SymphonyTech ELN

Table of Contents

1. Getting Started

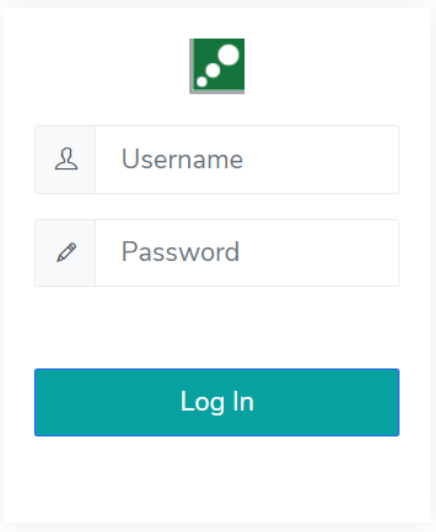
1.1. Login Page

Login Page

Login page is landing page of the application.

Features:

- User must input user name, password and click on the ‘Login’ button to get re-directed to the Application module master.
- User may also have a facility to save user name in the system locally. Please note that this may clear off on clearing Internet cache/browsing data and passwords.



Login Page

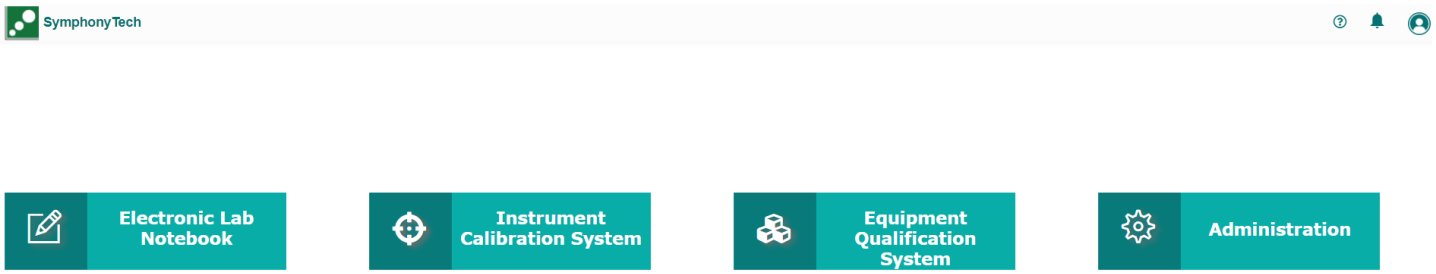
1.2. Application Module Master

Application Module Master

This will be the Home Page once a user logs into the application.

Features:

- This page displays all modules in form of Buttons (List will vary depending on user privileges). User can access a module by clicking on its icon.
- User can route back to this page by clicking on the SymphonyTech Logo on the top left corner.
- User can also click on 'Home' on the breadcrumb trail to access this page.



Application Module Master

1.3. Common features and Notes

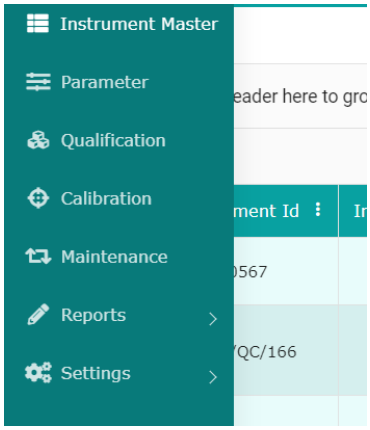
Common features on all pages of the web application

The below list of features is present on a fixed panel (top horizontal section, left vertical menu bar). These features are accessible during use of the web application.

❖ **Top horizontal section:**

- Logo of the company, on click, takes the user to the application module master.
- Three horizontal lines next to the company logo, on click, expand/collapse the left vertical menu bar. These appear on selection of one of the modules listed on the application module master.
- Center of this section displays page name.
- Help section may be accessed by clicking on the Question mark icon. This will list all the topics on how to operate the web application.
- Notification feature (Bell Icon) pops up alerts, updates, and notifications.
- User settings feature, on click, pops up has the below options:
  - Link to 'logout' of web application
- Breadcrumb trails (e.g., Home > ICS > Instrument Master) are placed below the three horizontal lines on top left to keep track and maintain awareness of location on the web page.

❖ **Left vertical Menu Bar:**



- This Menu bar, on moving the pointer on the bar, expands to show the menu bar with options to navigate on click.

❖ **Additional features common on all pages:**

- Mandatory fields on all pages are highlighted with an Asterisk.
- Audit trail is captured for all modules of the product in a separate module 'Administrator'.
- Search and filter options are provided for each module internally.
- Custom fields setting in settings menu for ICS, EQS Modules is provided to add new columns in existing master tables. These additional fields will be ‘alphanumeric only’ fields.
- Buttons commonly used throughout the web application:
  - Save: This button, on click, will save entry in the database. This will also make an entry in the audit trail of the corresponding module.
  - Next: This button, on click, will route the user to the next screen in flow of web application.
  - Back: This button, on click, will route the user to the previous page in flow of the web application.
  - Cancel: This button, on click, will cancel the action being performed and route the user to landing page of the current section.
  - Add: This button, on click, will add a record in the corresponding folder and in the database.
  - Browse: This button, on click, will route the user to the file manager of the local directory.
  - Export: This button, on click, will Export results from the given page on the local machine in selected format for reporting purposes.

1.4. Risks and assumptions

Risks and assumptions

- Manual entries have been verified before entering in the system.
- This is a browser-based system and needs an Internet connection for functioning.
- Uncommitted data on browser will not be saved. A separate option is provided to save data whenever user feels necessary. Form may not allow saving unless mandatory fields are populated.
- Modification in features enlisted here-in may be based on discussion between both parties. The document will be modified accordingly.

- Infrastructural activities (e.g., Back-up and recovery of data, Hosting, Load balancing, etc.) are out of purview of this system and should be handled by the IT service providers.
- Modification of front-end screens may require development effort and additional time to implement.
- All due dates are Non-editable, auto-calculated date displays.
- ICS and EQS modules are dependent on data from ELN till the extend of pulling out a report of all experiments that used instruments in their process.
- ELN Module is dependent on data from EQS, ICS and IMS modules for equipment, instruments, material lists respectively.
- Features seen in a user profile may be unavailable for another user based on privileges.
- Please note that the Functional requirements and corresponding system design is subject to minor modifications based on technical feasibility and mutual agreement.
- Please note that definition of the term 'Application' in the document does not refer to a downloadable/installable software but a browser-based application hosted on web.
- Field restrictions seen in the module are as per user requirements. Validations may not be placed due to the same reason.
- Audit trail records are view only format and are not editable as per compliance.
- User once added to the system cannot be removed as the records associated with that individual are required for record keeping.

2. Help_ICS_V1.0

SYMPHONYTECH - ELECTRONIC LABORATORY NOTEBOOK
HELP SECTION
FOR
INSTRUMENT CALIBRATION SYSTEM

Document Number: Help-001

Version Number: 1.0

Version Date: November 02, 2020

VERSION HISTORY

Development and distribution of this Help Document will be controlled and tracked by SymphonyTech Biologics Pvt Ltd (SBx). This document is being created for presenting details on how to use Instrument Calibration System (ICS) module for SymphonyTech - ELN product.

Version Number	Implemented by	Revision date	Approved by	Approval date	Description of change
1	SBx	02-Nov-20			Help Section for ICS

2.1. Introduction

Introduction

Welcome to the Instrument Calibration System. This module is designed to keep log of information about instruments and their use in a systematic and traceable manner. This will help to accurately monitor instruments in correlation to the respective standards and talk with the modules tracking experiment and manufacturing data.

This guide will provide detailed information of the requested behavior and how the system will function.

Terms, Acronyms, and definitions

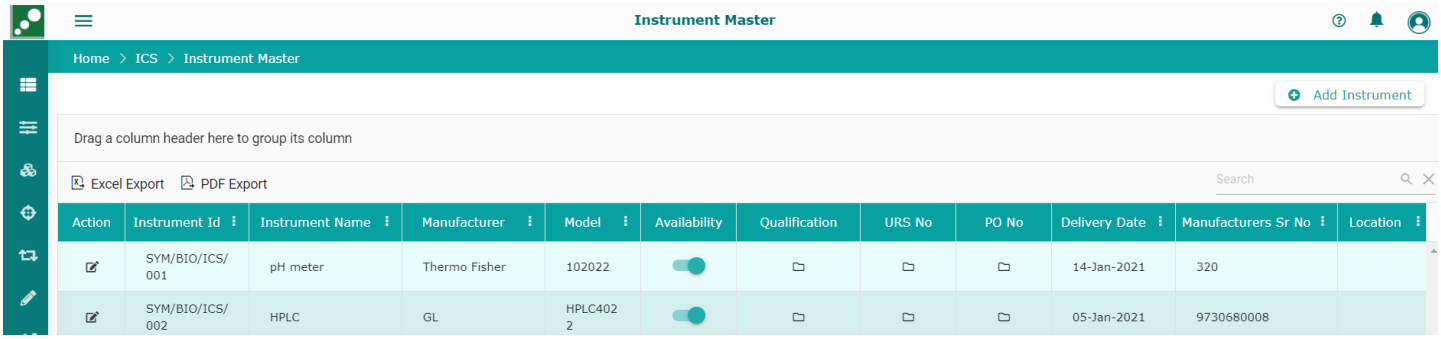
Term	Definition	Description
ICS	Instrument Calibration System	This module will track Instrument calibration to accurately monitor instruments in correlation to the respective standards and talk with ELN module

ELN	Electronic Laboratory Notebook	Secure browser-based platform to record and manage laboratory data all in one place and to replace paper lab notebooks
EQS	Equipment Qualification System	Module for performing Qualification for fitness of use as well as tracking of continued capability of equipment for its stated purpose
IMS	Inventory Management System	Module for logging inventory of consumable (Incoming/Outgoing) material used during experiments and for validating within expiry dates of each lot.
SBx	SymphonyTech Biologics Pvt Ltd, Pune	
ID	Identity	
PO	Purchase Order	
DQ	Design Qualification	
FAT	Factory acceptance Test	
IA	Impact Analysis	
IQ	Installation Qualification	
IO	Installation Operation Qualification	
OP	Operation performance Qualification	
OQ	Operational Qualification	
PQ	Performance Qualification	
RQ	Re qualification	
SAT	Site Acceptance Test	
AMC	Annual Maintenance Contract	
CMC	Comprehensive Maintenance Contract	
PM	Preventive Maintenance	
WO	Work Order	
SOP	Standard Operating Procedure	
IOP	Instrument Operating Procedure	
EOP	Equipment Operating Procedure	
PV	Performance Verification	

2.2. Instrument Master

Instrument Master

Instrument Master page will be a summary of master data of all Instruments in a go.

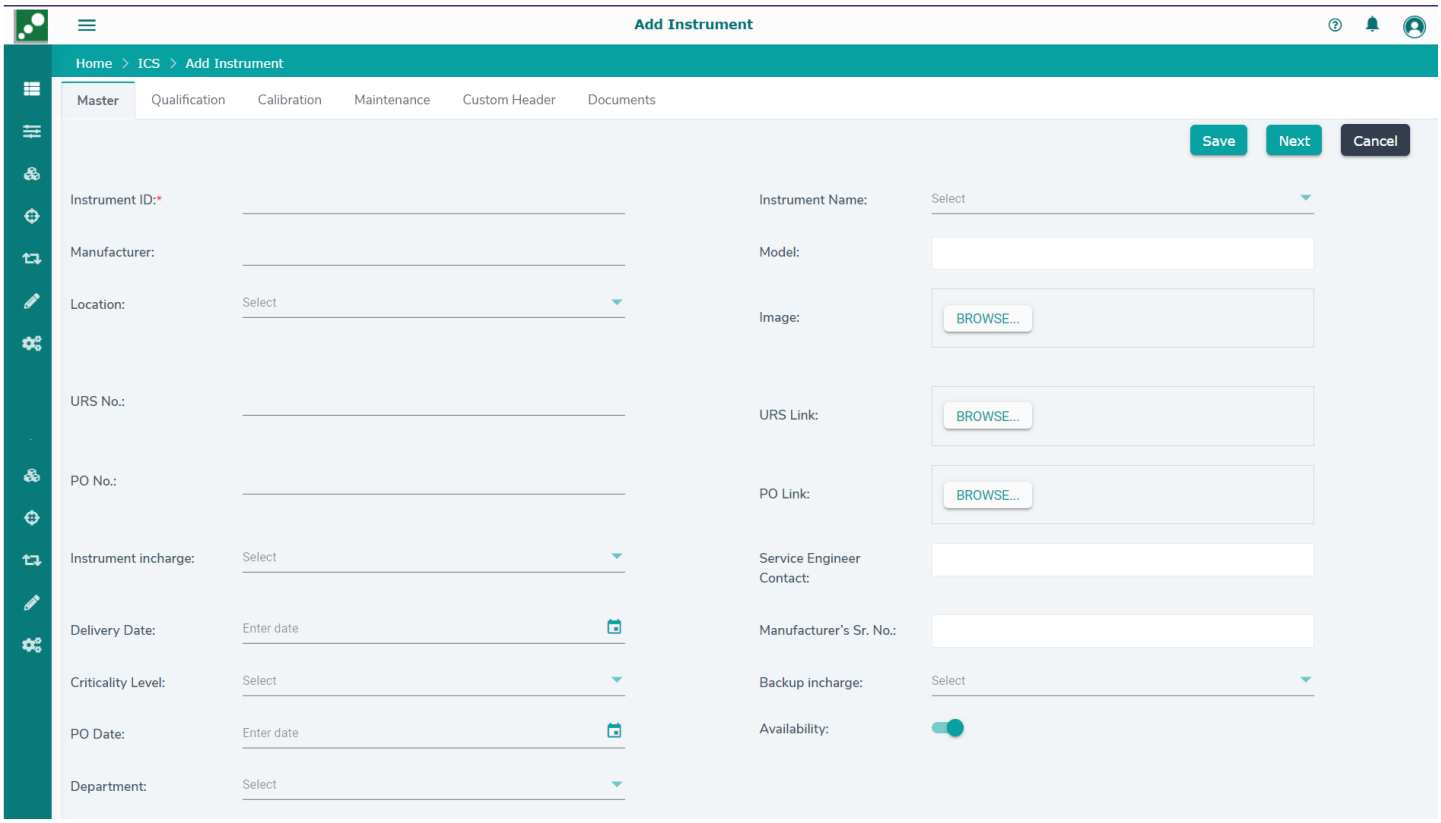


Features:

- Instrument master details are displayed once user clicks on the **Instrument master** page. User may group instrument entries by dragging and dropping the header that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may also export the list in excel format by clicking on the 'Excel export' button above the list.

- Clicking on '**Add Instrument**' button routes to a web page (form) with a blank input canvas where the instrument master details may be filled and saved. While adding an instrument, the below tabs may be populated as primary information for the instrument:

  - **Master**: This page has all primary information that may be required to register the instrument in the system.



  - **Instrument ID**: This field is a mandatory requirement that a user must fill to enable saving the entry. This text box accepts alphabets, Numbers and special characters. Existing list of instrument IDs will start reflecting in a selection box on typing 1 character in the text box. User may select and edit the entry further.

  - **Instrument Name**: This field is an optional requirement. User can select from available list of instrument names in the drop-down. This list is pre-populated in the Settings>User settings>Instrument Name tab (described in detail in the settings section of help).

  - **Manufacturer**: This field is an optional requirement. A user may fill if and when the information is available. This text box accepts alphabets, Numbers and special characters. Existing list of manufacturers will start

reflecting in a selection box on typing 1 character in the text box. User may select and edit the entry further.

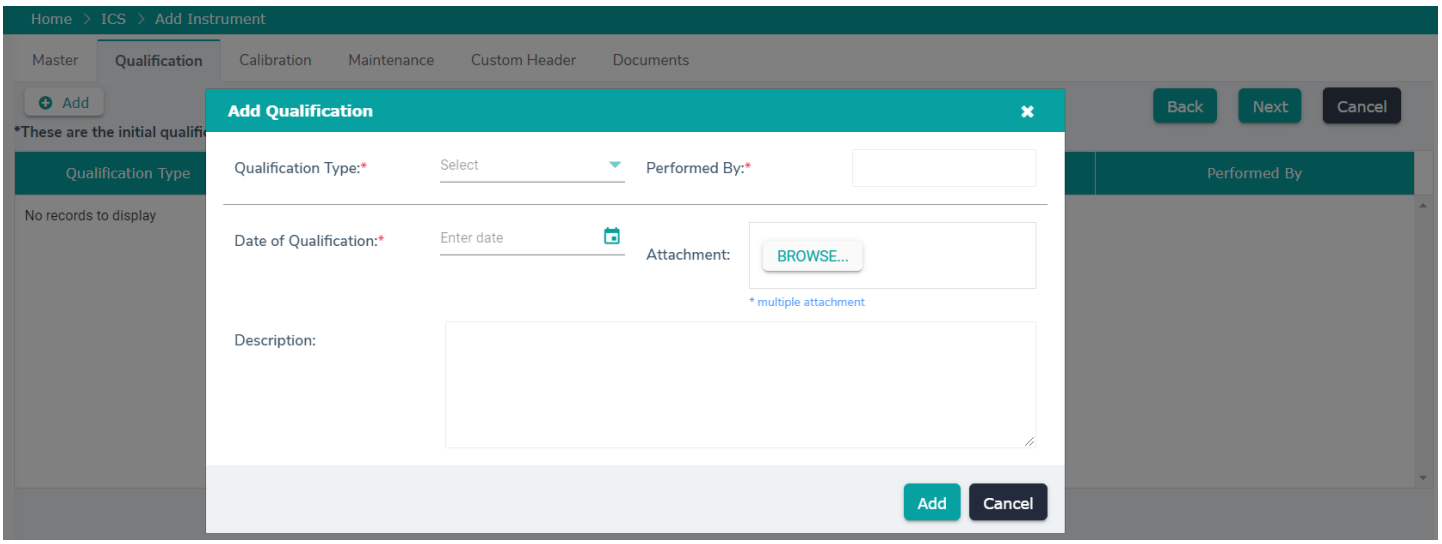
- **Model**: This field is an optional requirement. A user may fill if and when the information is available. This text box accepts alphabets, Numbers and special characters.
- **Location**: This field is an optional requirement. User can select from available list of locations in the drop-down. This list is pre-populated in the Settings>User settings>Location tab (described in detail in the settings section of help).
- **Image**: An image may be browsed from the local file manager on user's device and uploaded as part of the instrument entry. Here, only 1 entry is permitted at a given point in time. File type has not been restricted while uploading.
- **URS No**.: User requirement specification number may be mentioned here. This field is an optional requirement. A user may fill if and when the information is available. This text box accepts alphabets, Numbers and special characters. Existing list of URS numbers will start reflecting in a selection box on typing 1 character in the text box. User may select and edit the entry further.
- **URS Link**: User requirement specification document corresponding to the number added in URS No. may be browsed from the local file manager on the user's device and uploaded as part of the instrument entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
- **PO No**.: Purchase Order number may be mentioned here. This field is an optional requirement. A user may fill if and when the information is available. This text box accepts alphabets, Numbers and special characters. Existing list of PO numbers will start reflecting in a selection box on typing 1 character in the text box. User may select and edit the entry further.
- **PO Link**: Purchase Order document corresponding to the number added in PO No. may be browsed from the local file manager on the user's device and uploaded as part of the instrument entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
- **Instrument In-charge**: A user may select an employee in charge of the instrument. This list is pre-populated from the existing employee list. All alerts and notifications will be sent to this person's ID once appointed.
- **Service Engineer Contact**: User may enter a phone number of the service engineer for reference. Field has not been number-locked. This will enable the user to type names and numbers of more than one engineer, if need be.
- **Delivery Date**: User may select the date of the instrument delivery in the company campus.
- **Manufacturer's Sr. No.**: User may enter the manufacturer's serial number for reference.
- **Criticality Level**: User can select Criticality level (A, B or C) from the drop-down as per instrument type.
    - **Group A:** Group A includes standard equipment / instrument with no measurement capability or usual requirement for calibration. Functionality can be assessed by visual observation of its operation. Examples: magnetic stirrers, vortex mixers, and centrifuges.
    - **Group B:** Group B includes standard equipment and instruments providing measured values as well as equipment controlling physical parameters (such as temperature, pressure, or flow) that need calibration. Examples: water bath, cooling centrifuge, pipettes and autoclave.
    - **Group C:** Group C includes instrument and computerized analytical systems which make critical measurements that are quality descriptors of the analyte and store data. Examples: HPLC, plate reader, flow cytometer etc.
- **Backup in-charge**: User can select a backup for the instrument in-charge who will also get the alerts and notifications and may address them in case the primary in-charge isn't available. This list is also pre-populated from the existing employee list.
- **PO Date**: User may select the date of when the Purchase Order was issued for the instrument.
- **Availability**: Availability toggle-switch is embedded for each entry of an instrument. Availability may also be

toggled on the instrument master landing page against the instrument ID and set the status. Availability will have the below 2 options:

- ON – Instrument is Available for use.
- OFF – Instrument is unavailable for use. On clicking OFF, a pop-up will appear where the user can fill details manually. Possible reasons may vary from Preventive maintenance, broken down, Calibration and likes.

