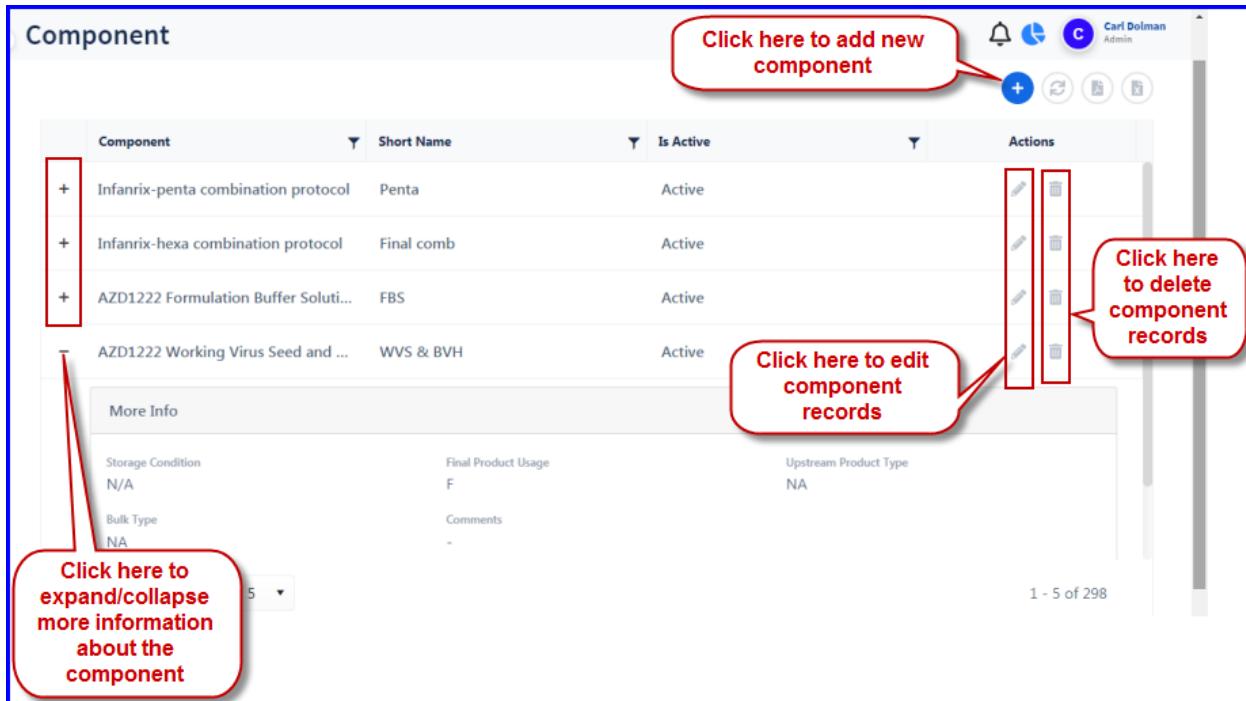
3.7.3 Component Master

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

3.7.3.1 Adding a New component

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

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



The screenshot shows the 'Component' master screen. At the top, there is a header with a 'Component' title, a search bar, and a user profile for 'Carl Dolman Admin'. Below the header is a table with columns: Component, Short Name, Is Active, and Actions. The table contains four rows of component data. To the right of the table is a 'More Info' section with fields for Storage Condition (N/A), Final Product Usage (F), Comments, and Upstream Product Type (NA). A red box highlights the 'More Info' section with the text 'Click here to expand/collapse more information about the component'. A red callout bubble points to the 'Actions' column with the text 'Click here to add new component'. Another red callout bubble points to the 'Actions' column with the text 'Click here to edit component records'. A third red callout bubble points to the 'Actions' column with the text 'Click here to delete component records'.

FIGURE: Component Master Screen

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

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

Add Component

Cancel Save

Component *

AZD1222 Master Virus Seed and Bulk Virus Harvest

Short Name *

MVS & BVH

Comments

Is Active

Storage Condition *

N/A

Final Product Usage *

F

Upstream Product Type

Select Record...

Bulk Type

NA

FIGURE: Add Component Dialog

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

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

11. Click **Save**.

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

3.7.3.2 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.

3.8 Test Management

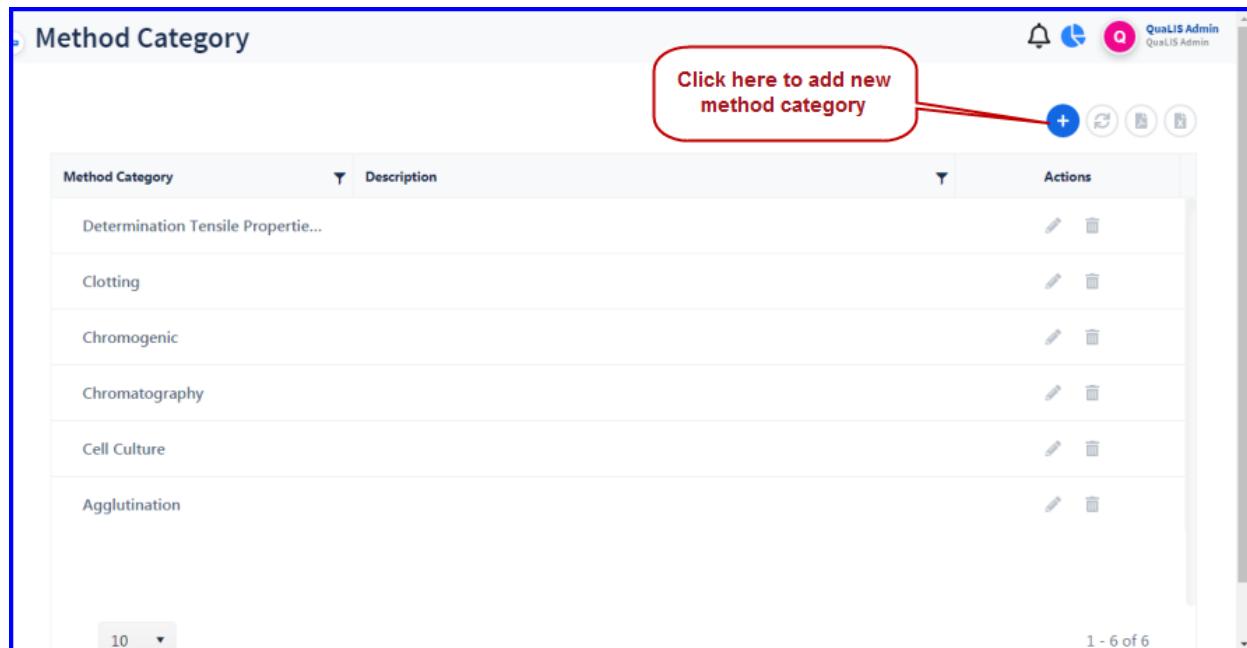
3.8.1 Method Category Master

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:



The screenshot shows a table titled 'Method Category' with columns for 'Method Category', 'Description', and 'Actions'. The 'Actions' column contains edit and delete icons. A red callout bubble points to the 'Add' button in the top right corner of the table header, which is labeled 'Click here to add new method category'.

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

FIGURE: Method Category Master Screen

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

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



The dialog has a title 'Add Method Category' and buttons 'Cancel' and 'Save'. It contains three text input fields: 'Method Category *' (with 'Appearance' typed), 'Description' (with a long text block), and 'Appearance' (with a long text block).

FIGURE: Add Method Category Dialog

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

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

3.8.1.2 Editing and Deleting Method Category

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

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

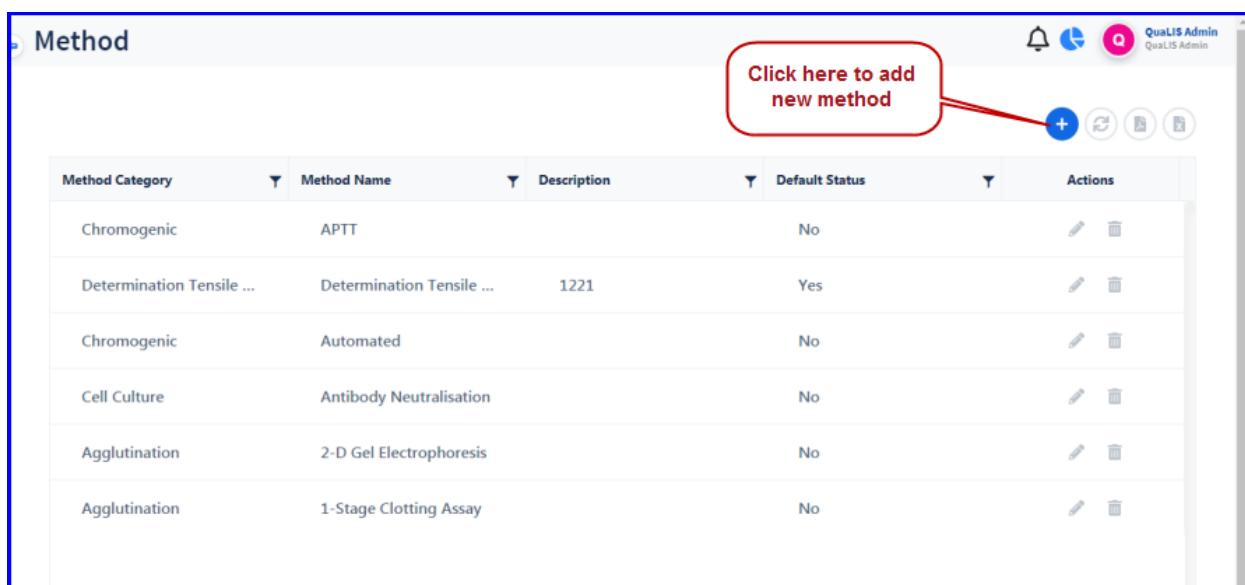
3.8.2 Method Master

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

3.8.2.1 Adding a New Method

To create a new method, follow these steps:

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



The screenshot shows the 'Method' master screen. At the top, there is a header with the title 'Method'. Below the header is a button labeled 'Click here to add new method' with a red arrow pointing to it. The main area is a table with columns: 'Method Category', 'Method Name', 'Description', 'Default Status', and 'Actions'. The table contains the following data:

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

FIGURE: Method Master Screen

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

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



The screenshot shows the 'Add Method' dialog box. It has a title bar 'Add Method' and a 'Save' button. The form contains fields for 'Method Category' (Chromogenic), 'Method Name' (APTT), 'Description' (empty), and 'Default Status' (off). The 'Save' button is highlighted in blue.

FIGURE: Add Method Dialog

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

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

3.8.2.2 Editing and Deleting Method

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

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

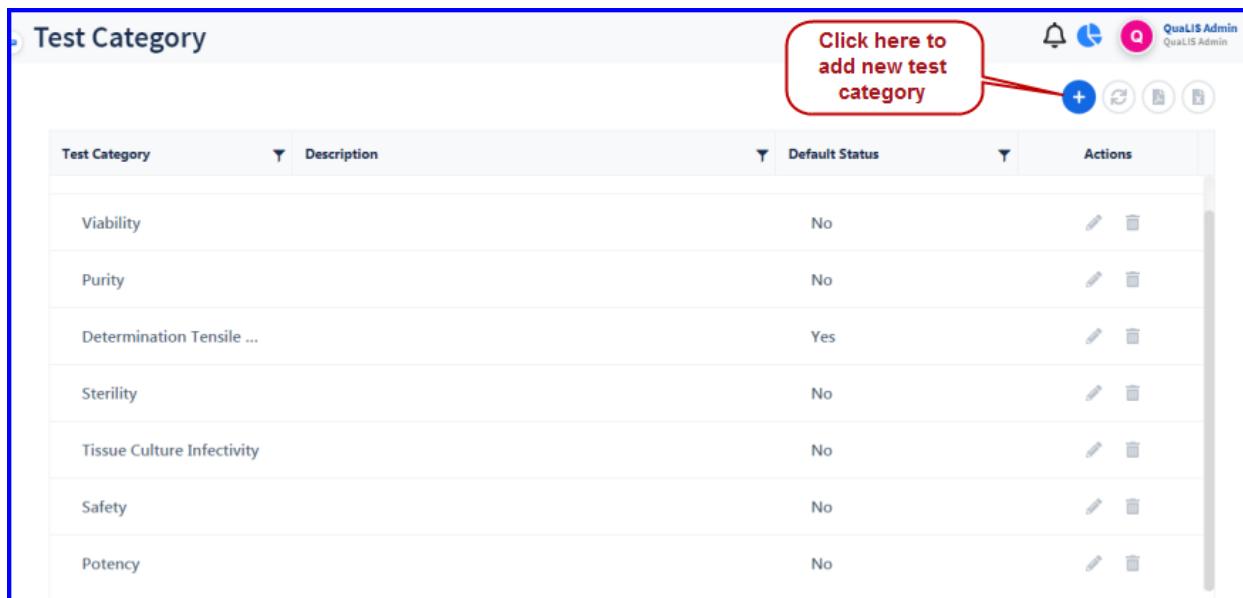
3.8.3 Test Category Master

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

3.8.3.1 Adding a New Test Category

To create a new test category, follow these steps:

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



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

FIGURE: Test Category Master Screen

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

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

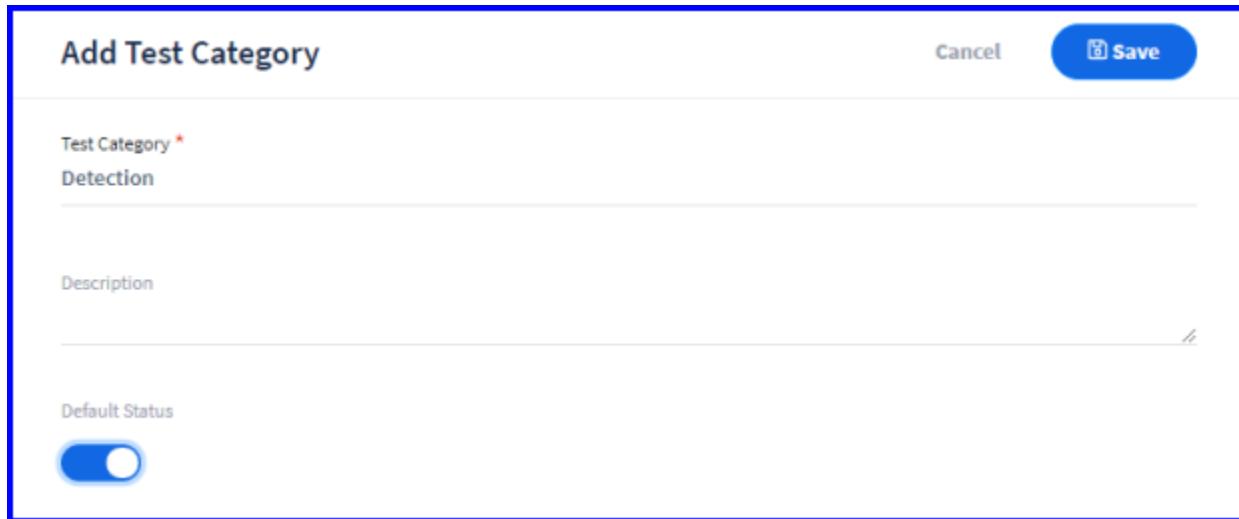


FIGURE: Add Test Category Dialog

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:

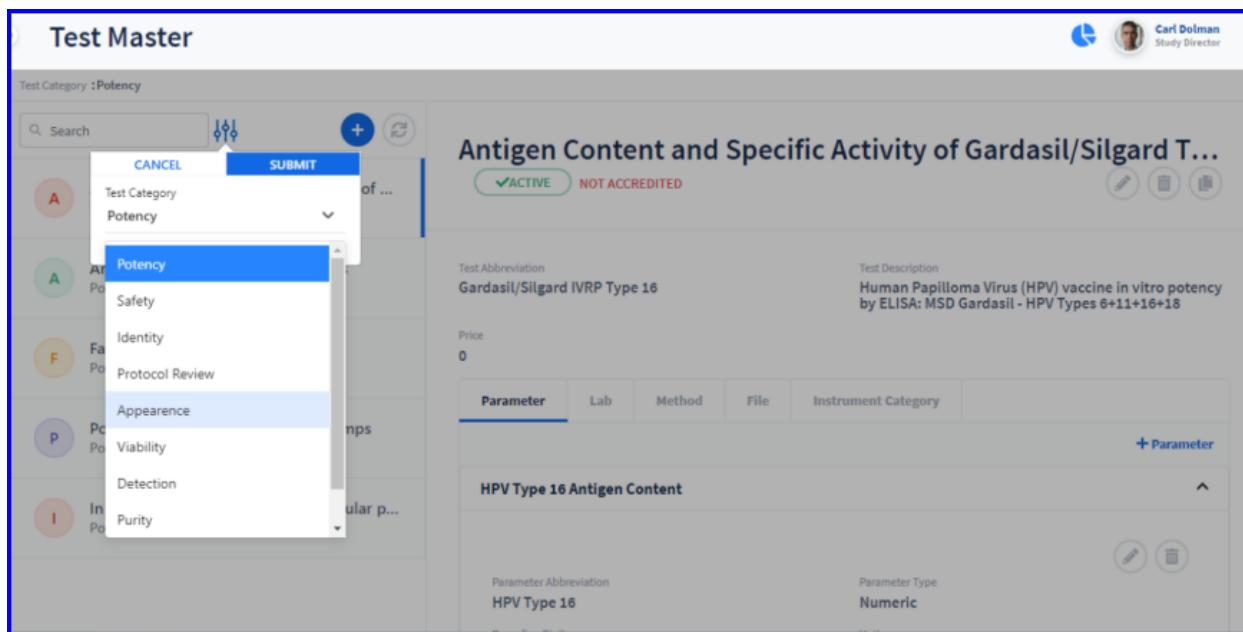
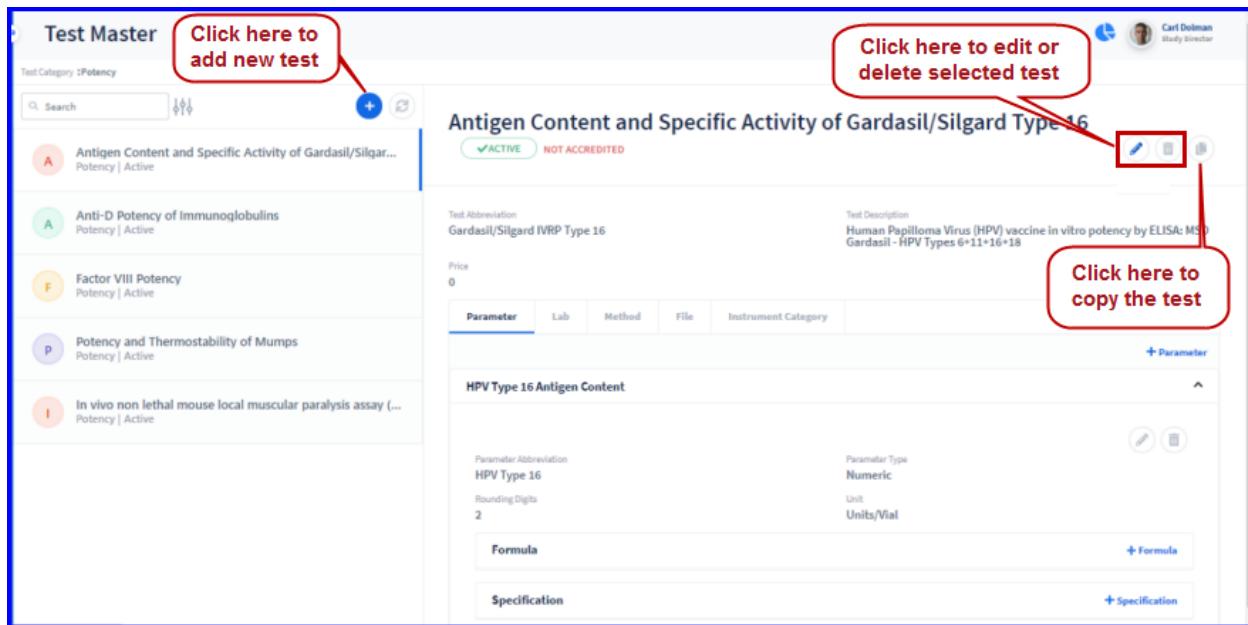


FIGURE: Test Master Screen

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:



The screenshot shows the 'Test Master' interface. On the left, a list of tests is displayed under the 'Potency' category. The first test listed is 'Antigen Content and Specific Activity of Gardasil/Silgard...'. On the right, a detailed view of this test is shown. The test is labeled 'ACTIVE' and 'NOT ACCREDITED'. The test abbreviation is 'Gardasil/Silgard IVRP Type 16' and the description is 'Human Papilloma Virus (HPV) vaccine in vitro potency by ELISA: M50 Gardasil - HPV Types 6*11*16*18'. The 'Parameter' tab is selected, showing details for 'HPV Type 16 Antigen Content'. A red box highlights the 'Parameter' tab, and another red box highlights the 'Edit' icon (pencil) in the top right corner of the detailed view.

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:

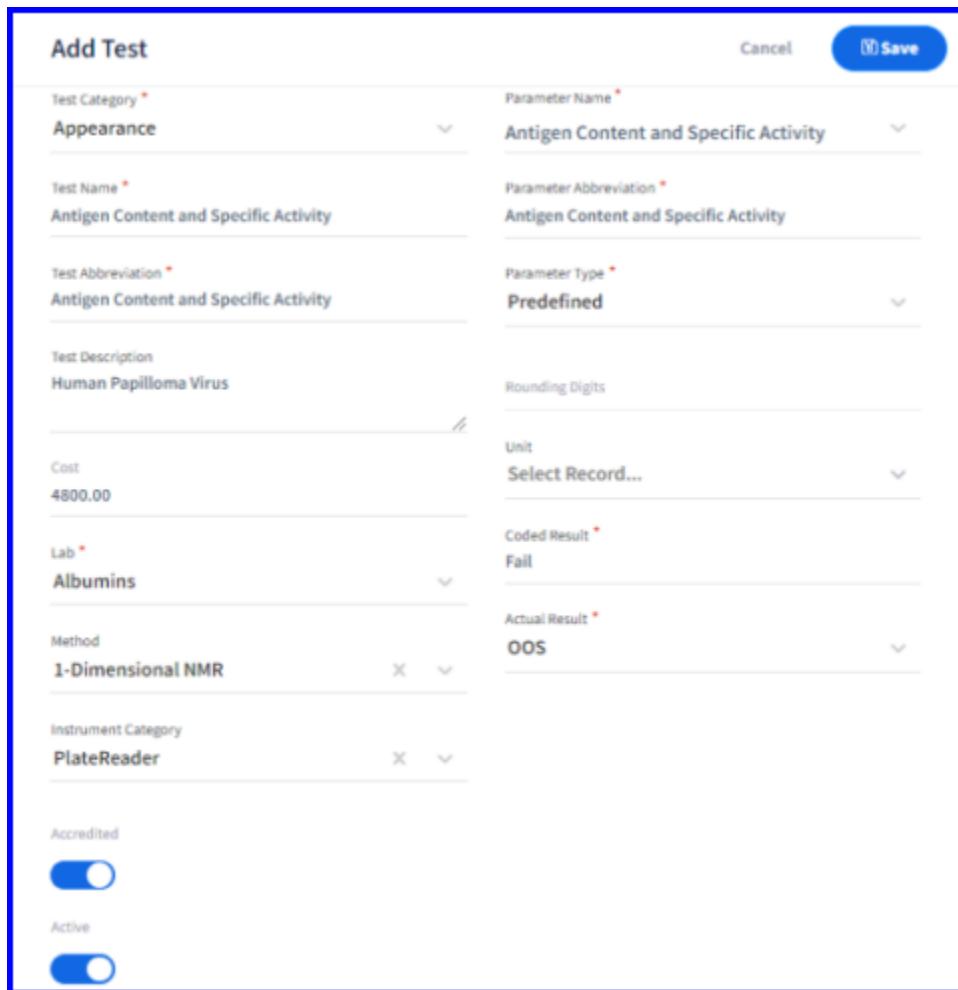


FIGURE: Add Test Dialog

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:

Antigen Content and Specific Activity of Gardasil/Silgard Type 16

ACTIVE NOT ACCREDITED

Test Abbreviation: Gardasil/Silgard IVRP Type 16

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

Price: 0

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

HPV Type 16 Antigen Content

Parameter Abbreviation: HPV Type 16

Parameter Type: Numeric

Rounding Digits: 2

Unit: Units/Vial

Formula: [+ Formula](#)

Specification: [+ Specification](#)

Click here to add new parameter

[+ Parameter](#)

FIGURE: Parameter Tab

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

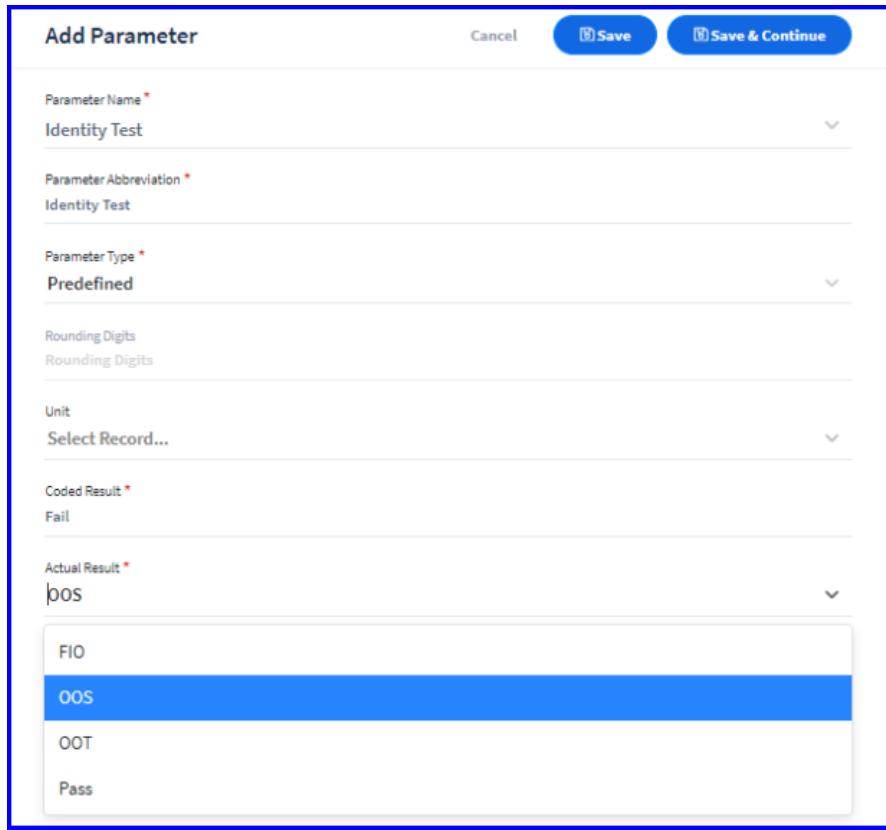


FIGURE: Add Parameter Dialog

4. In the **Parameter Name** field, type a parameter to add to the test.
5. In the **Parameter Abbreviation** field, type an abbreviation for the parameter.
6. From the **Parameter Type** field, select parameter type. i.e. Numeric / Character /Predefined. Based on the selected parameter type, fill in the following mandatory fields:
 - In the **Rounding Digits** field, mention the number of digits allowed for rounding (For numeric parameters).
 - From the **Unit** field, select the unit for measurement of the sample/test.
 - In the **Coded Result** field, type the code for result: Example: Pass / Fail.
 - In the **Actual Result** field, select the code from the list.
7. Fill in other fields as required.
8. Click **Save** to save the parameter.

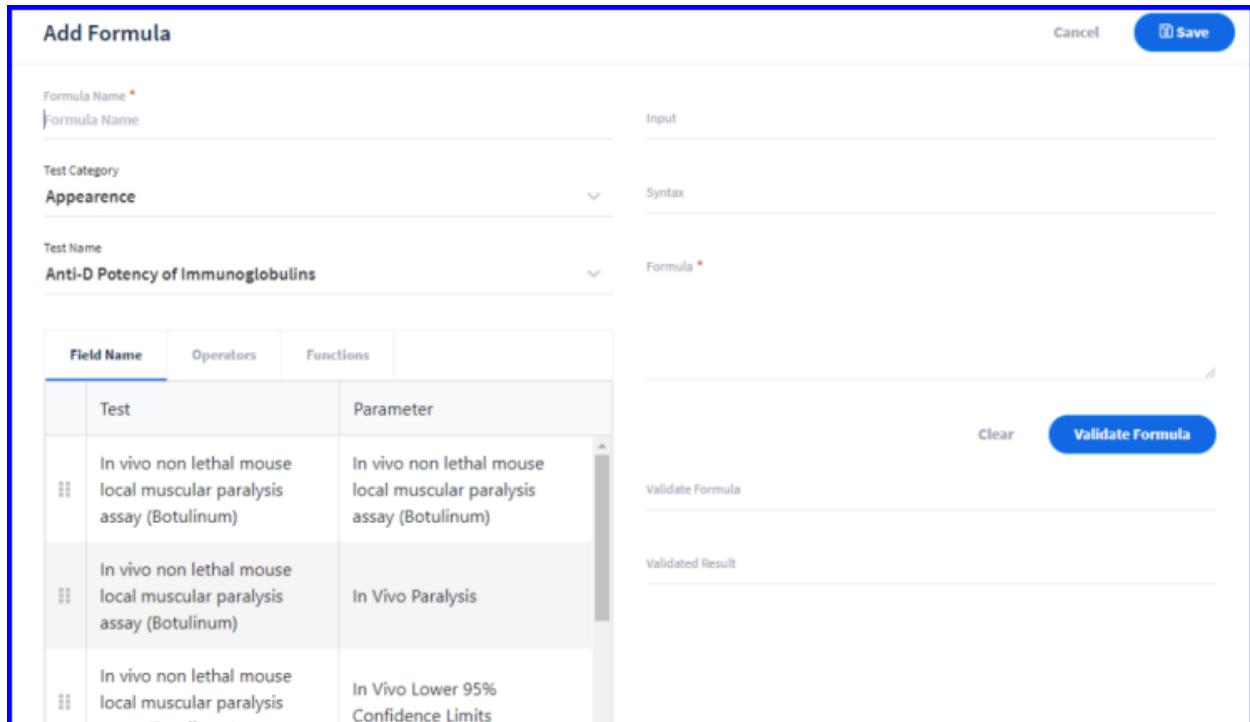
9. Click **Save and Continue** to add another parameter to the test.

You can see the parameter you just added listed in the Parameter tab.

3.8.4.4 Add Formula

Once you add parameters to the test, you can add formula to the selected parameter. To do so, follow these steps:

1. In the **Parameter** tab, select numeric parameter and then click **+ Formula**. The **Add Formula** screen appears as shown in the figure:



The screenshot shows the 'Add Formula' interface. At the top, there are fields for 'Formula Name' (with a red asterisk), 'Test Category' (set to 'Appearance'), and 'Test Name' (set to 'Anti-D Potency of immunoglobulins'). Below these are four tabs: 'Input', 'Syntax', 'Formula' (with a red asterisk), and 'Validate Formula'. A 'Validate Result' section is also present. On the left, there is a table with columns 'Field Name', 'Operators', 'Functions', and 'Input'. The table contains three rows of data:

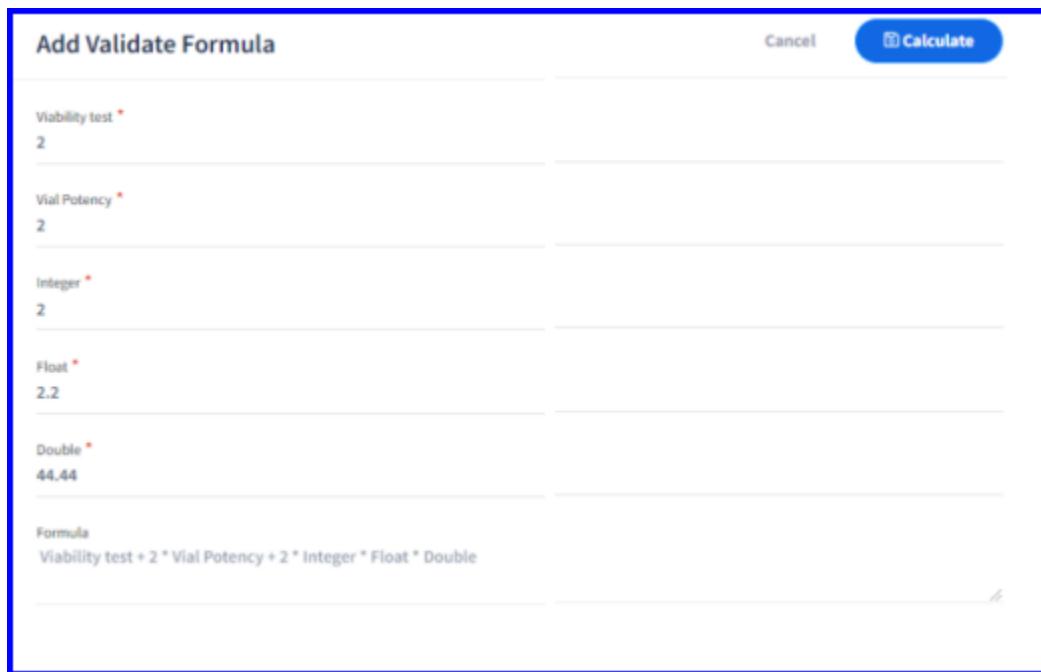
Field Name	Operators	Functions	Input
In vivo non lethal mouse local muscular paralysis assay (Botulinum)			In vivo non lethal mouse local muscular paralysis assay (Botulinum)
In vivo non lethal mouse local muscular paralysis assay (Botulinum)			In Vivo Paralysis
In vivo non lethal mouse local muscular paralysis			In Vivo Lower 95% Confidence Limits

FIGURE: Add Formula Screen

You can create and test formula using the fields, operators and functions available in the formula screen.

2. In the **Formula Name** field, type name for the formula you create.
3. In the **Test Category** field, select the test category you want to create formula.
4. In the **Test Name** field, select the test you want to create formula.
5. Use the **Field Name**, **Operators**, **Functions** and **Input** fields to create a formula.

6. You can click  that appears near the fields, operators and functions to drag **Field Name**, **Operators** and **Functions** and drop in the **Formula** field.
7. In the **Input** field, type a numeric value and then press ENTER to add to the formula.
8. The **Syntax** field gives you suggestions when you type a formula.
9. Click **Clear** to clear formula if required. When you click **Clear**, the entire formula is cleared and you need to build the formula from the scratch.
10. Click **Validate Formula** to validate the formula. The **Add Validate Formula** dialog appears as shown in the figure:



The screenshot shows the 'Add Validate Formula' dialog box. It has a title bar with 'Add Validate Formula' and buttons for 'Cancel' and 'Calculate'. Below the title bar are five input fields with validation requirements (indicated by a red asterisk):

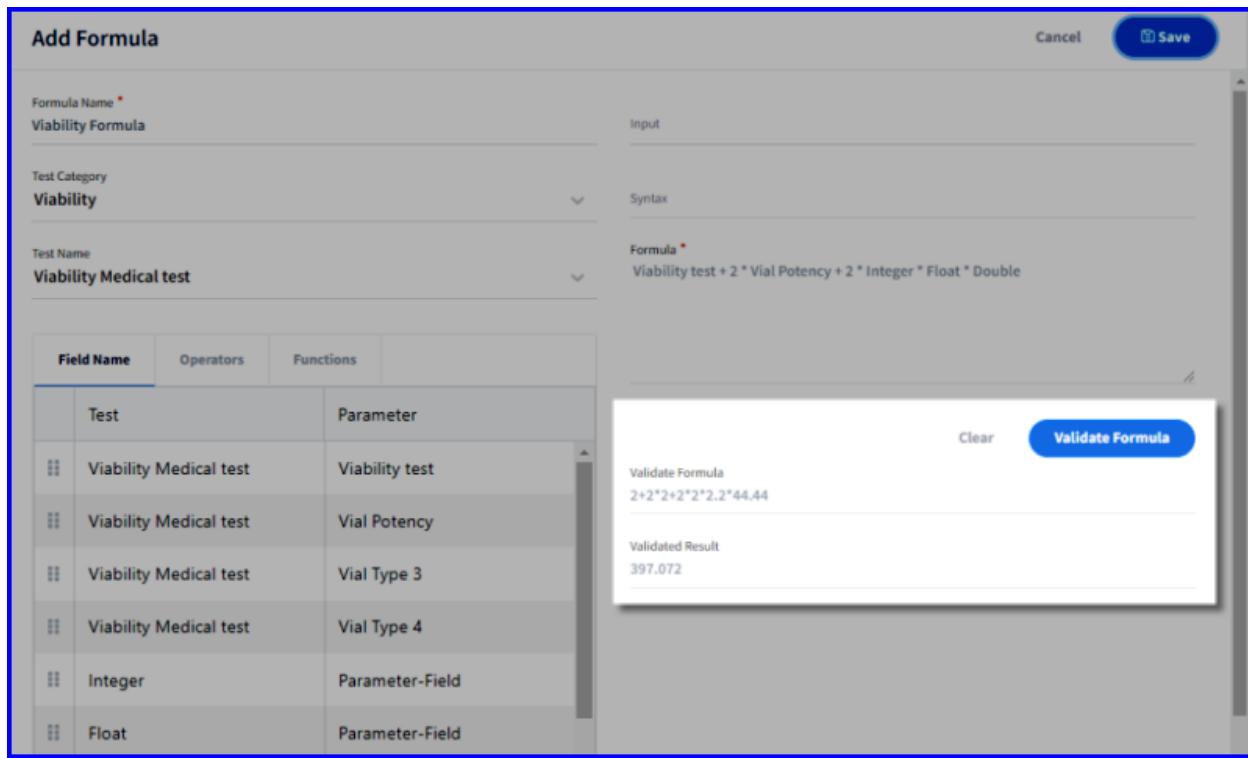
- Viability test: Value 2
- Vial Potency: Value 2
- Integer: Value 2
- Float: Value 2.2
- Double: Value 44.44

Below these fields is a 'Formula' field containing the expression: `Viability test + 2 * Vial Potency + 2 * Integer * Float * Double`.

FIGURE: Validate Formula

11. Fields in the formula appears. Type value for the fields and then click **Calculate**.

You can see the validated result as shown in the figure:



The screenshot shows the 'Add Formula' dialog box. At the top, there are fields for 'Formula Name' (Viability Formula), 'Test Category' (Viability), and 'Test Name' (Viability Medical test). Below these, a table lists fields and their types:

Field Name	Operators	Functions
Test		Parameter
Viability Medical test		Viability test
Viability Medical test		Vial Potency
Viability Medical test		Vial Type 3
Viability Medical test		Vial Type 4
Integer		Parameter-Field
Float		Parameter-Field

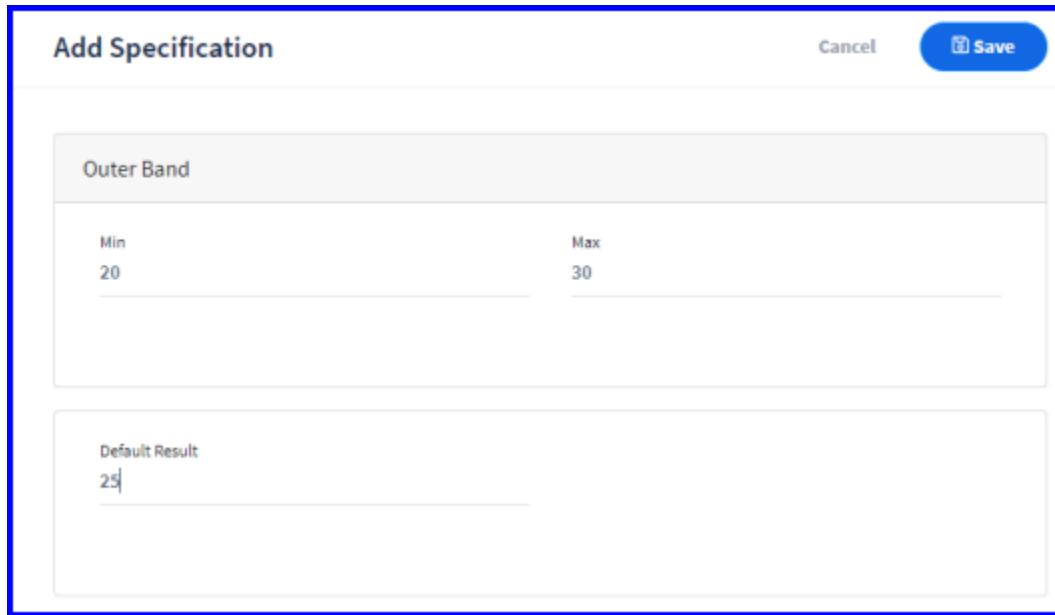
On the right, there is a validation result window with a 'Validate Formula' button. The validation result shows the formula $2+2*2+2*2*2.2*44.44$ and the validated result 397.072.

FIGURE: Result Calculated

3.8.4.5 Add Specifications to the Parameter

Once you add formula to the test, you can add specifications to the parameter. To do so, follow these steps:

1. Click **+ Specification**. The **Add Specification** dialog appears as shown in the figure:



Outer Band

Min
20

Max
30

Default Result
25

Save

FIGURE: Add Specification Dialog

You need to set minimum and maximum values for the outer band here.

2. In the **Min** field, type minimum value for the outer band.
3. In the **Max** field, type maximum value for the outer band.
4. In the **Default Result** field, type default value for the test.
5. Click **Save**.

You can add only one specification for the test.

3.8.4.6 Map Labs to Test

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

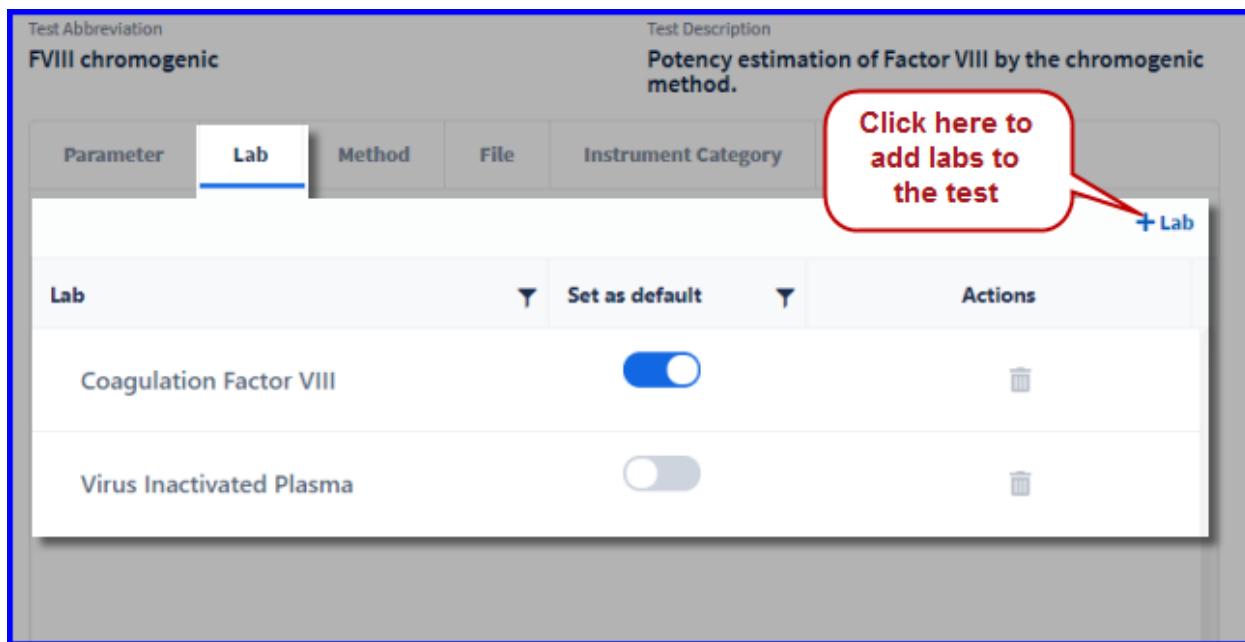


FIGURE: Test master – Lab Tab

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

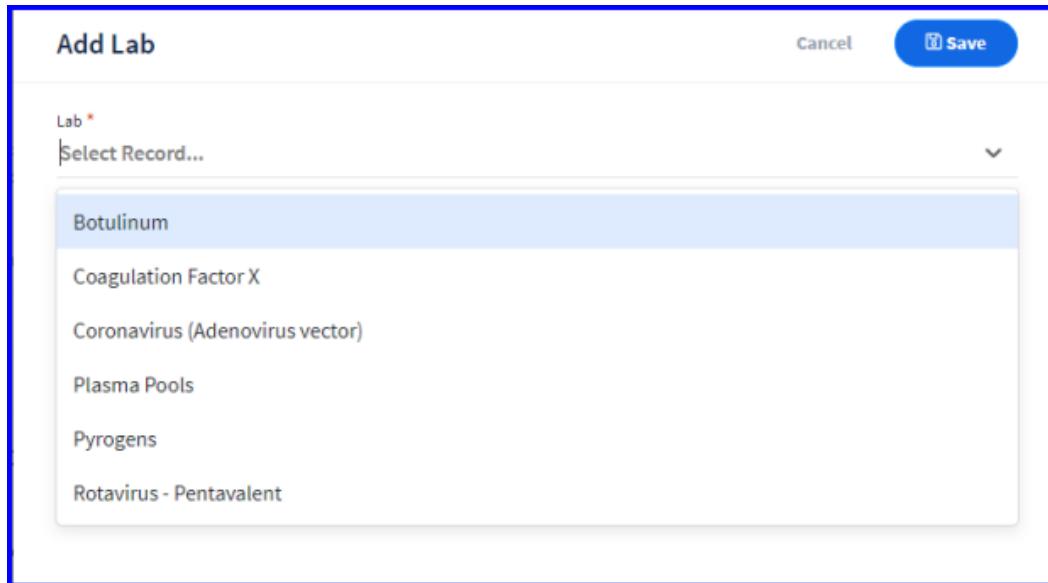


FIGURE: Test master – Add Lab Dialog

4. In the **Lab** field, click to select the lab/s to map to the selected test.
5. Click **Save**. You can see the lab you just added to the test listed in the **Lab** tab as shown in the figure:

Parameter	Lab	Method	File	Instrument Category	
+ Lab					
Lab				Set as default	Actions
Cholera				<input type="checkbox"/>	
Albumins				<input checked="" type="checkbox"/>	

FIGURE: Labs Added to the Selected Test

Each lab added appears in a row with **Set as default** and **Actions** fields.

6. You can turn on **Set as default** option to make the lab default lab.
7. Click  to delete the lab.

3.8.4.7 Add Methods to Test

1. In the **Test Master** screen, select the test you want to add method/s.
2. Go to the **Method** tab.
3. Click . The **Add Method** screen appears as shown in the figure:

Add Method
[Cancel](#)
 Save

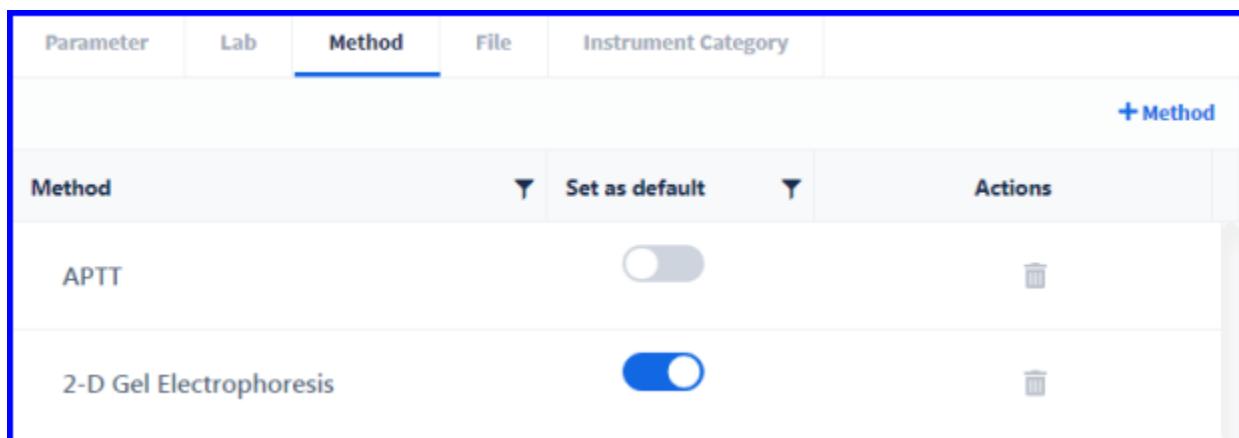
Method *

2-D Gel Electrophoresis 
APTT 
 

1-Stage Clotting Assay
Antibody Neutralisation
Automated
Determination Tensile Properties Method

FIGURE: Test master – Add Method Screen

4. You can see the list of methods available here. Click to select the method/s to map to the selected test.
5. Click **Save**. You can see the method you just added to the test listed in the **Method** tab as shown in the figure:



Parameter	Lab	Method	File	Instrument Category
+ Method				
Method		Set as default		Actions
APTT		<input type="checkbox"/>		
2-D Gel Electrophoresis		<input checked="" type="checkbox"/>		

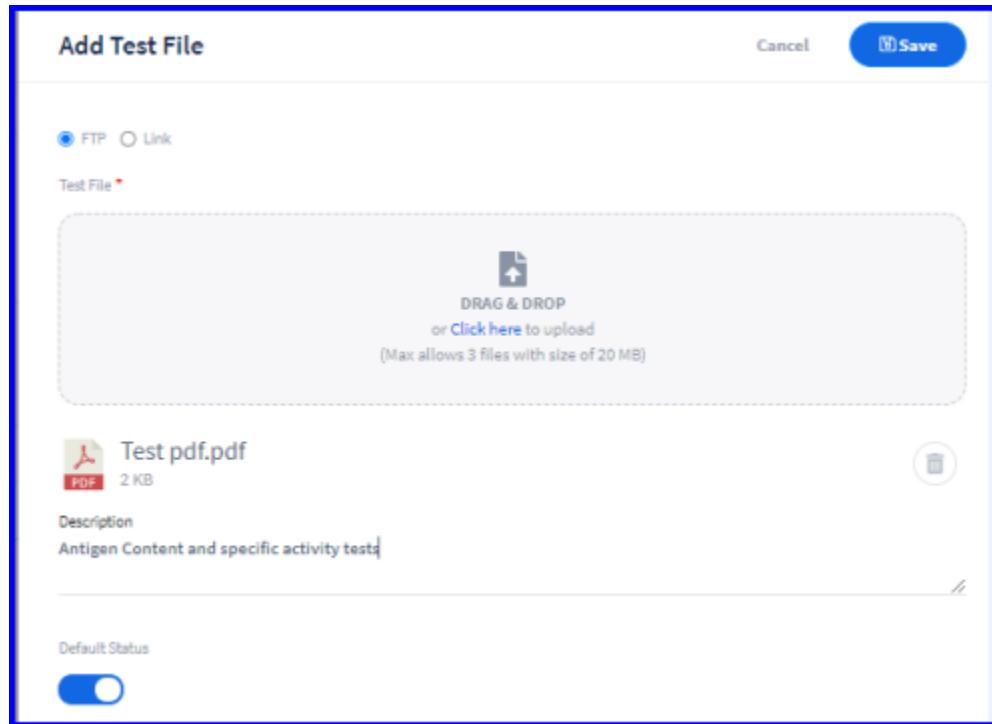
FIGURE: Test master – List of Add Methods Added to the Test

Each method added appears in a row with **Set as default** and **Actions** fields.

6. You can turn on **Set as default** option to make the method default method.
7. Click  to delete the method.

3.8.4.8 Attach Files to Test

1. In the **Test Master** screen, select the test you want to attach file/s.
2. Go to the **File** tab. The **File** tab appears.
3. Click **+ File**. The **Add Test File** screen appears as shown in the figure:



Add Test File

FTP Link

Test File *

DRAG & DROP
or [Click here](#) to upload
(Max allows 3 files with size of 20 MB)

 **Test pdf.pdf**
2 KB 

Description
Antigen Content and specific activity tests

Default Status 

Save

FIGURE: Test master – Add Test File Screen

4. Click **FTP** to upload file from the local drive.
 - In the **Test File** field, drag and drop the file or click **Click here** and locate the file from the local drive.
5. Click **Link** to upload a link. The screen appears as shown in the figure:



FTP Link

File Name *

Link Name *

<https://mail.google.com/>

Description

Default Status 

FIGURE: Test master – Add Test File – Link Option

- In the **File Name** field, type the file name.

- In the **Link Name** field, paste the link.
6. In the **Description** field, type description for the test file if any.
 7. Click to turn on the **Default Status** option to make the test file category active.
 8. Click **Save**. You can see the file you just added to the test listed in the **File** tab

3.8.4.9 Attach Instruments to Test

1. In the **Test Master** screen, select the test you want to map instrument categories.
2. Go to the **Instrument Categories** tab. The **Instrument Category** tab appears as shown in the figure:

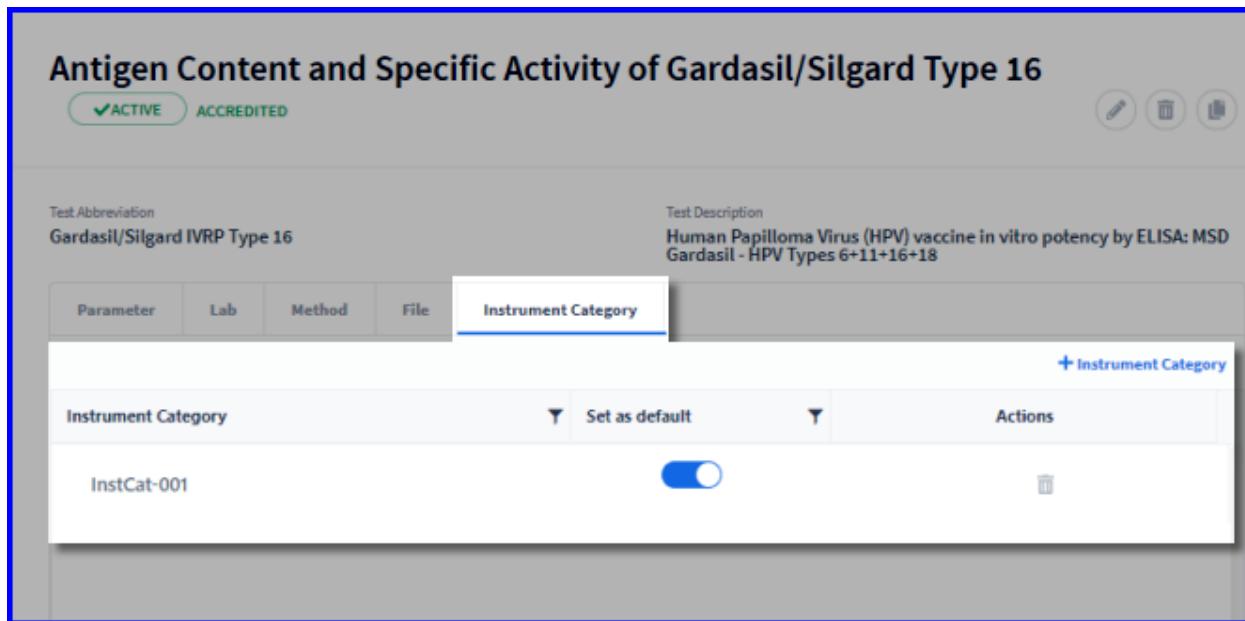


FIGURE: Test Master – Instrument Category Tab

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

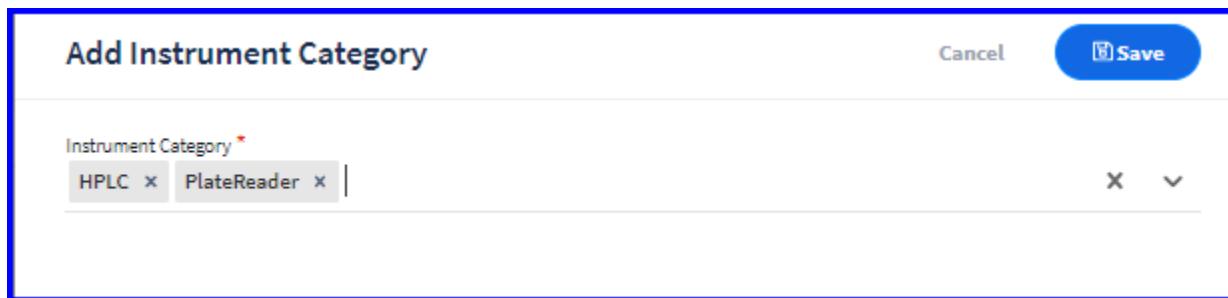


FIGURE: Add Instrument Category Dialog

4. In the **Instrument Category** field, click to select the instrument categories to map to the selected test.
5. Click **Save**. You can see the instrument categories you just added to the test listed in the **Instrument Categories** tab.

Each instrument category added appears in a row with **Set as default** and **Actions** fields.

6. You can turn on **Set as default** option to make the instrument category default instrument category.
7. Click  to delete the instrument category.

3.9 Instrument Management

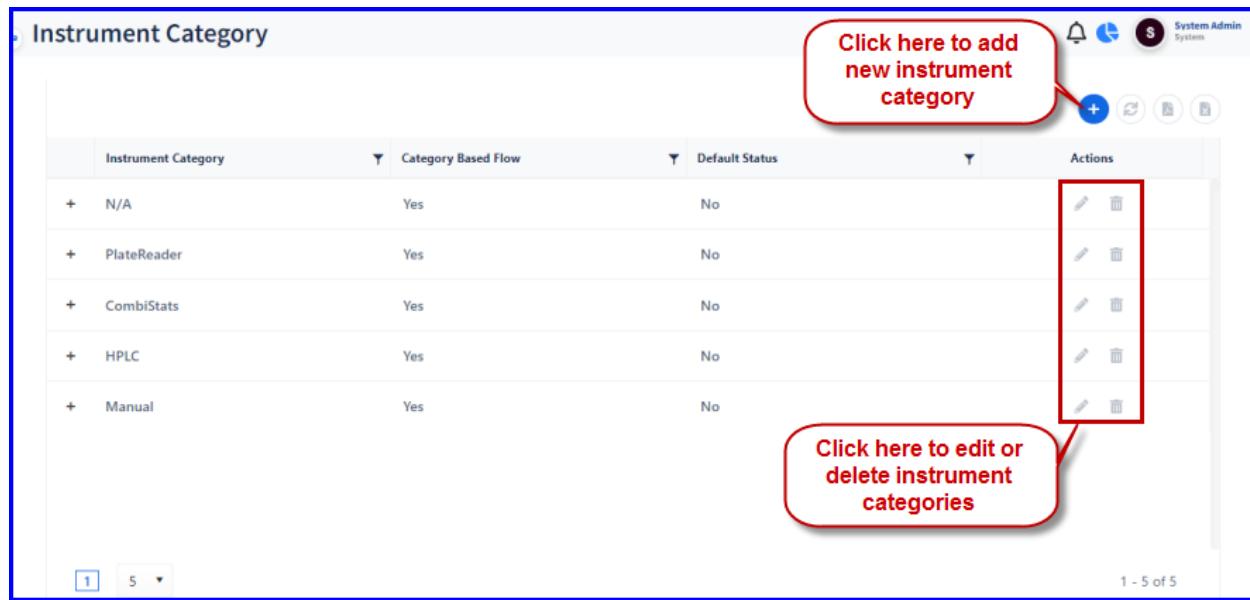
3.9.1 Instrument Category

Instrument category master is used to create and manage instrument categories that are used to group instruments.

3.9.1.1 Creating a New Instrument Category

To create a new instrument category, follow these steps:

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



The screenshot shows a table titled 'Instrument Category' with columns: 'Instrument Category', 'Category Based Flow', 'Default Status', and 'Actions'. The table contains five rows with data: N/A (Yes, No), PlateReader (Yes, No), CombiStats (Yes, No), HPLC (Yes, No), and Manual (Yes, No). A red callout box points to the top right of the table area with the text 'Click here to add new instrument category'. Another red callout box points to the 'Actions' column of the first row with the text 'Click here to edit or delete instrument categories'.

Instrument Category	Category Based Flow	Default Status	Actions
+	N/A	Yes	No
+	PlateReader	Yes	No
+	CombiStats	Yes	No
+	HPLC	Yes	No
+	Manual	Yes	No

FIGURE: Instrument Category Master Screen

In the Instrument Category master screen you can see the list of instrument categories created. Options to edit and delete instrument category appears in each record.

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

Instrument Category *

Interfacer

Description

Interfacer Inst Category

Technique *

ELISA

Interface type *

LogiLab

Category Based Flow

Default Status

FIGURE: Add Instrument Category Dialog

3. In the **Instrument Category** field, type the instrument category name you want to create.
4. In the **Description** field, type the description.
5. In the **Technique** field, select the technique name to map instrument.
6. In the **Interface Type** field, select Logilab / Interfacer. Here you group the instrument if it is Interfacer instrument or LogiLab instrument.
7. Click to check **Category Based Flow** field if applicable.
8. Click to turn on the **Default Status** option to make the instrument category active.
9. Click **Save**.

You can see the instrument category you just created listed in the Instrument Category master.

3.9.1.2 Editing and Deleting Instrument Category

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

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

3.9.2 Instrument Master

Instrument master is used to add and manage instruments in Qualis LIMS. Instruments are grouped under Instrument Categories.