- **Department**: Department list is populated from the pre-populated department list in the administration module. This module is separately described in detail. User can select a department from the available options in the drop-down which is assigned to the instrument.

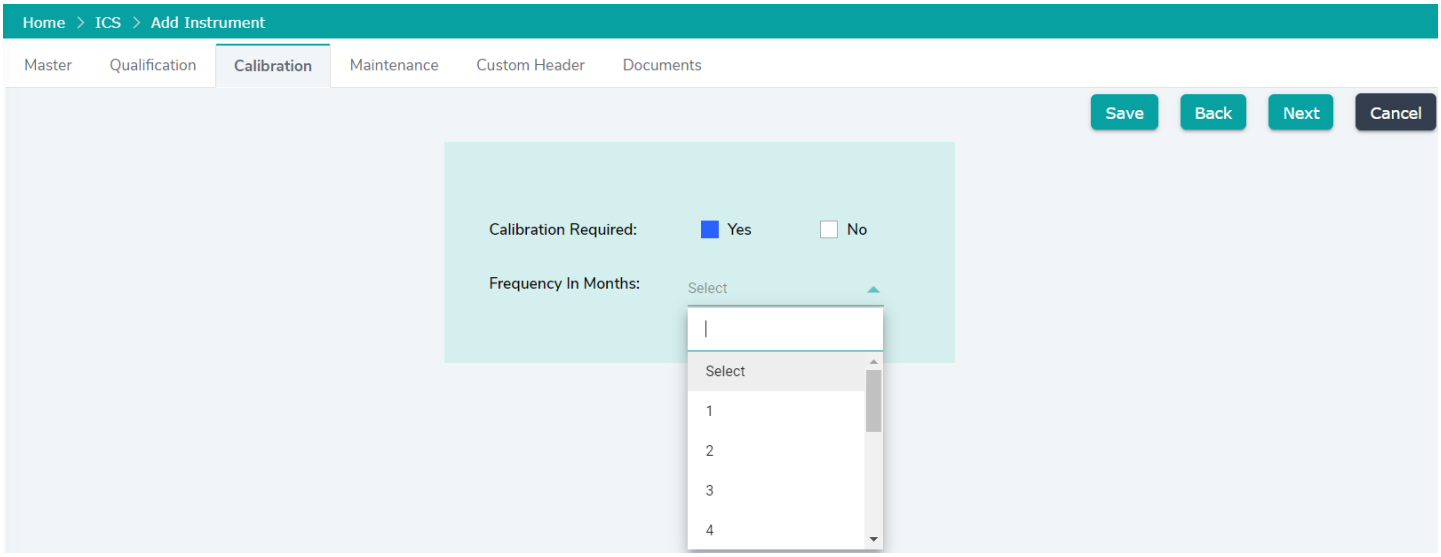
➢ **Qualification**: A list of qualifications added for the instrument will reflect on this page (tab) along with a folder of attached documents linked to the entry. User may input details of qualifications performed for the instrument before the instrument registration in the master in this section.



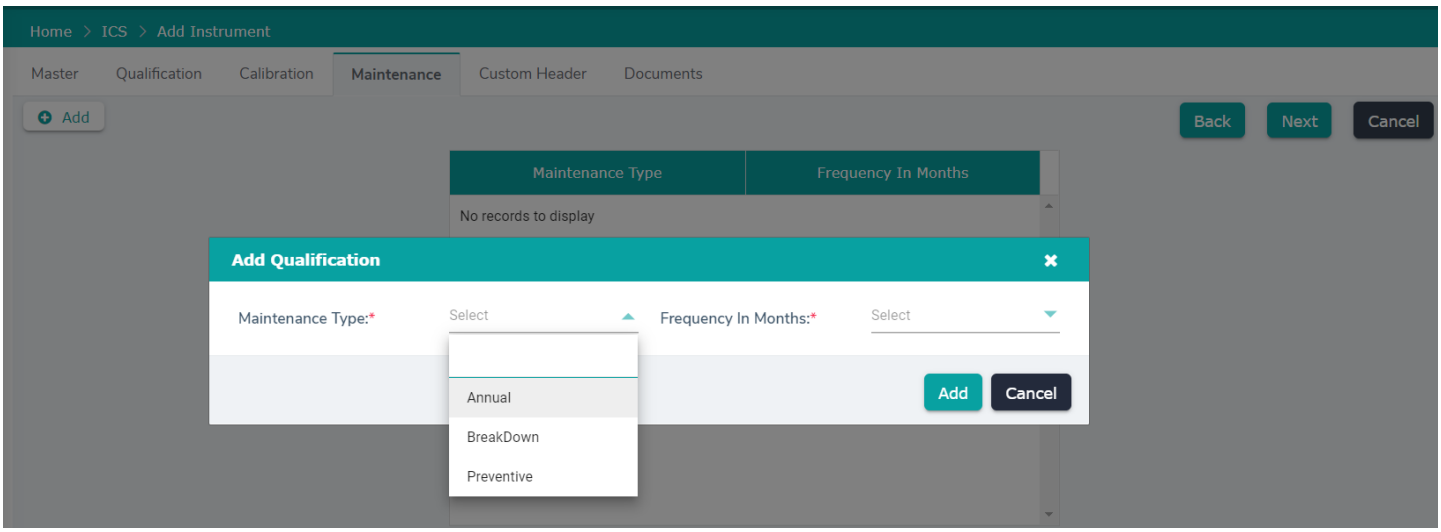
'**Add Qualification**' button will route the user to a pop-up screen where he/she can enter the below details:

- **Qualification type**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may select the type of qualification from the drop-down list (The options locked for this category are DQ, FAT, IA, IQ, IO, OP, OQ, PQ, RQ, SAT, URS).
- **Performed by**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the name of person who performed the said qualification.
- **Date of Qualification**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the date when the said qualification was performed. This will be the end date of qualification in case the activity extends to more than a day.
- **Attachment**: User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the instrument qualification entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
- **Description**: User may enter additional description if and when available.

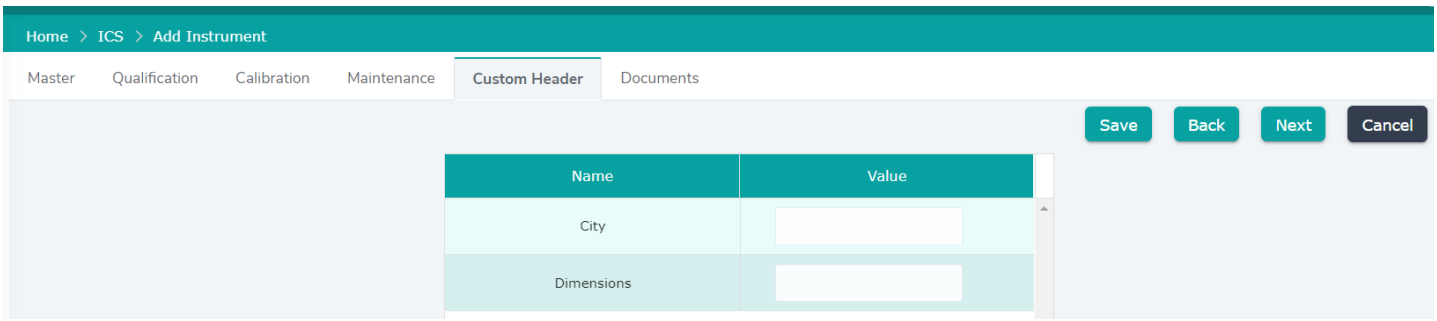
➢ **Calibration**: Primary detail of if the Instrument needs to be calibrated may be selected from the options (Yes/No) here. User must enter the frequency of calibration in months in case calibration is required (option 'Yes' is selected).



- **Maintenance**: Primary detail of if the instrument needs maintenance to be scheduled may be selected from available options (Annual, Breakdown, Preventive). User may select a frequency in months for the maintenance type 'Preventive'. Frequency for Annual maintenance and Breakdown is fixed to 12 months and the option NA (not applicable) respectively. Once an entry for maintenance is created here, it will start reflecting in the Maintenance section (described in the topic Maintenance) for the instrument. Further details of maintenance performed may be entered in that section.



- **Custom Header**: This feature has been provided in case the module needs an additional entry made which isn't available in the module's design. This will be treated as another column for all entries being made for any/all instruments. A custom header column may be added from the settings>user settings> custom header section. User may enter alphabets, number or special characters as values for the defined custom header.



- **Documents**: Any additional attachments for the instrument may be uploaded in this section.

- Instrument details may be accessed and edited on clicking the (Pencil icon) in the actions column for the instrument. Edit Instrument feature will open a canvas like 'Add instrument' with pre-populated data present for the selected instrument from the database.

Note:

- Tabs for Qualification, Calibration and Maintenance are for primarily noting the initial activity for the instrument. A separate sub menu has been provided to make changes or add information for these activities. These topics have been described in the next few topics.
- Qualification types:

DQ	:	Design Qualification
FAT	:	Factory Acceptance Test
IA	:	Impact Assessment
IQ	:	Installation Qualification
IO	:	Installation Operation (Qualification)
OP	:	Operation Performance (Qualification)
OQ	:	Operation Qualification
PQ	:	Performance Qualification
RQ	:	Requalification
SAT	:	Site Acceptance Test
URS	:	User Requirement Specification

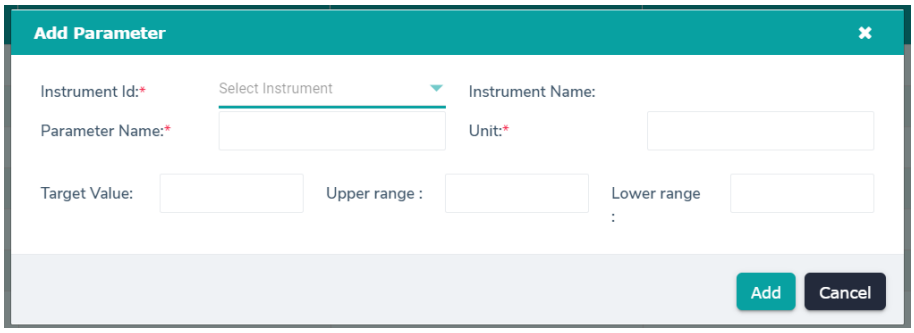
2.3. Parameters

Parameters

Parameters page will be used to monitor the instrument health by tracking its performance within the norms set for each of its parameters. A range (upper and lower) and a target value needs to be set for each parameter of instrument initially. The system will send email alerts and Notifications (as set per equipment) for all readings which go out of this set boundary. Reports and data sheets can be extracted using this data.

While adding a parameter for instruments, below entries may be filled:

- **Instrument ID**: ID of the Instrument for which the parameter needs to be set may be selected here. This is a mandatory field which needs to be filled to save the entry. This drop-down will list all instruments which have been added in the master list.
- **Instrument Name**: Name of the Instrument will be auto-populated once the instrument ID is selected.
- **Parameter Name**: This is a mandatory field which must be filled to save the entry. Here, the user may write name of the parameter to be linked with the instrument manually. This text-box allows alphabets, numbers and special characters.
- **Unit**: This is a mandatory field which must be filled to save the entry. Here, the user may write name of the unit for the corresponding parameter manually. This text-box allows alphabets, numbers and special characters.
- **Upper Range**: Here, the user may fill a value above which the parameter reading should not be accepted by the system. The reading equal to this value will still be accepted by the system. upper range will not be permitted to be set lower than the target or the lower range.
- **Lower Range**: Here, the user may fill a value below which the parameter reading should not be accepted by the system. The reading equal to this value will still be accepted by the system. Lower range will not be permitted to be set higher than the target or upper range.
- **Target Value**: User may set a target value which is ideal for the parameter in any given conditions. Target value will not be permitted to be set greater than the upper range or lower than the lower range.



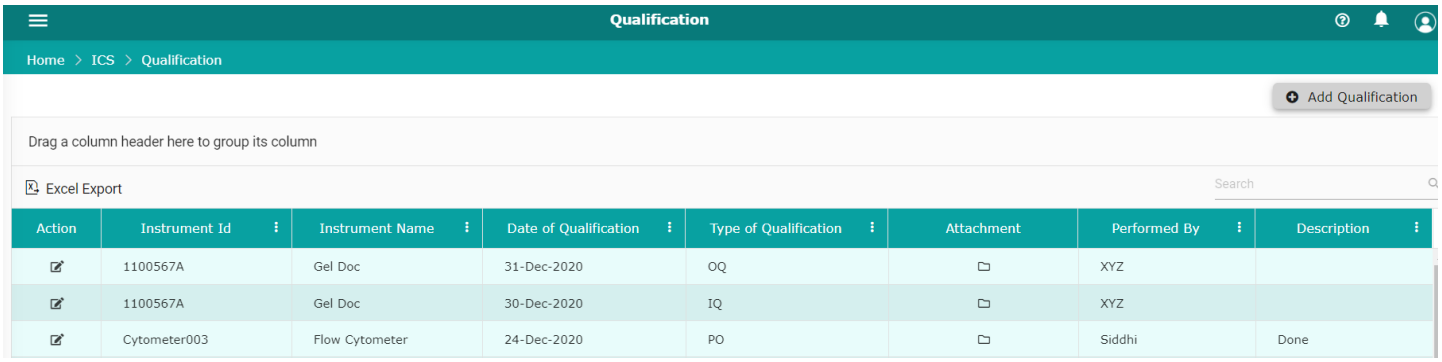
Once these parameters are added in the system, they will start reflecting on the landing page for parameters against the instrument ID.

2.4. Qualification

Qualification

Qualification page will summarize the qualification history of all instruments at one go. Qualification may be chosen from available types (DQ, FAT, IA, IQ, IO, OP, OQ, PQ, RQ, SAT, URS). This list will also include all entries made while registering the instrument in the master list for the first time. The said entries may be edited here as well. This section will have the following features:

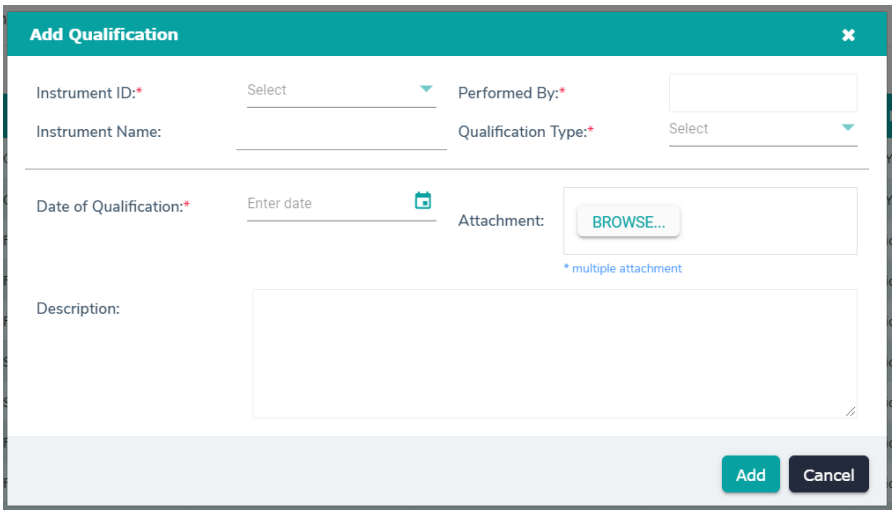
- Qualification details of all instruments are enlisted on the qualification landing page. User may group qualification entries by dragging and dropping the header that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may also export the list in excel format by clicking on the 'Excel export' button above the list.



- '**Add Qualification**' button, on click, pops up a window with a blank input canvas where qualification details for the instrument may be filled and saved. While adding an entry, the below tabs may be populated:
  - **Instrument ID**: ID of the Instrument for which qualification needs to be entered during the lifespan of the instrument may be selected here. This is a mandatory field which needs to be filled to save the entry. This drop-down will list all instruments which have been added in the master list.
  - **Performed by**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the name of person who performed the said qualification.
  - **Instrument Name**: Name of the Instrument will be auto-populated once the instrument ID is selected.
  - **Qualification type**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may select the type of qualification from the drop-down list (The options locked for this category are DQ, FAT, IA, IQ, IO, OP, OQ, PQ, RQ, SAT, URS).
  - **Date of Qualification**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the date when the said qualification was performed. This will be the end date of

qualification in case the activity extends to more than a day.

- **Attachment**: User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the instrument qualification entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
- **Description**: User may enter additional description if and when available.