3.9.2.1 Adding a New Instrument

To create a new instrument, follow these steps:

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

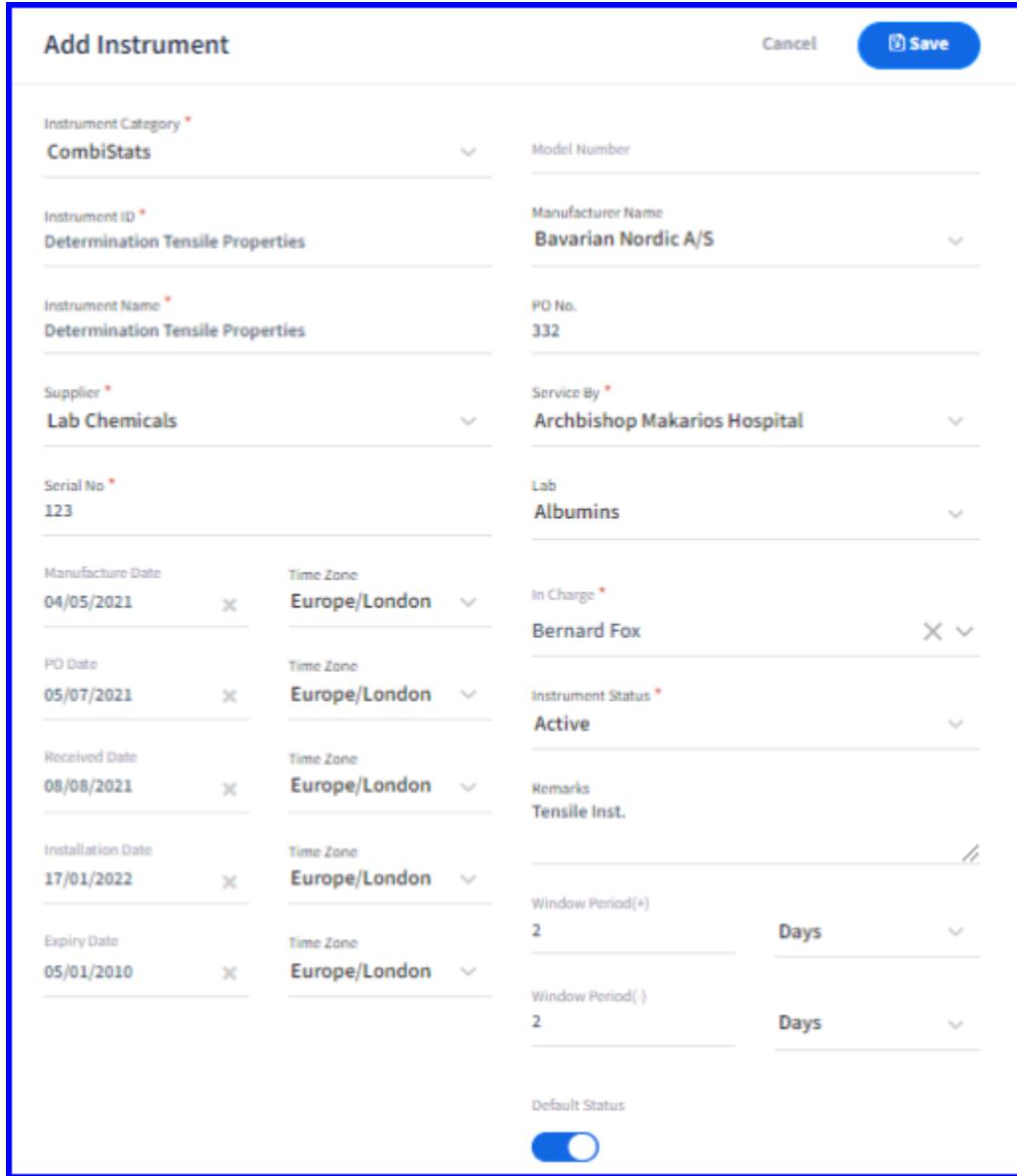


FIGURE: Instrument Master Screen

2. In the filter , select the **Instrument Category** and then click **Submit**. Instruments that are added to the selected instrument category will appear.

Options to edit and delete instruments appear in each record.

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



Add Instrument

Instrument Category *: CombiStats

Instrument ID *: Determination Tensile Properties

Instrument Name *: Determination Tensile Properties

Supplier *: Lab Chemicals

Serial No *: 123

Manufacture Date: 04/05/2021

PO Date: 05/07/2021

Received Date: 08/08/2021

Installation Date: 17/01/2022

Expiry Date: 05/01/2010

Time Zone: Europe/London

Time Zone: Europe/London

Time Zone: Europe/London

Time Zone: Europe/London

Model Number:

Manufacturer Name: Bavarian Nordic A/S

PO No.: 332

Service By *: Archbishop Makarios Hospital

Lab: Albumins

In Charge *: Bernard Fox

Instrument Status *: Active

Remarks: Tensile Inst.

Window Period(+): 2 Days

Window Period(-): 2 Days

Default Status:

Save

FIGURE: Add Instrument Dialog

4. In the **Instrument Category** field, select the instrument category to which you create the instrument.
5. In the **Instrument ID** field, type a unique identification number for the instrument.
6. In the **Instrument Name** field, type the name of the instrument.

7. In the **Supplier** field, select the instrument supplier name.
8. In the **Service By** field, select the vendor who will service the instrument.
9. In the **Serial No** field, type the serial number of the instrument.
10. In the **In Charge** field, select the person in charge for the instrument.
11. In the **Window +** and **Window-** fields, mention the window period for the test.

Note: The window period for a test designed to detect a specific disease (particularly infectious disease) is the time between first infection and when the test can reliably detect that infection.

12. Fill in other fields appropriately
13. In the **Instrument Status** field, select **Active** to make the instrument active.
14. Click to turn on the **Default Status** option to keep the instrument active by default.
15. Click **Save**.

You can see the instrument you just created listed in the Instrument master.

3.9.2.2 Editing and Deleting Instrument

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

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

3.10 Material Management

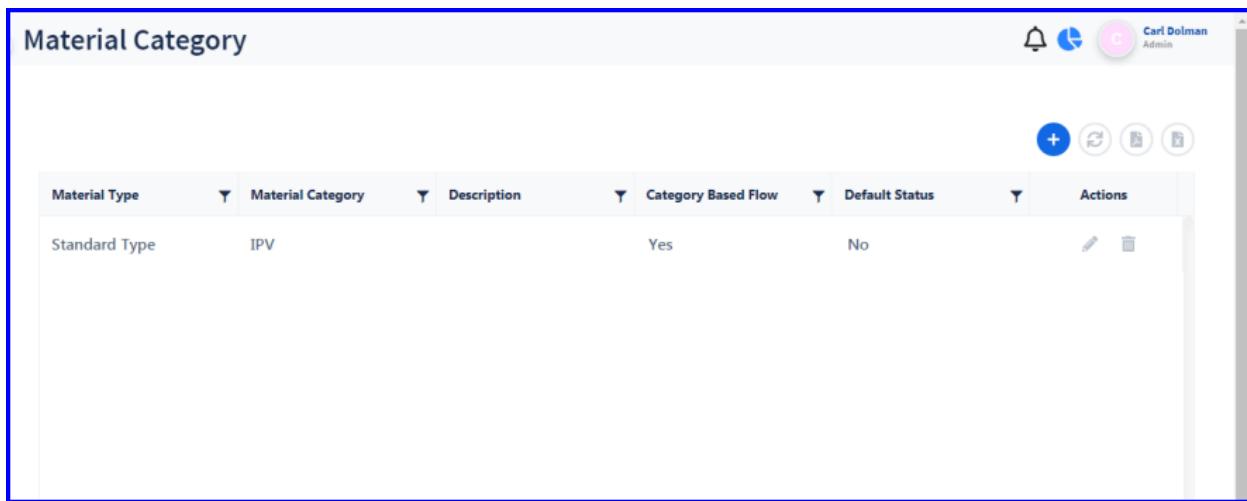
3.10.1 Material Category Master

Material Category master is used to add and manage material categories. Material category is used in various forms and master to group materials.

3.10.1.1 Adding a New Material Category

To create a new material category, follow these steps:

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



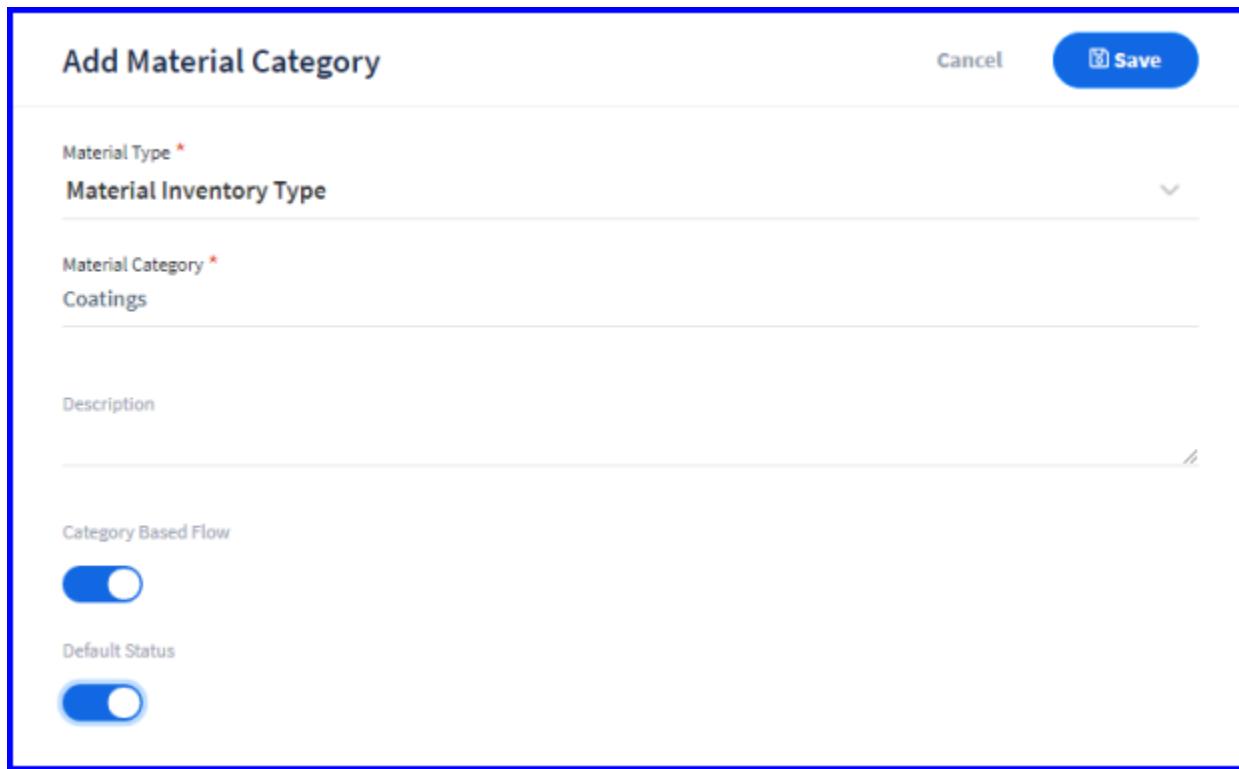
The screenshot shows the 'Material Category' master screen. At the top, there is a header with the title 'Material Category' and a user profile for 'Carl Dolman Admin'. Below the header is a toolbar with several icons: a blue circle with a plus sign, a copy icon, a print icon, and a refresh icon. The main area is a table with the following columns: 'Material Type', 'Material Category', 'Description', 'Category Based Flow', 'Default Status', and 'Actions'. There is one record displayed: 'Standard Type' under 'Material Type', 'IPV' under 'Material Category', 'Yes' under 'Category Based Flow', 'No' under 'Default Status', and 'Actions' with edit and delete icons. The table has a light gray background with white rows and columns.

Material Type	Material Category	Description	Category Based Flow	Default Status	Actions
Standard Type	IPV		Yes	No	 

FIGURE: Material Category Master Screen

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

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



Add Material Category

Material Type *

Material Inventory Type

Material Category *

Coatings

Description

Category Based Flow

Default Status

Cancel Save

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:

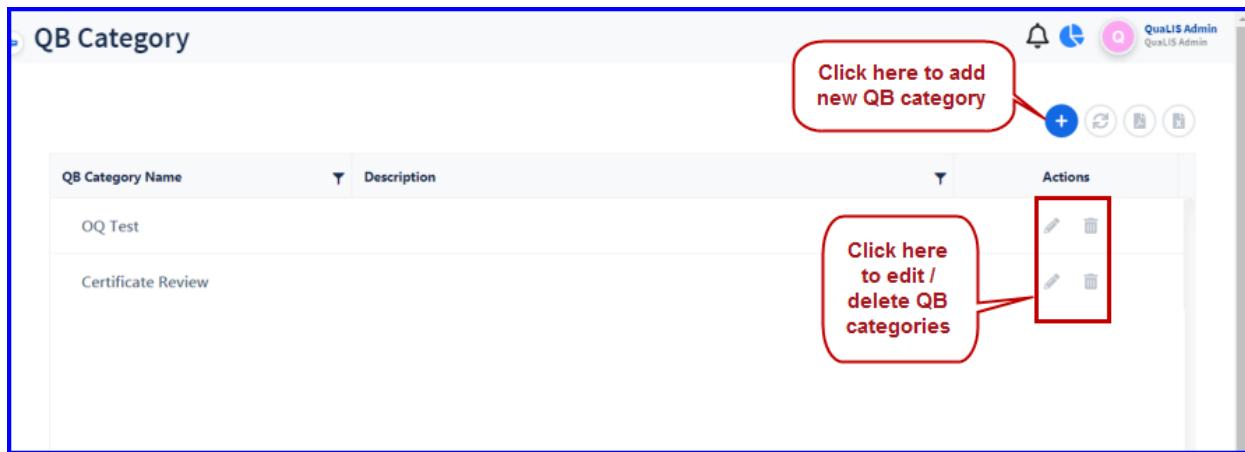


FIGURE: QB Category Master Screen

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.

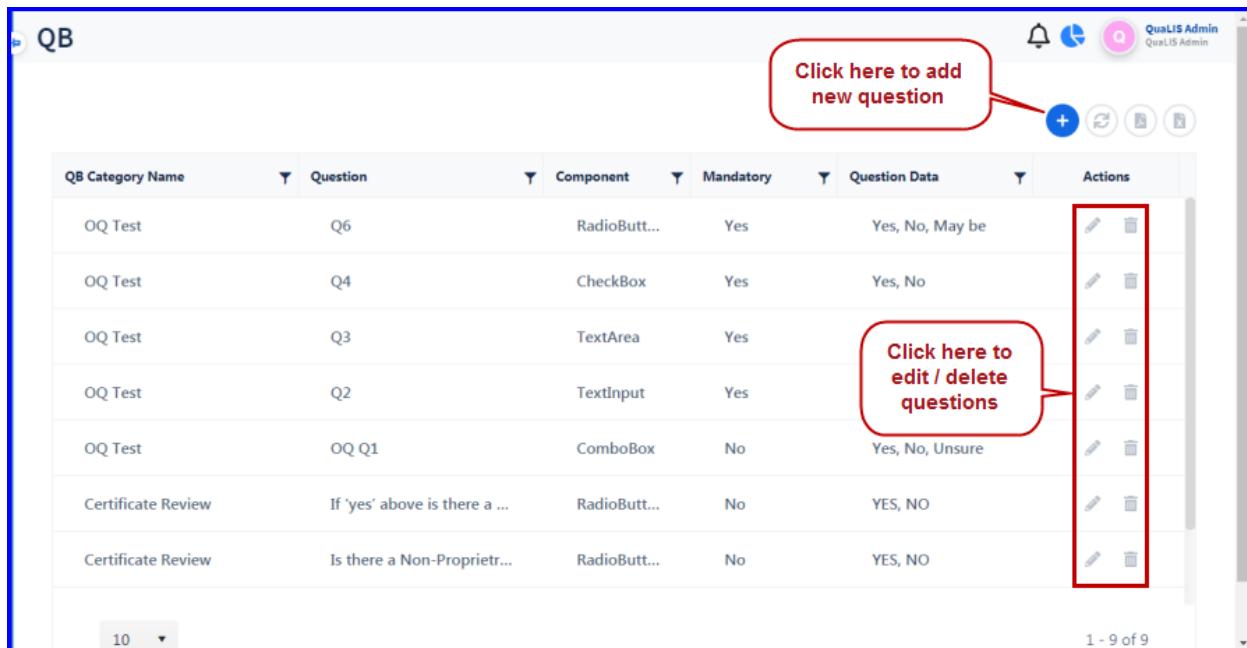
3.11.2 QB Master

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:



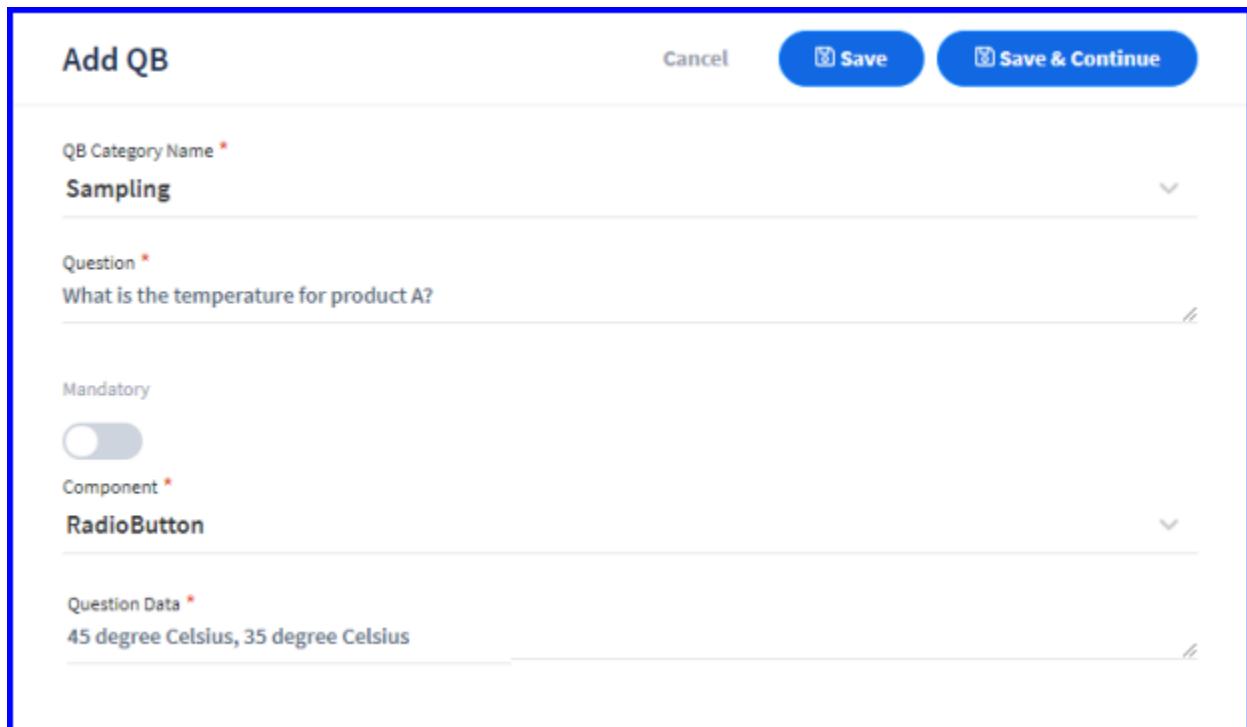
The screenshot shows a table titled 'QB' with the following columns: QB Category Name, Question, Component, Mandatory, Question Data, and Actions. The 'Actions' column contains icons for edit and delete. Two red callout boxes highlight these icons: one pointing to the 'edit' icon with the text 'Click here to add new question' and another pointing to the 'edit' and 'delete' icons with the text 'Click here to edit / delete questions'.

QB Category Name	Question	Component	Mandatory	Question Data	Actions
QQ Test	Q6	RadioButt...	Yes	Yes, No, May be	 
QQ Test	Q4	CheckBox	Yes	Yes, No	 
QQ Test	Q3	TextArea	Yes		 
QQ Test	Q2	TextInput	Yes		 
QQ Test	QQ Q1	ComboBox	No	Yes, No, Unsure	 
Certificate Review	If 'yes' above is there a ...	RadioButt...	No	YES, NO	 
Certificate Review	Is there a Non-Proprietr...	RadioButt...	No	YES, NO	 

FIGURE: QB Master Screen

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

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



The 'Add QB' screen has the following fields:

- QB Category Name ***: Sampling
- Question ***: What is the temperature for product A?
- Mandatory**: A toggle switch is turned off.
- Component ***: RadioButton
- Question Data ***: 45 degree Celsius, 35 degree Celsius

At the top right are 'Cancel', 'Save', and 'Save & Continue' buttons.

FIGURE: Add Question Screen

3. In the **QB Category Name** field, select the category.
4. In the **Question** field, type the question you want to add to the QB.
5. Check to select the **Mandatory** field to make the question mandatory in the QB.
6. In the **Component** field, select the type of question. i.e Combo field, radio button, Text Area etc.
7. In the **Question Data** field, type the text/value for component selected. For example, for component: Radio button, you can type Yes/No.
8. Click **Save**.

You can see the question you just added listed in the QB master.

3.11.2.2 Editing and Deleting Questions in QB

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

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

3.11.3 Checklist

Checklist master is used to create and manage checklists.

3.11.3.1 Creating a New Checklist

To create a new checklist, follow these steps:

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

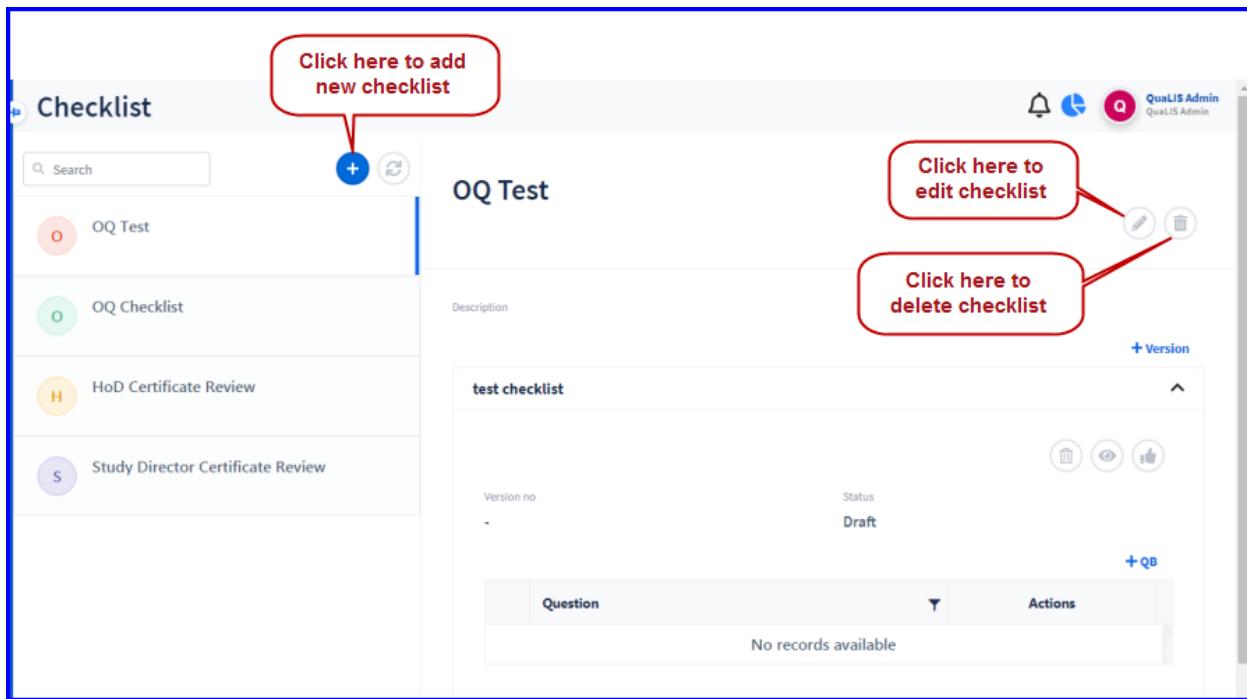
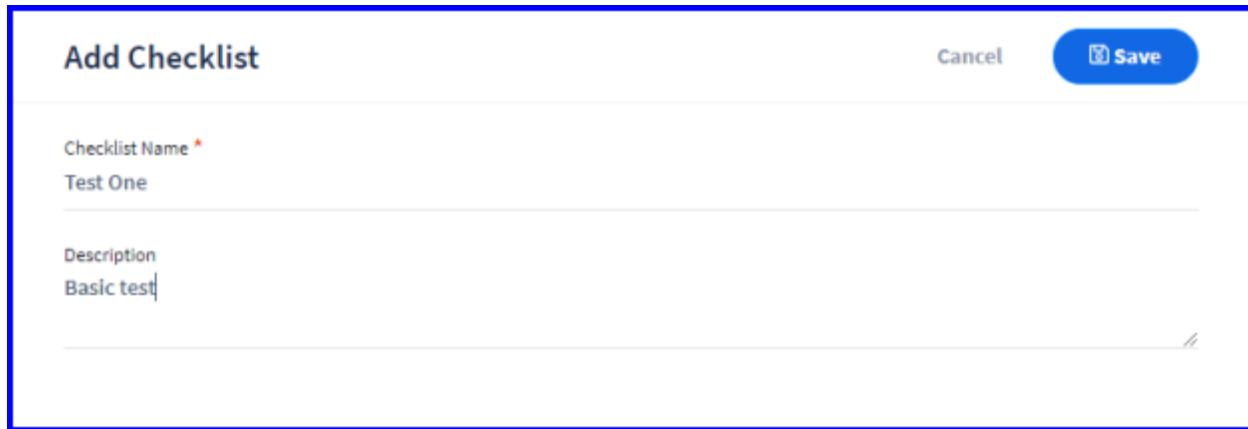


FIGURE: Checklist Master Screen

In the checklist master screen you can see the list of checklists created. Options to edit and delete appear in each record as shown in the above figure.

Creating a checklist consists of the following steps:

- Add a draft version of the checklist.
 - Add questions to the check list draft.
 - Approve checklist draft.
2. In the Checklist master screen, click . The **Add Checklist** screen appears as shown in the figure:



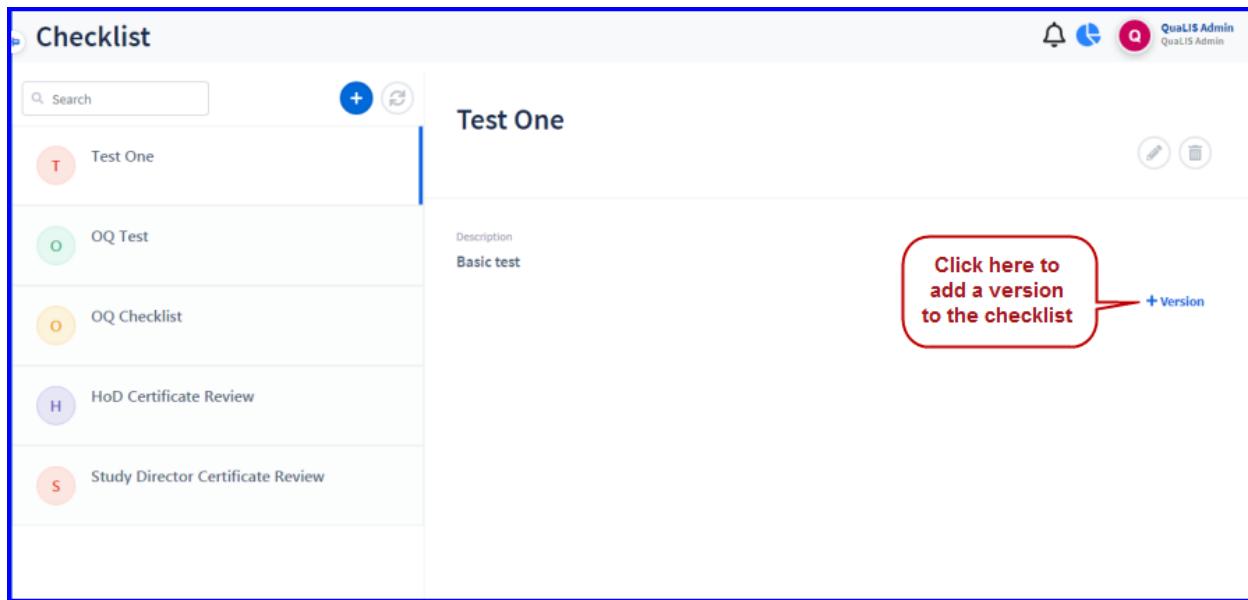
The screenshot shows the 'Add Checklist' dialog box. At the top left is the title 'Add Checklist'. At the top right are two buttons: 'Cancel' and a blue 'Save' button with a checkmark icon. The dialog contains two text input fields. The first field is labeled 'Checklist Name *' and contains the text 'Test One'. The second field is labeled 'Description' and contains the text 'Basic test'. There is also a large, empty text area below these fields.

FIGURE: Add Checklist Dialog

3. In the **Checklist Name** field, type a name for the checklist you create.
4. In the **Description** field, type the description.
5. Click **Save**.

You can see the checklist you just created listed in the Checklist master.

6. Select the checklist, click **+ Version** as shown in the figure:



The screenshot shows the 'Checklist' master page. At the top left is the title 'Checklist'. At the top right are three user icons: a bell, a person, and a gear, followed by the text 'Qualis Admin'. The main area is a table with a list of checklists. The first row, 'Test One', is selected and highlighted with a blue border. To the right of the table, there is a detailed view of 'Test One'. This view includes the 'Description' field with the value 'Basic test'. At the bottom right of this view, there is a red callout bubble with the text 'Click here to add a version to the checklist' pointing to a blue '+ Version' button. The table has columns for 'Icon', 'Name', and 'Actions'.

Icon	Name	Actions
T	Test One	 
O	OQ Test	
O	OQ Checklist	
H	HoD Certificate Review	
S	Study Director Certificate Review	

FIGURE: Adding Version to the Checklist

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

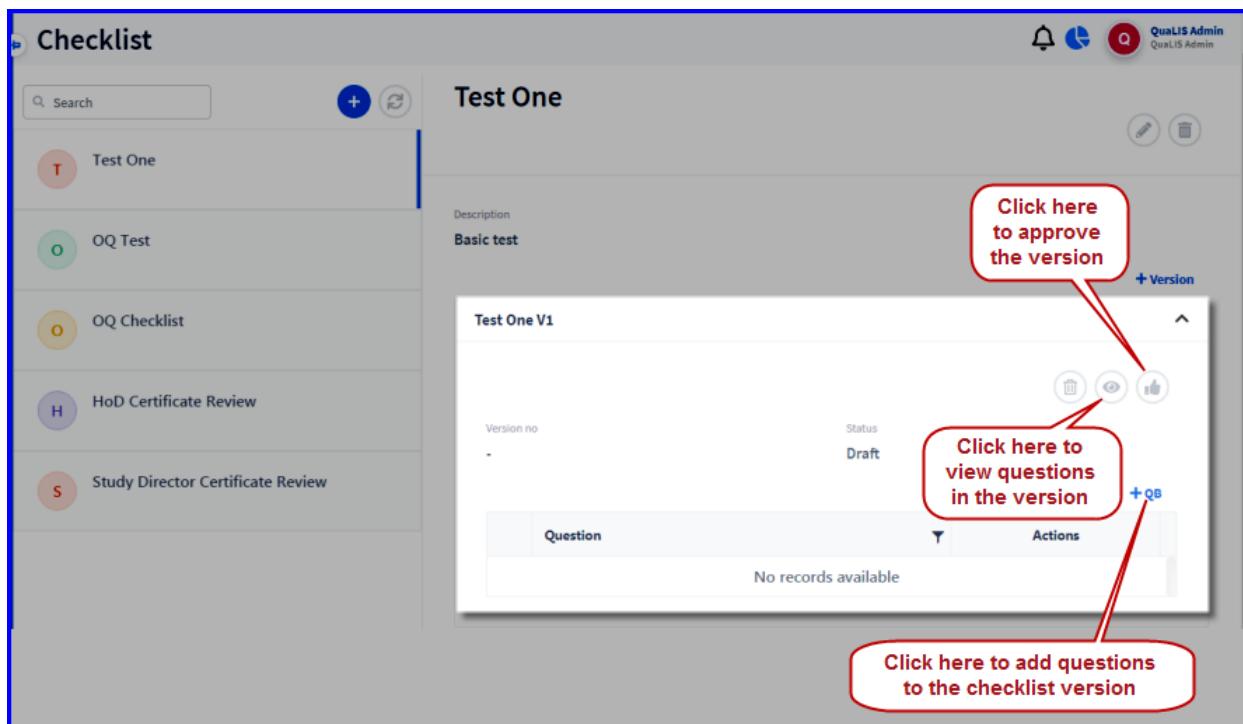


The screenshot shows a dialog box titled "Add Checklist Version". It has a "Checklist Version Name" field containing "Test One V1" with a red asterisk indicating it is required. There are "Cancel" and "Save" buttons at the top right. The entire dialog is highlighted with a thick blue border.

FIGURE: Add Checklist Version Dialog

8. In the **Checklist Version Name** field, type the name for the version.
9. Click **Save**.

The check list version is created and appears as shown in the figure:



The screenshot shows the "Checklist" module. On the left, a sidebar lists items: "Test One" (selected, highlighted in orange), "OQ Test", "OQ Checklist", "Hod Certificate Review", and "Study Director Certificate Review". The main area shows "Test One" details: "Description: Basic test". Below is a list of versions: "Test One V1" (Version no: -, Status: Draft). A callout box points to the "Like" icon with the text "Click here to approve the version". Another callout box points to the "Eye" icon with the text "Click here to view questions in the version". A third callout box points to the "plus" icon with the text "Click here to add questions to the checklist version". The entire screenshot is highlighted with a thick blue border.

FIGURE: Checklist version in Draft State

Approve checklist draft: Select a checklist version in draft state and then click .

View Checklist Items: Once the checklist is approved, click  to view list of questions in the checklist.

You can add multiple drafts to a checklist.

10. Select the draft checklist to add questions and click **+QB** as shown in the figure:

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

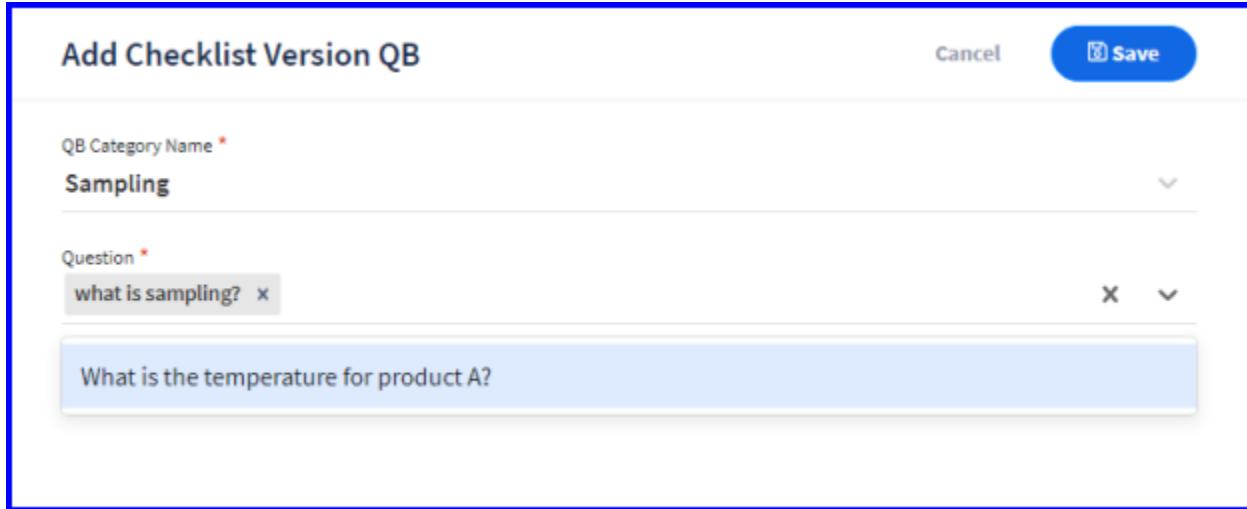


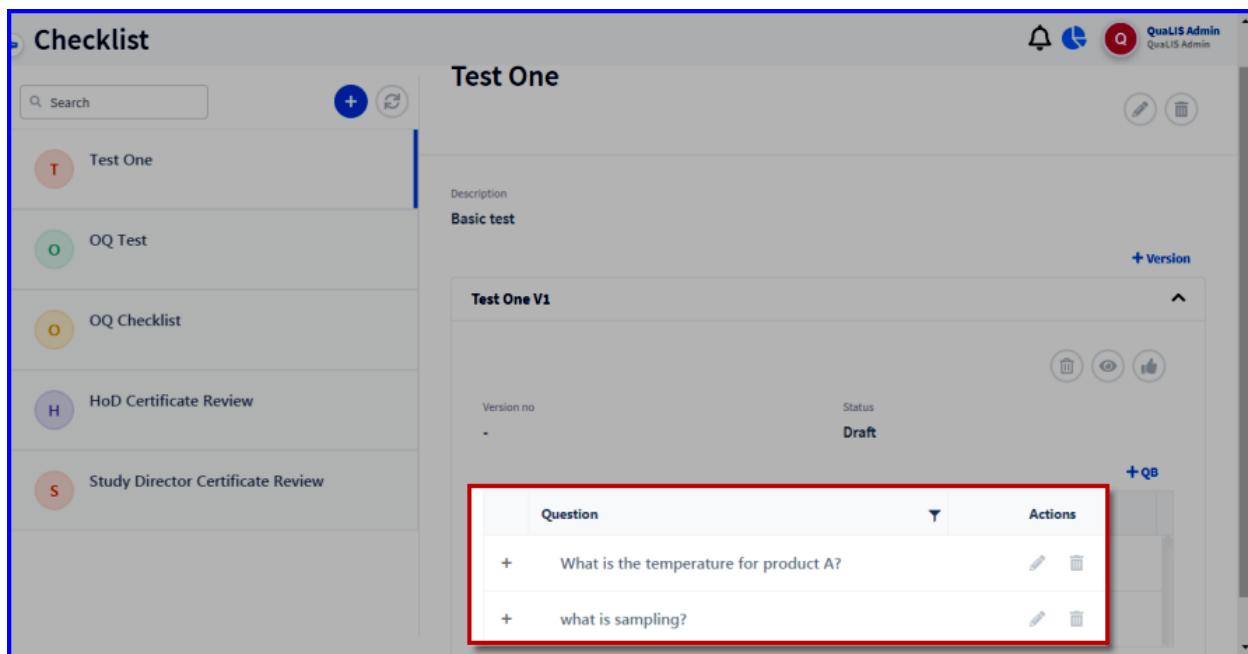
FIGURE: Add Question to Checklist Screen

Here you can add questions to the checklist.

12. Select the **QB Category Name**. Questions from the selected category appear.

13. In the Question field, select the questions to add to the checklist. You can add multiple questions.

14. Click **Save**. The questions added appears as shown in the figure:



The screenshot shows the Qualis LIMS Checklist module. On the left, a sidebar lists several checklist items: 'Test One' (selected), 'OQ Test', 'OQ Checklist', 'HoD Certificate Review', and 'Study Director Certificate Review'. The main area is titled 'Test One' and shows a 'Basic test' description. A 'Test One V1' version is displayed, which is currently in 'Draft' status. The version details include 'Version no.' (empty) and 'Status' (Draft). Below this, a table lists two questions with edit and delete icons:

Question	Actions
+ What is the temperature for product A?	 
+ what is sampling?	 

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.

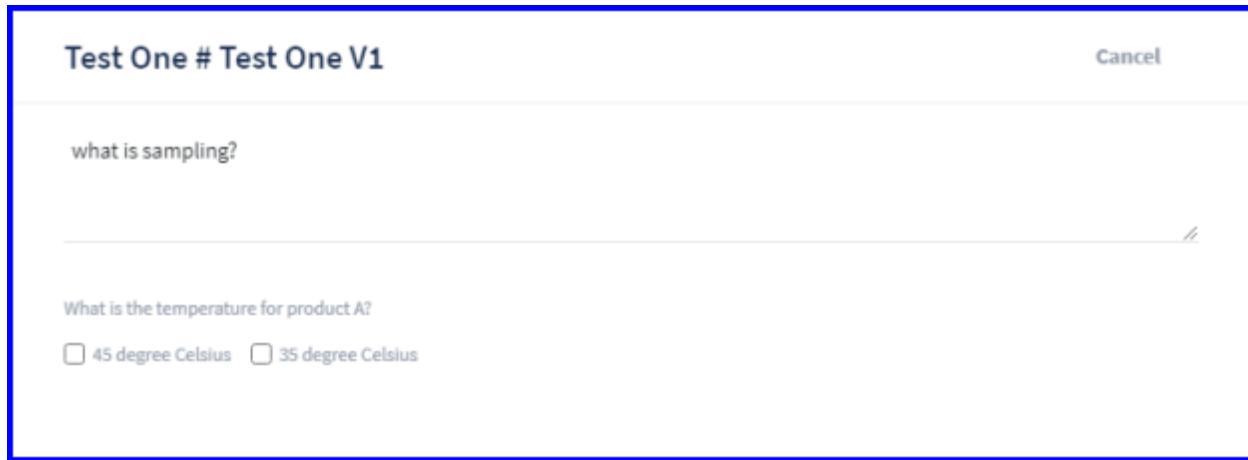
1. To edit checklist details, in the Checklist master screen, click  to edit the Checklist record. In the **Edit Checklist** screen, do required changes and then click **Save**.
2. To delete a checklist, in the Checklist master screen, click  to delete the checklist record.

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:



Test One # Test One V1

what is sampling?

What is the temperature for product A?

45 degree Celsius 35 degree Celsius

Cancel

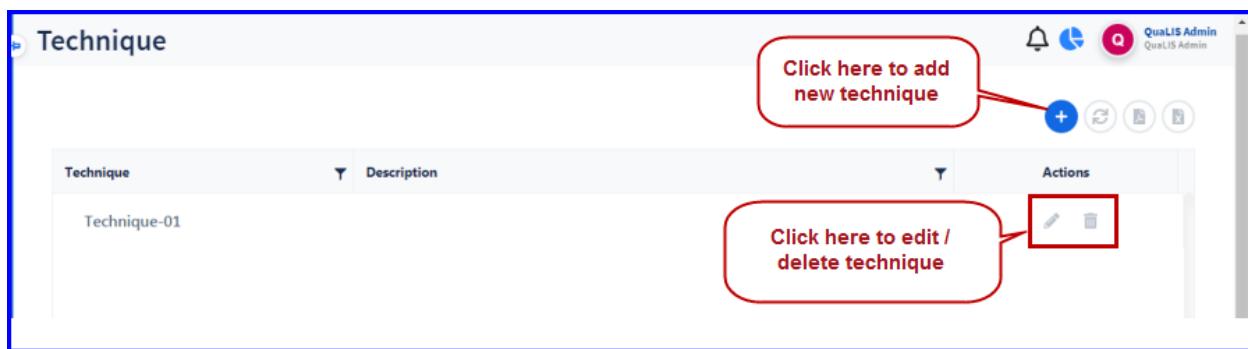
FIGURE: View Checklist Items

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:



Technique	Description	Actions
Technique-01		+ Edit Delete

FIGURE: Technique Master Screen

In the Technique master screen you can see the list of techniques created. Options to edit and delete techniques appear in the action menu.

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



The screenshot shows the 'Add Technique' dialog box. At the top, it says 'Add Technique' and has 'Cancel' and 'Save' buttons. The 'Technique *' field contains 'QC Technique'. The 'Description' field contains 'QC'.

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:

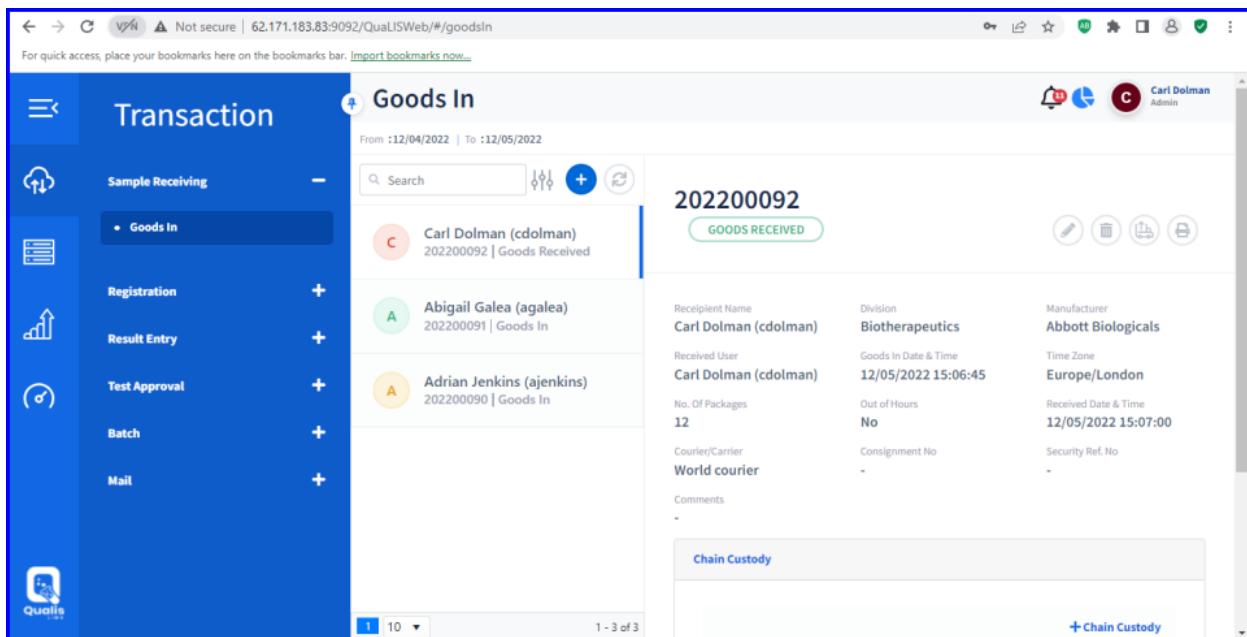


FIGURE: Goods In Screen

To add goods details, follow these steps:

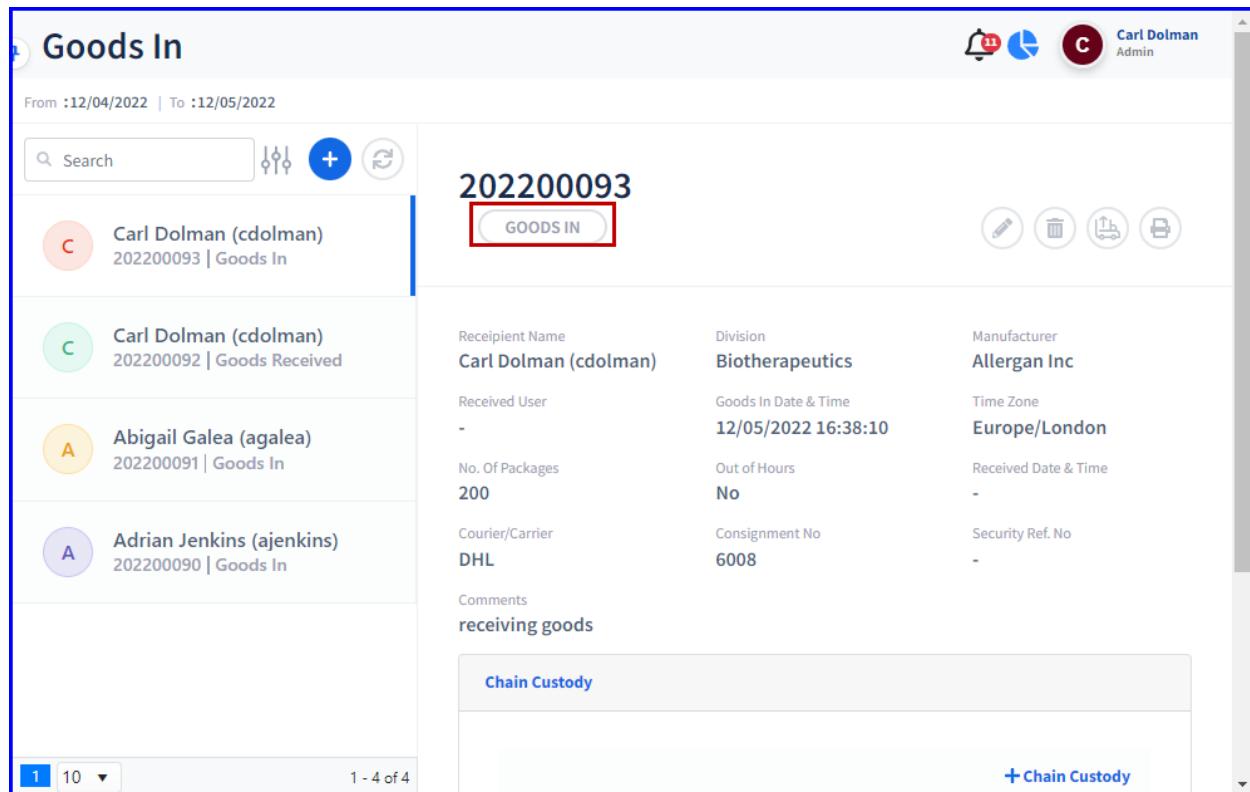
2. In the **Goods In** screen, click  . The **Add Goods In** screen appears as shown in the figure:

Add Goods In
Cancel
 Save
 Save & Continue

Manufacturer * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="Allergan Inc"/>	Goods In Date & Time * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="12/05/2022 16:38:10"/>
Recipient Name * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="Carl Dolman (cdolman)"/>	Time Zone * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="Europe/London"/>
Division * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="Biotherapeutics"/>	Out of Hours <input style="width: 20px; height: 20px;" type="checkbox"/>
No. Of Packages * <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="200"/>	Security Ref. No <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text"/>
Courier/Carrier <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="DHL"/>	Comments <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="receiving goods"/>
Consignment No <input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text" value="6008"/>	<input style="width: 100%; border: 1px solid #ccc; padding: 2px;" type="text"/>

FIGURE: Add Goods In Screen

3. In the **Manufacturer Name** field, type the manufacturer of the goods.
4. In the **Recipient Name** field, select the user who receives the goods. Based on the selected recipient, the Division appears.
5. In the **No. Of Packages** field, type number of packages receiving.
6. In the **Courier/Carrier** field, select the courier or carrier name that delivers the goods to the company.
7. In the **Consignment No** field, type the consignment number.
8. If the time of receiving the goods is out of office hours, then click to turn on the **Out of Hours** option. If the **Out of Hours** option is turned on, then the **Security Ref. No** field becomes mandatory. Type the security reference number.
9. In the **Comments** field, type your comments if any.
10. Click **Save**. The goods are added and appear in the **Goods In** screen with status showing as **GOODS IN** as shown in the figure:



From :12/04/2022 | To :12/05/2022

Search

Recipient Name	Division	Manufacturer
Carl Dolman (cdolman) 202200093 Goods In	Biotherapeutics	Allergan Inc
Carl Dolman (cdolman) 202200092 Goods Received	Goods In Date & Time	Time Zone
Abigail Galea (agalea) 202200091 Goods In	12/05/2022 16:38:10	Europe/London
Adrian Jenkins (ajenkins) 202200090 Goods In	Out of Hours	Received Date & Time
	No	-
	Comments	Security Ref. No
receiving goods	Consignment No	-
	6008	
Chain Custody		
+ Chain Custody		

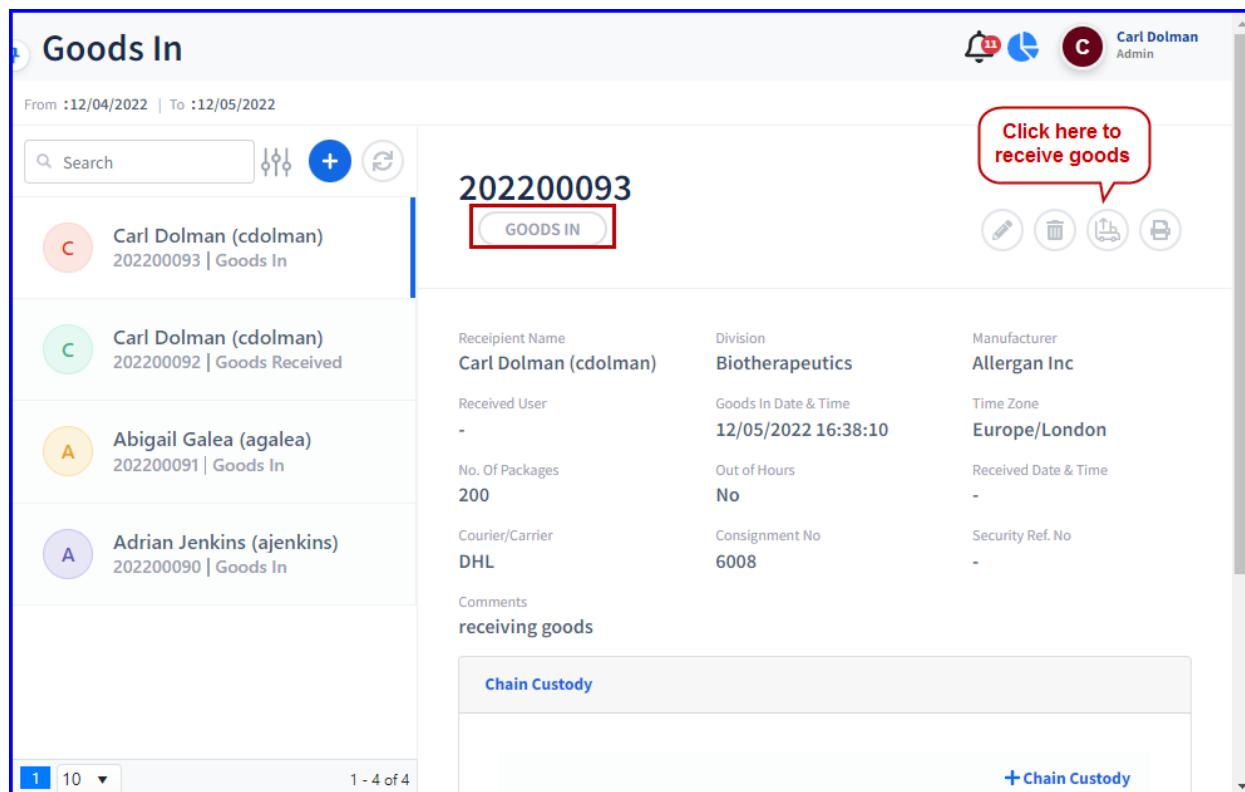
1 10 ▾ 1 - 4 of 4

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:



The screenshot shows the Qualis LIMS Goods In module. At the top, there is a search bar and a date range selector (From: 12/04/2022, To: 12/05/2022). Below the search bar, a list of incoming shipments is displayed:

- Carl Dolman (cdolman) 202200093 | Goods In
- Carl Dolman (cdolman) 202200092 | Goods Received
- Abigail Galea (agalea) 202200091 | Goods In
- Adrian Jenkins (ajenkins) 202200090 | Goods In

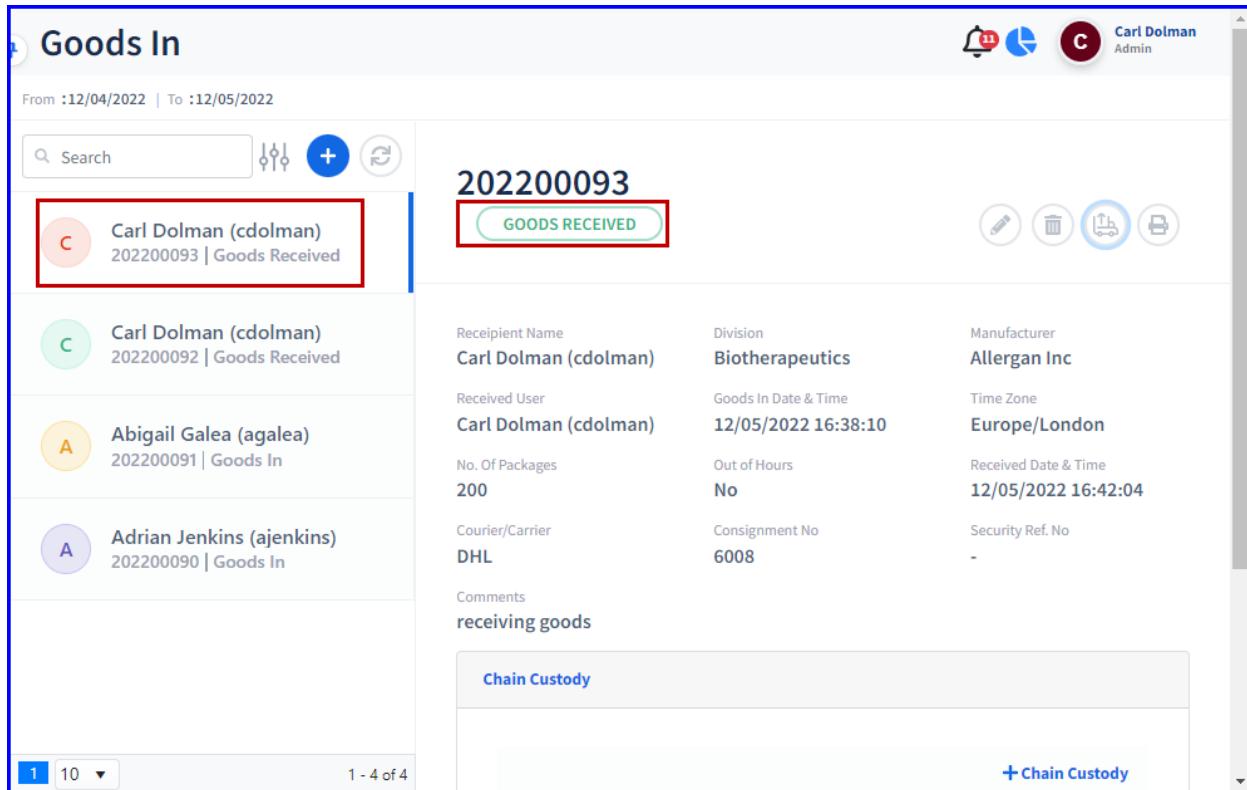
On the right, a detailed view of the shipment with ID 202200093 is shown. The status is highlighted with a red box and labeled "GOODS IN". The detailed information includes:

Recipient Name	Division	Manufacturer
Carl Dolman (cdolman)	Biotherapeutics	Allergan Inc
Received User	Goods In Date & Time	Time Zone
-	12/05/2022 16:38:10	Europe/London
No. Of Packages	Out of Hours	Received Date & Time
200	No	-
Courier/Carrier	Consignment No	Security Ref. No
DHL	6008	-
Comments		
receiving goods		

Below the detailed view, there is a section for "Chain Custody" with a "Chain Custody" button. At the bottom left, there is a page navigation bar showing page 1 of 10.

FIGURE: Receiving Goods

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



The screenshot shows the 'Goods In' screen with a list of received records on the left and a detailed view of a selected record on the right. The selected record is '202200093' for 'Carl Dolman (cdolman)'. The 'GOODS RECEIVED' button is highlighted with a red box. The detailed view includes fields for Recipient Name, Division, Manufacturer, Received User, Goods In Date & Time, Time Zone, No. Of Packages, Out of Hours, Received Date & Time, Courier/Carrier, Consignment No, and Security Ref. No. A comment 'receiving goods' is also present. A 'Chain Custody' section is shown at the bottom right, with a '+ Chain Custody' button.

Recipient Name	Division	Manufacturer
Carl Dolman (cdolman)	Biotherapeutics	Allergan Inc
Received User	Goods In Date & Time	Time Zone
Carl Dolman (cdolman)	12/05/2022 16:38:10	Europe/London
No. Of Packages	Out of Hours	Received Date & Time
200	No	12/05/2022 16:42:04
Courier/Carrier	Consignment No	Security Ref. No
DHL	6008	-
Comments receiving goods		
Chain Custody		

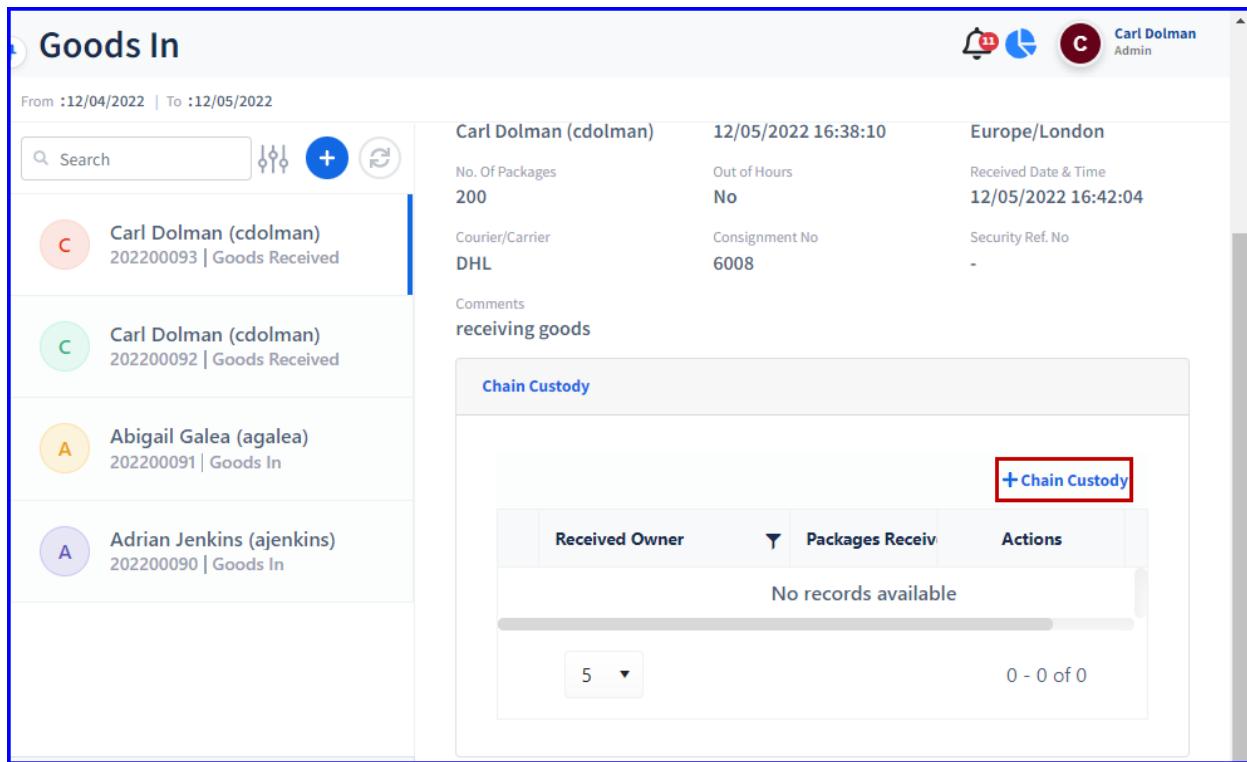
FIGURE: Record in GOODS RECEIVED State

4.1.3 **Chain Custody**

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

To receive goods in storage, follow these steps:

1. In the **Goods In** screen, open the record to split and receive goods in storage.
2. Click **+ Chain Custody** as shown in the figure:



The screenshot shows the Qualis LIMS Goods In module. At the top, there is a search bar with a magnifying glass icon, a date range selector (From: 12/04/2022 | To: 12/05/2022), and a blue plus sign button. To the right, there are notification icons (bell with 10 notifications, blue circle with a checkmark, and a red circle with a minus sign), and a user profile for Carl Dolman (Admin).

The main area displays a list of recent activities:

- Carl Dolman (cdolman) 202200093 | Goods Received
- Carl Dolman (cdolman) 202200092 | Goods Received
- Abigail Galea (agalea) 202200091 | Goods In
- Adrian Jenkins (ajenkins) 202200090 | Goods In

On the right, detailed information for the most recent activity (Carl Dolman, 202200093) is shown:

Carl Dolman (cdolman)	12/05/2022 16:38:10	Europe/London
No. Of Packages	Out of Hours	Received Date & Time
200	No	12/05/2022 16:42:04
Courier/Carrier	Consignment No	Security Ref. No
DHL	6008	-

Comments: receiving goods

Chain Custody

A red box highlights the '+ Chain Custody' button in the top right corner of the Chain Custody section. The section contains a table with the following columns: Received Owner, Packages Receiv, and Actions. The message 'No records available' is displayed below the table. At the bottom, there is a page number '5' and a status '0 - 0 of 0'.