- Instrument Qualification details may be accessed after saving and edited on clicking (Pencil icon) in the actions column for the instrument. Edit Instrument qualification feature will open a canvas like 'Add qualification' with pre-populated data present for the selected instrument from the database.

Notes:

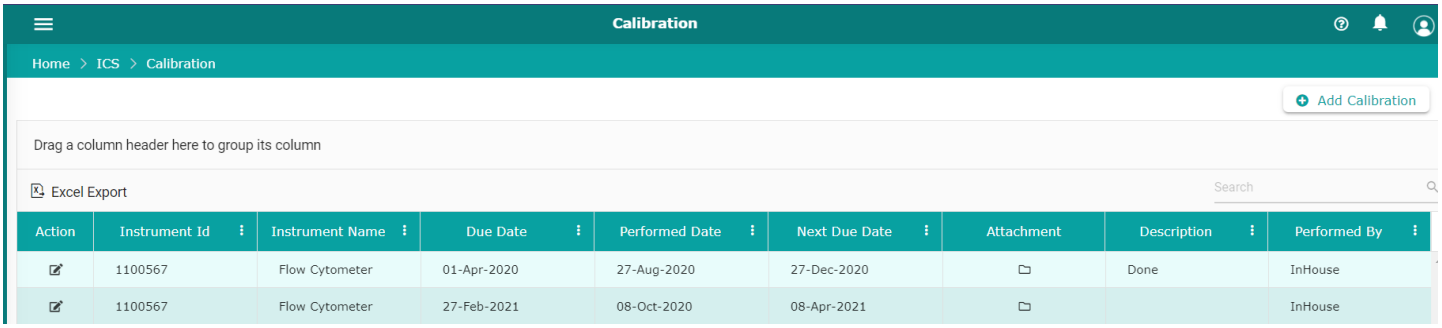
DQ	:	Design Qualification
FAT	:	Factory Acceptance Test
IA	:	Impact Assessment
IQ	:	Installation Qualification
IO	:	Installation Operation (Qualification)
OP	:	Operation Performance (Qualification)
OQ	:	Operation Qualification
PQ	:	Performance Qualification
RQ	:	Requalification
SAT	:	Site Acceptance Test
URS	:	User Requirement Specification

2.5. Calibration

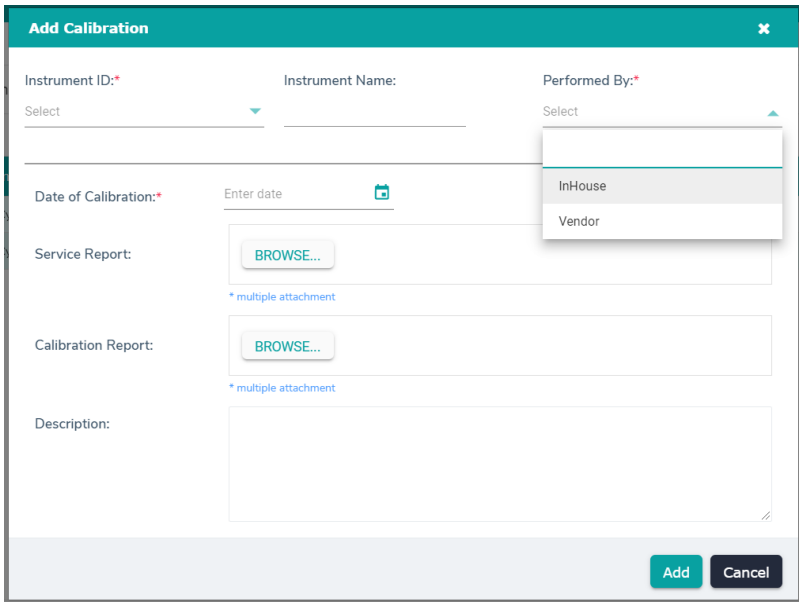
Calibration

Calibration page will summarize the Calibration history of all instruments at one go. Calibration may be chosen from available Calibrations (In-house, Vendor calibrated). It will have the following features on the page:

- Calibration list of all instruments is enlisted on this page. User may group calibration entries by dragging and dropping the header that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may also export the list in excel format by clicking on the 'Excel export' button above the list.



- ‘**Add Calibration**’ button, on click, pops up a window with a blank input canvas where calibration details for the instrument may be filled and saved. While adding an entry, the below tabs may be populated:
  - **Instrument ID**: ID of the Instrument for which qualification needs to be entered during the lifespan of the instrument may be selected here. This is a mandatory field which needs to be filled to save the entry. This drop-down will list all instruments which have been added in the master list.
  - **Instrument Name**: Name of the Instrument will be auto-populated once the instrument ID is selected.
  - **Performed by**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may select from the options (In-house, Vendor) in the drop-down.
  - **Date of Calibration**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the date when the said calibration was performed. This will be the end date of calibration in case the activity extends to more than a day.
  - **Service Report**: This is the report presented on day of the service/worksheet. User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the instrument calibration entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
  - **Calibration Report**: This is the report generated after the Calibration is completed and registered by the vendor/in-house personnel. This report may be added after the entry is created by editing the calibration entry on the calibration landing page. User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the instrument calibration entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
  - **Description**: User may enter additional description if and when available.



- Instrument Calibration details may be accessed after saving and edited on clicking (Pencil icon) in the actions column for the instrument. Edit Instrument calibration feature will open a canvas like 'Add calibration' with

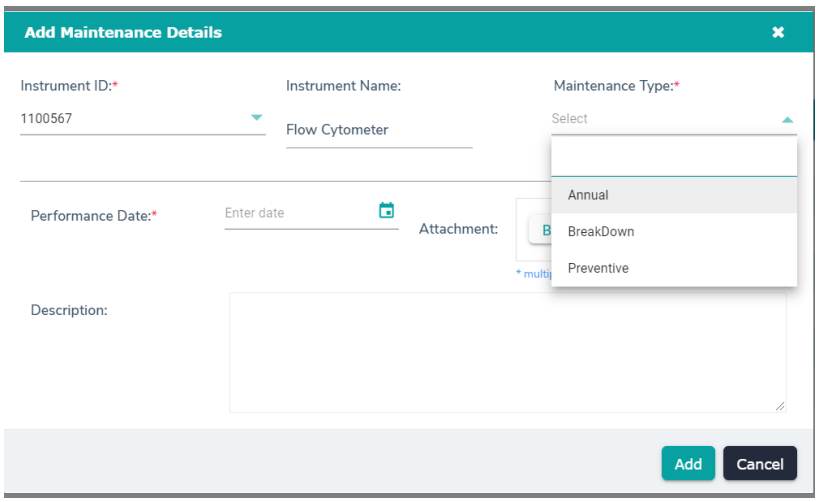
pre-populated data present for the selected instrument from the database.

2.6. Maintenance

Maintenance

Maintenance page will summarize the Maintenance history of all instruments at one go. Maintenance may be chosen from available types (Preventive Maintenance, Annual maintenance, Breakdown). It will have the following features on the page:

- Maintenance list of all instruments is enlisted on this page. User may group maintenance entries by dragging and dropping the header that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may also export the list in excel format by clicking on the 'Excel export' button above the list.
- '**Add Details**' button, on click, pops up a window with a blank input canvas where maintenance details for the instrument may be filled and saved. While adding an entry, the below tabs may be populated:
  - **Instrument ID**: ID of the Instrument for which maintenance needs to be entered during the lifespan of the instrument may be selected here. This is a mandatory field which needs to be filled to save the entry. This drop-down will list all instruments which have been added in the master list.
  - **Instrument Name**: Name of the Instrument will be auto-populated once the instrument ID is selected.
  - **Maintenance type**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may select the type of maintenance from the drop-down list. The options in this drop-down will be populated from the options (out of Annual, Breakdown, Preventive) set while registering the instrument for maintenance in the instrument master.
  - **Performance date**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the date when the said maintenance was performed. This will be the end date of maintenance in case the activity extends to more than a day.
  - **Attachment**: User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the instrument maintenance entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
  - **Description**: User may enter additional description if and when available.



- Instrument maintenance details may be accessed after saving and edited on clicking (Pencil icon) in the actions column for the instrument. Edit Instrument maintenance feature will open a canvas like 'Add details'

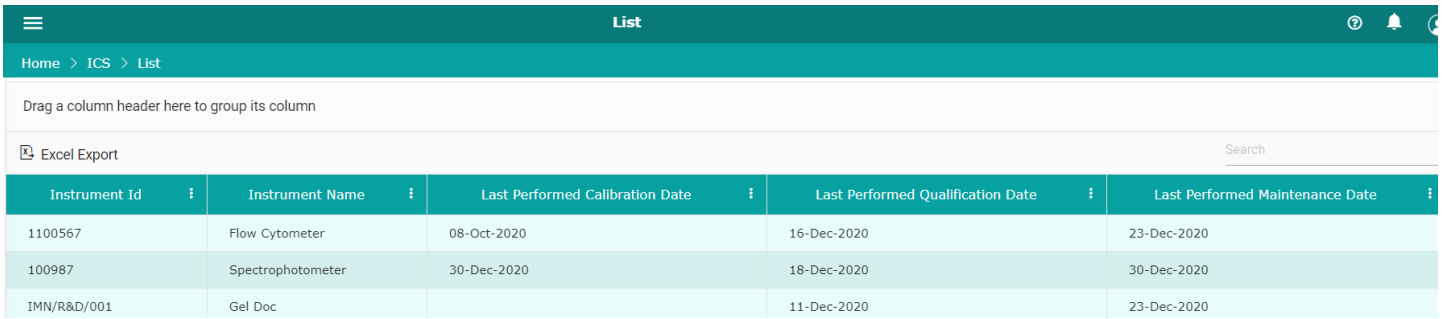
with pre-populated data present for the selected instrument from the database.

2.7. Reports

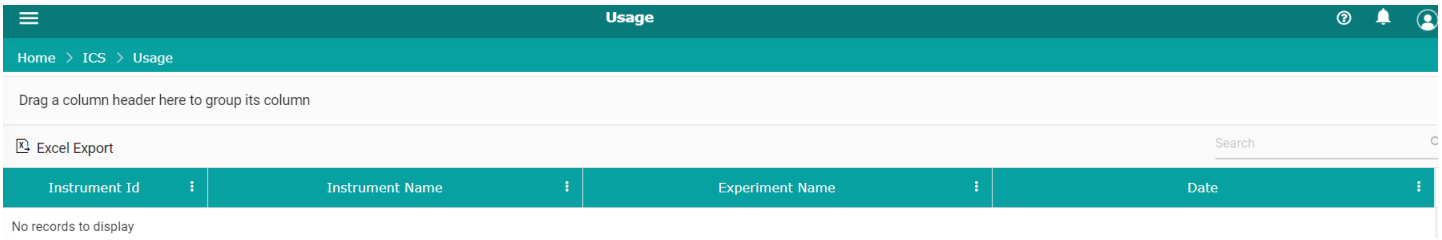
Reports

Following reporting features will be provided in this module.

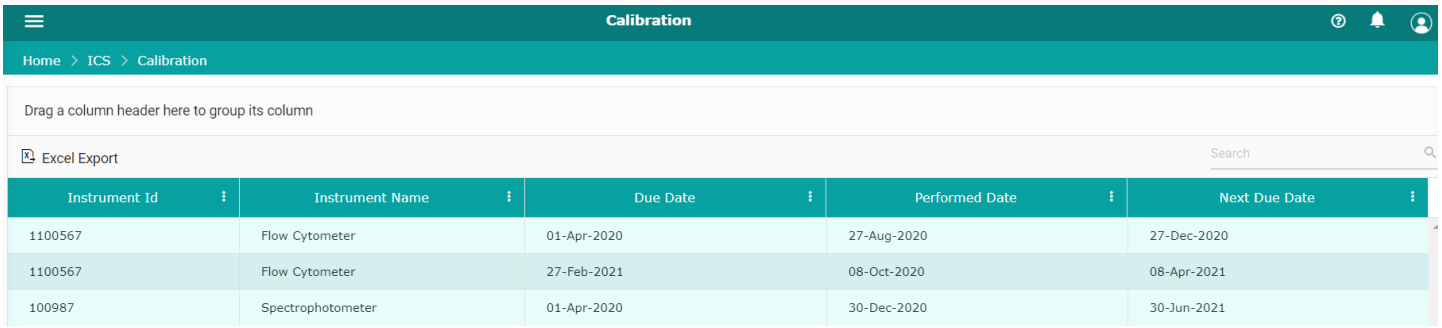
- **List**: This report will enlist all Instruments with the latest calibration/maintenance/qualification record dates. Please note that the report will start listing an instrument only after at least one of the activities (Calibration, maintenance, qualification) has been performed. User may group entries by dragging and dropping the headers (Instrument ID, Instrument Name, Last performed calibration date, last performed qualification date, last performed maintenance date) that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may export the list in excel format by clicking on the 'Excel export' button above the list.



- **Usage**: This report will show history of Instrument usage in experiments performed in Electronic Laboratory Notebook. User may group entries by dragging and dropping the headers (Instrument ID, Instrument Name, Experiment ID, Experiment Name, Date) that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may export the list in excel format by clicking on the 'Excel export' button above the list.



- **Calibration**: This report will show Calibration details of Instruments listing the due dates. User may group entries by dragging and dropping the headers (Instrument ID, Instrument Name, Due date, Performed Date, Next due date) that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may export the list in excel format by clicking on the 'Excel export' button above the list.

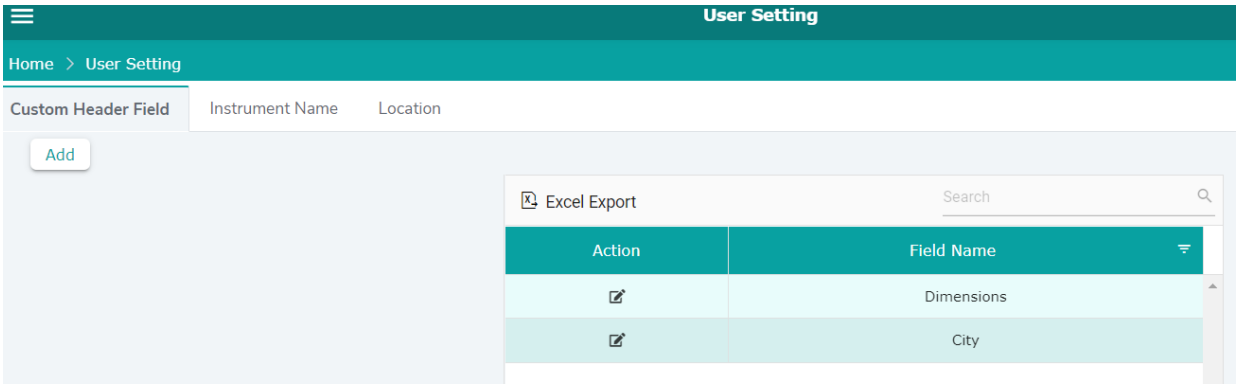


2.8. Settings

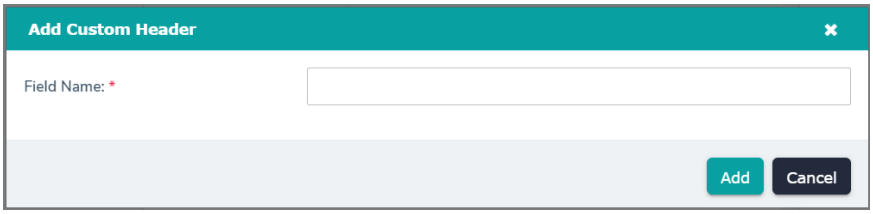
Settings

Following features are provided as part of the user settings in this module:

- **Custom Header Field**: This feature has been provided in case the module needs an additional entry made which isn't available in the module's design. This will be treated as another column for all entries being made for any/all instruments once the said custom header entry is added in the database. User may enter alphabets, number or special characters as values for the defined custom header.

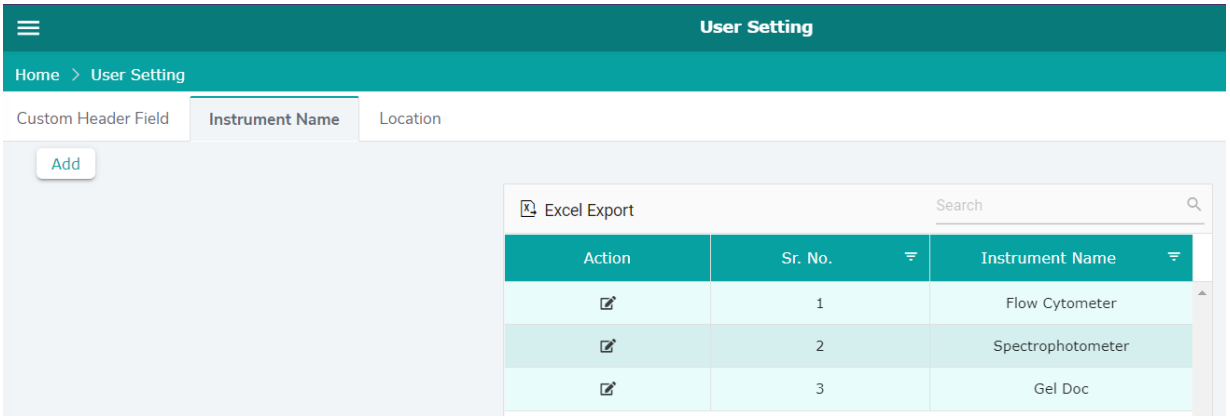


Custom Header listing



Adding a new custom header entry

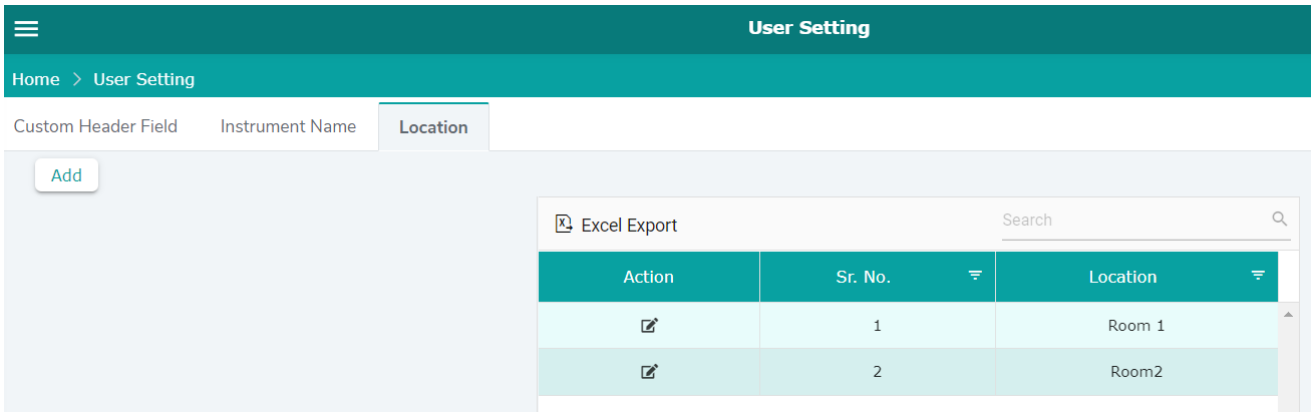
- **Instrument Name**: Instrument names may be added using this setting. An instrument name will start reflecting in the instrument master>Add instrument>Instrument name drop-down once it is added here. User may enter alphabets, number or special characters as values here.



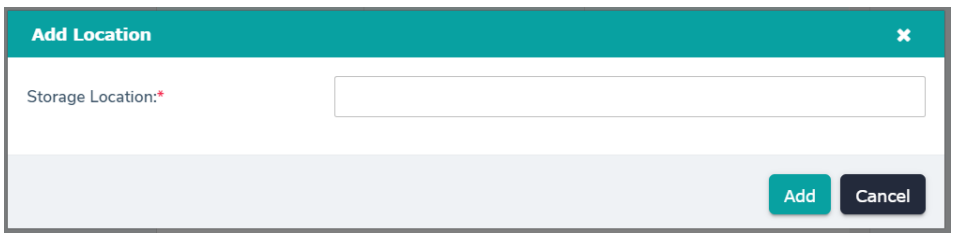
Instrument Name listing

Adding a new instrument type

o **Location**: Placement locations may be added to the list here. These will start reflecting in the Instrument Master>Add instrument>Location drop-down once it is added here. User may enter alphabets, number or special characters as values here.



Location listing



Adding a new location to the list

3. Help_EQS_V1.0

SYMPHONYTECH - ELECTRONIC LABORATORY NOTEBOOK
HELP SECTION
FOR
EQUIPMENT QUALIFICATION SYSTEM

Document Number: Help-001

Version Number: 1.0

Version Date: November 16, 2020

VERSION HISTORY

Development and distribution of this Help Document will be controlled and tracked by SymphonyTech Biologics Pvt Ltd (SBx) based on changes approved by both parties. This document is being created for presenting details on how to use Equipment Qualification System (EQS) module for SymphonyTech - ELN product.

Version Number	Implemented by	Revision date	Approved by	Approval date	Description of change
1	SBx	16-Nov-20			Help Section for EQS

3.1. Introduction

Introduction

Welcome to the Equipment Qualification System. This module is designed to keep log of information about Equipment and their use in a systematic and traceable manner. This will help to accurately monitor Equipment in correlation to the respective standards.

This guide will provide detailed information of the requested behavior and how the system will function.

Terms, Acronyms and definitions

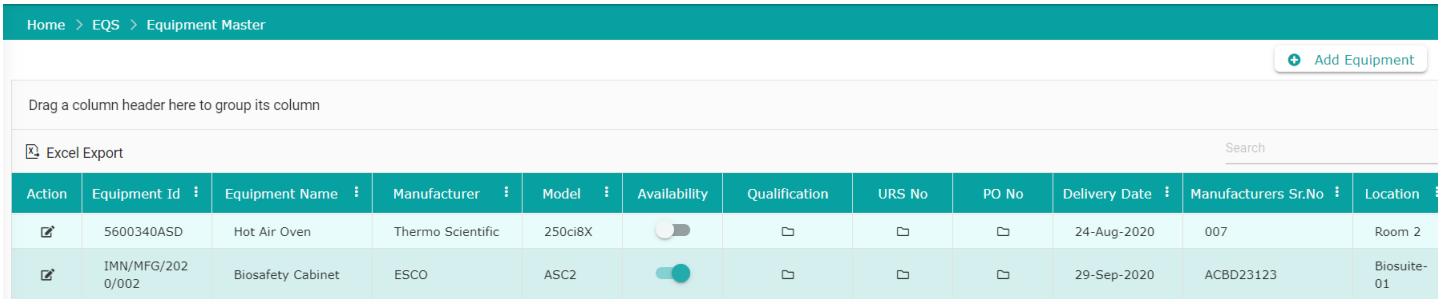
Term	Definition	Description

ICS	Instrument Calibration System	This module will track Instrument calibration to accurately monitor instruments in correlation to the respective standards and talk with ELN module
ELN	Electronic Laboratory Notebook	Secure browser-based platform to record and manage laboratory data all in one place and to replace paper lab notebooks
EQS	Equipment Qualification System	Module for performing Qualification for fitness of use as well as tracking of continued capability of equipment for its stated purpose
IMS	Inventory Management System	Module for logging inventory of consumable (Incoming/Outgoing) material used during experiments and for validating within expiry dates of each lot.
SBx	SymphonyTech Biologics Pvt Ltd, Pune	
ID	Identity	
PO	Purchase Order	
DQ	Design Qualification	
FAT	Factory acceptance Test	
IA	Impact Analysis	
IQ	Installation Qualification	
IO	Installation Operation Qualification	
OP	Operation performance Qualification	
OQ	Operational Qualification	
PQ	Performance Qualification	
RQ	Re qualification	
SAT	Site Acceptance Test	
AMC	Annual Maintenance Contract	
CMC	Comprehensive Maintenance Contract	
PM	Preventive Maintenance	
WO	Work Order	
SOP	Standard Operating Procedure	
IOP	Instrument Operating Procedure	
EOP	Equipment Operating Procedure	
PV	Performance Verification	

3.2. Equipment Master

Equipment Master

Equipment Master page will be a summary of master data of all Equipment in a go.

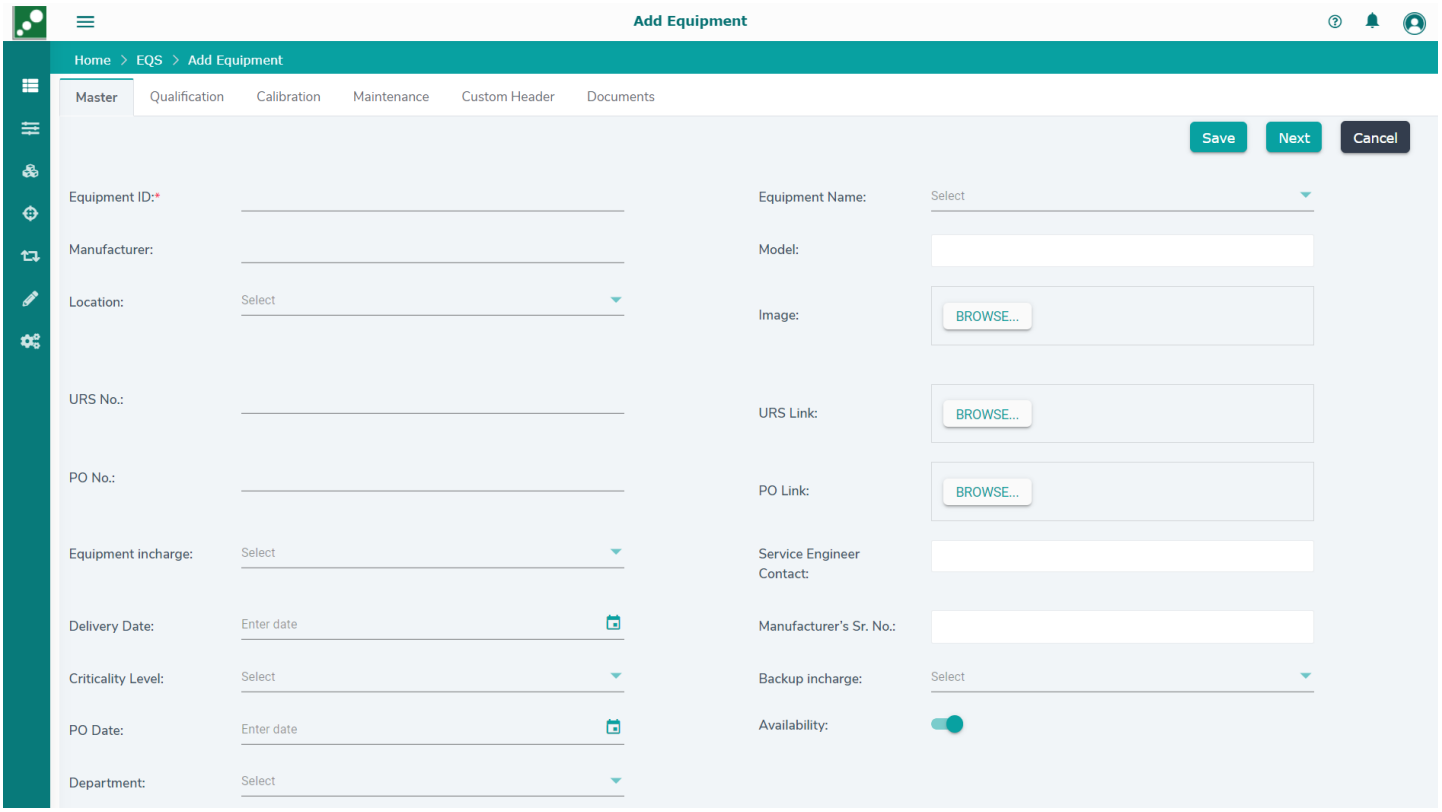


Features:

- Equipment master details are displayed once user clicks on the **Equipment master** page. User may group Equipment entries by dragging and dropping the header that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may also export the list in excel format by clicking on the 'Excel export' button above the list.

- Clicking on '**Add Equipment**' button routes to a web page (form) with a blank input canvas where the Equipment master details may be filled and saved. While adding an Equipment, the below tabs may be populated as primary information for the Equipment:

  - **Master**: This page has all primary information that may be required to register the Equipment in the system.



  - **Equipment ID**: This field is a mandatory requirement that a user must fill to enable saving the entry. This text box accepts alphabets, Numbers and special characters. Existing list of Equipment IDs will start reflecting in a selection box on typing 1 character in the text box. User may select and edit the entry further.

  - **Equipment Name**: This field is an optional requirement. User can select from available list of Equipment names in the drop-down. This list is pre-populated in the Settings>User settings>Equipment Name tab (described in detail in the settings section of help).

  - **Manufacturer**: This field is an optional requirement. A user may fill if and when the information is available. This text box accepts alphabets, Numbers and special characters. Existing list of manufacturers will start reflecting in a selection box on typing 1 character in the text box. User may select and edit the entry further.

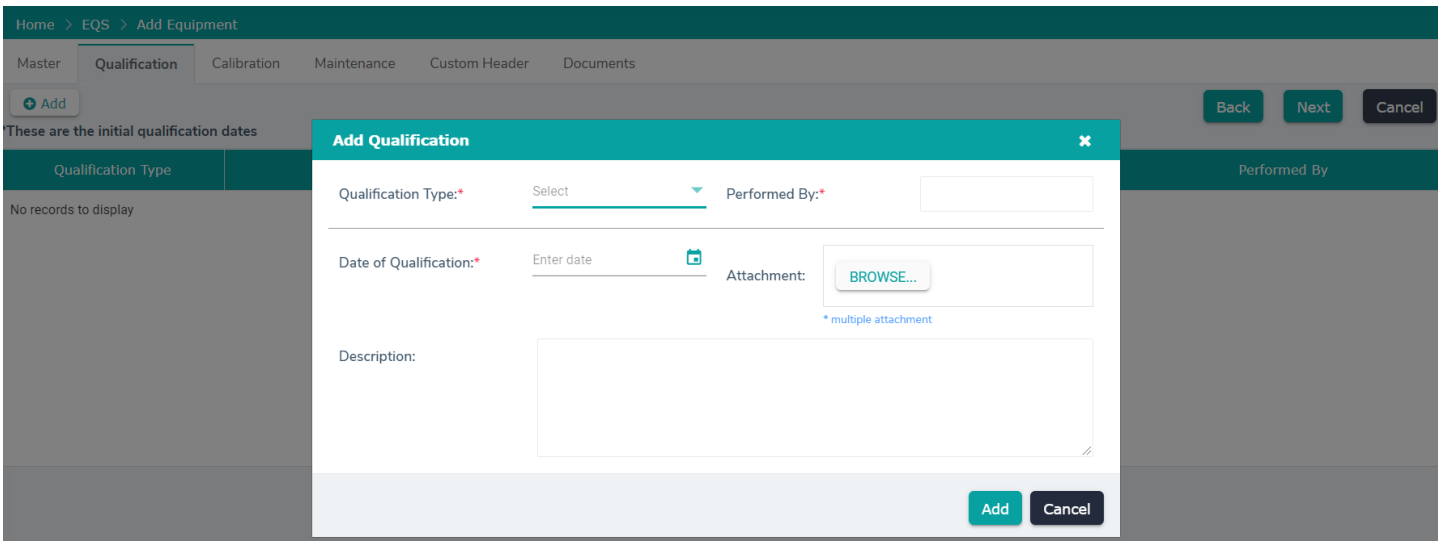
- **Model**: This field is an optional requirement. A user may fill if and when the information is available. This text box accepts alphabets, Numbers and special characters.
- **Location**: This field is an optional requirement. User can select from available list of locations in the drop-down. This list is pre-populated in the Settings>User settings>Location tab (described in detail in the settings section of help).
- **Image**: An image may be browsed from the local file manager on user's device and uploaded as part of the Equipment entry. Here, only 1 entry is permitted at a given point in time. File type has not been restricted while uploading.
- **URS No**.: User requirement specification number may be mentioned here. This field is an optional requirement. A user may fill if and when the information is available. This text box accepts alphabets, Numbers and special characters. Existing list of URS numbers will start reflecting in a selection box on typing 1 character in the text box. User may select and edit the entry further.
- **URS Link**: User requirement specification document corresponding to the number added in URS No. may be browsed from the local file manager on the user's device and uploaded as part of the Equipment entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
- **PO No**.: Purchase Order number may be mentioned here. This field is an optional requirement. A user may fill if and when the information is available. This text box accepts alphabets, Numbers and special characters. Existing list of PO numbers will start reflecting in a selection box on typing 1 character in the text box. User may select and edit the entry further.
- **PO Link**: Purchase Order document corresponding to the number added in PO No. may be browsed from the local file manager on the user's device and uploaded as part of the Equipment entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
- **Equipment In-charge**: A user may select an employee in charge of the Equipment. This list is pre-populated from the existing employee list. All alerts and notifications will be sent to this person's ID once appointed.
- **Service Engineer Contact**: User may enter a phone number of the service engineer for reference. Field has not been number-locked. This will enable the user to type names and numbers of more than one engineer, if need be.
- **Delivery Date**: User may select the date of the Equipment delivery in the company campus.
- **Manufacturer's Sr. No.**: User may enter the manufacturer's serial number for reference.
- **Criticality Level**: User can select Criticality level (A, B or C) from the drop-down as per Equipment type.
    - **Group A:** Group A includes standard equipment / instrument with no measurement capability or usual requirement for calibration. Functionality can be assessed by visual observation of its operation. Examples: magnetic stirrers, vortex mixers, and centrifuges.
    - **Group B:** Group B includes standard equipment and instruments providing measured values as well as equipment controlling physical parameters (such as temperature, pressure, or flow) that need calibration. Examples: water bath, cooling centrifuge, pipettes and autoclave.
    - **Group C:** Group C includes instrument and computerized analytical systems which make critical measurements that are quality descriptors of the analyte and store data. Examples: HPLC, plate reader, flow cytometer etc.
- **Backup in-charge**: User can select a backup for the Equipment in-charge who will also get the alerts and notifications and may address them in case the primary in-charge isn't available. This list is also pre-populated from the existing employee list.
- **PO Date**: User may select the date of when the Purchase Order was issued for the Equipment.
- **Availability**: Availability toggle-switch is embedded for each entry of an Equipment. Availability may also be toggled on the Equipment master landing page against the Equipment ID and set the status. Availability will

have the below 2 options:

- ON – Equipment is Available for use.
- OFF – Equipment is unavailable for use. On clicking OFF, a pop-up will appear where the user can fill details manually. Possible reasons may vary from Preventive maintenance, broken down, Calibration and likes.

▪ **Department**: Department list is populated from the pre-populated department list in the administration module. This module is separately described in detail. User can select a department from the available options in the drop-down which is assigned to the Equipment.

➢ **Qualification**: A list of qualifications added for the Equipment will reflect on this page (tab) along with a folder of attached documents linked to the entry. User may input details of qualifications performed for the Equipment before the Equipment registration in the master in this section.



'**Add Qualification**' button will route the user to a pop-up screen where he/she can enter the below details:

▪ **Qualification type**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may select the type of qualification from the drop-down list (The options locked for this category are DQ, FAT, IA, IQ, IO, OP, OQ, PQ, RQ, SAT, URS).

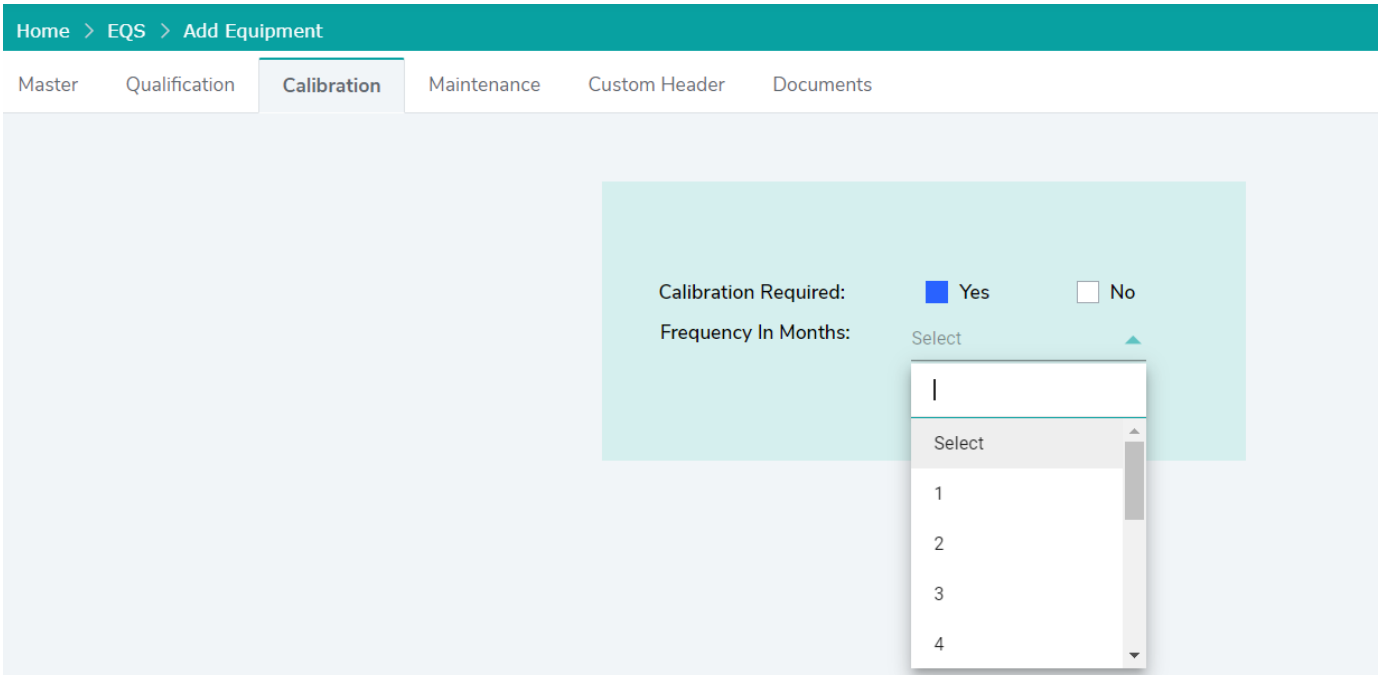
▪ **Performed by**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the name of person who performed the said qualification.