FIGURE: Chain custody Option

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

Add Chain Custody

Cancel **Save**

Goods In Details		
RMS No	Manufacturer	Recipient Name
202200093	Allergan Inc	Carl Dolman (cdolman)
Division	Received User	
Biotherapeutics	Carl Dolman (cdolman)	

Packages Received *

50

Received Date *

12/05/2022

Time Zone *

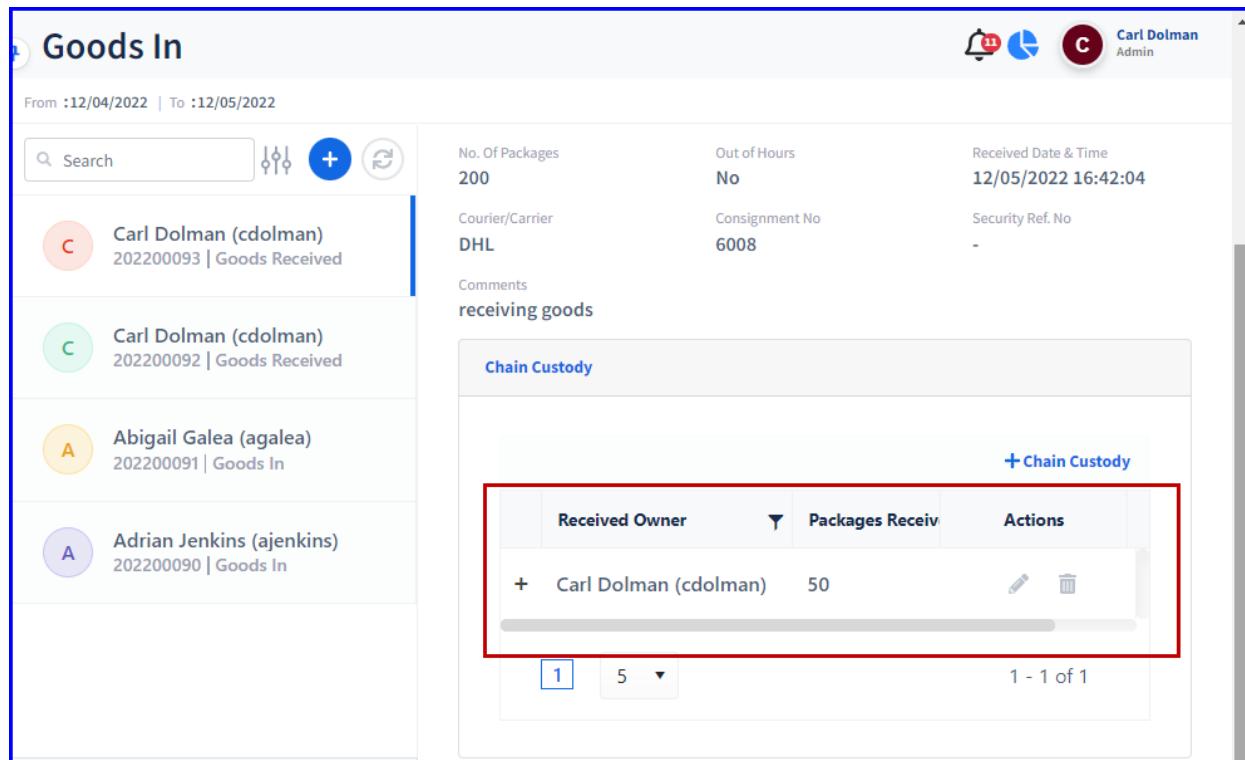
Europe/London

Comments

receiving 50 packages

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:



From :12/04/2022 | To :12/05/2022

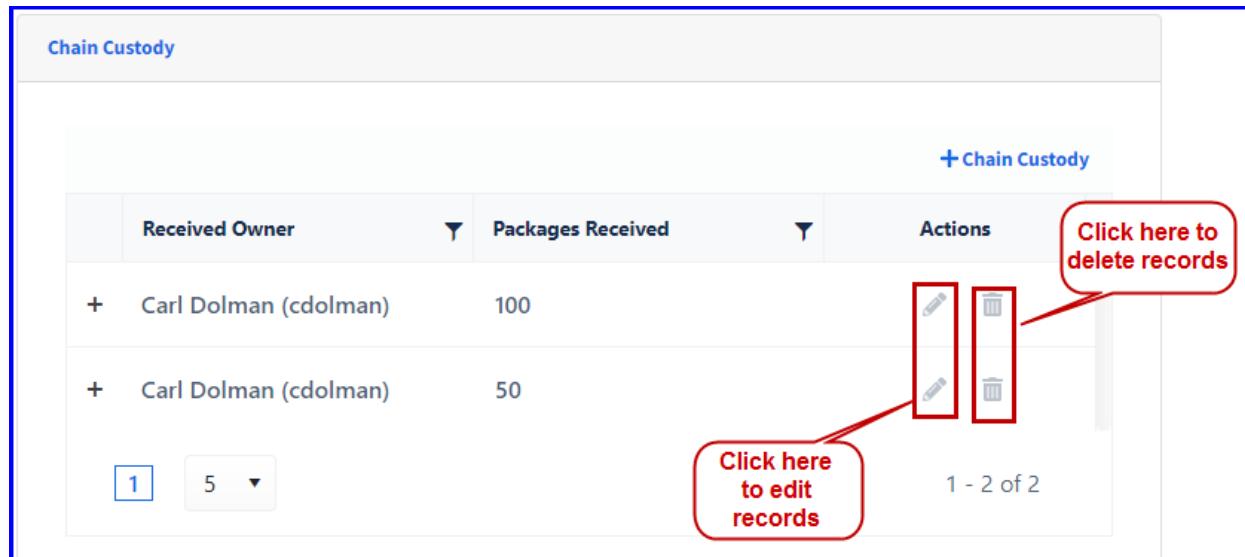
Search Filter Add Print

Received Owner	Packages Received	Actions
Carl Dolman (cdolman)	50	Edit Delete

1 - 1 of 1

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:



Received Owner	Packages Received	Actions
Carl Dolman (cdolman)	100	Edit Delete
Carl Dolman (cdolman)	50	Edit Delete

1 - 2 of 2

FIGURE: Edit and Delete Options for Chain Custody Records

4.1.4 Registration

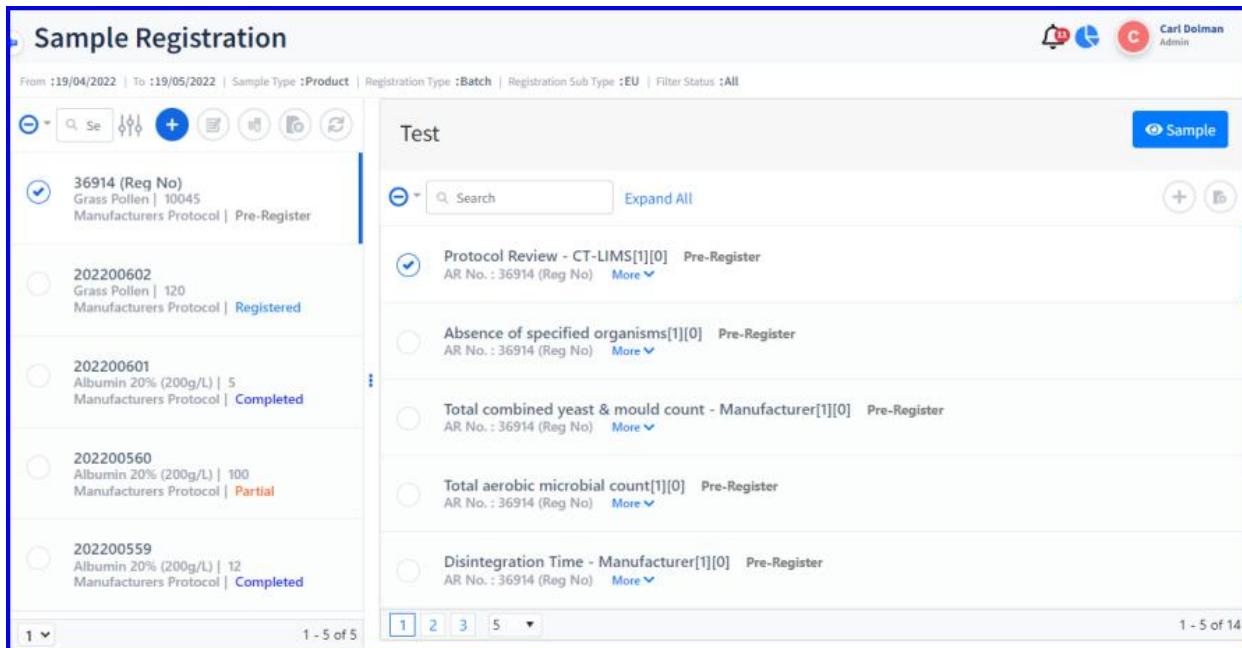
Sample Registration screen is where you add and register sample details. Once you pre-register samples, you can register, add tests and attach files to the samples and then accept the sample to register it. If required, you can cancel the sample registration or quarantine the sample for some reason.

Following is the list of color codes for the sample records in each status:

- Pre-register - Grey
- Registered - Blue
- Completed - Dark blue
- Partial - Red
- Quarantined - Orange
- Cancelled / Rejected - Red

To register a sample, follow these steps:

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



The screenshot shows the 'Sample Registration' screen. The left panel lists samples with their registration numbers, descriptions, and status (e.g., Pre-Register, Registered, Completed, Partial, Quarantined, Rejected). The right panel shows a list of tests for a specific sample, including their names, descriptions, and status. The interface includes various buttons for search, filter, and sample management.

FIGURE: Sample Registration Screen

Click  in the Filter dialog, select **From** and **To** date, **Sample Type**: Product, **Registration Type**: Batch / Non Batch / Plasma Pool, **Registration Sub Type** and **Filter Status**. And then click **SUBMIT** as shown in the figure:

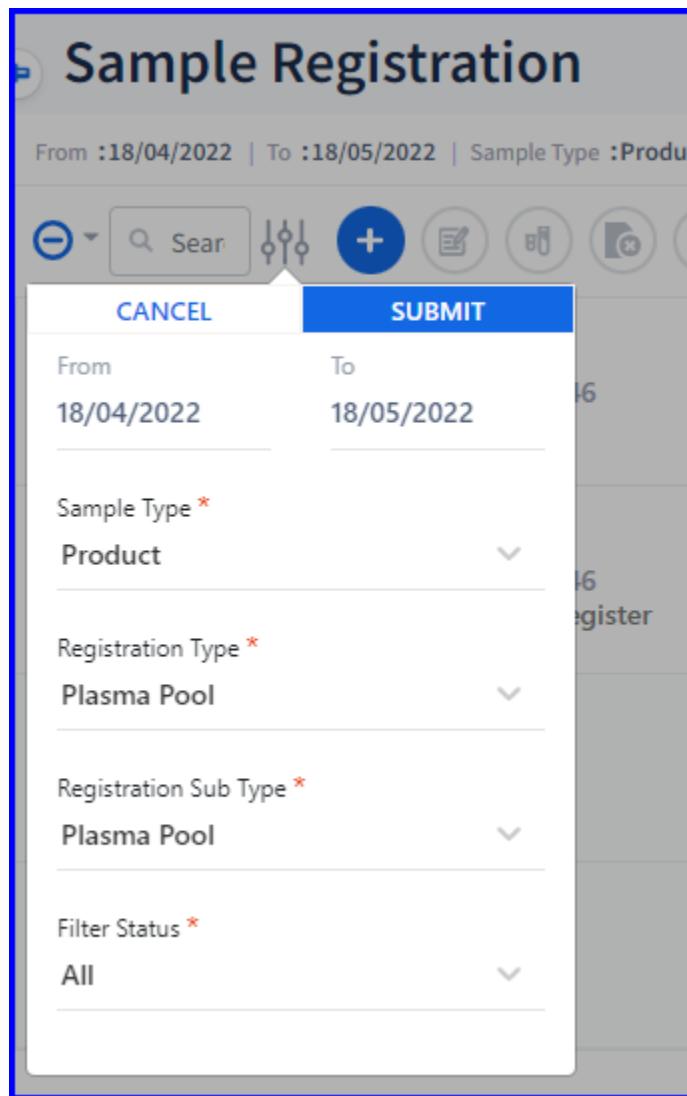


FIGURE: Using Filter in Registration Screen

List of samples registered for the selected criteria appears. You can register sample for the selected Registration Type and Registration Sub Type.

2. Click  to register a sample. The screen appears as shown in the figure:

Add Plasma Pool(Plasma Pool)

Study plan for the selected product appears here

Click here to get components from the study plan

Click here to add Manufacturer Lot No in Edit dialog

View list of tests in the selected component

Add tests to the component if required

Click here to add source of the sample

Component

Component Name	Manuf Lot No	No Of Container	Pool/Bulk Volume	Plasma Master File #	Actions
Final Lot Protocol Revi...	10046	1	1		 
OCABR Certificate	10046	1	1		 

Test

Test Name	Lab	Source	Method	Actions
Protocol signed and d...	Coronavirus m...	NIBSC	MAH A	
Protocol review - WB ...	Coronavirus m...	NIBSC	MAH A	

Source

Source	Actions
No records available	

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:

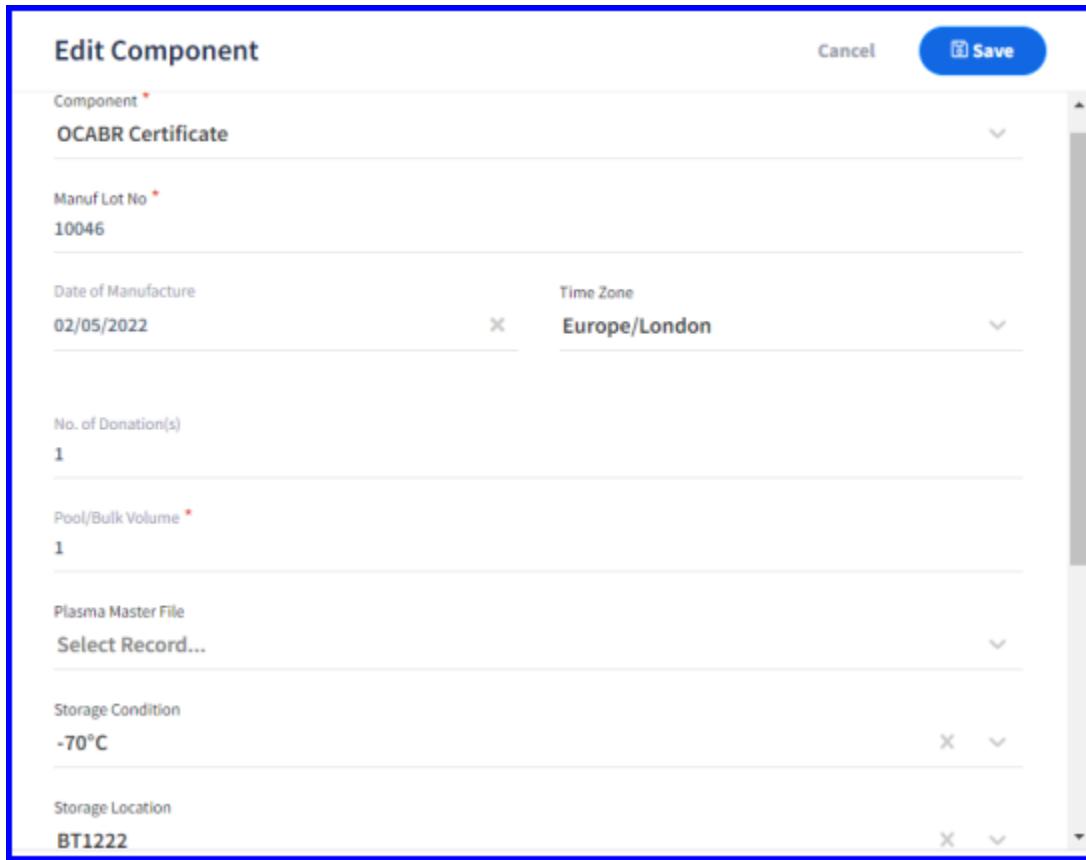


FIGURE: Edit Component Dialog

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:

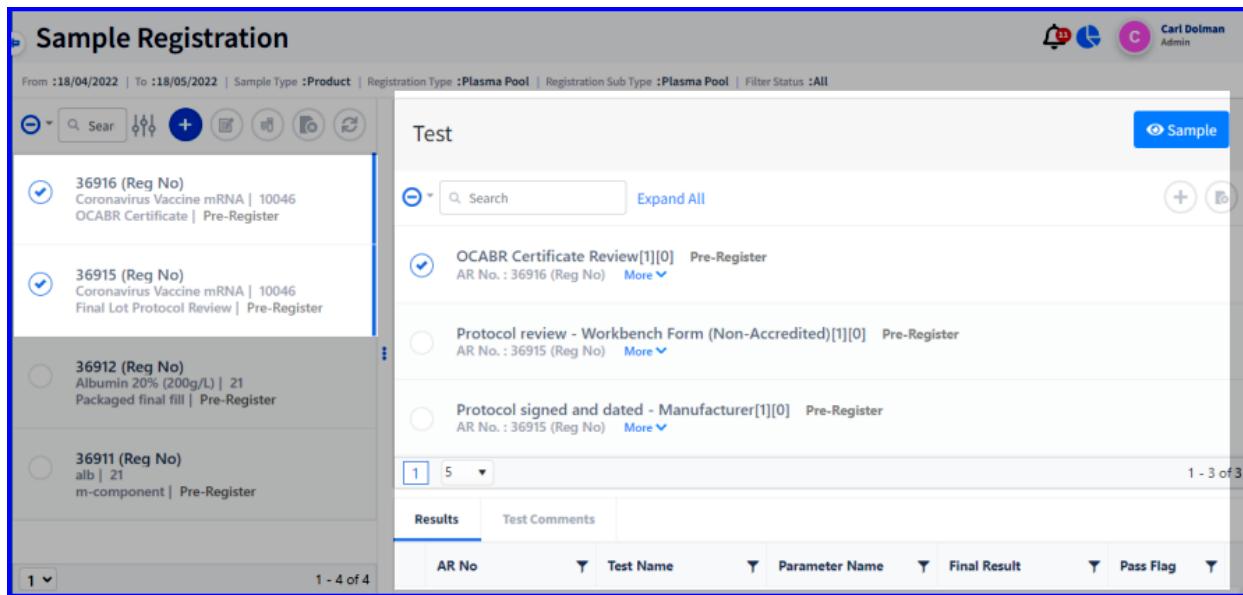


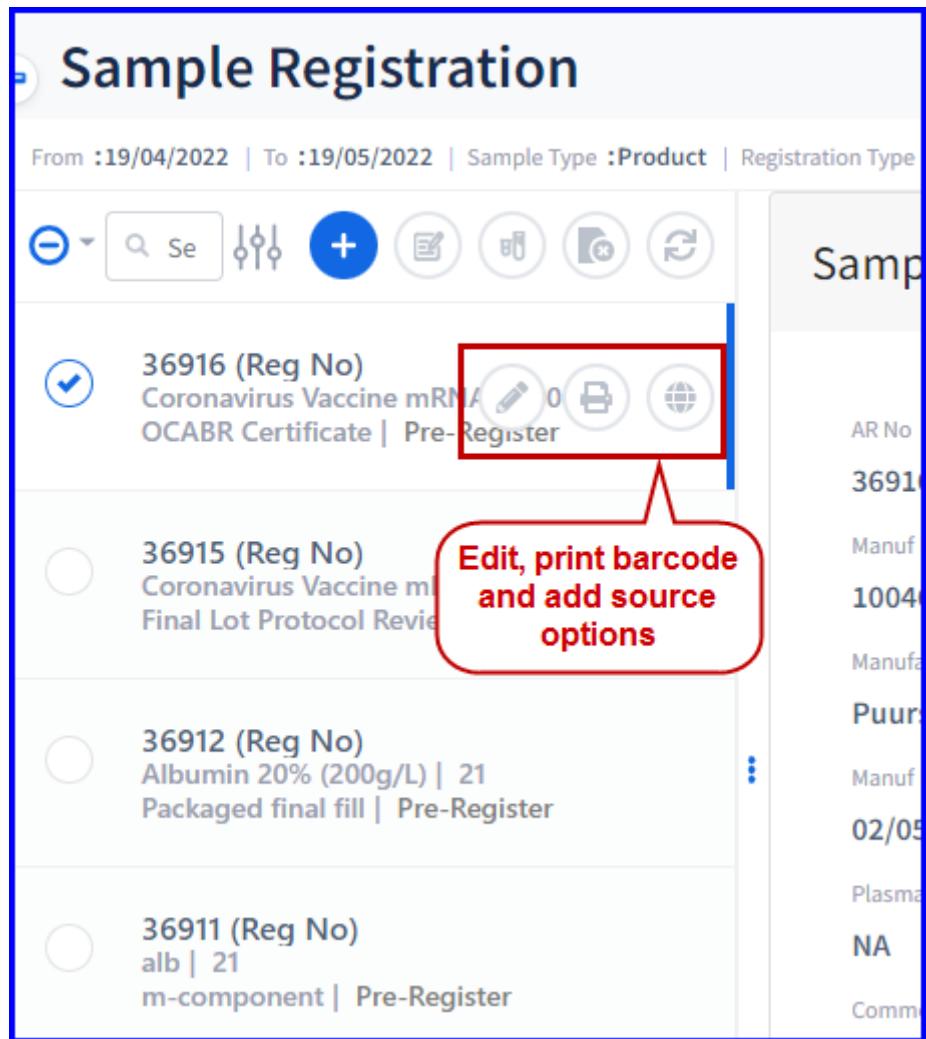
FIGURE: Registered Sample

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:



Sample Registration

From :19/04/2022 | To :19/05/2022 | Sample Type :Product | Registration Type

Sample Registration

36916 (Reg No)
Coronavirus Vaccine mRNA
OCABR Certificate | Pre-Register

36915 (Reg No)
Coronavirus Vaccine mRNA
Final Lot Protocol Review

36912 (Reg No)
Albumin 20% (200g/L) | 21
Packaged final fill | Pre-Register

36911 (Reg No)
alb | 21
m-component | Pre-Register

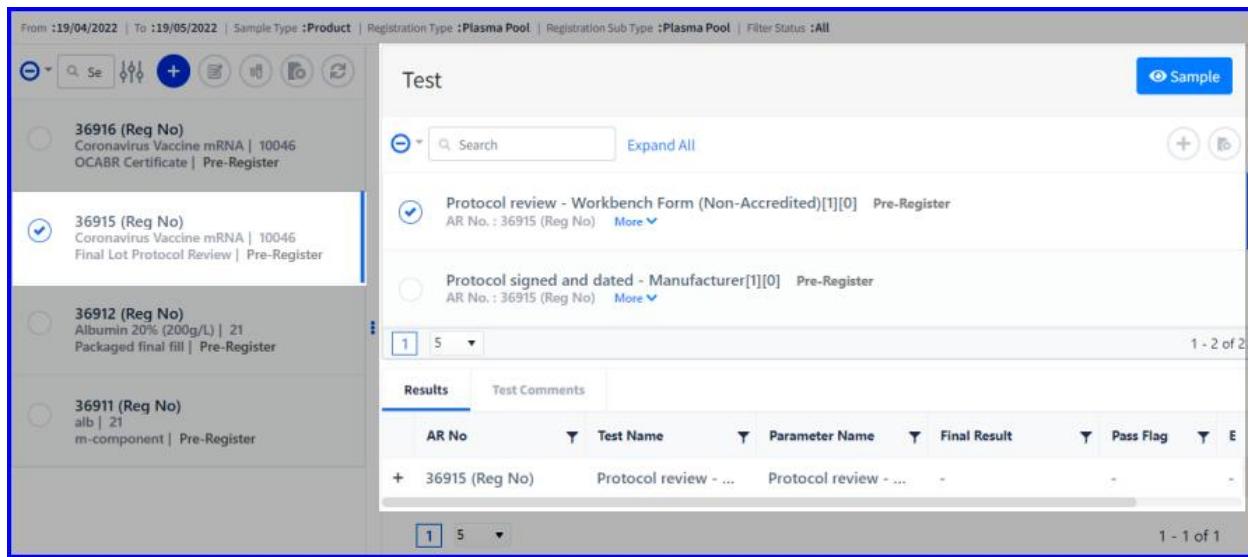
Edit, print barcode and add source options

Sample ID	Sample Name	Registration Type	Manufacturer	Manufacture Date	Plasma Type	Comments
36916	Coronavirus Vaccine mRNA	OCABR Certificate Pre-Register	1004	02/05	Plasma	NA
36915	Coronavirus Vaccine mRNA	Final Lot Protocol Review	1004	02/05	Plasma	NA
36912	Albumin 20% (200g/L) 21	Packaged final fill Pre-Register	1004	02/05	Plasma	NA
36911	alb 21	m-component Pre-Register	1004	02/05	Plasma	NA

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:



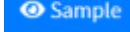
AR No.	Test Name	Parameter Name	Final Result	Pass Flag	E
36915 (Reg No)	Protocol review - ...	Protocol review - ...	-	-	-

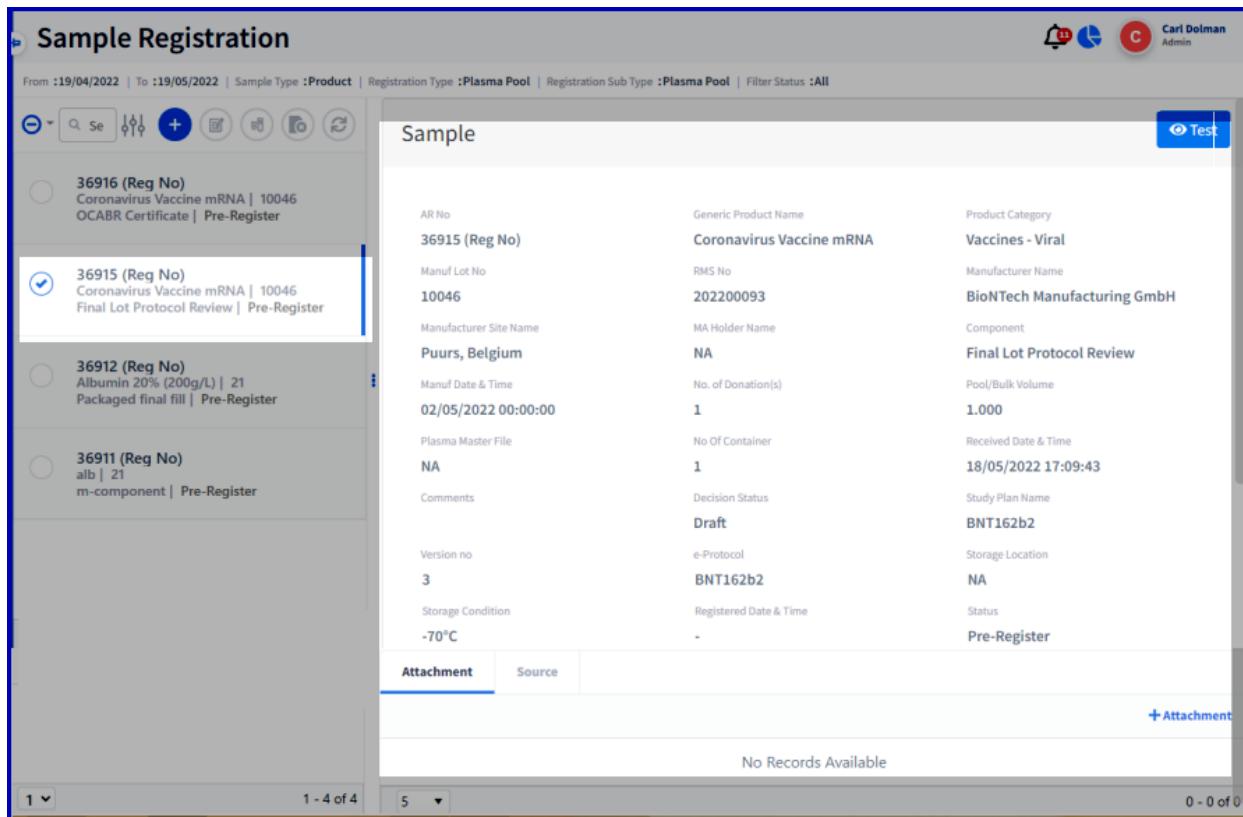
FIGURE: Viewing Tests Added to the Sample

Click  to add more test(s) to the selected sample registered.

Select a test and then click  to cancel / Reject test.

4.1.4.3 Viewing Sample Details

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



The screenshot shows the 'Sample Registration' screen. On the left, a list of samples is displayed, including:

- 36916 (Reg No) - Coronavirus Vaccine mRNA | 10046 OCABR Certificate | Pre-Register
- 36915 (Reg No)** - **Coronavirus Vaccine mRNA | 10046** Final Lot Protocol Review | Pre-Register (selected)
- 36912 (Reg No) - Albumin 20% (200g/L) | 21 Packaged final fill | Pre-Register
- 36911 (Reg No) - alb | 21 m-component | Pre-Register

The right panel shows the details for the selected sample (36915):

AR No	36915 (Reg No)	Generic Product Name	Coronavirus Vaccine mRNA	Product Category	Vaccines - Viral
Manuf Lot No	10046	RMS No	202200093	Manufacturer Name	BioNTech Manufacturing GmbH
Manufacturer Site Name	Puurs, Belgium	MA Holder Name	NA	Component	Final Lot Protocol Review
Manuf Date & Time	02/05/2022 00:00:00	No. of Donation(s)	1	Pool/Bulk Volume	1.000
Plasma Master File	NA	No Of Container	1	Received Date & Time	18/05/2022 17:09:43
Comments		Decision Status	Draft	Study Plan Name	BNT162b2
Version no	3	e-Protocol	BNT162b2	Storage Location	NA
Storage Condition	-70°C	Registered Date & Time	-	Status	Pre-Register
Attachment		Source			
+ Attachment					
No Records Available					

Navigation: 1 - 4 of 4 | 5 - 5 of 5 | 0 - 0 of 0

FIGURE: Viewing Sample Details

Click **+ Attachment** to add attachments to the sample.

4.1.4.4 Register Sample

In the Pre-Register state, you can accept the sample.