▪ **Date of Qualification**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the date when the said qualification was performed. This will be the end date of qualification in case the activity extends to more than a day.

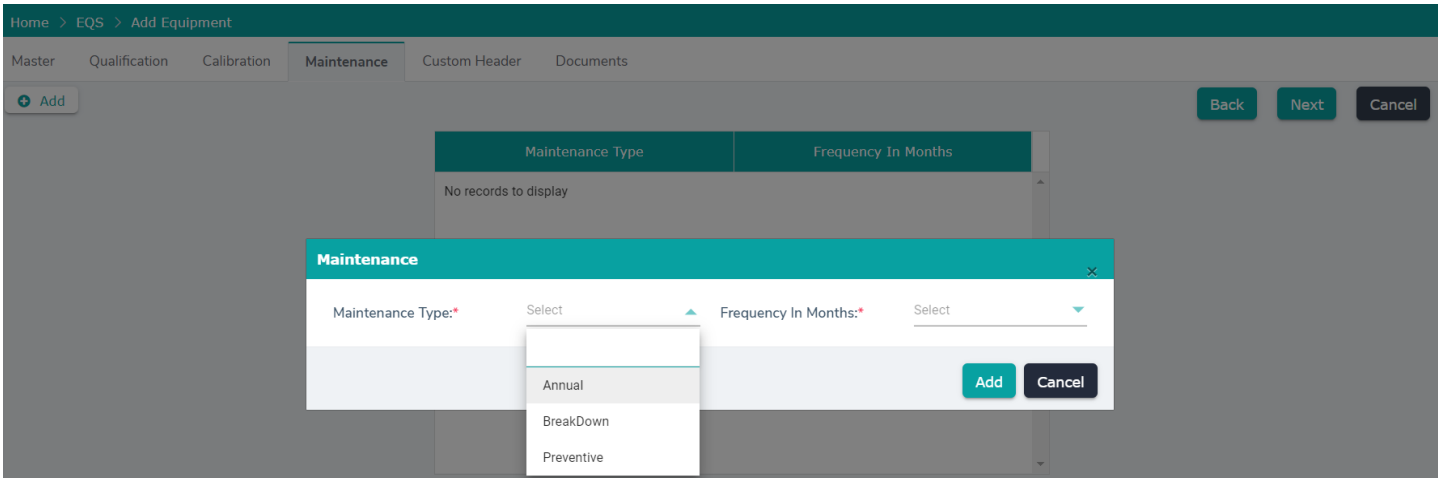
▪ **Attachment**: User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the Equipment qualification entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.

▪ **Description**: User may enter additional description if and when available.

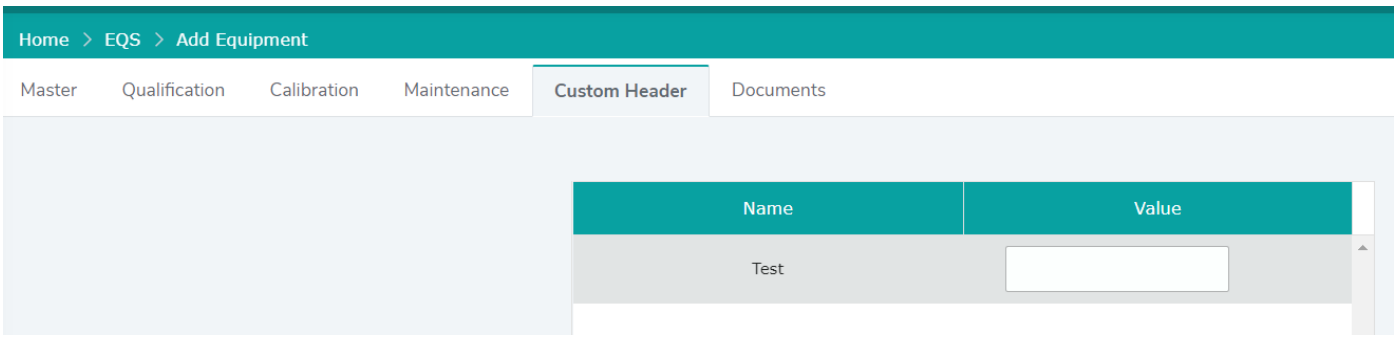
➢ **Calibration**: Primary detail of if the Equipment needs to be calibrated may be selected from the options (Yes/No) here. User must enter the frequency of calibration in months in case calibration is required (option 'Yes' is selected).



- **Maintenance**: Primary detail of if the Equipment needs maintenance to be scheduled may be selected from available options (Annual, Breakdown, Preventive). User may select a frequency in months for the maintenance type 'Preventive'. Frequency for Annual maintenance and Breakdown is fixed to 12 months and the option NA (not applicable) respectively. Once an entry for maintenance is created here, it will start reflecting in the Maintenance section (described in the topic Maintenance) for the Equipment. Further details of maintenance performed may be entered in that section.



- **Custom Header**: This feature has been provided in case the module needs an additional entry made which isn't available in the module's design. This will be treated as another column for all entries being made for any/all Equipment. A custom header column may be added from the settings>user settings> custom header section. User may enter alphabets, number or special characters as values for the defined custom header.



- **Documents**: Any additional attachments for the Equipment may be uploaded in this section.

- Equipment details may be accessed and edited on clicking the (Pencil icon) in the actions column for the

Equipment. Edit Equipment feature will open a canvas like 'Add Equipment' with pre-populated data present for the selected Equipment from the database.

Note:

- Tabs for Qualification, Calibration and Maintenance are for primarily noting the initial activity for the Equipment. A separate sub menu has been provided to make changes or add information for these activities. These topics have been described in the next few topics.
- Qualification types:

DQ	:	Design Qualification
FAT	:	Factory Acceptance Test
IA	:	Impact Assessment
IQ	:	Installation Qualification
IO	:	Installation Operation (Qualification)
OP	:	Operation Performance (Qualification)
OQ	:	Operation Qualification
PQ	:	Performance Qualification
RQ	:	Requalification
SAT	:	Site Acceptance Test
URS	:	User Requirement Specification

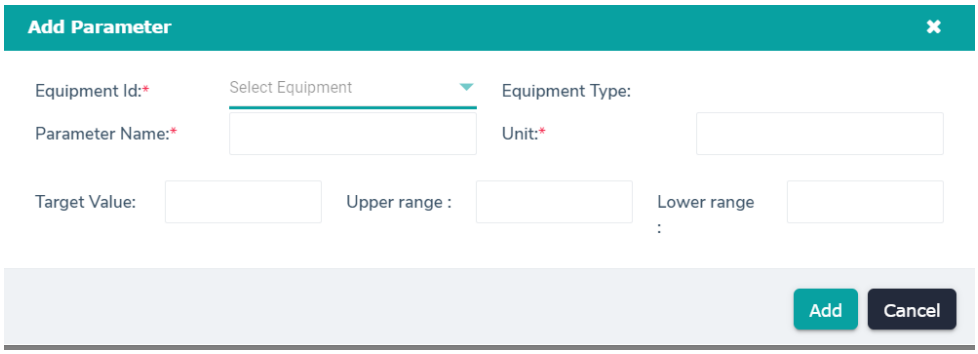
3.3. Parameters

Parameters

Parameters page will be used to monitor the Equipment health by tracking its performance within the norms set for each of its parameters. A range (upper and lower) and a target value needs to be set for each parameter of Equipment initially. The system will send email alerts and Notifications (as set per equipment) for all readings which go out of this set boundary. Reports and data sheets can be extracted using this data.

While adding a parameter for Equipment, below entries may be filled:

- **Equipment ID**: ID of the Equipment for which the parameter needs to be set may be selected here. This is a mandatory field which needs to be filled to save the entry. This drop-down will list all Equipment which have been added in the master list.
- **Equipment Name**: Name of the Equipment will be auto-populated once the Equipment ID is selected.
- **Parameter Name**: This is a mandatory field which must be filled to save the entry. Here, the user may write name of the parameter to be linked with the Equipment manually. This text-box allows alphabets, numbers and special characters.
- **Unit**: This is a mandatory field which must be filled to save the entry. Here, the user may write name of the unit for the corresponding parameter manually. This text-box allows alphabets, numbers and special characters.
- **Upper Range**: Here, the user may fill a value above which the parameter reading should not be accepted by the system. The reading equal to this value will still be accepted by the system. upper range will not be permitted to be set lower than the target or the lower range.
- **Lower Range**: Here, the user may fill a value below which the parameter reading should not be accepted by the system. The reading equal to this value will still be accepted by the system. Lower range will not be permitted to be set higher than the target or upper range.
- **Target Value**: User may set a target value which is ideal for the parameter in any given conditions. Target value will not be permitted to be set greater than the upper range or lower than the lower range.



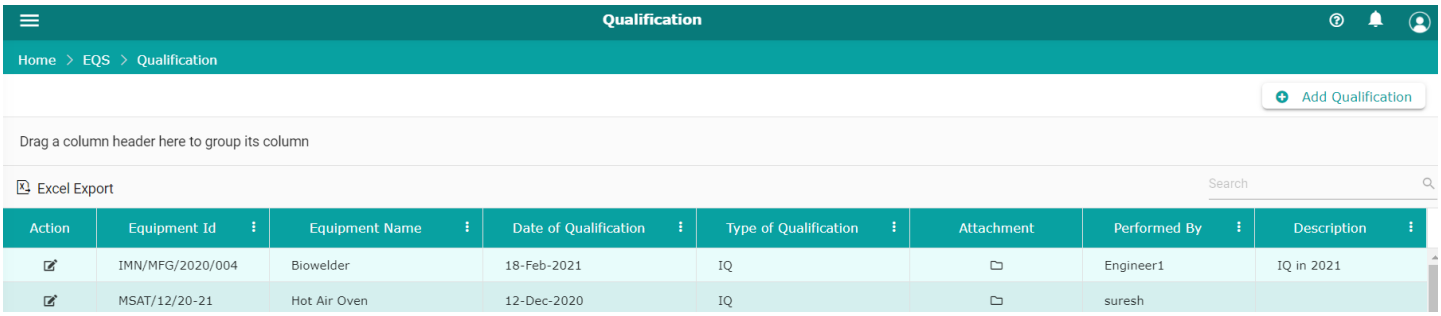
Once these parameters are added in the system, they will start reflecting on the landing page for parameters against the Equipment ID.

3.4. Qualification

Qualification

Qualification page will summarize the qualification history of all Equipment at one go. Qualification may be chosen from available types (DQ, FAT, IA, IQ, IO, OP, OQ, PQ, RQ, SAT, URS). This list will also include all entries made while registering the Equipment in the master list for the first time. The said entries may be edited here as well. This section will have the following features:

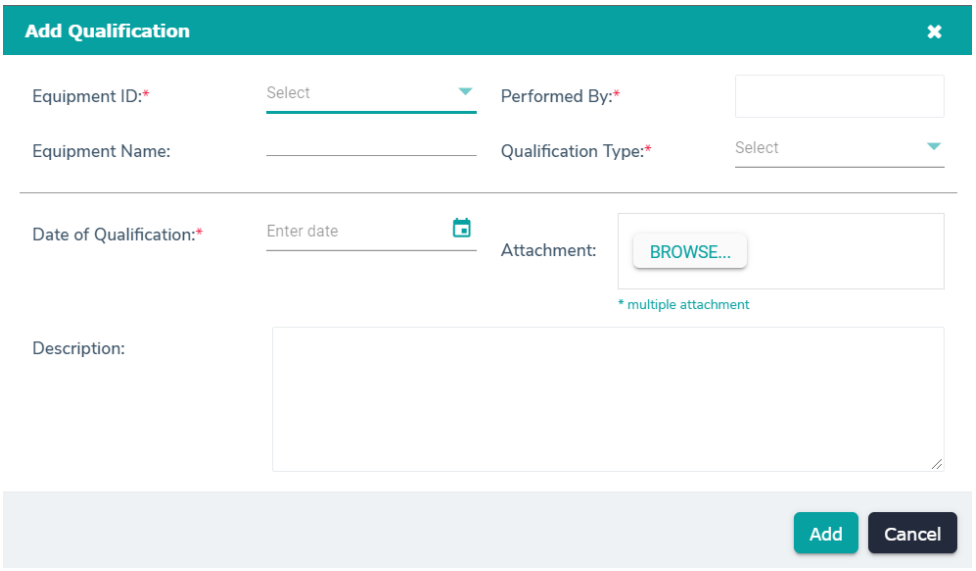
- Qualification details of all Equipment are enlisted on the qualification landing page. User may group qualification entries by dragging and dropping the header that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may also export the list in excel format by clicking on the 'Excel export' button above the list.



- '**Add Qualification**' button, on click, pops up a window with a blank input canvas where qualification details for the Equipment may be filled and saved. While adding an entry, the below tabs may be populated:
  - **Equipment ID**: ID of the Equipment for which qualification needs to be entered during the lifespan of the Equipment may be selected here. This is a mandatory field which needs to be filled to save the entry. This drop-down will list all Equipment which have been added in the master list.
  - **Performed by**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the name of person who performed the said qualification.
  - **Equipment Name**: Name of the Equipment will be auto-populated once the Equipment ID is selected.
  - **Qualification type**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may select the type of qualification from the drop-down list (The options locked for this category are DQ, FAT, IA, IQ, IO, OP, OQ, PQ, RQ, SAT, URS).
  - **Date of Qualification**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the date when the said qualification was performed. This will be the end date of

qualification in case the activity extends to more than a day.

- **Attachment**: User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the Equipment qualification entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
- **Description**: User may enter additional description if and when available.



- Equipment Qualification details may be accessed after saving and edited on clicking (Pencil icon) in the actions column for the Equipment. Edit Equipment qualification feature will open a canvas like 'Add qualification' with pre-populated data present for the selected Equipment from the database.

Notes:

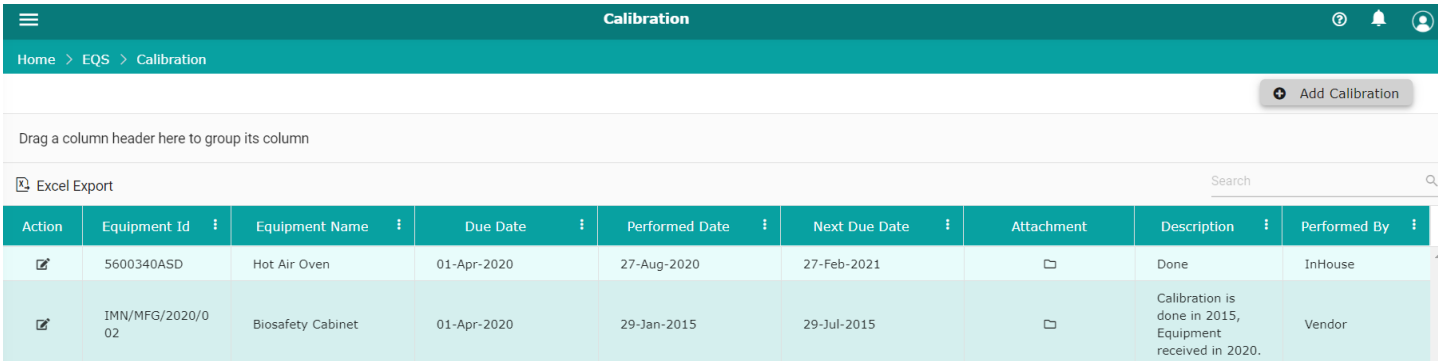
DQ	:	Design Qualification
FAT	:	Factory Acceptance Test
IA	:	Impact Assessment
IQ	:	Installation Qualification
IO	:	Installation Operation (Qualification)
OP	:	Operation Performance (Qualification)
OQ	:	Operation Qualification
PQ	:	Performance Qualification
RQ	:	Requalification
SAT	:	Site Acceptance Test
URS	:	User Requirement Specification

3.5. Calibration

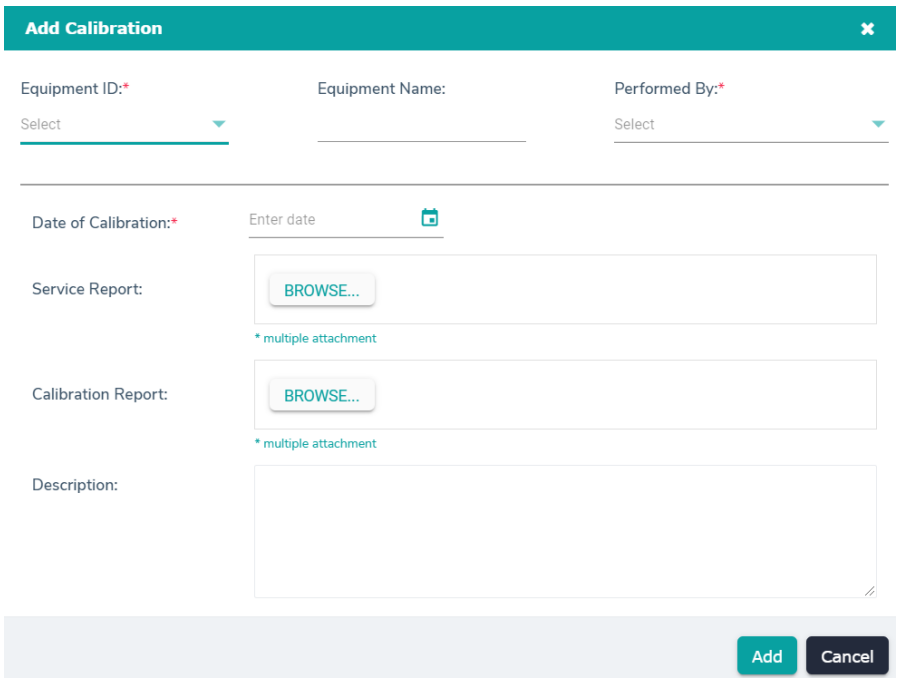
Calibration

Calibration page will summarize the Calibration history of all Equipment at one go. Calibration may be chosen from available Calibrations (In-house, Vendor calibrated). It will have the following features on the page:

- Calibration list of all Equipment is enlisted on this page. User may group calibration entries by dragging and dropping the header that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may also export the list in excel format by clicking on the 'Excel export' button above the list.



- ‘**Add Calibration**’ button, on click, pops up a window with a blank input canvas where calibration details for the Equipment may be filled and saved. While adding an entry, the below tabs may be populated:
  - **Equipment ID**: ID of the Equipment for which qualification needs to be entered during the lifespan of the Equipment may be selected here. This is a mandatory field which needs to be filled to save the entry. This drop-down will list all Equipment which have been added in the master list.
  - **Equipment Name**: Name of the Equipment will be auto-populated once the Equipment ID is selected.
  - **Performed by**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may select from the options (In-house, Vendor) in the drop-down.
  - **Date of Calibration**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the date when the said calibration was performed. This will be the end date of calibration in case the activity extends to more than a day.
  - **Service Report**: This is the report presented on day of the service/worksheet. User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the Equipment calibration entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
  - **Calibration Report**: This is the report generated after the Calibration is completed and registered by the vendor/in-house personnel. This report may be added after the entry is created by editing the calibration entry on the calibration landing page. User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the Equipment calibration entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
  - **Description**: User may enter additional description if and when available.



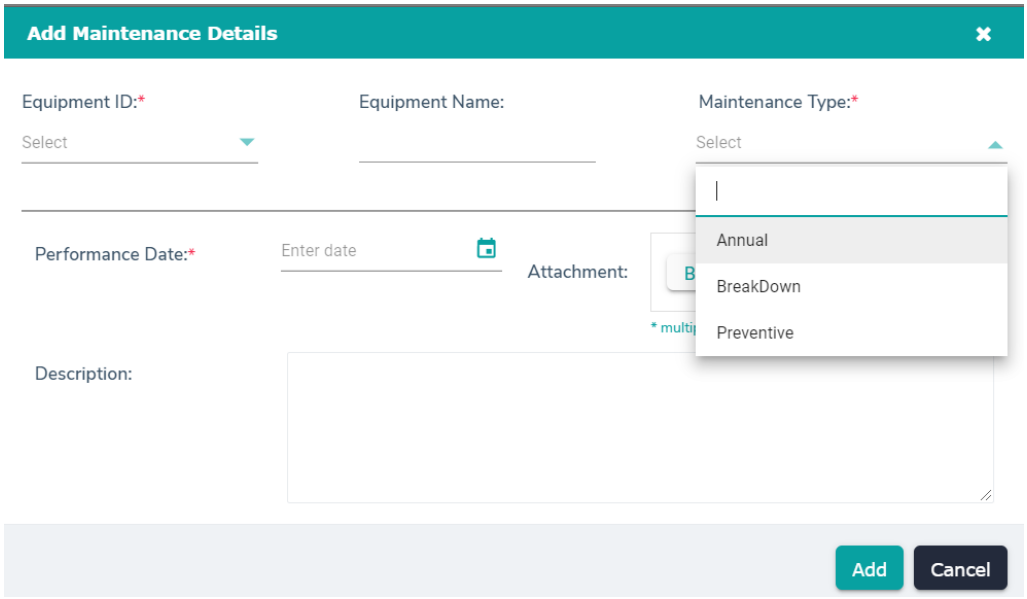
- Equipment Calibration details may be accessed after saving and edited on clicking  (Pencil icon) in the actions column for the Equipment. Edit Equipment calibration feature will open a canvas like 'Add calibration' with pre-populated data present for the selected Equipment from the database.

3.6. Maintenance

Maintenance

Maintenance page will summarize the Maintenance history of all Equipment at one go. Maintenance may be chosen from available types (Preventive Maintenance, Annual maintenance, Breakdown). It will have the following features on the page:

- Maintenance list of all Equipment is enlisted on this page. User may group maintenance entries by dragging and dropping the header that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may also export the list in excel format by clicking on the 'Excel export' button above the list.
- '**Add Details**' button, on click, pops up a window with a blank input canvas where maintenance details for the Equipment may be filled and saved. While adding an entry, the below tabs may be populated:
    - **Equipment ID**: ID of the Equipment for which maintenance needs to be entered during the lifespan of the Equipment may be selected here. This is a mandatory field which needs to be filled to save the entry. This drop-down will list all Equipment which have been added in the master list.
    - **Equipment Name**: Name of the Equipment will be auto-populated once the Equipment ID is selected.
    - **Maintenance type**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may select the type of maintenance from the drop-down list. The options in this drop-down will be populated from the options (out of Annual, Breakdown, Preventive) set while registering the Equipment for maintenance in the Equipment master.
    - **Performance date**: This field is a mandatory requirement that a user must fill to enable saving the entry. User may enter the date when the said maintenance was performed. This will be the end date of maintenance in case the activity extends to more than a day.
    - **Attachment**: User may browse for relevant documentation for reference from the local file manager on the device and upload it as part of the Equipment maintenance entry. Multiple document attachment is permitted for this field. File type has not been restricted while uploading.
    - **Description**: User may enter additional description if and when available.



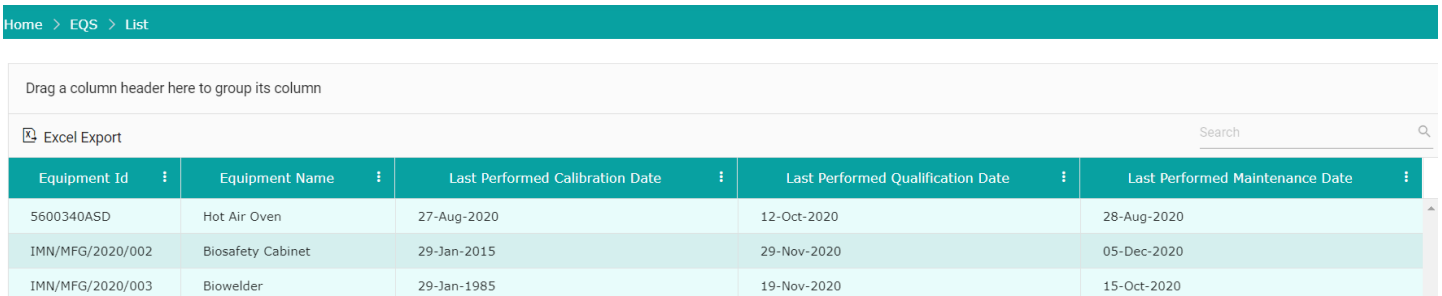
- Equipment maintenance details may be accessed after saving and edited on clicking (Pencil icon) in the actions column for the Equipment. Edit Equipment maintenance feature will open a canvas like 'Add details' with pre-populated data present for the selected Equipment from the database.

3.7. Reports

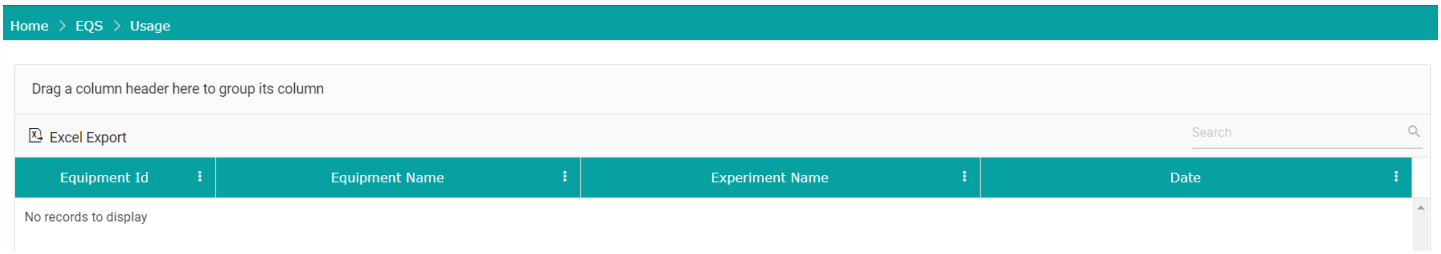
Reports

Following reporting features will be provided in this module.

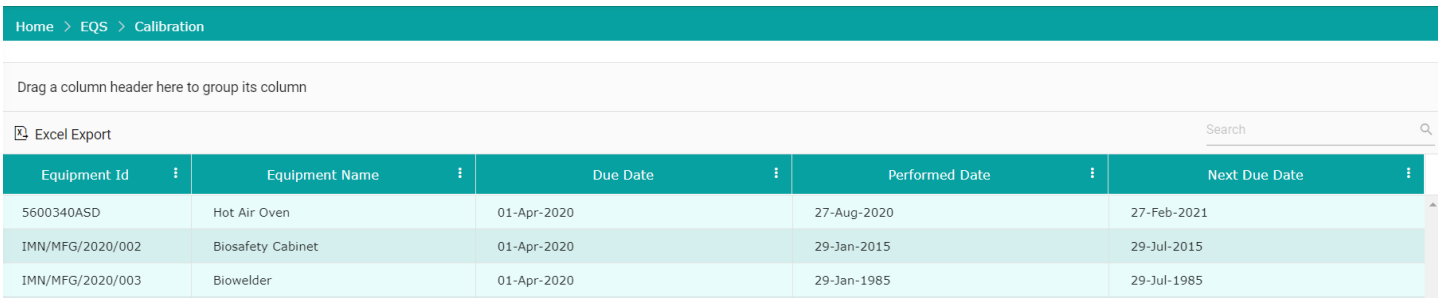
- **List**: This report will enlist all Equipment with the latest calibration/maintenance/qualification record dates. Please note that the report will start listing an Equipment only after at least one of the activities (Calibration, maintenance, qualification) has been performed. User may group entries by dragging and dropping the headers (Equipment ID, Equipment Name, Last performed calibration date, last performed qualification date, last performed maintenance date) that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may export the list in excel format by clicking on the 'Excel export' button above the list.



- **Usage**: This report will show history of Equipment usage in experiments performed in Electronic Laboratory Notebook. User may group entries by dragging and dropping the headers (Equipment ID, Equipment Name, Experiment ID, Experiment Name, Date) that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may export the list in excel format by clicking on the 'Excel export' button above the list.



- **Calibration**: This report will show Calibration details of Equipment listing the due dates. User may group entries by dragging and dropping the headers (Equipment ID, Equipment Name, Due date, Performed Date, Next due date) that needs to be grouped on the panel above the list. Multiple headers may be selected to further narrow down groups here. User may also group/Sort/filter/arrange entries by clicking on the three dots next to the header that needs to be used. To remove filter/group, user may click on the same portion of the header and select clear. User may export the list in excel format by clicking on the 'Excel export' button above the list.

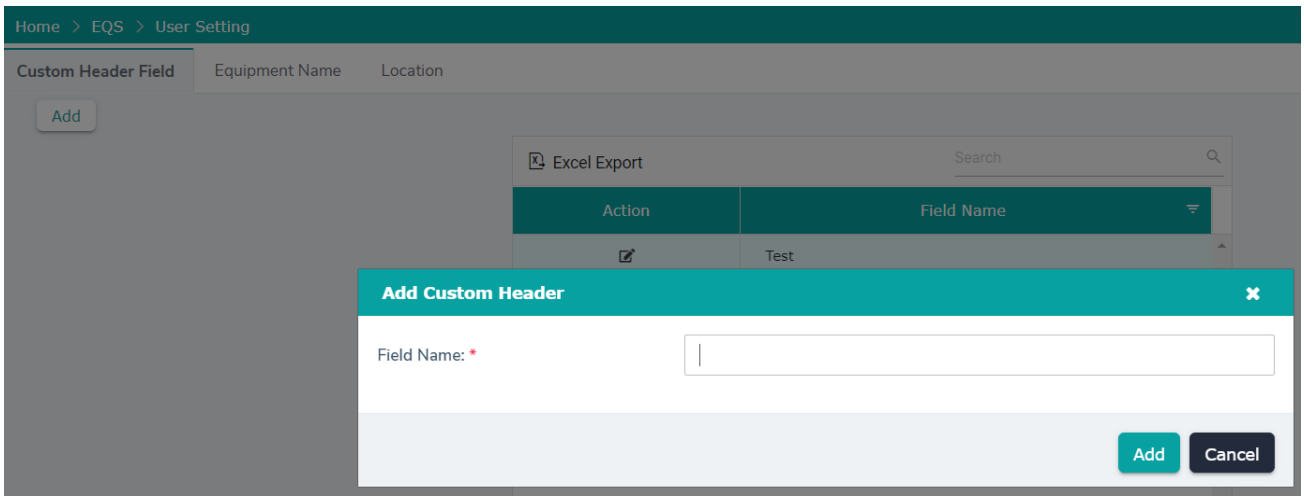


3.8. Settings

Settings

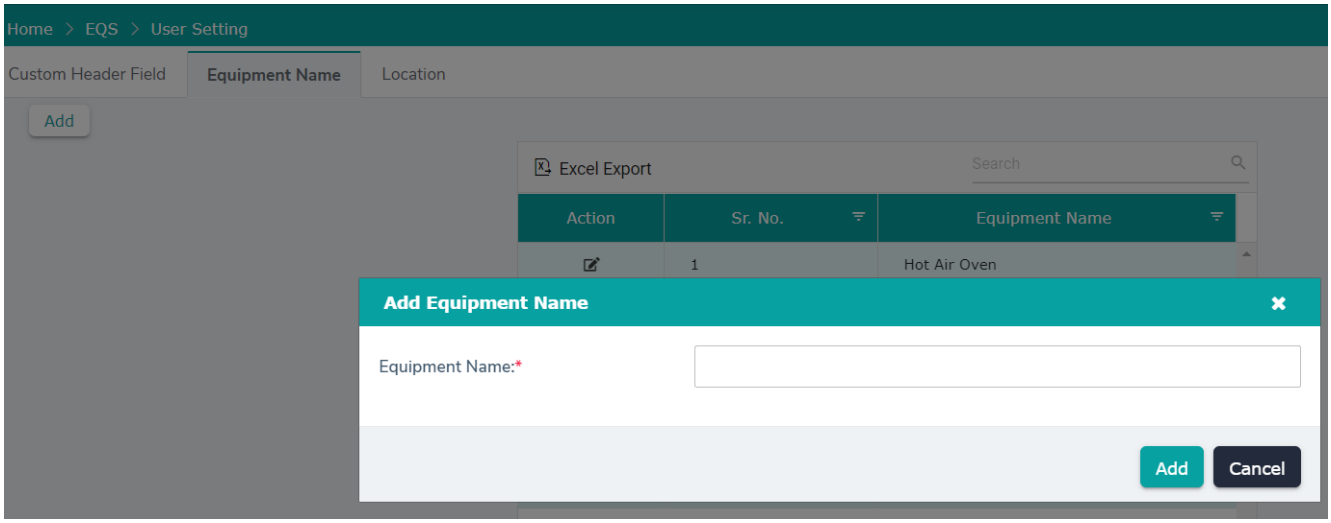
Following features are provided as part of the user settings in this module:

- **Custom Header Field**: This feature has been provided in case the module needs an additional entry made which isn't available in the module's design. This will be treated as another column for all entries being made for any/all Equipment once the said custom header entry is added in the database. User may enter alphabets, number or special characters as values for the defined custom header.



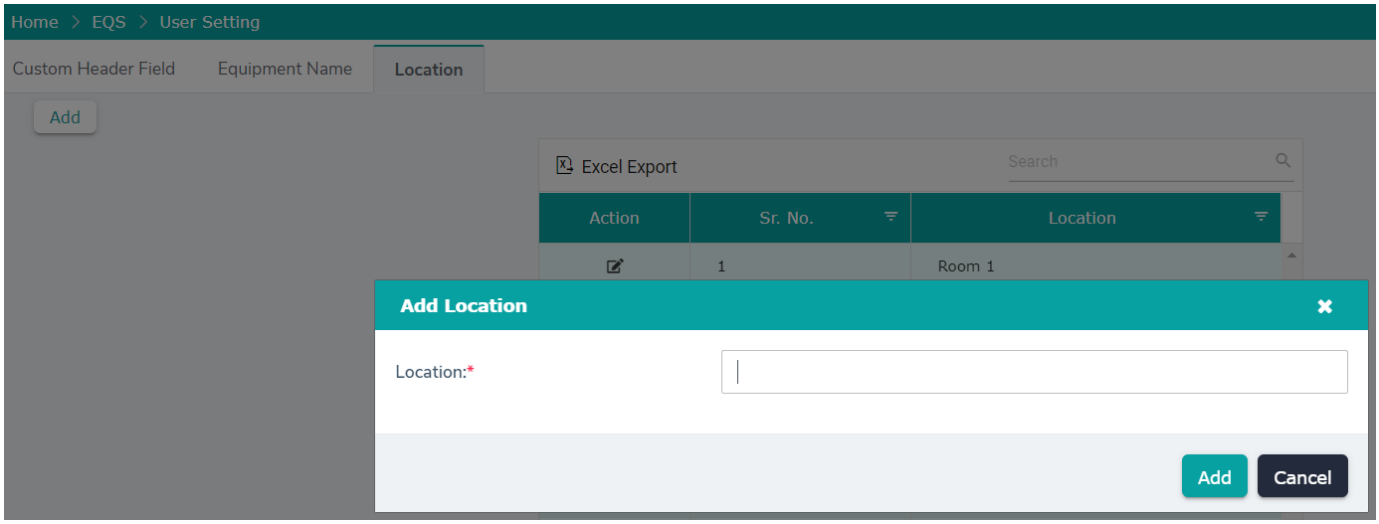
Adding a new custom header entry

- **Equipment Name**: Equipment names may be added using this setting. An Equipment name will start reflecting in the Equipment master>Add Equipment>Equipment name drop-down once it is added here. User may enter alphabets, number or special characters as values here.



Adding a new Equipment type

- **Location**: Placement locations may be added to the list here. These will start reflecting in the Equipment Master>Add Equipment>Location drop-down once it is added here. User may enter alphabets, number or special characters as values here.



Adding a new location to the list

4. Help_ELN_V1.0

SYMPHONYTECH - ELECTRONIC LABORATORY NOTEBOOK
HELP SECTION
FOR
ELECTRONIC LABORATORY NOTEBOOK

Document Number: Help-001

Version Number: 1.0

Version Date: January 25, 2021

VERSION HISTORY

Development and distribution of this Help Document will be controlled and tracked by SymphonyTech Biologics Pvt Ltd (SBx) based on changes approved by both parties. This document is being created for presenting details on how to use Electronic Laboratory Notebook (ELN) module for SymphonyTech - ELN product.

Version Number	Implemented by	Revision date	Approved by	Approval date	Description of change
1	SBx	25-Jan-21			Help Section for ELN

4.1. Introduction

Introduction

Welcome to the Electronic Laboratory Notebook Module. This is a platform to record and manage laboratory data all in one place and to replace paper lab notebooks. This will help to monitor research/experiment progress, capture structured/unstructured data, manage product details on a secure portal.