1. In the Sample Registration screen, select a sample that is in the **Pre Register** state and then click  to accept the sample as shown in the figure:

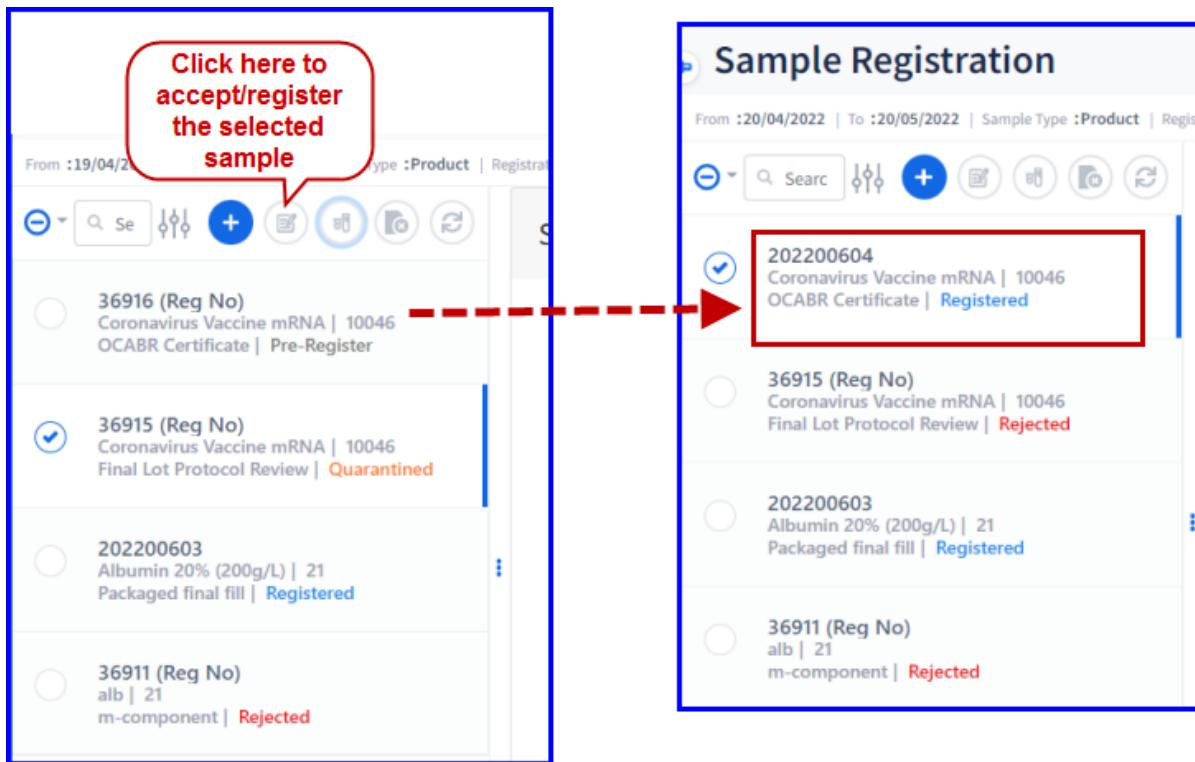


FIGURE: Accepting Sample

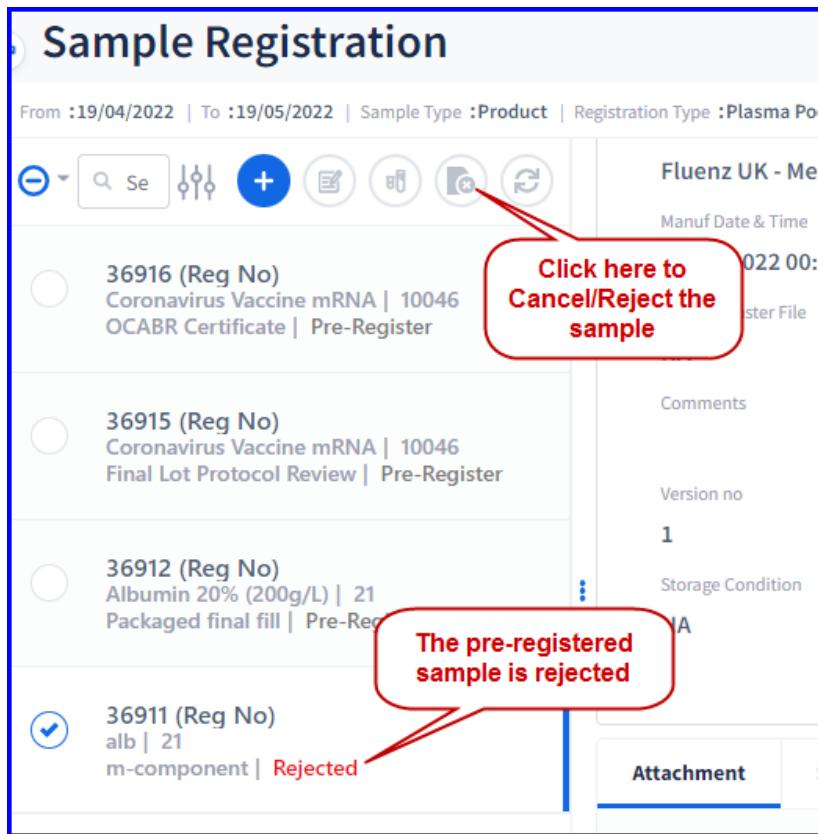
2. In the **Confirmation** dialog, click **Ok**.

The accepted sample appears as **Registered** and the AR No is generated as shown in the above figure.

4.1.4.5 Cancel/Reject

You can cancel/reject the sample before or after registration.

1. To cancel/reject the sample, in the **Sample Registration** screen, select the sample and then click  as shown in the figure:



Sample Registration

From :19/04/2022 | To :19/05/2022 | Sample Type :Product | Registration Type :Plasma Pool

		Fluenz UK - Me	Manuf Date & Time	Comments	Version no	Storage Condition	Attachment
<input type="radio"/>	36916 (Reg No) Coronavirus Vaccine mRNA 10046 OCABR Certificate Pre-Register		022 00:				
<input type="radio"/>	36915 (Reg No) Coronavirus Vaccine mRNA 10046 Final Lot Protocol Review Pre-Register				1		
<input type="radio"/>	36912 (Reg No) Albumin 20% (200g/L) 21 Packaged final fill Pre-Reg					IA	
<input checked="" type="radio"/>	36911 (Reg No) alb 21 m-component Rejected						

FIGURE: Cancel / Reject Sample

2. If you cancel/reject sample in the preregister stage then the sample is rejected.
3. If you cancel/reject sample in the registered stage then the sample is cancelled

4.1.4.6 Quarantine

You can quarantine the sample that is in the Pre-register state.

1. To quarantine the sample, in the **Sample Registration** screen, select the sample and then click  as shown in the figure:

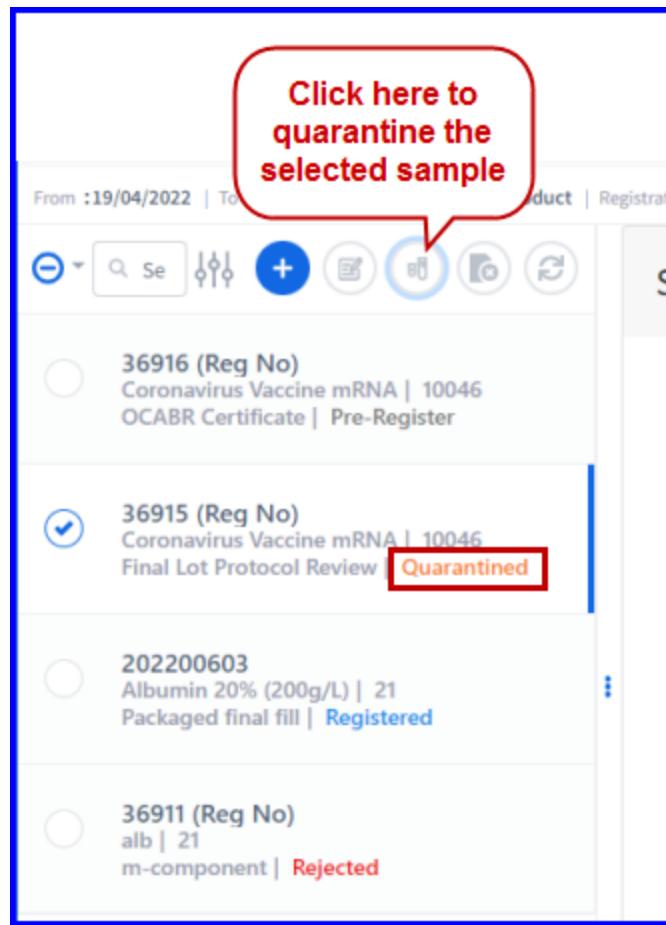
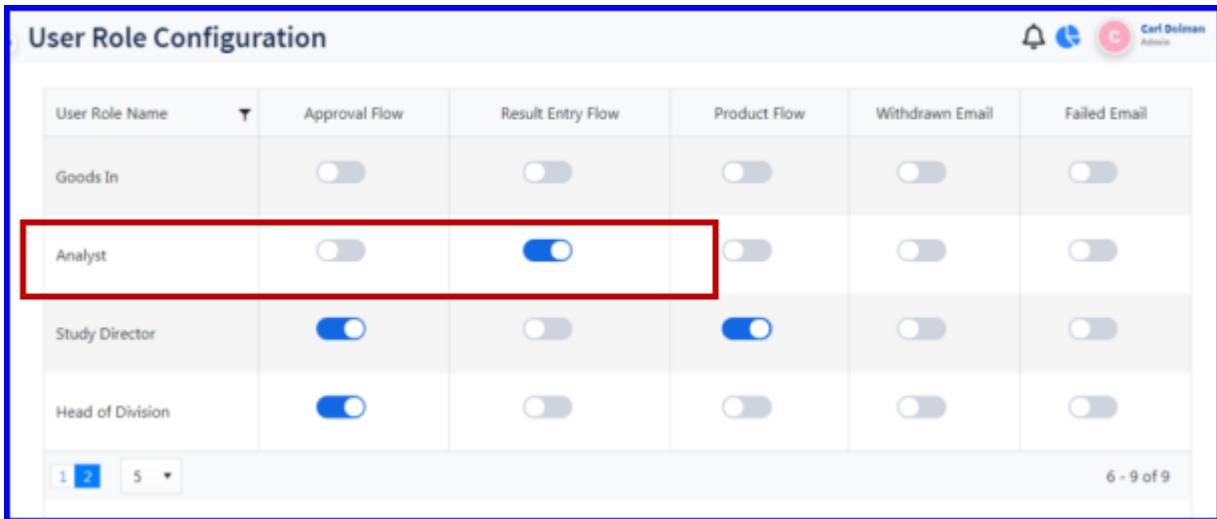


FIGURE: Quarantine Sample

The status of the sample appears as **Quarantined**. You can accept a quarantined sample to register it or cancel/reject it.

4.2 Result Entry

The result entry flow will be available for the users enabled in the User Role Configuration screen as shown in the figure:

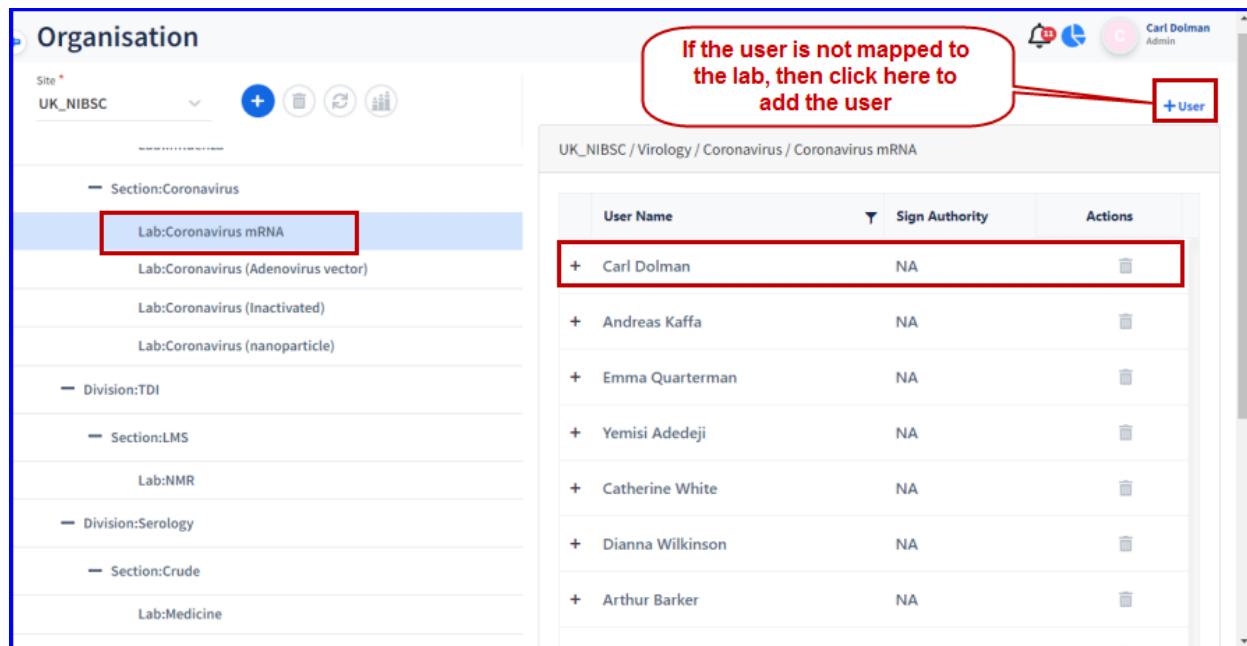


The screenshot shows a table titled 'User Role Configuration' with columns: User Role Name, Approval Flow, Result Entry Flow, Product Flow, Withdrawn Email, and Failed Email. The 'Result Entry Flow' column for the 'Analyst' role is highlighted with a red box. The 'Analyst' row is also highlighted with a red box. The table has a footer with page numbers 1, 2, 5, and a total of 6 - 9 of 9.

User Role Name	Approval Flow	Result Entry Flow	Product Flow	Withdrawn Email	Failed Email
Goods In	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Analyst	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study Director	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Head of Division	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FIGURE: User Role Configuration Screen Showing Result Entry Flow

Also ensure that the user is mapped to the lab the test is mapped to as shown in the Organisation screen:



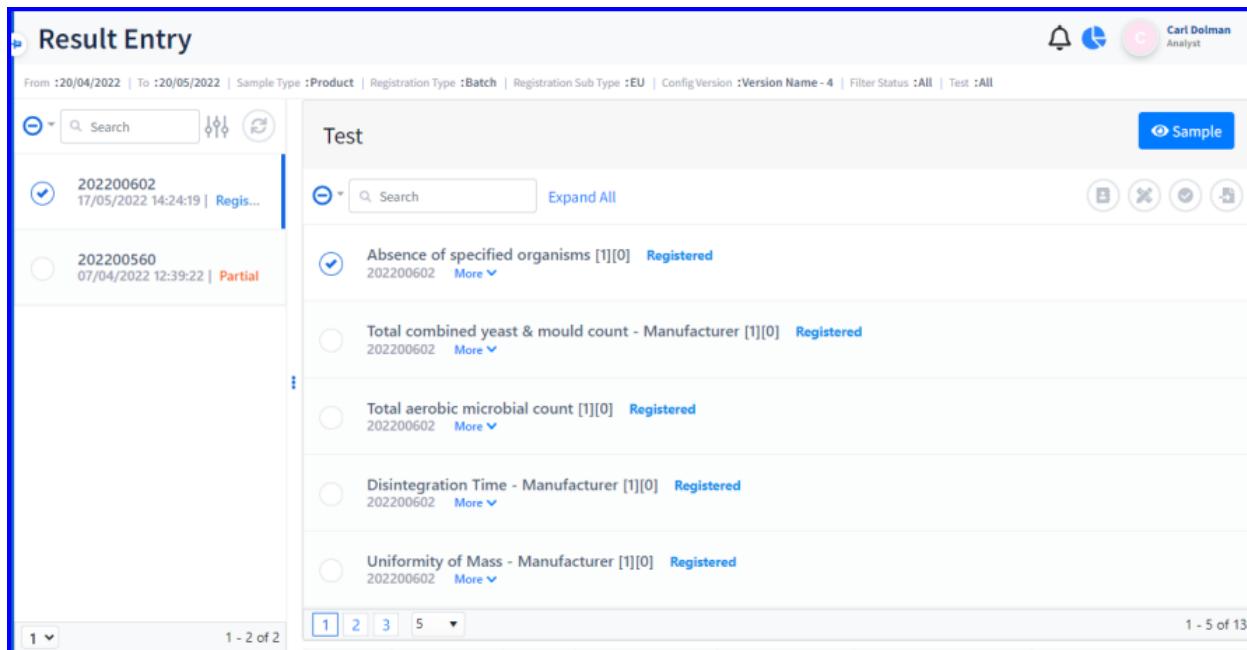
The screenshot shows the 'Organisation' screen. On the left, there is a tree view of sites and sections. A red box highlights the 'Lab:Coronavirus mRNA' node under the 'Section:Coronavirus' section. On the right, a list of users is shown for the 'UK_NIBSC / Virology / Coronavirus / Coronavirus mRNA' lab. A red box highlights the first user, 'Carl Dolman'. A callout bubble with the text 'If the user is not mapped to the lab, then click here to add the user' points to the 'User' button in the top right corner of the user list table.

User Name	Sign Authority	Actions
Carl Dolman	NA	
Andreas Kaffa	NA	
Emma Quarterman	NA	
Yemisi Adedeji	NA	
Catherine White	NA	
Dianna Wilkinson	NA	
Arthur Barker	NA	

FIGURE: Organisation Screen Showing User Mapped to the Test Lab

For registered samples, you can enter results. To do so, follow these steps:

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



Result Entry

From :20/04/2022 | To :20/05/2022 | Sample Type :Product | Registration Type :Batch | Registration Sub Type :EU | Config Version :Version Name - 4 | Filter Status :All | Test :All

Test

Sample

Search

Expand All

Absence of specified organisms [1][0] Registered
202200602 More

Total combined yeast & mould count - Manufacturer [1][0] Registered
202200602 More

Total aerobic microbial count [1][0] Registered
202200602 More

Disintegration Time - Manufacturer [1][0] Registered
202200602 More

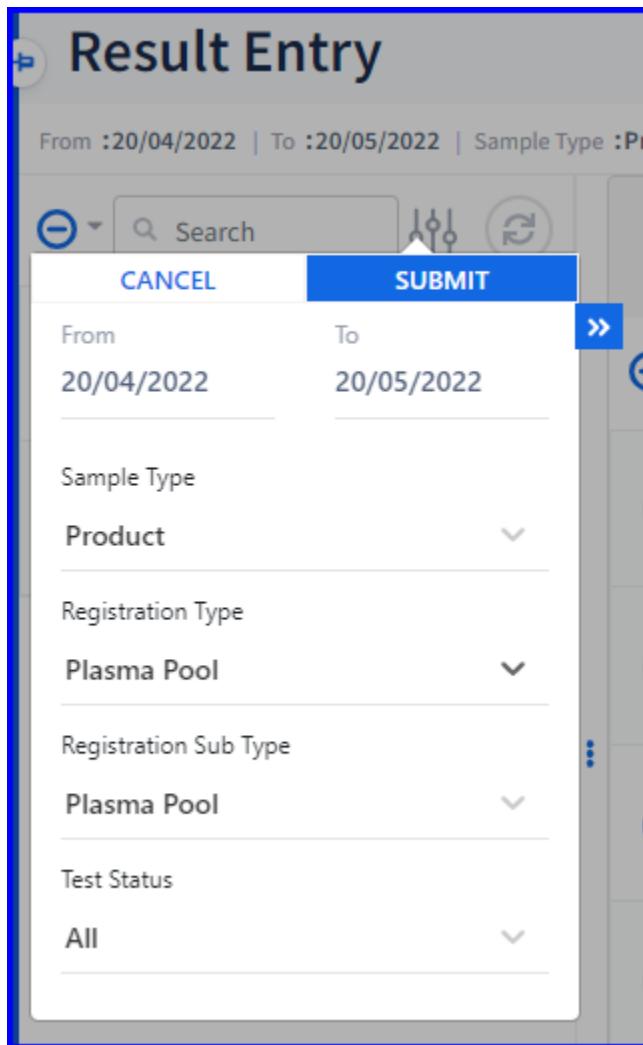
Uniformity of Mass - Manufacturer [1][0] Registered
202200602 More

1 - 2 of 2

1 - 5 of 13

FIGURE: Result Entry Screen

Click  in the Filter dialog, select **From** and **To** date, **Sample Type**: Product, **Registration Type**: Batch / Non Batch / Plasma Pool, **Registration Sub Type** and **Filter Status**. And then click **SUBMIT** as shown in the figure:

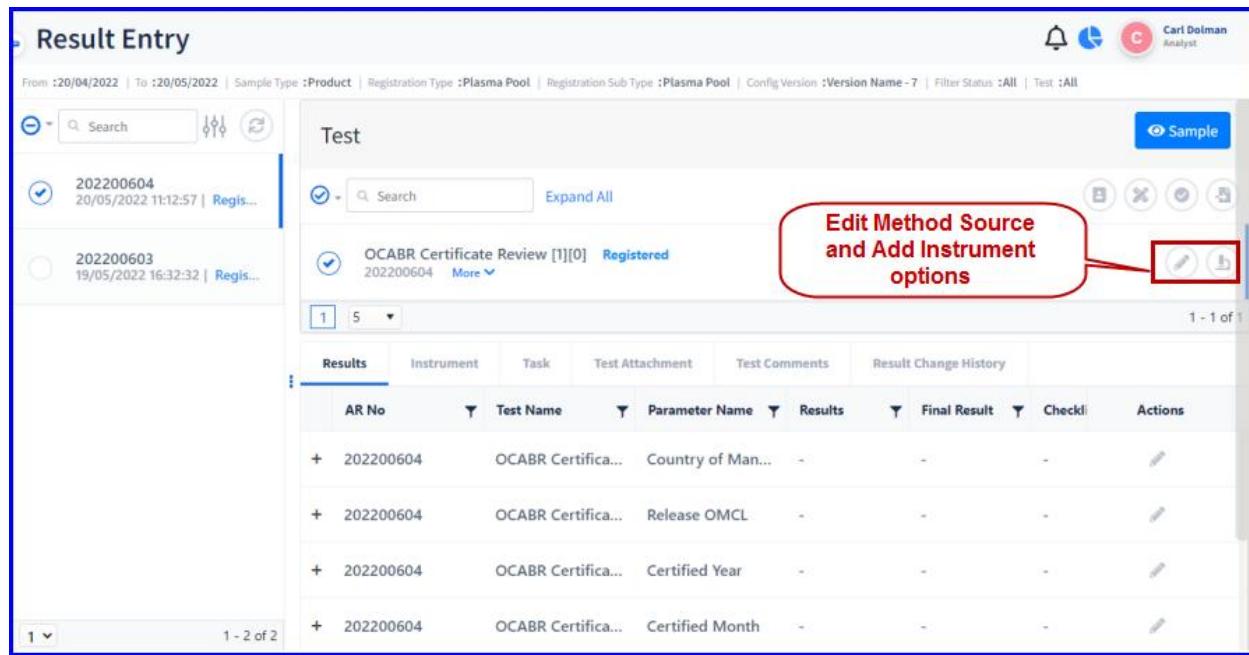


The screenshot shows the 'Result Entry' screen with a search bar at the top. Below the search bar are two buttons: 'CANCEL' and 'SUBMIT'. The 'SUBMIT' button is highlighted in blue. Below these buttons are two date fields: 'From' (20/04/2022) and 'To' (20/05/2022). To the right of these fields is a double arrow icon. The main body of the screen contains several dropdown menus and labels:

- Sample Type: Product
- Registration Type: Plasma Pool
- Registration Sub Type: Plasma Pool
- Test Status: All

FIGURE: Using Filter in Result Entry Screen

Registered samples in the Sample Registration screen appears on the left panel and list of tests added to the selected sample appears on the right side as shown in the figure:



The screenshot shows the 'Result Entry' screen in Qualis LIMS. At the top, there are search and filter options, and a user profile for 'Carl Dolman Analyst'. Below this, a list of registered samples is shown. A specific sample, '202200604', is selected and expanded. The expanded view shows the test details: 'OCABR Certificate Review [1][0] Registered 202200604'. A red callout box with the text 'Edit Method Source and Add Instrument options' points to the 'Edit' icon in the toolbar of this expanded view. Below the expanded view is a table of test results, with the first four rows visible. The table columns are: AR No, Test Name, Parameter Name, Results, Final Result, Checklist, and Actions.

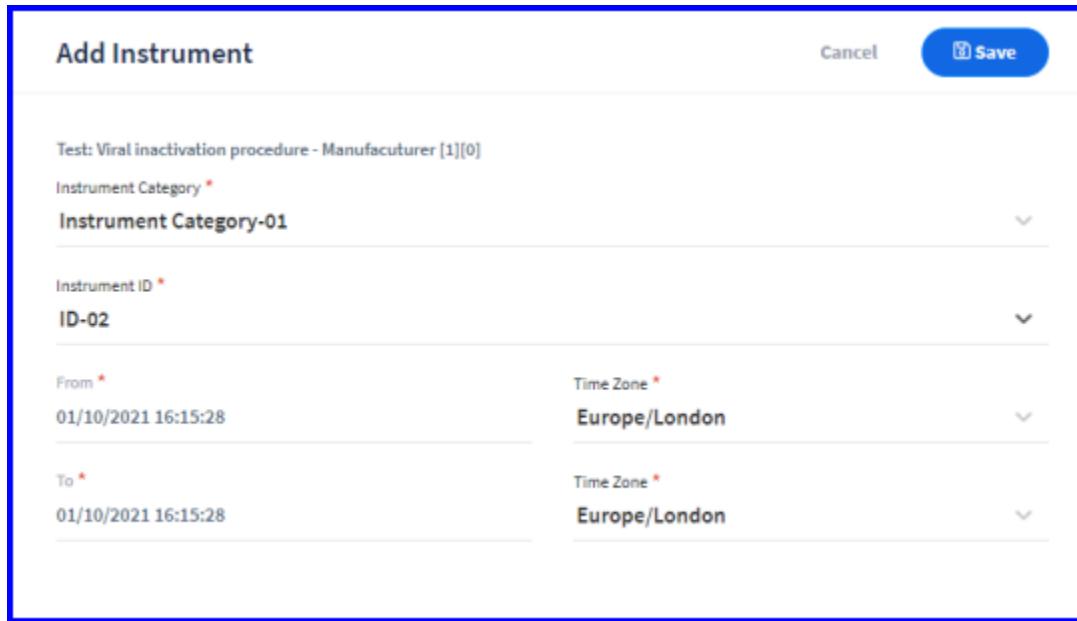
AR No	Test Name	Parameter Name	Results	Final Result	Checklist	Actions
202200604	OCABR Certifica...	Country of Man...	-	-	-	
202200604	OCABR Certifica...	Release OMCL	-	-	-	
202200604	OCABR Certifica...	Certified Year	-	-	-	
202200604	OCABR Certifica...	Certified Month	-	-	-	

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

Edit Method Source

4.2.1 Adding Instruments

1. When you mouse over a test in the list you can see option for adding instrument to the test.
2. Mouse over a test and click . The Add Instrument dialog appears as shown in the figure:



Add Instrument

Test: Viral inactivation procedure - Manufacuturer [1][0]

Instrument Category *

Instrument Category-01

Instrument ID *

ID-02

From *

01/10/2021 16:15:28

Time Zone *

Europe/London

To *

01/10/2021 16:15:28

Time Zone *

Europe/London

Cancel  Save

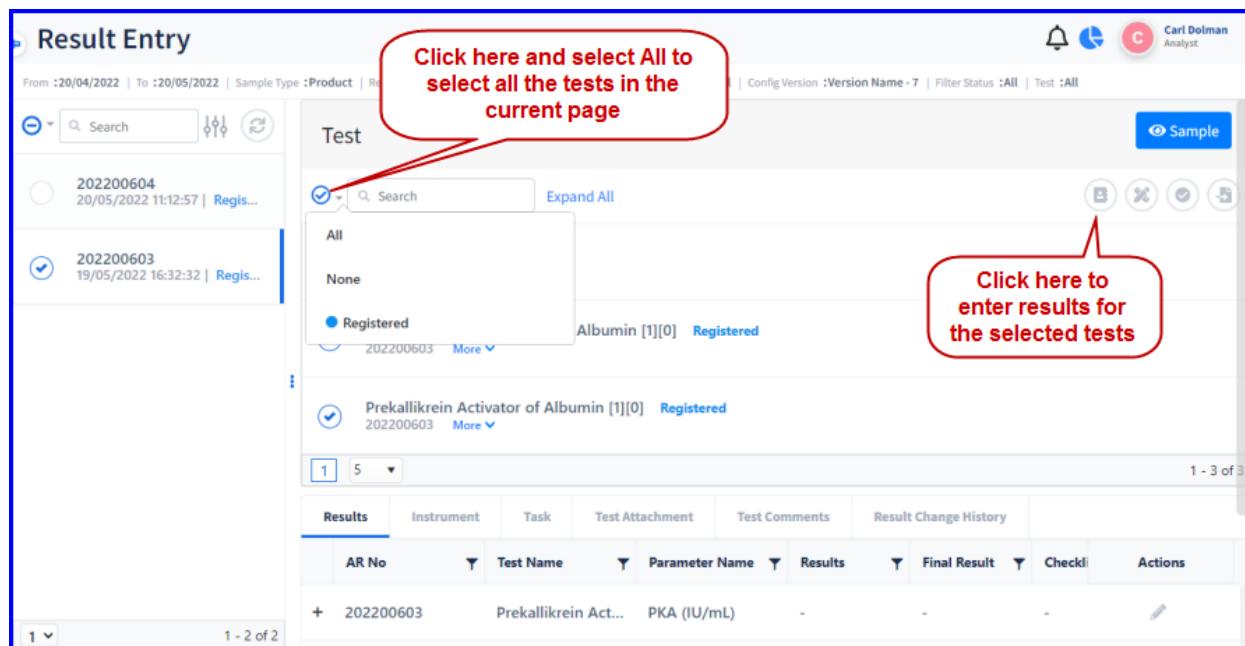
FIGURE: Add Instrument Dialog

3. In the **Instrument Category** field, select instrument category.
4. In the **Instrument** field, select the instrument to add to the selected test.
5. In the **From** and **To** date and time fields select date and time range to block the instrument for the test.
6. Click **Save**. The instrument will be added to the test and blocked for the given date and time range.

4.2.2 Result Entry

You can enter results for each test individually or select multiple tests from the list for result entry.

1. Select test(s) and then click . To select all the tests click  that appears near search box and then select **All** to select all the test in the page as shown in the figure:



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

Result Entry

202200603

Appearance [1][0]

Appearance

Complies

PASS

202200603

Molecular size distribution of Albumin [1][0]

P&A (%)

.2

PASS

202200603

Prekallikrein Activator of Albumin [1][0]

PKA (IU/mL)

20

PASS

Cancel

FIGURE: Result Entry for Multiple Tests

3. Enter results for all the test in the dialog and then click **Save**. Same way, you can go to the next page and then select tests for result entry.

Note: If you have selected one test, the Result Entry dialog will prompt for the selected single test.

4.2.3 Result Entry Screen Tabs

Following tabs are available in the Result Entry screen:

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

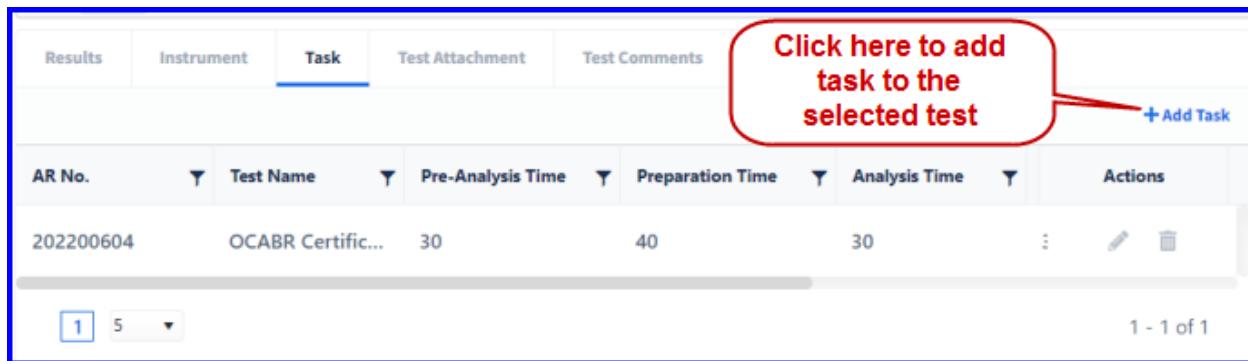
Results	Instrument	Task	Test Attachment	Test Comments	Result Change History		
AR No	Test Name	Parameter Name	Results	Final Result	Checkli	Actions	
+ 202200604	OCABR Certifica...	Country of Man...	Belgium	Belgium	-		
+ 202200604	OCABR Certifica...	Release OMCL	AT_BASG_B	AT_BASG_B	-		
+ 202200604	OCABR Certifica...	Certified Year	2022	2022	-		
+ 202200604	OCABR Certifica...	Certified Month	April	April	-		
+ 202200604	OCABR Certifica...	Certified Day	02	02	-		

4.2.3.1 Instruments

View instruments added to the selected tests.