This guide will provide detailed information of the requested behavior and how the system will function.

Terms, Acronyms, and definitions

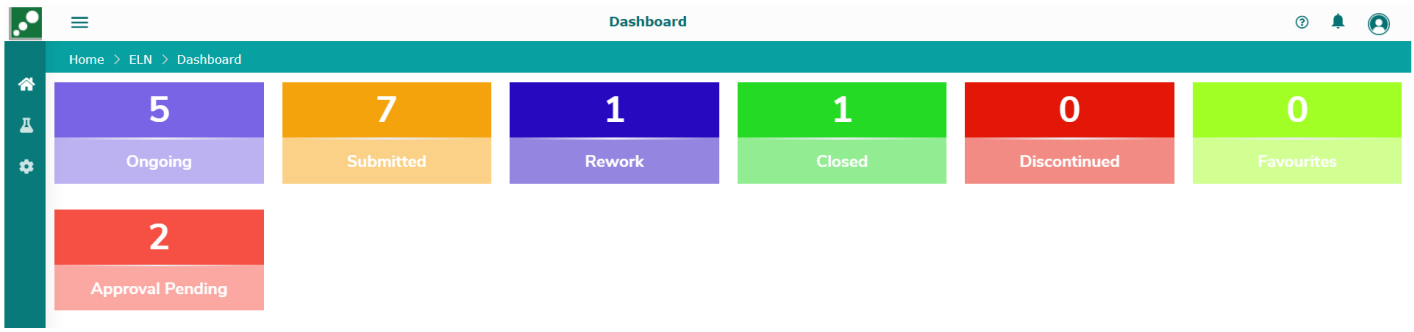
Term	Definition	Description

ICS	Instrument Calibration System	This module will track Instrument calibration to accurately monitor instruments in correlation to the respective standards and talk with ELN module
ELN	Electronic Laboratory Notebook	Secure browser-based platform to record and manage laboratory data all in one place and to replace paper lab notebooks
EQS	Equipment Qualification System	Module for performing Qualification for fitness of use as well as tracking of continued capability of equipment for its stated purpose
IMS	Inventory Management System	Module for logging inventory of consumable (Incoming/Outgoing) material used during experiments and for validating within expiry dates of each lot.
SBx	SymphonyTech Biologics Pvt Ltd, Pune	

4.2. ELN Dashboard

ELN Dashboard

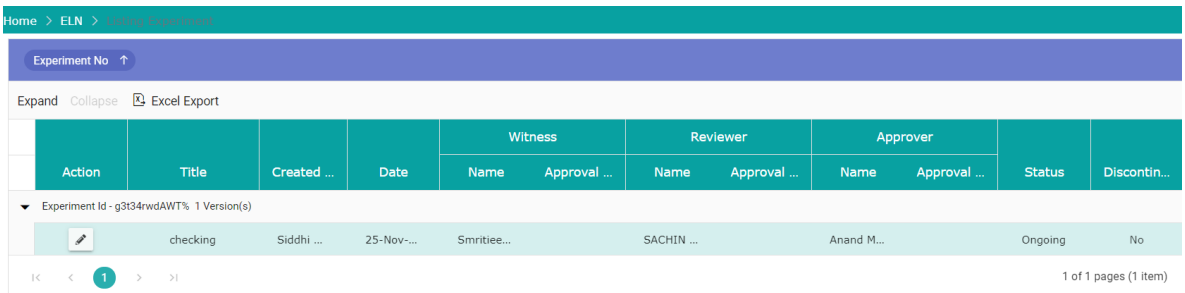
ELN Landing page Dashboard can have cards for experiments and pending actions. The cards will enumerate the number of experiments/actions pending from the user's end. Details of each feature are as below.



ELN Home page

Features:

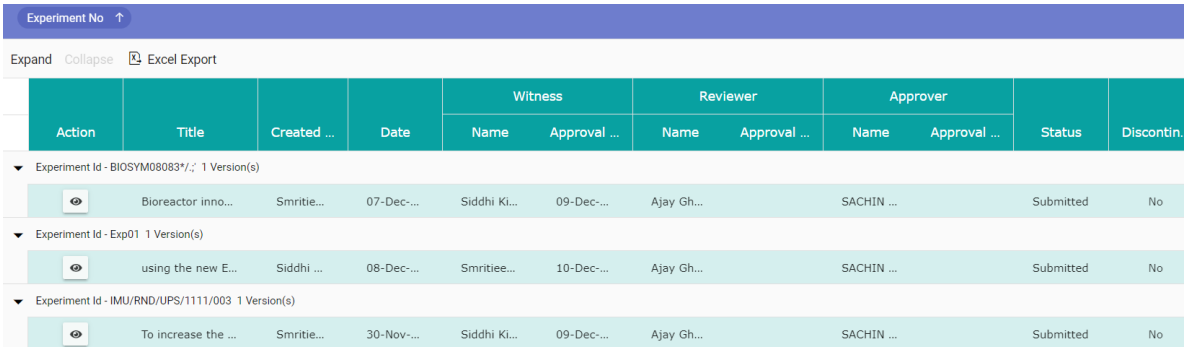
- **Ongoing Experiments**: This card will list all ongoing experiments under the user's login. Details of experiment (Title, created by, date of creation, prepared by, start date) will be listed along with its status (Witness, review) and status date. User can click on the experiment ID to edit the experiment or view further details (based on privileges – Pen Edit/Eye view symbols).



Ongoing experiments section

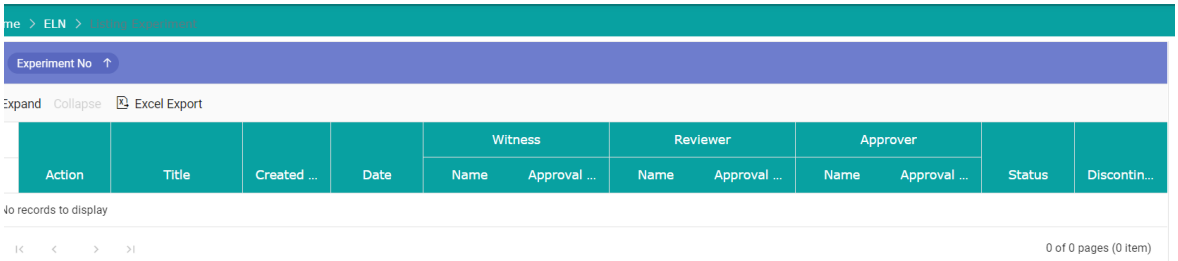
- **Submitted Experiments:** All experiments submitted for approval cycle by a user will be reflecting on this page. One can track status of all experiments submitted by him/her. Details of experiment (Title, created by, date of

creation, prepared by, start date) will be listed along with its status (Witness, review) and status date. User can click on the experiment ID to edit the experiment or view further details (based on privileges – Pen Edit/Eye view symbols).



Submitted experiments

- **Rework:** Rework suggested by any of the approvers, witnesses, reviewers by all experiments (including other users) will be listed on this page. If the rework is addressed to you, you will be able to edit the experiment as required. For all others, this will be a read-only format. Details of experiment (Title, created by, date of creation, prepared by, start date) will be listed along with its status (Witness, review) and status date. User can click on the experiment ID to edit the experiment or view further details (based on privileges – Pen Edit/Eye view symbols).

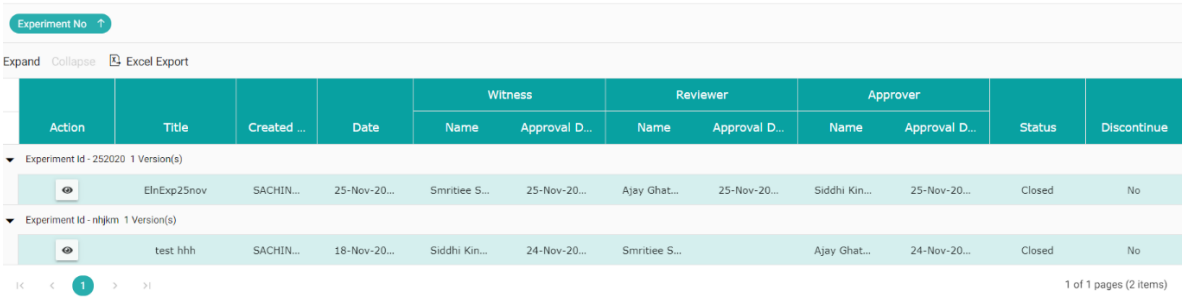


Rework section

- **Closed Experiments**: Once the approver signs off the experiment, it will move to the closed experiments section. Details of experiment (Title, created by, date of creation, prepared by, start date, status) will be listed here. User can click on the experiment/version number to open the experiment in read-only view.

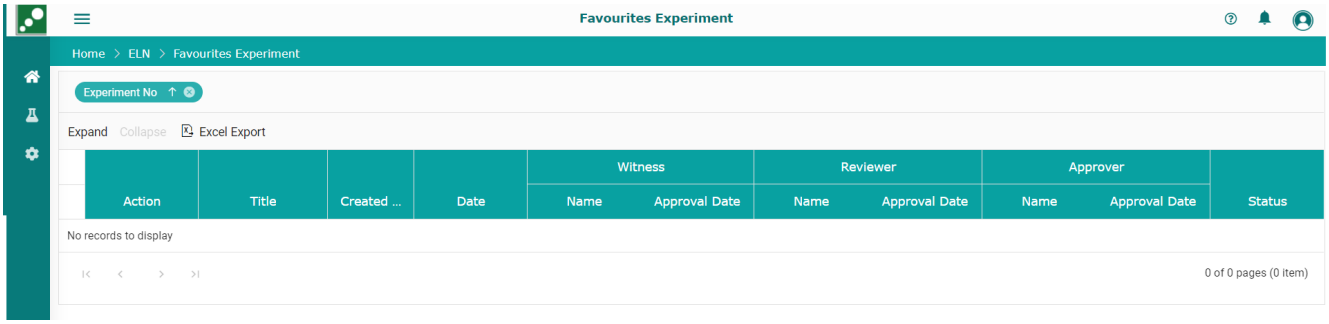
Closed experiments section

- **Discontinued Experiments**: A user can discontinue an experiment mid-way before the final approval is completed for valid reasons. This will go through an approval cycle which will require his/her immediate manager and Department head along with the QA head to approve this dismissal. Details of experiment (Title, created by, date of creation, prepared by, start date, Date of discard) will be listed here. User can click on the experiment/version number to open the experiment in read-only view.



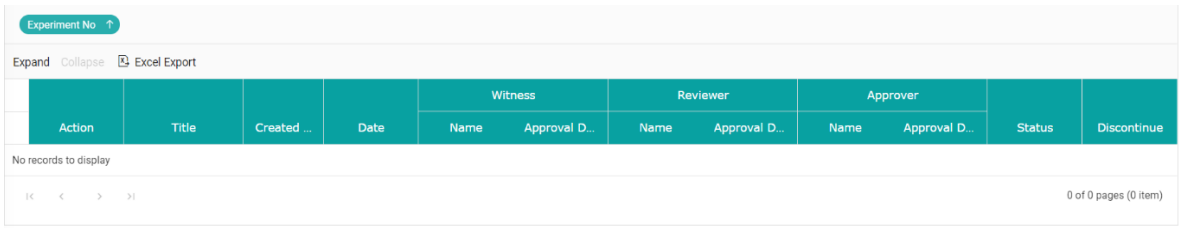
Closed experiments section

- **Favorites**: An experiment may be marked as favorite to have it reflected in this user's quick access card. Here, a user may mark an experiment created by all users and access it based on read privileges.



Favorites section

- **Approval Pending**: In this section, user will be able to view all actions (witness, review, approve) pending for him/her to sign-off. It will have details of items (Program code, Target ID, Experiment/version ID, Aim, prepared by) along with which action is pending at the user's end. Once signed-off/marked for rework, this item will not appear in the pending action section for the reviewer/approver but move to the user's Pending actions card.



Pending Actions section

4.3. New Experiments

New Experiments

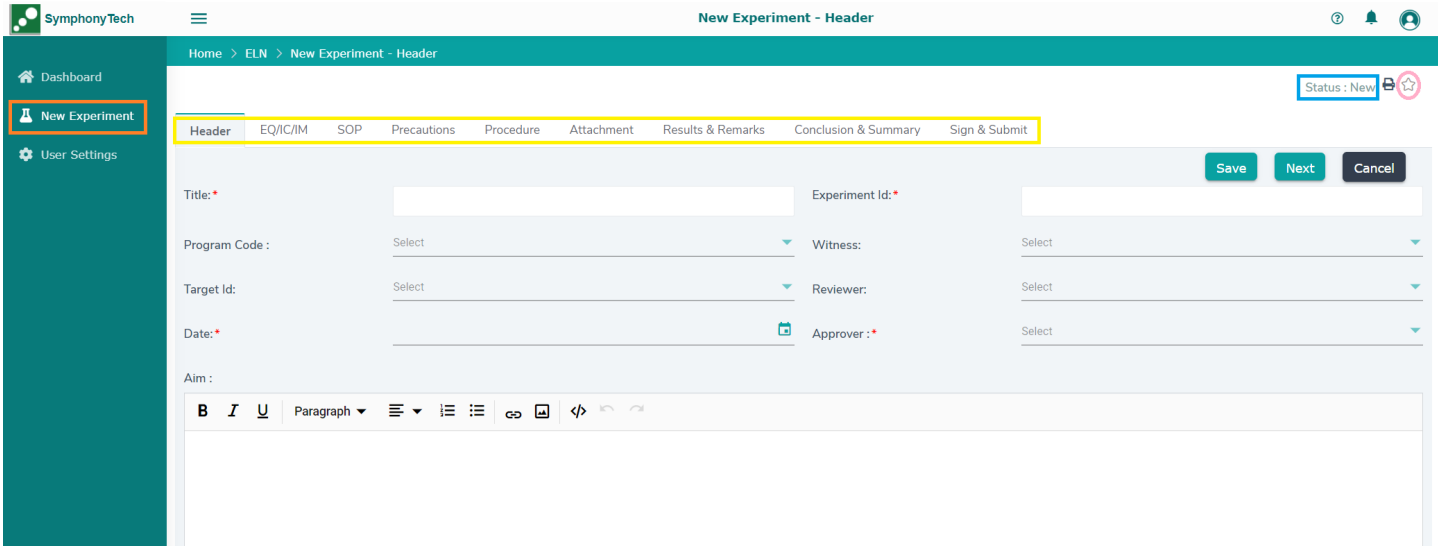
New Experiments can be created by accessing this sub-menu (marked with orange box in below screen shot for reference).

Features:

- New Experiments layout will be designed in a tabs format (marked with yellow box in below screen shot for reference).
- Additionally, this page will consistently reflect the status of the experiment (marked with blue box in below screen shot for reference). Status types may be 'ongoing', 'submitted', 'closed', 'discontinued').
- User can mark an experiment as favorite (**) by clicking on the Star icon on the top right corner of the screen (marked with pink box in below screen shot for reference). Experiments marked favorite will reflect in the 'Favorite experiments' card on the home page of ELN (Dashboard). An experiment may be marked favorite

throughout its life cycle (running, closed, or discontinued).

- A report of the experiment can be previewed and exported to the local device on clicking the icon ( ) next to the status on top right corner at any given state of the experiment.
- An ongoing experiment may be discontinued at user discretion with valid justification (the 'Discontinue' button will start appearing next to the favorites icon on the top right corner once an instance of the experiment is initially saved.
- A user may create new version of the same experiment at any given point in life of the experiment. On click, the latest content of the experiment will be replicated as is with a new version number.
- A provision to jot down comments is provided as a tab in the procedure section. Reviewers and approver may also provide remarks (provided in the sign and submit - rework section) while reviewing it.
- A provision has been made to save information of each tab while proceeding in the experiment. An entry will be made in the audit trail for each action in case of changes.



New Experiments Page

Description of tabs present for a new experiment:

❖ **Header**:

- This section will encompass preliminary information of the experiment as seen in the above screen shot for new experiments page.
- 'Version number', 'prepared by' and 'date of creation' sections will be recorded in the Audit trail.
- User can manually write Title, Experiment ID, Aim and rationale of the experiment in this section.
- User can select entries from drop downs provided for program code (from list of codes created in user settings), target ID (from list of IDs created in the user settings), Date of experiment (from the date picker). User can also select Witness, Reviewer, Approver from list of available users.
- Once all mandatory fields (Title, Experiment ID, Date, Approver) are filled, a user may go ahead and save the experiment to get it listed in the ongoing experiments card and proceed further right away. User can also save and edit the experiment later by accessing the instance from the ongoing experiments card.

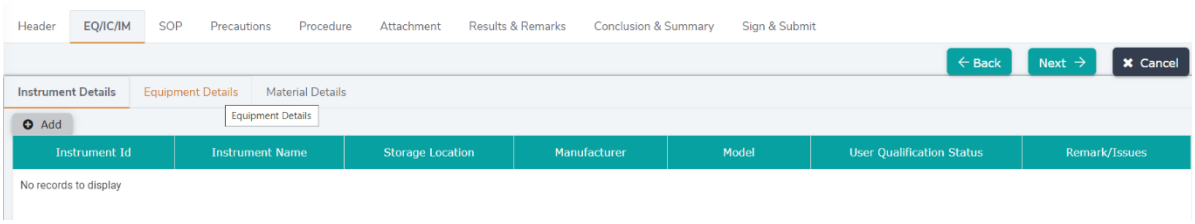
❖ **EQ/IC/IM**:

- User may select Instruments (list of instruments populated from Instrument Calibration System (ICS) module), Equipment (list of equipment populated from Equipment Qualification System (EQS) module) and Materials (list of materials populated from the Inventory management system (IMS) module) that will be used for the experiment in this section (on the 3 separate tabs seen in screen shot).

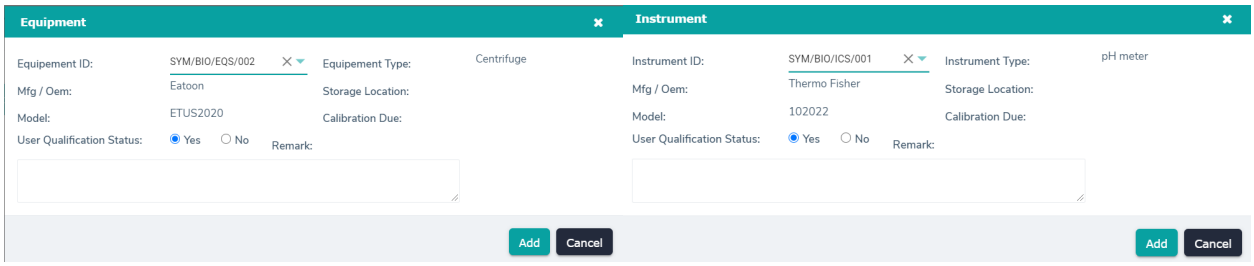
- Details like Type, manufacturer, calibration due, model will be auto populated for Instruments and equipment on selecting IDs, name, and storage location (Will be visible on installation of IMS module) from the drop down options.