Results	Instrument	Task	Test Attachment	Test Comments	Result Change History		
AR No	Test Name	Instrument Category	Instrument Name				
202200604	OCABR Certificate Review [1...]	Manual	fdsafds				
1 5 ▾							1 - 1 of 1

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



Click here to add task to the selected test

+ Add Task

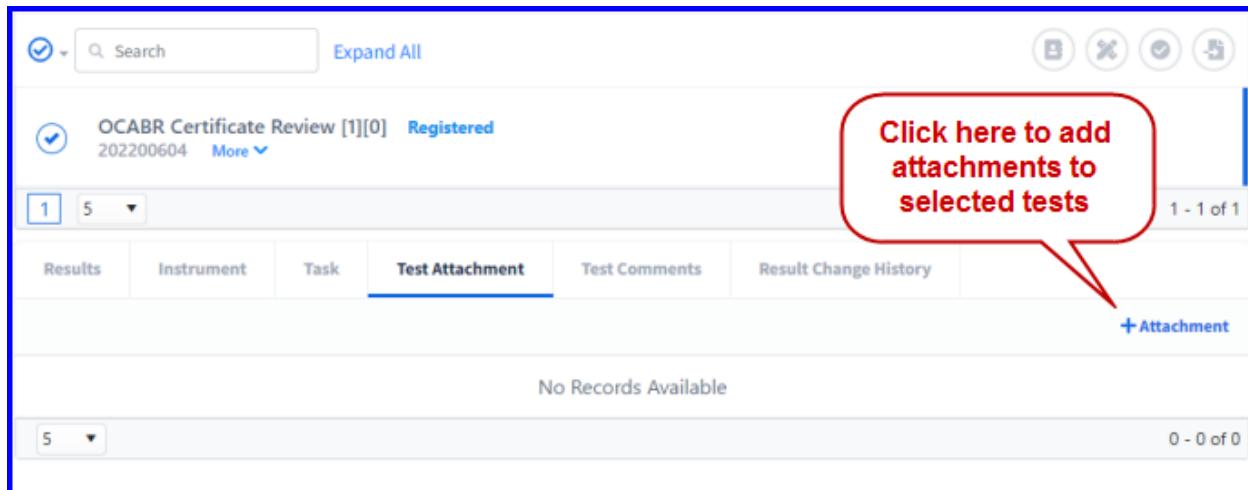
AR No.	Test Name	Pre-Analysis Time	Preparation Time	Analysis Time	Actions
202200604	OCABR Certific...	30	40	30	 

1 5 ▾ 1 - 1 of 1

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:



Click here to add attachments to selected tests

+ Attachment

Results	Instrument	Task	Test Attachment	Test Comments	Result Change History
No Records Available					

5 ▾ 0 - 0 of 0

FIGURE: Attaching files to tests

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

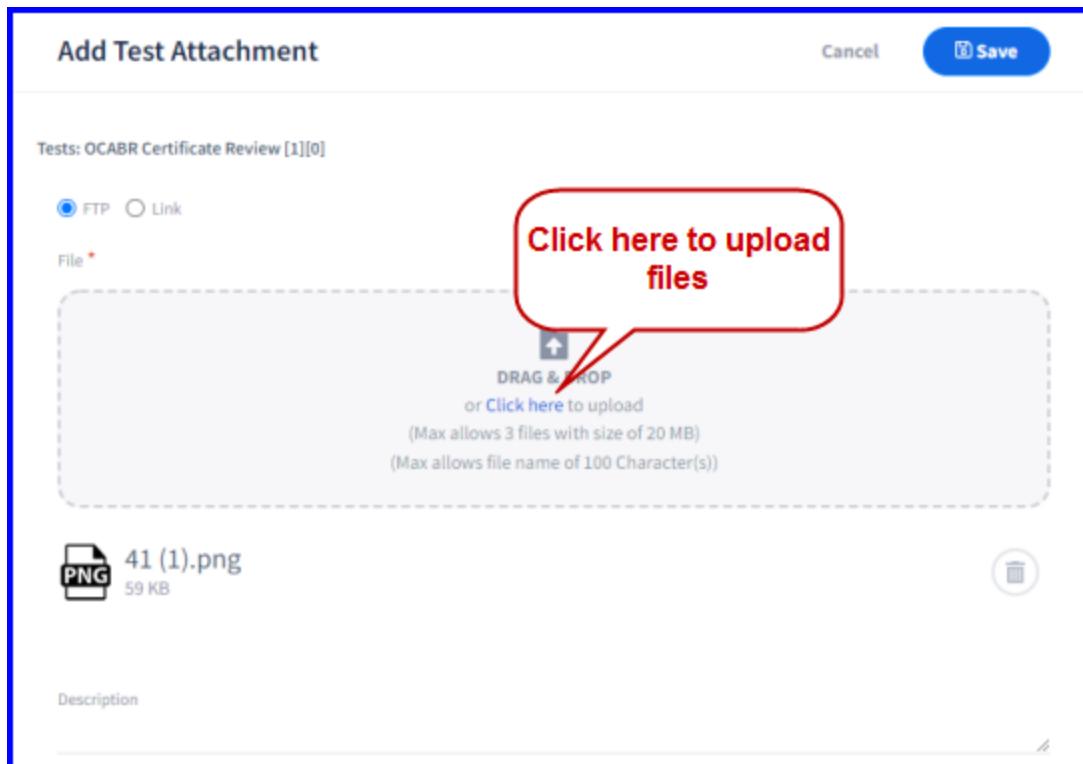


FIGURE: Add Test Attachment Dialog

Do any one of the following:

Select **FTP**. Then drag and drop a file to attach. Or Click [Click here](#) to locate and attach the file and then click **Save**.

Or

Select **Link**. Type the **File Name** and paste the link in the **Link Name** field and then click **Save**.

The file is attached to the test(s) as shown in the figure:

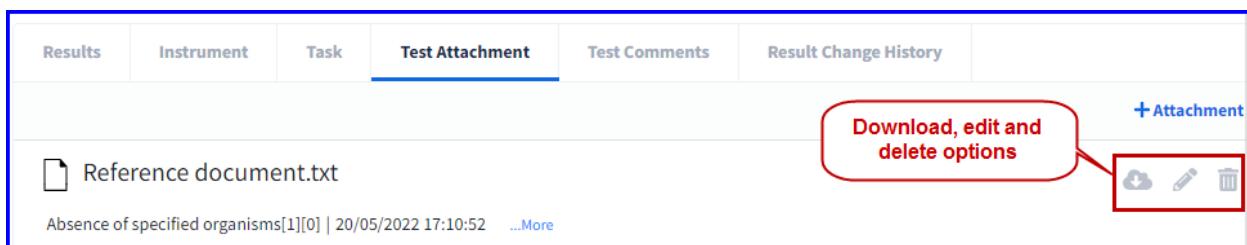
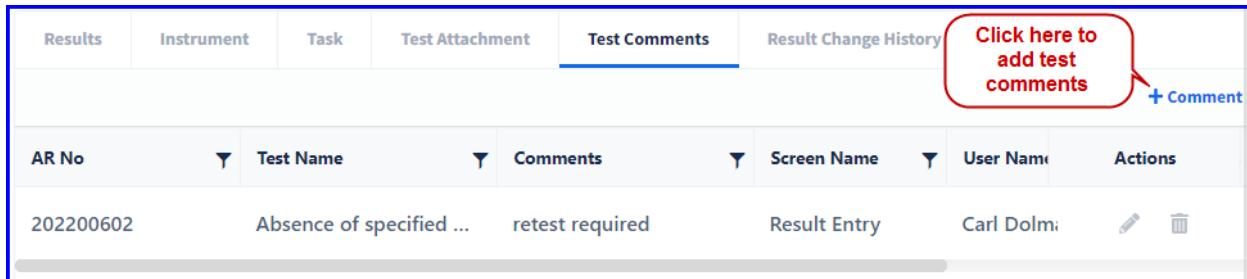


FIGURE: Attachment Added to the selected Test(s)

4.2.3.3 Test Comments

Test Comments tab enables you to add test comments to the selected test(s).

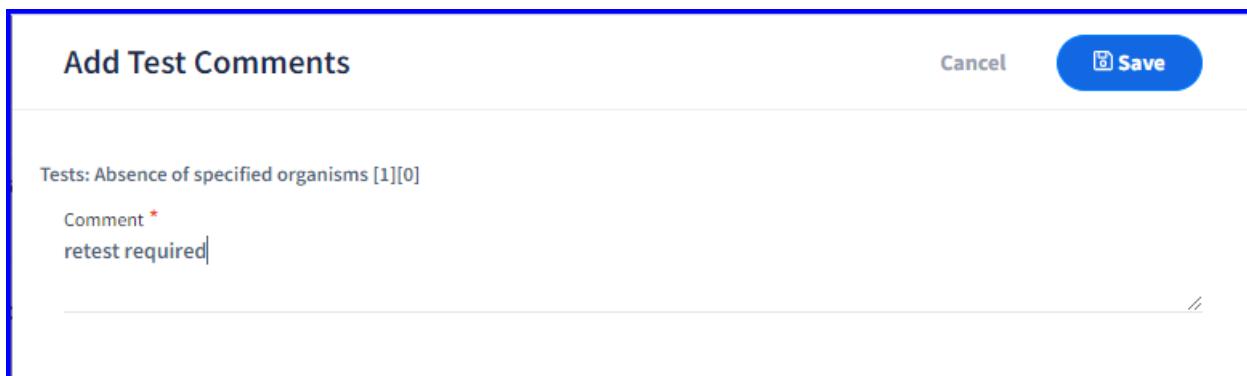
1. Select test(s) to add comments and then click **+ Comment** as shown in the figure:



Results	Instrument	Task	Test Attachment	Test Comments	Result Change History		
AR No	Test Name	Comments	Screen Name	User Name	Actions		
202200602	Absence of specified ...	retest required	Result Entry	Carl Dolm...	 		

FIGURE: Adding Test Comments

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



Add Test Comments

Cancel 

Tests: Absence of specified organisms [1][0]

Comment *

retest required

FIGURE: Add Test Comments Dialog

2. In the **Comment** field, type your comments. This comment will be added to all the tests selected.

4.2.3.4 Result Change History:

Result Change History tab helps you to view history of changes done to the selected test results.

Results	Instrument	Task	Test Attachment	Test Comments	Result Change History			
	AR No	Test Name	Parameter Name	Form Name	Results	Final Result	Remark	
+	202200604	OCABR Certifica...	Release OMCL	Result Entry by ...	N/A	N/A		
+	202200604	OCABR Certifica...	Certified Year	Result Entry by ...	N/A	N/A		
+	202200604	OCABR Certifica...	Certified Month	Result Entry by ...	N/A	N/A		
+	202200604	OCABR Certifica...	Certified Day	Result Entry by ...	N/A	N/A		
+	202200604	OCABR Certifica...	OCABR Certifica...	Result Entry by ...	N/A (NIBSC...	N/A (NIBSC...		

FIGURE: Result Change History Tab

4.2.3.5 Fill Default Results

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

Test								
<input checked="" type="checkbox"/> <input type="checkbox"/> Search Expand All Sample								
<input checked="" type="checkbox"/> OCABR Certificate Review [1][0] Registered 202200604 More Click here to fill default results								
1 5 1 - 1 of 1								
Results	Instrument	Task	Test Attachment	Test Comments	Result Change History			
	AR No	Test Name	Parameter Name	Form Name	Results	Final Result	Remark	
+	202200604	OCABR Certifica...	Release OMCL	Result Entry by ...	N/A	N/A		

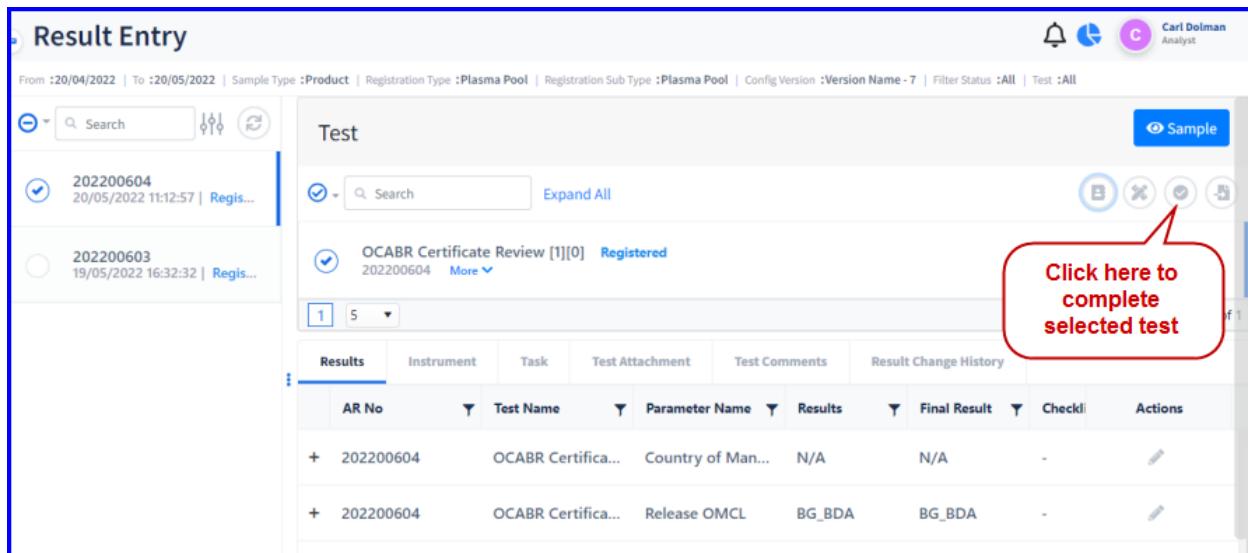
FIGURE: Filling Default Results to Selected Test(s)

Default result that is given in the test master will be filled as result.

4.2.3.6 Complete Test

Once you add test result, task, attachment and comments to the test/tests you can complete the test.

1. To complete the test, select the test or tests from the list and then click as shown in the figure:



Result Entry

From :20/04/2022 | To :20/05/2022 | Sample Type :Product | Registration Type :Plasma Pool | Registration Sub Type :Plasma Pool | Config Version :Version Name - 7 | Filter Status :All | Test :All

Test

202200604 20/05/2022 11:12:57 | Regis...

202200603 19/05/2022 16:32:32 | Regis...

OCABR Certificate Review [1][0] Registered 202200604 More

1 5

Results

AR No	Test Name	Parameter Name	Results	Final Result	Checklist	Actions
202200604	OCABR Certifica...	Country of Man...	N/A	N/A	-	Edit
202200604	OCABR Certifica...	Release OMCL	BG_BDA	BG_BDA	-	Edit

Click here to complete selected test

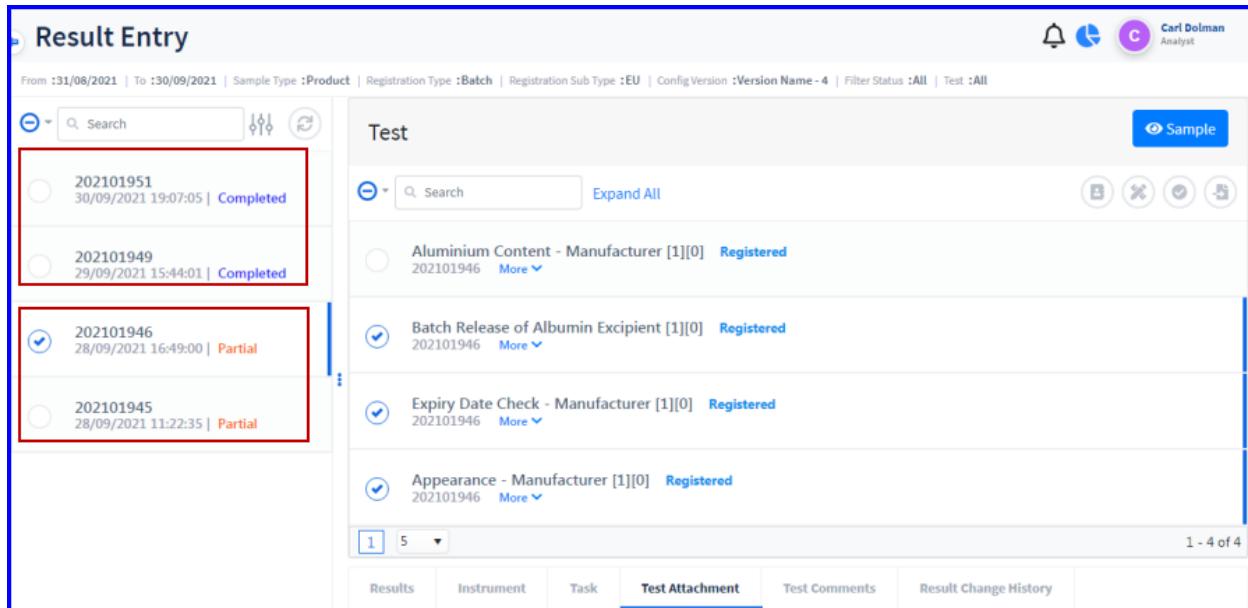
FIGURE: Completing Tests

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:



Result Entry

From :31/08/2021 | To :30/09/2021 | Sample Type :Product | Registration Type :Batch | Registration Sub Type :EU | Config Version :Version Name - 4 | Filter Status :All | Test :All

Test

202101951 30/09/2021 19:07:05 | **Completed**

202101949 29/09/2021 15:44:01 | **Completed**

202101946 28/09/2021 16:49:00 | **Partial**

202101945 28/09/2021 11:22:35 | **Partial**

Aluminium Content - Manufacturer [1][0] Registered 202101946 More

Batch Release of Albumin Excipient [1][0] Registered 202101946 More

Expiry Date Check - Manufacturer [1][0] Registered 202101946 More

Appearance - Manufacturer [1][0] Registered 202101946 More

1 5

Test Attachment

FIGURE: Sample with Completed and Partial Status

4.3 Test approval

To receive completed samples from the result entry screen, ensure that the following configurations are done appropriately:

4.3.1 User Role Configuration

The test approval flow will be available for the users enabled in the User Role Configuration screen as shown in the figure:

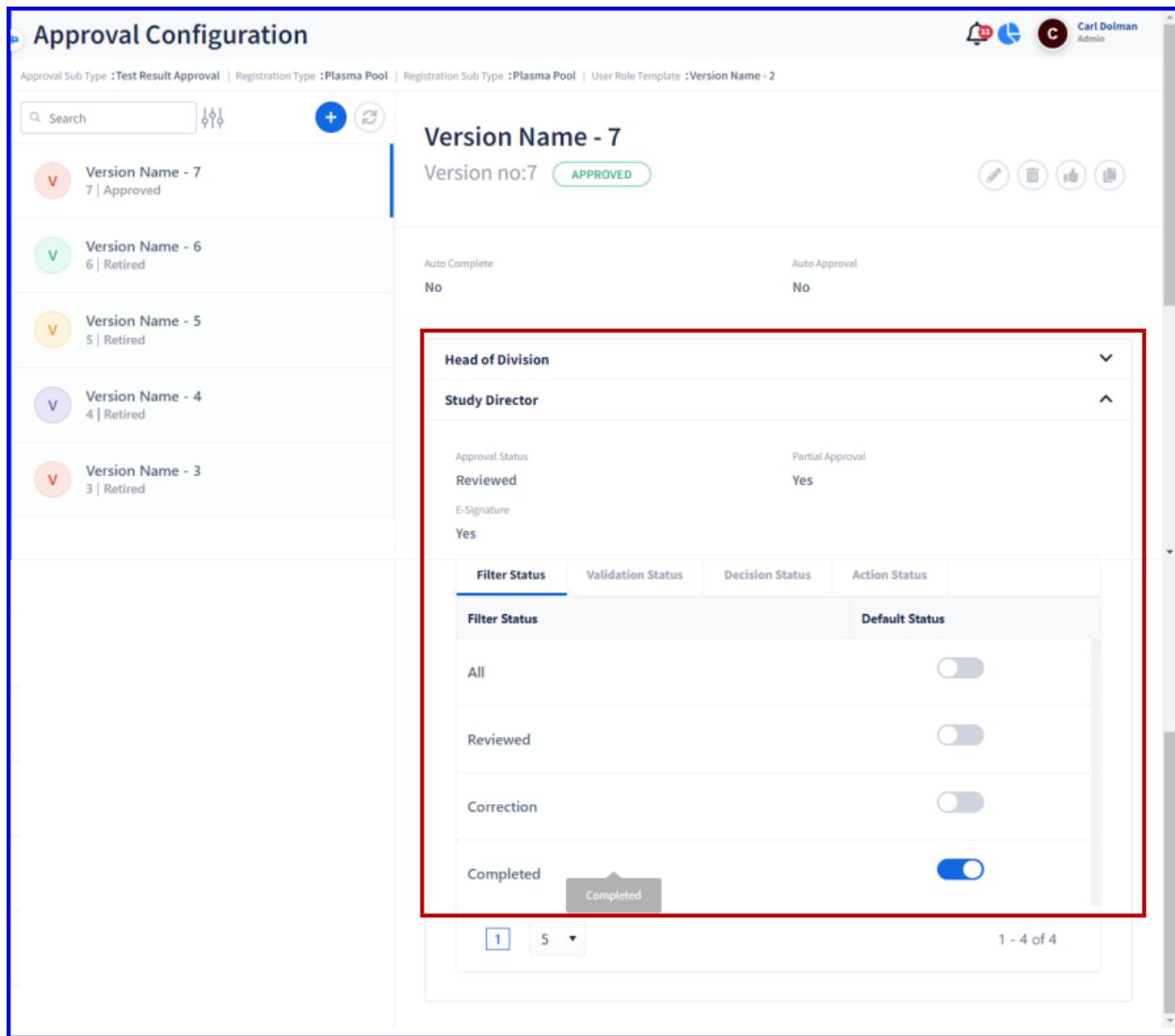


User Role Name	Approval Flow	Result Entry Flow	Product Flow	Withdrawn Email	Failed Email
Goods In	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Analyst	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study Director	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Head of Division	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FIGURE: User Role Configuration Screen Showing Approval Flow

4.3.2 Approval Configuration

Once result entry is done, the completed samples will appear in the next user in the approval flow as configured in the Approval Configuration screen as shown in the figure:



The screenshot shows the 'Approval Configuration' screen. On the left, a list of versions is displayed:

- Version Name - 7 | Approved
- Version Name - 6 | Retired
- Version Name - 5 | Retired
- Version Name - 4 | Retired
- Version Name - 3 | Retired

On the right, the details for 'Version Name - 7' are shown. The status is 'APPROVED'. The 'Head of Division' and 'Study Director' sections are expanded. Under 'Head of Division', there is a table for 'Filter Status' with the following data:

Filter Status	Validation Status	Decision Status	Action Status
All	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Correction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Completed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The 'Completed' status is highlighted with a red border. The 'Action Status' column for 'Completed' has a blue border.

FIGURE: Approval Configuration Screen Showing User in the Approval Flow

4.3.3 User Mapping

In the User Mapping screen, you can map user for the approval flow in the user level. Samples completed in the result entry screen by a selected user will go to the user selected in the next level in the approval configuration as shown in the figure:

User Mapping

Filter
Head of Division

UK_NIBSC

U
C
Carl Dolman
Admin

User Name	Login Id	Division	Actions
Carl Dolman	cdolman	Biotherapeutics	
Sjoerd Rijpkema	srijpkem	Bacteriology	
Barbara Bolgiano	BBolgian	Bacteriology	
Mei Mei Ho	mho	Bacteriology	
Kevin Markey	kmarkey	Bacteriology	
Fatme Mawas	fmawas	Bacteriology	
Paul Stickings	pstickin	Bacteriology	
Nicola Rose	nrose	Virology	
Gill Cooper	GCooper	Virology	
Dianna Wilkinson	dwilkins	Virology	

1
2
10
▼
1 - 10 of 16

Study Director
+

User Name	Login Id	Division	Actions
Paul Stickings	pstickin	Bacteriology	

1
5
▼
1 - 1 of 1

Analyst
+

User Name	Login Id	Division	Actions
Sunil Maharjan	smaharja	Bacteriology	
Shalini Rajagopal	srajagop	Bacteriology	
Robert Tierney	rtierney	Bacteriology	
Yvonne Liu	yliu	Bacteriology	

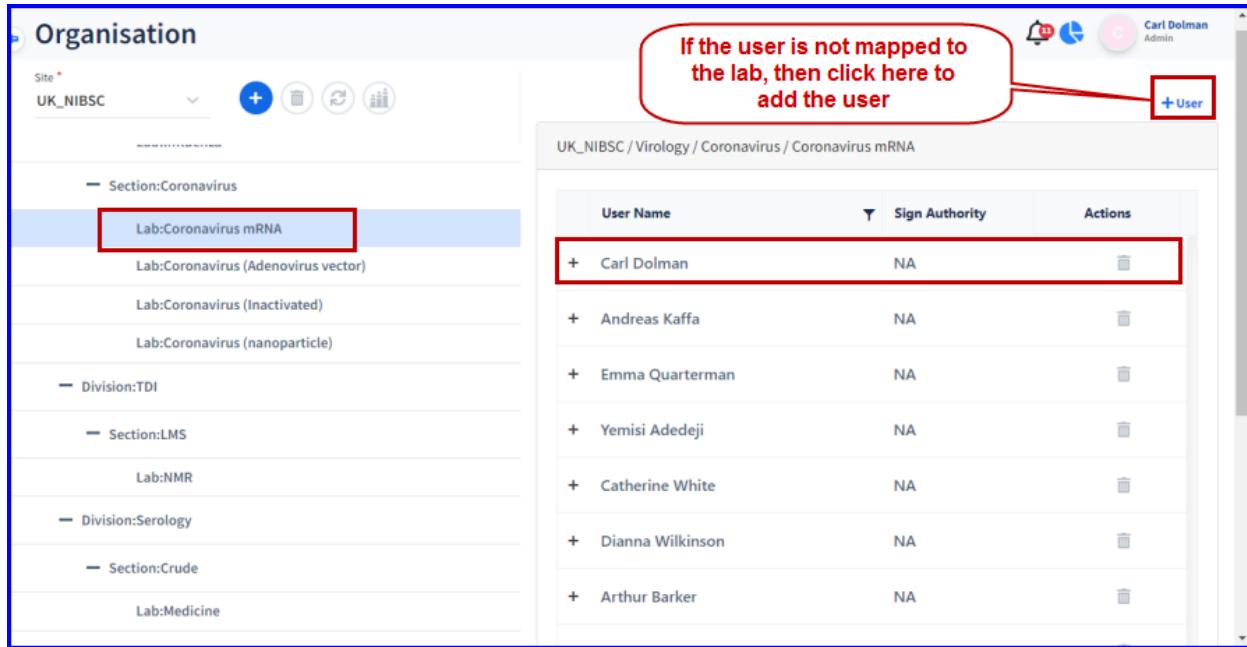
1
5
▼
1 - 4 of 4

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

238

4.3.4 Organization Mapping

Tests are mapped to labs in the test master. Users have to be mapped to that particular lab to receive tests/samples in the result entry and test approval screen as shown in the figure:



The screenshot shows the 'Organisation' screen in Qualis LIMS. On the left, a tree view shows the site 'UK_NIBSC' and various sections like 'Coronavirus', 'TDI', 'LMS', 'NMR', 'Serology', 'Crude', and 'Medicine'. Under 'Coronavirus', 'Lab:Coronavirus mRNA' is selected and highlighted with a red box. On the right, a list of users is shown with a red box around the first user, 'Carl Dolman'. A callout bubble above the list says: 'If the user is not mapped to the lab, then click here to add the user'. The user list table has columns for 'User Name', 'Sign Authority', and 'Actions'.

User Name	Sign Authority	Actions
Carl Dolman	NA	
Andreas Kaffa	NA	
Emma Quarterman	NA	
Yemisi Adedeji	NA	
Catherine White	NA	
Dianna Wilkinson	NA	
Arthur Barker	NA	

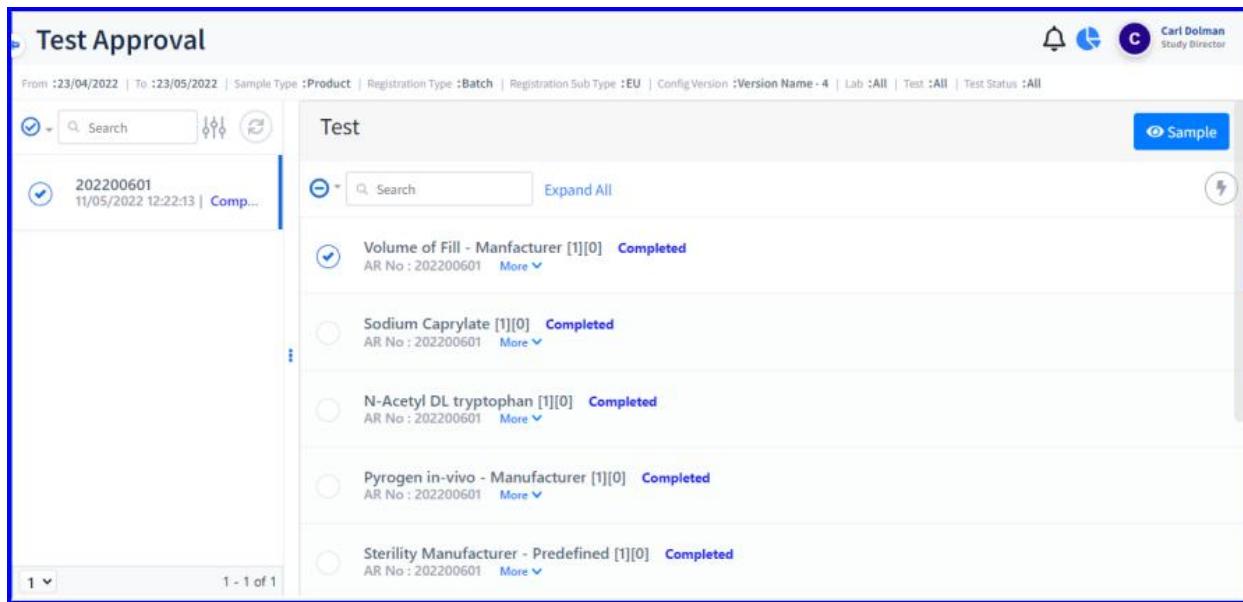
FIGURE: Organisation Screen Showing User Mapped to a Selected Lab

Once result entry is done, the completed samples will appear in the next user queue in the approval flow as configured in the Approval Configuration screen as shown in the figure:

4.4 Reviewing Test Results

To review the result entry, follow these steps:

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



Test Approval

From :23/04/2022 | To :23/05/2022 | Sample Type :Product | Registration Type :Batch | Registration Sub Type :EU | Config Version :Version Name - 4 | Lab :All | Test :All | Test Status :All

Carl Dolman
Study Director

Test

202200601
11/05/2022 12:22:13 | Comp...

Search | |

Volume of Fill - Manufacturer [1][0] **Completed**
AR No : 202200601 More

Sodium Caprylate [1][0] **Completed**
AR No : 202200601 More

N-Acetyl DL tryptophan [1][0] **Completed**
AR No : 202200601 More

Pyrogen in-vivo - Manufacturer [1][0] **Completed**
AR No : 202200601 More

Sterility Manufacturer - Predefined [1][0] **Completed**
AR No : 202200601 More

1 | 1 - 1 of 1

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:

Test Approval

From :23/04/2022 | To :23/05/2022 | Sample Type :Product | Registration Type :Plas

CANCEL	SUBMIT
From 23/04/2022	To 23/05/2022
Sample Type Product	Config Version Version Name - 7
Registration Type Plasma Pool	Lab All
Registration Sub Type Plasma Pool	Test All
Test Status Completed	All OCABR Certificate Review

FIGURE: Using Filter

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

The screenshot shows the 'Test Approval' screen in LIMS Qualis. The main area displays a table of test results for AR No: 202200604. The first row is highlighted with a red box. The table has columns for AR No, Test Name, Parameter Name, Final Result, Checklist, and Actions. The 'Actions' column contains icons for Recalc, Retest, and Review. The 'Review' icon is highlighted with a blue box. The top right corner shows a user profile for Carl Dolman, Study Director. The top bar includes a search bar and filter options. The bottom left shows a navigation menu with icons for Home, Test, Sample, and Report.

AR No	Test Name	Parameter Name	Final Result	Checklist	Actions
202200604	OCABR Certificate ...	Country of Manufa...	N/A	-	
202200604	OCABR Certificate ...	Release OMCL	BG_BDA	-	
202200604	OCABR Certificate ...	Certified Year	2021	-	
202200604	OCABR Certificate ...	Certified Month	March	-	

FIGURE: Test Approval Screen Showing Filtered Records

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

- Recommend recalculation: The tests go to the previous user(Analyst) and appear in **ReCalc** state.
- Recommend retest: The tests go to the previous user and appear in **Retest** **ReTest** state.
- Complete review: Tests appear as **Reviewed** state.

4.4.1 Changing Decision Status

Before you recommend Recalc, Retest or finish review, you must change decision status of the sample. To do so follow these steps:

In the Test Approval screen, select a sample, click and then click **Pass / Fail / Withdraw** as shown in the figure:

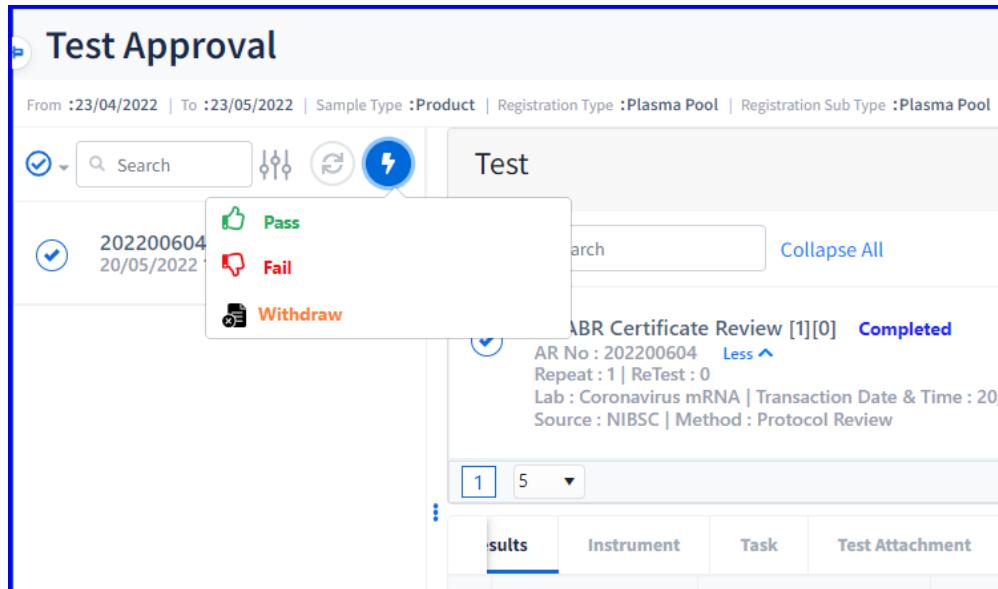
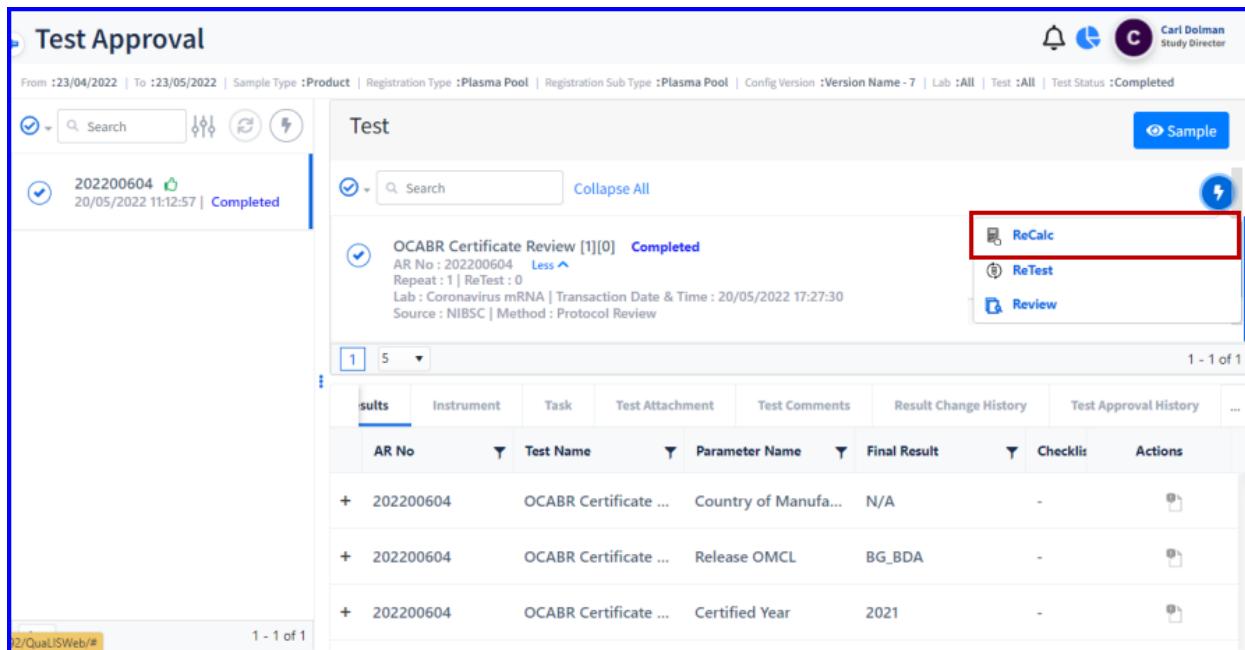


FIGURE: Changing Decision Status

4.4.2 Recommend Recalculation

Reviewer can recommend recalculation if required. To recommend recalculation, follow these steps:

1. In the Test Approval screen, select the sample, click  and then click **ReCalc** as shown in the figure:

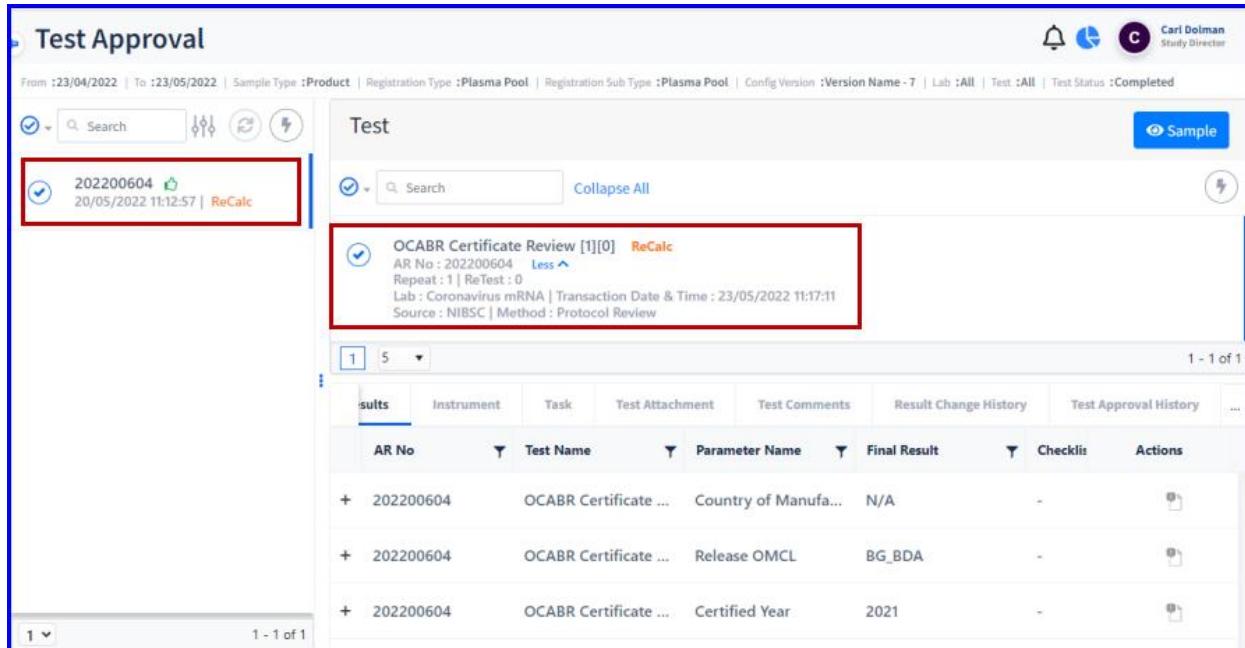


The screenshot shows the 'Test Approval' page with a blue border. At the top, there are search and filter options, and a header bar with a user profile for 'Carl Dolman, Study Director'. The main area is titled 'Test' and shows a list of tests. A specific test entry for 'OCABR Certificate Review [1][0]' is highlighted with a red box. The status of this test is 'Completed' but is also labeled 'ReCalc' in the status column. Below the list is a table with columns: AR No, Test Name, Parameter Name, Final Result, Checklist, and Actions. The table contains three rows of data.

AR No	Test Name	Parameter Name	Final Result	Checklist	Actions
202200604	OCABR Certificate ...	Country of Manufa...	N/A	-	
202200604	OCABR Certificate ...	Release OMCL	BG_BDA	-	
202200604	OCABR Certificate ...	Certified Year	2021	-	

FIGURE: Recommend Recalculation

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



This screenshot is identical to the one above, showing the 'Test Approval' page with a blue border. The 'ReCalc' state is explicitly highlighted for the first test entry in the list, and the 'ReCalc' status is also present in the table below.

AR No	Test Name	Parameter Name	Final Result	Checklist	Actions
202200604	OCABR Certificate ...	Country of Manufa...	N/A	-	
202200604	OCABR Certificate ...	Release OMCL	BG_BDA	-	
202200604	OCABR Certificate ...	Certified Year	2021	-	

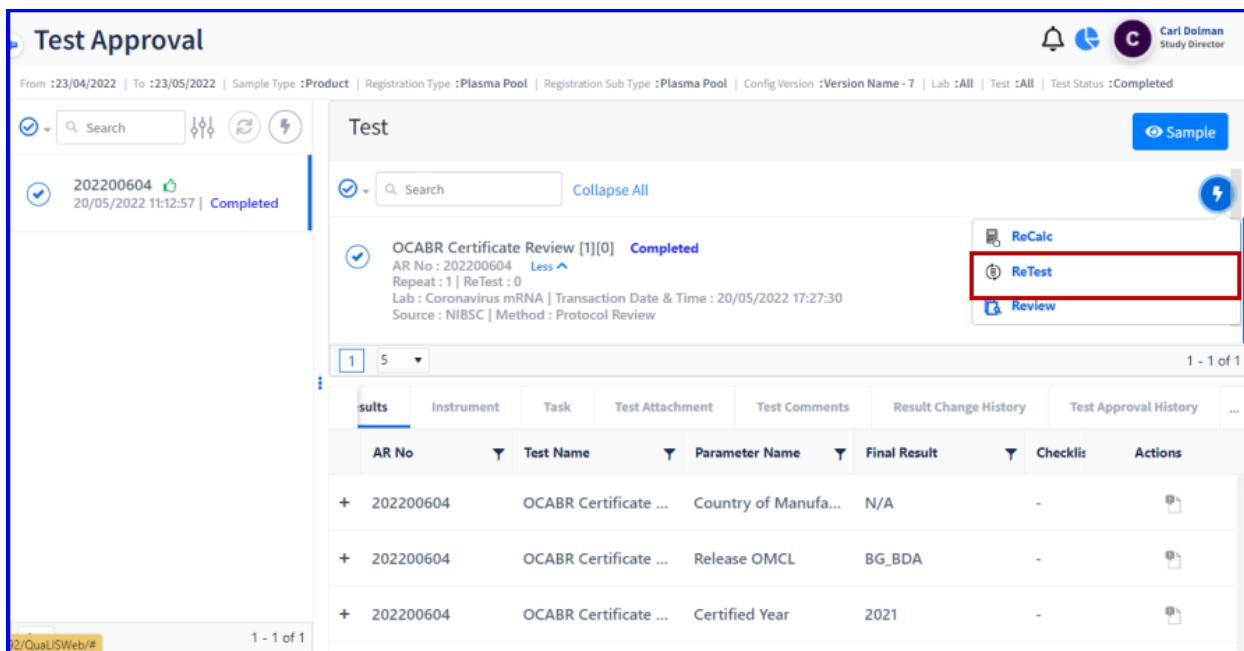
FIGURE: Sample in the ReCalc State

At this state, the sample goes to the previous(Analyst) user for recalculation in the Result Entry screen. The User can recalculate and then enter recalculated results in the result entry screen and complete. The completed test comes to review again.

4.4.3 Recommend ReTest

Reviewer can recommend retest and should specify number of times the test has to be carried.

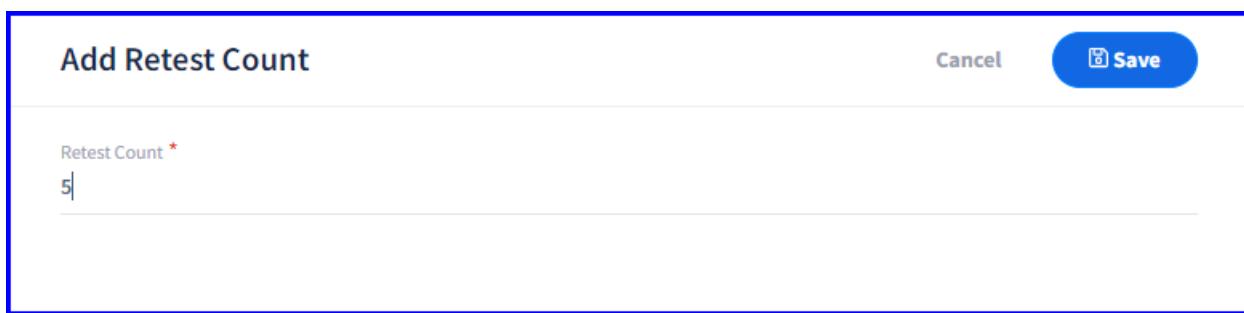
1. In the Test Approval screen, select the sample, click  and then click **ReTest** as shown in the figure:



The screenshot shows the 'Test Approval' screen. On the left, a sidebar shows a sample with AR No: 202200604, status: Completed, and a timestamp: 20/05/2022 11:12:57. The main area displays a table of test results for this sample. On the right, there is a toolbar with several buttons: 'ReCalc', 'ReTest' (which is highlighted with a red box), and 'Review'. The 'ReTest' button is a blue button with a lightning bolt icon.

FIGURE: Recommend ReTest

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

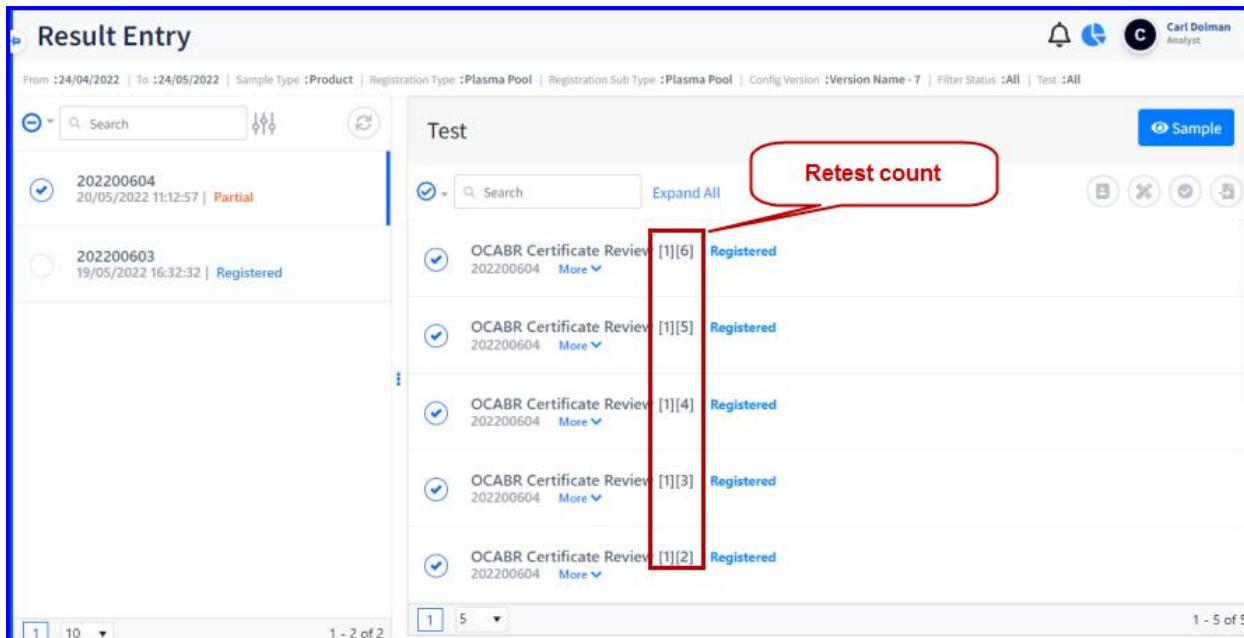


The dialog box is titled 'Add Retest Count'. It contains a single input field labeled 'Retest Count *' with the value '5' entered. At the top right are 'Cancel' and 'Save' buttons. The 'Save' button is highlighted with a blue border.

FIGURE: Add Retest Count Dialog

2. In the **Retest Count** field, type number of times the test has to be carried again and then click **Save**. The sample goes to the **ReTest** state.

At this state, the sample goes to the previous(Analyst) user for retest in the Result Entry screen and appears as shown in the figure:



The screenshot shows the 'Result Entry' screen. On the left, there is a sidebar with a search bar and a list of samples: '202200604' (20/05/2022 11:12:57 | Partial) and '202200603' (19/05/2022 16:32:32 | Registered). The main area is titled 'Test' and contains a list of five entries, each with a checkbox, a sample ID, a review date, and a status: 'OCABR Certificate Review [1][6] 202200604 More' (status: Registered), 'OCABR Certificate Review [1][5] 202200604 More' (status: Registered), 'OCABR Certificate Review [1][4] 202200604 More' (status: Registered), 'OCABR Certificate Review [1][3] 202200604 More' (status: Registered), and 'OCABR Certificate Review [1][2] 202200604 More' (status: Registered). A red box highlights the 'Retest count' field in the top right corner of the search bar. Another red box highlights the 'Registered' status of the sample in the list.

FIGURE: Result Entry Screen Showing Sample Registered for Retest

The sample is registered multiple times as per the retest count mentioned by the reviewer. The user can retest, enter results for each test in the result entry screen and then complete the tests. The completed tests comes to review again.

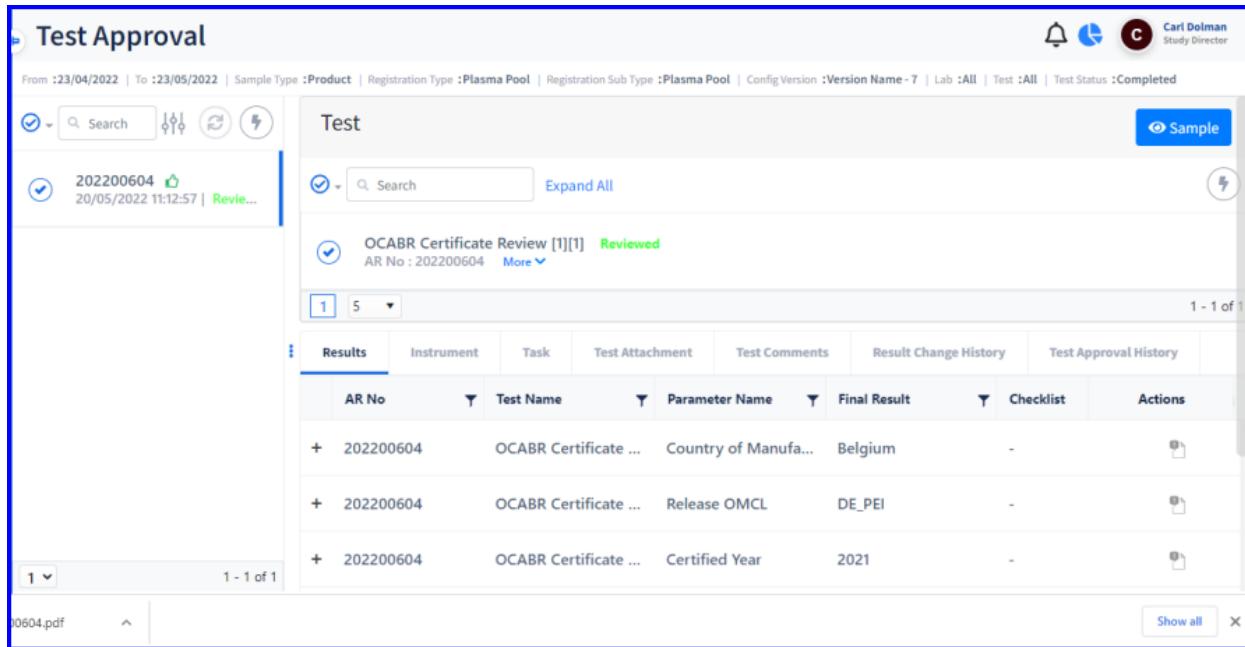
4.4.4 Review

The reviewer can review the test and complete review. Reviewed tests go to the next user in the approval configuration for approval.

To review test, follow these steps:

1. In the Test Approval screen, select the sample to be reviewed.
2. Select test(s) from the list to review.

3. Click  and then click **Review**. The selected tests status appears as **Reviewed** as shown in the figure:



The screenshot shows the 'Test Approval' screen. At the top, there are filter and search options. The main area displays a table of test results. One entry is highlighted with a blue checkmark and the status 'Reviewed'. The table columns include AR No, Test Name, Parameter Name, Final Result, Checklist, and Actions. The data in the table is as follows:

AR No	Test Name	Parameter Name	Final Result	Checklist	Actions
202200604	OCABR Certificate ...	Country of Manufa...	Belgium	-	
202200604	OCABR Certificate ...	Release OMCL	DE_PEI	-	
202200604	OCABR Certificate ...	Certified Year	2021	-	

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:

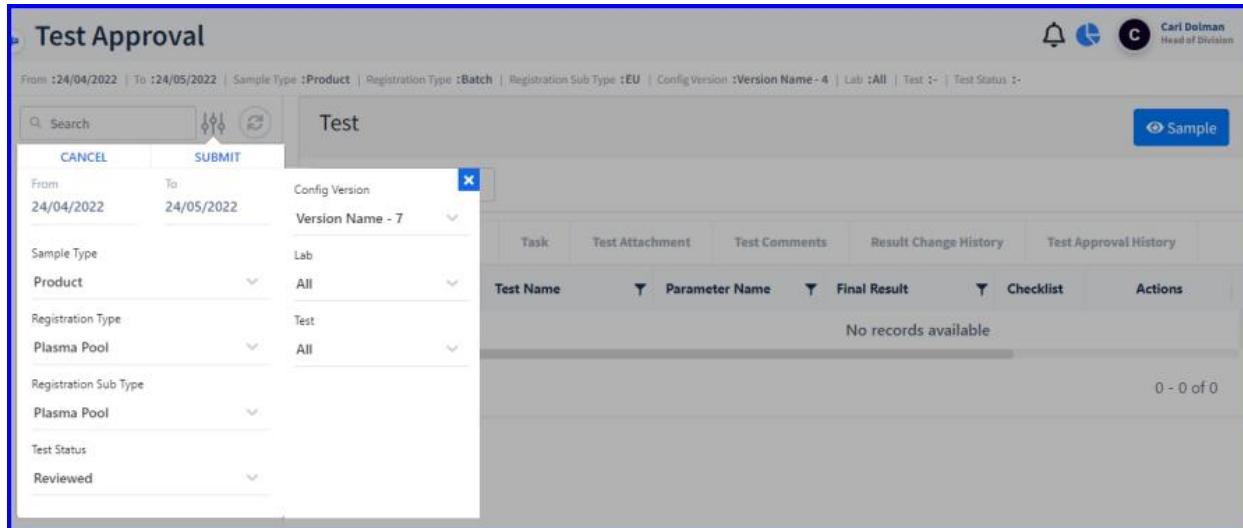


FIGURE: Using Filter

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

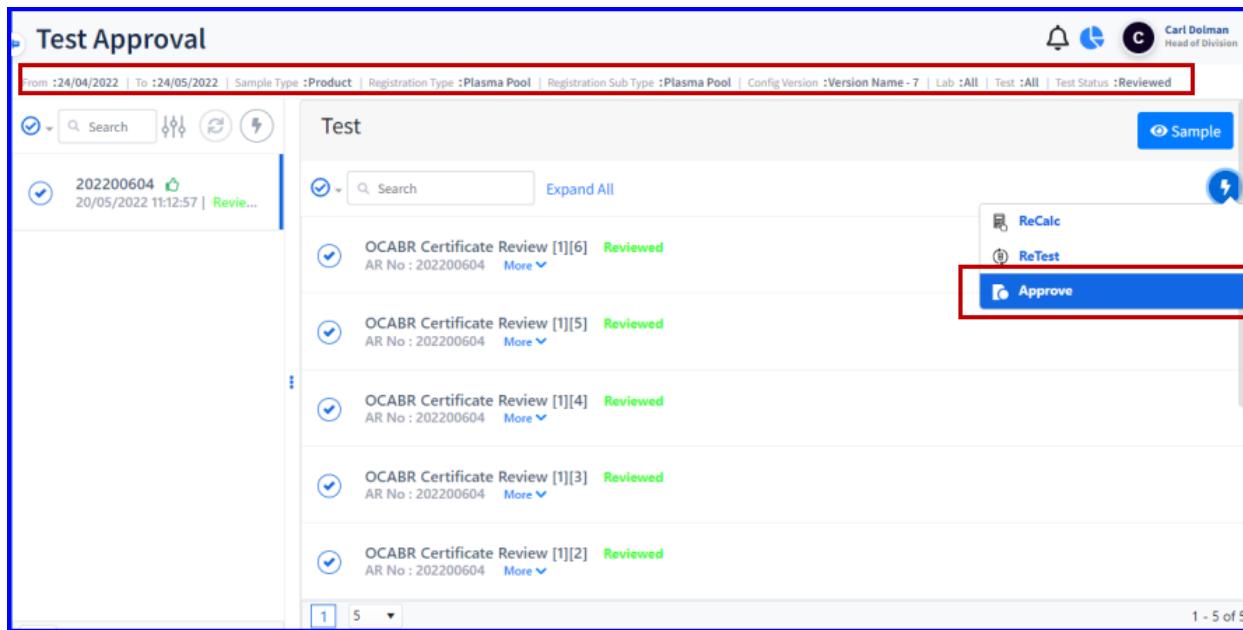
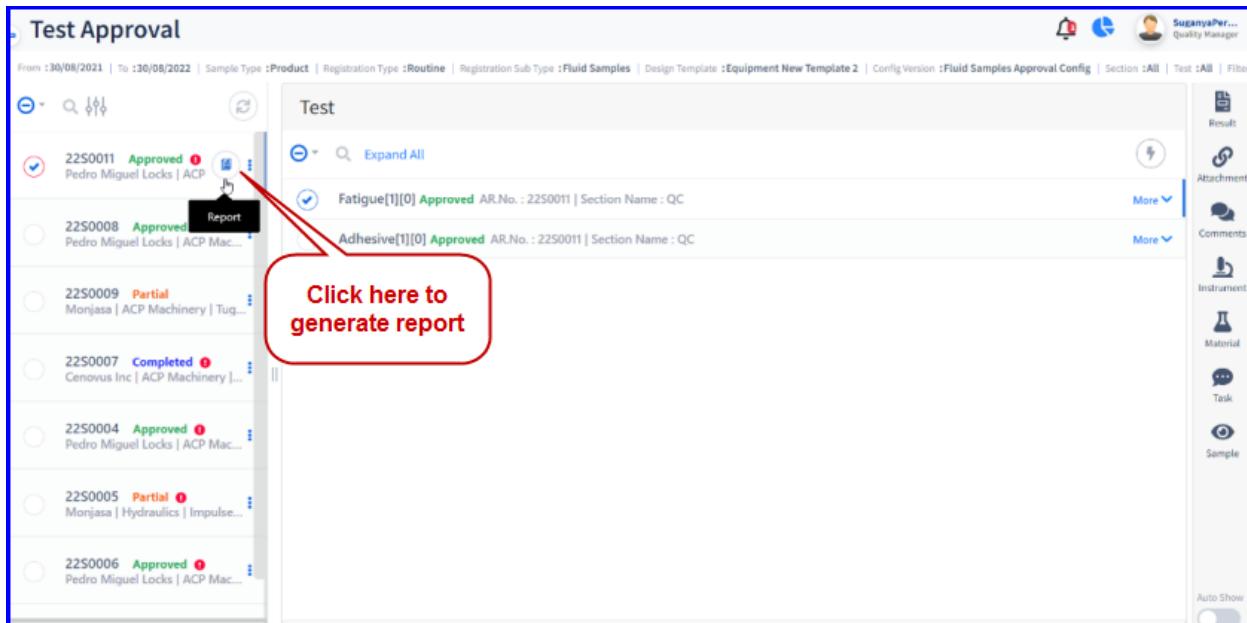


FIGURE: Test Approval Screen Showing Filtered Records

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:



The screenshot shows the 'Test Approval' module. On the left, a list of tests is displayed with their status (Approved, Partial, Completed) and a red circular icon with a '1' indicating pending actions. A red callout box with the text 'Click here to generate report' points to the 'Report' button next to the first test in the list. The right side of the screen shows a sidebar with navigation links for Result, Attachment, Comments, Instrument, Material, Task, and Sample. The top of the screen displays various search and filter options.

FIGURE: Generating Report

The report is generated and appears as shown in the figure:

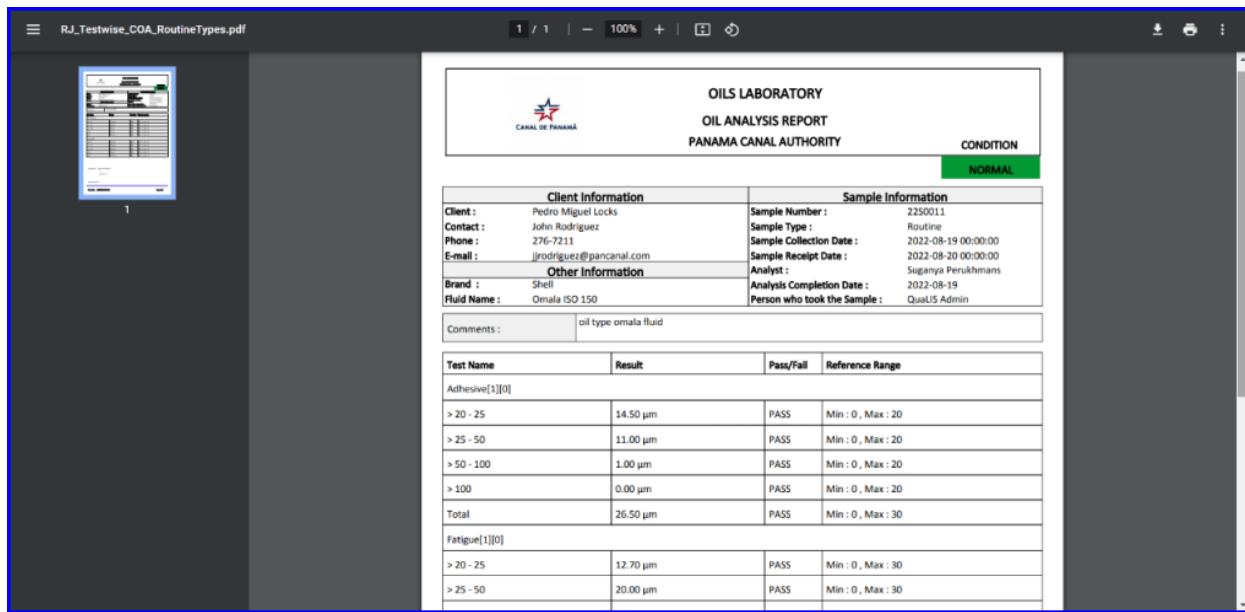


FIGURE: Report Generated