- User qualification status is set to 'Yes' by default and may be changed to 'No' manually. (This field will be auto populated from the Learning management System (LMS) module based on if the user has qualified in the SOP course for the corresponding instrument/equipment on launch of LMS module). User may also write additional remarks for addition of the device for the experiment in 'Remarks' section.

- Details like Manufacturer, catalog number, lot number, expiry date will be auto populated on selecting Material from drop down list.



Instrument, Equipment and Material selection section

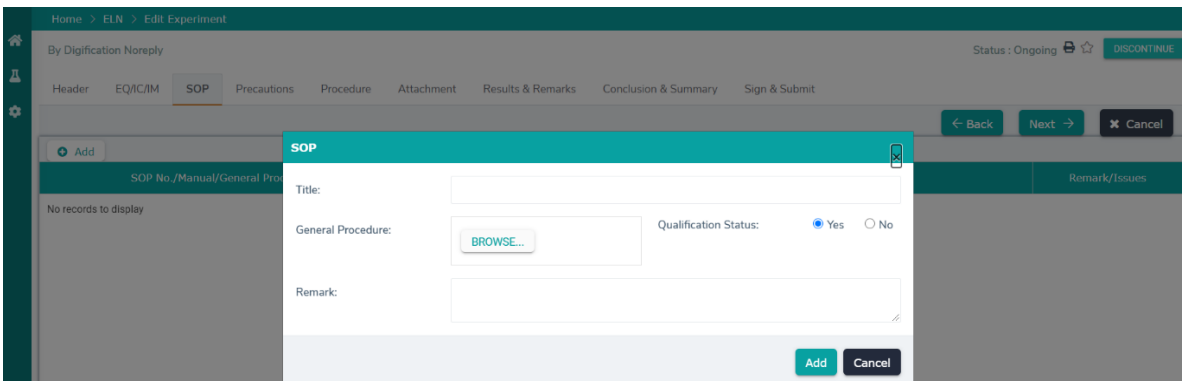


Add Equipment, Instrument screens

❖ **SOP**:

- All Standard Operating Procedure (SOP) documents may be referred to and linked to the experiment in this section. User may add a local copy of the document to be attached by clicking on browse (Once Electronic Quality management system (E-QMS) is launched, on browsing, the system will take the user to the Document management System section of the E-QMS module).

- 'Add' button, on click, will take the user to a pop-up where an attachment may be added by filling one of the following fields and filling up

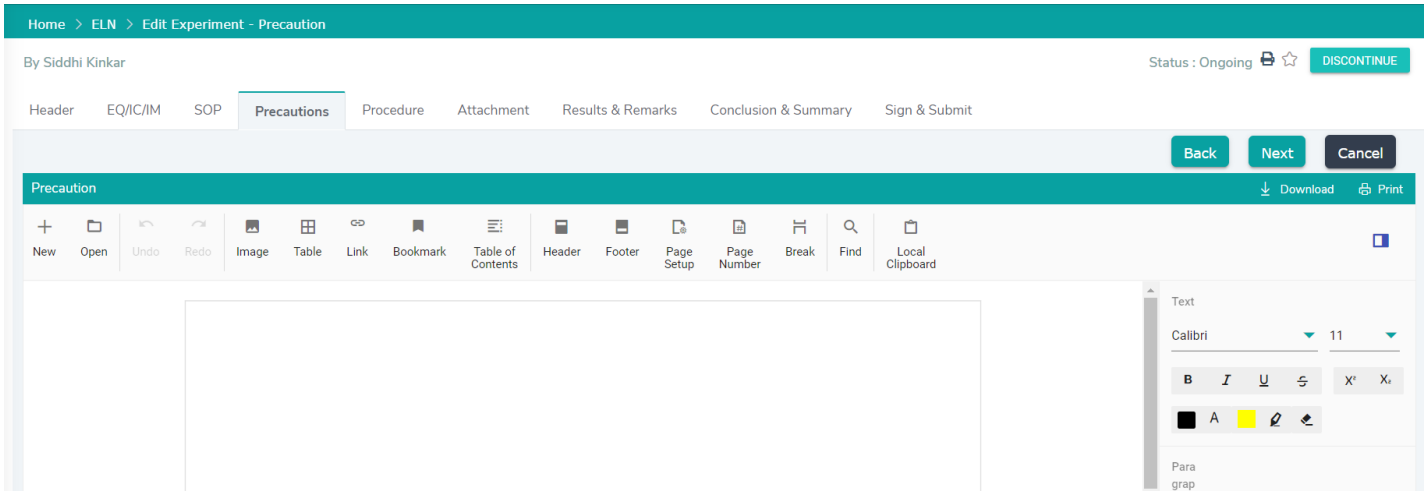


SOP section

❖ **Precautions**:

- Necessary precautions to be taken for the experiment may be mentioned in this section. Corresponding attachments (e.g. MSDS for materials used, etc.) may be attached in the adjoining section 'Attachment'

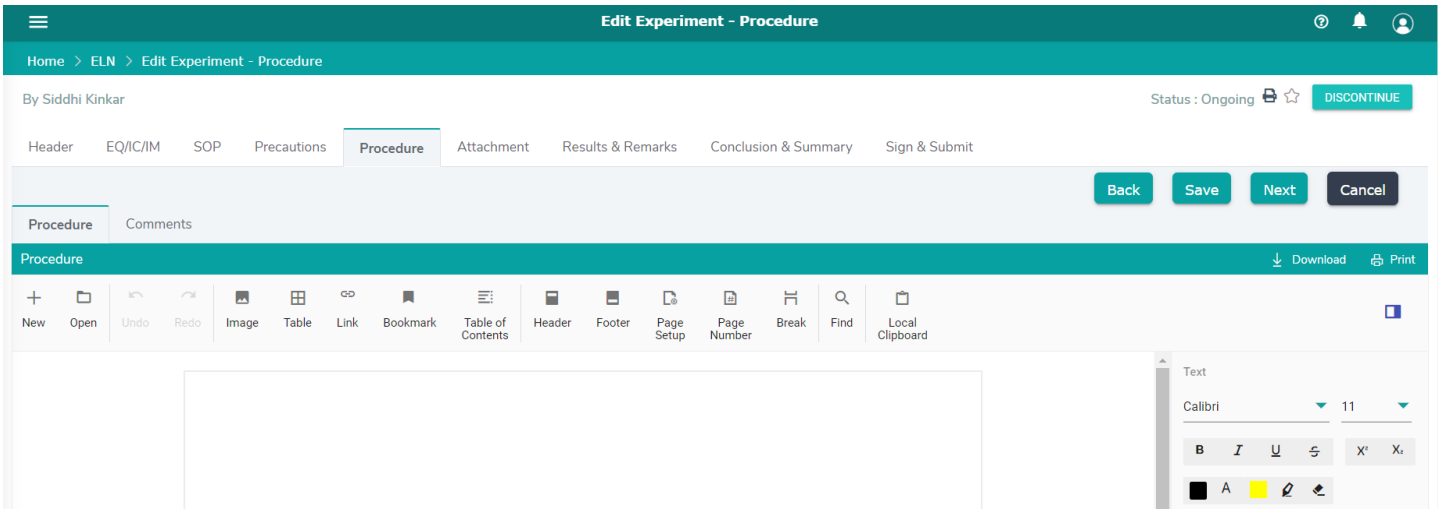
- This section allows the user to add multiple types of content (alphanumeric, images, tables, bookmarks, Table of content). Special symbols may also be pasted from local pads in this section.



Precautions section

❖ **Procedure**:

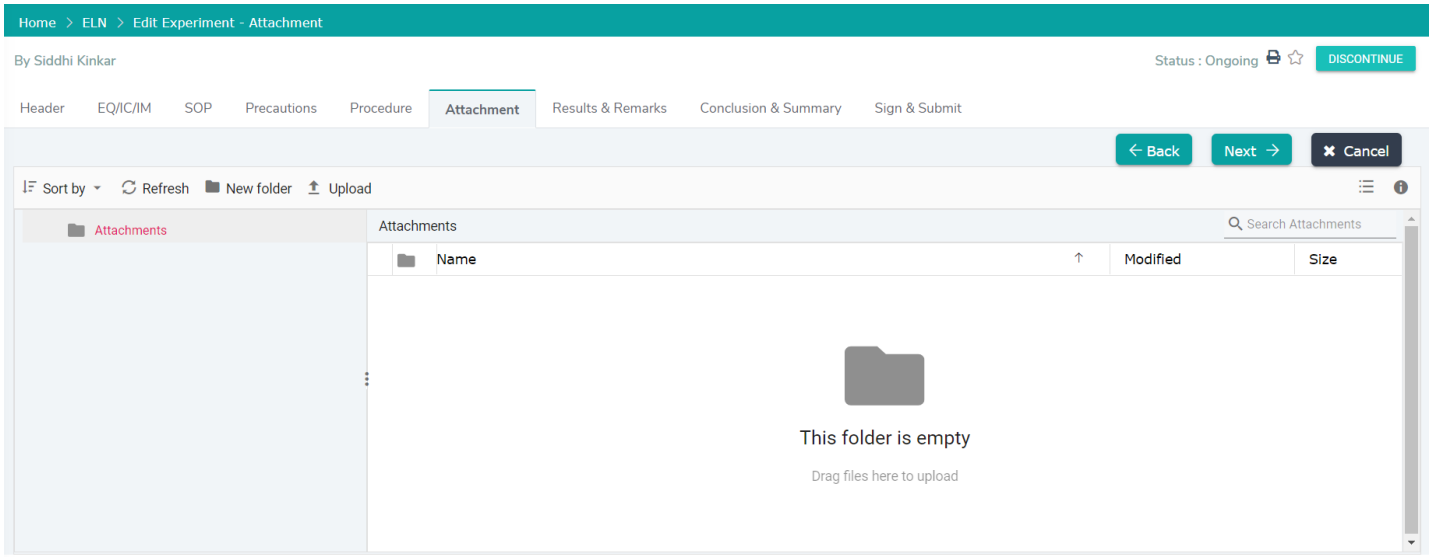
- Procedure of the experiment may be mentioned in this section.
- This section allows the user to add multiple types of content (alphanumeric, images, tables, bookmarks, Table of content). Special symbols may also be pasted from local pads in this section.
- A sub-section here, 'Comments', has been provided to write any additional comments which may be required for user's reference.



Procedure section

❖ **Attachments**:

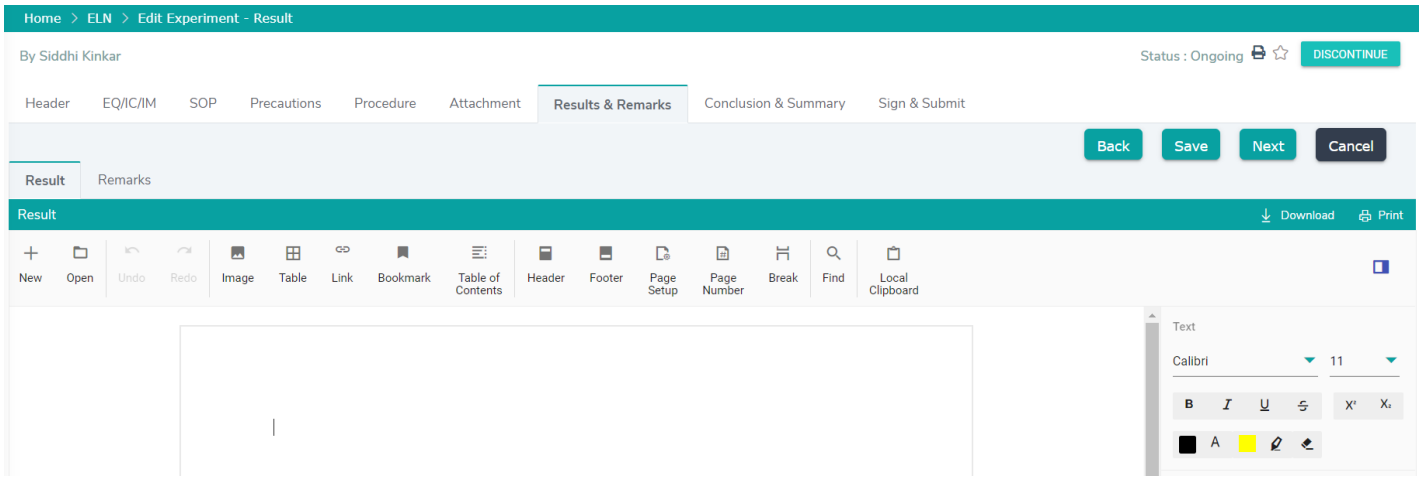
- This section has been provided to attach additional relevant documents other than SOPs that may be linked to the experiment. Files may be uploaded/dropped here (Pictures, Videos, Documents, Recordings).



Attachments section

❖ **Results & Remarks**:

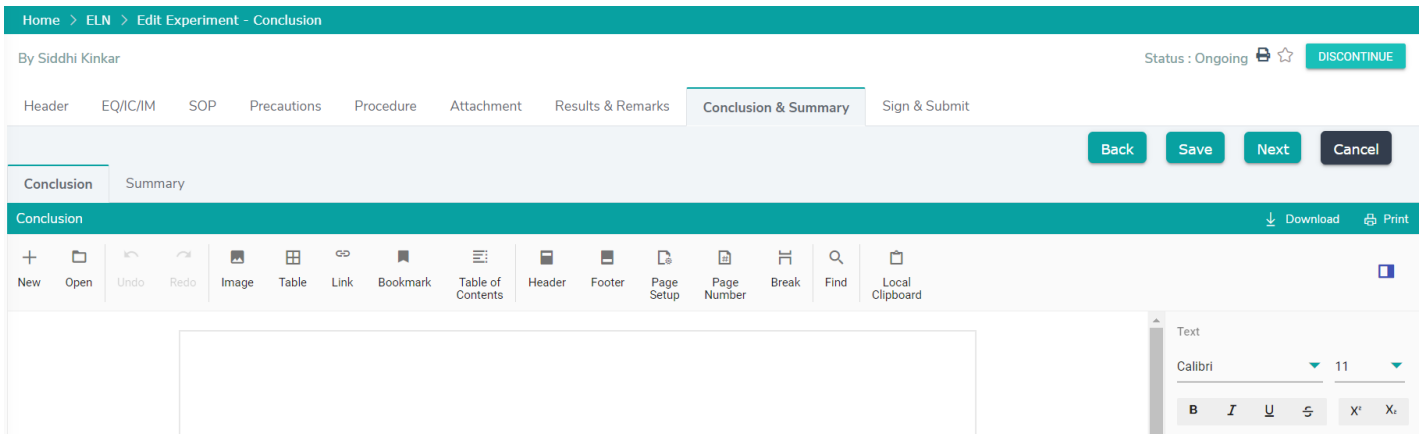
- Results and remarks will be separate sections where the user will be able to write notes, paste images, videos.
- Common symbols and Greek symbols will be provided.



Results and Remarks section

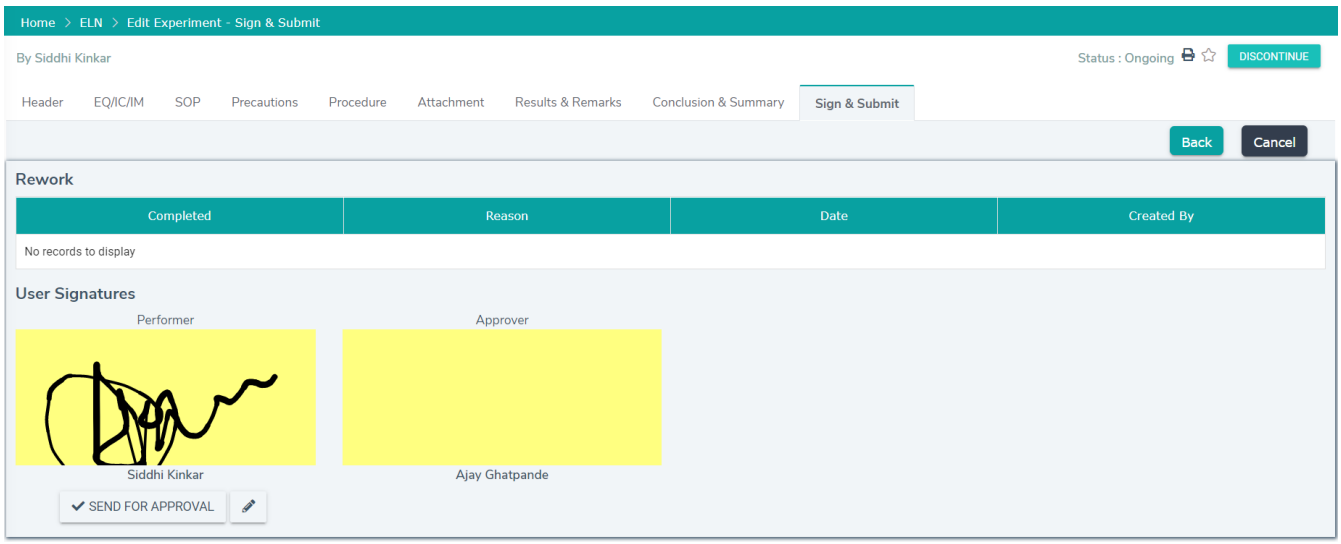
❖ **Conclusion & Summary**:

- Conclusion and summary will be separate sections where the user will be able to write notes, paste images, videos.
- Common symbols and Greek symbols will be provided.



❖ **Sign & Submit**:

- Unlike other sections which are editable for user and read-only for others, this section will have editable notes section ('Add rework') and a sign and submit facility for the users and witnesses, reviewers, approvers (selected by the user in the header).
- This screen will show a rework log section where witness, reviewer, approver may make an entry (seen in the below screen-shot) and send it back to the submitter in case they want to suggest modifications in the experiment. this section is activated only for the witness, reviewer, approver. In case of rework at any point in time (e.g. an approver sets a rework), all previous signatures are cleared and the approval process gets restarted (user -> Witness -> Reviewer -> Approver).
- All - Users, Witnesses, reviewers and approvers may sign and submit the experiment as per flow (user -> Witness -> Reviewer -> Approver). Please note that once the approver signs and submits the experiment, this version will be deemed final and may not be further edited. Another version of the same experiment may be created to make further changes as needed.
- Witnesses, reviewers and approvers can perform their designated actions only once the submitter signs and submits it ahead. In this version of ELN, it is not mandatory for the earlier signatory sign and submit the experiment ahead. scenarios may be as follows:
    - Reviewer may sign even when the witness hasn't signed the experiment and send it ahead to the approver.
    - Approver may sign even if the witness/reviewer have not signed and close the experiment).



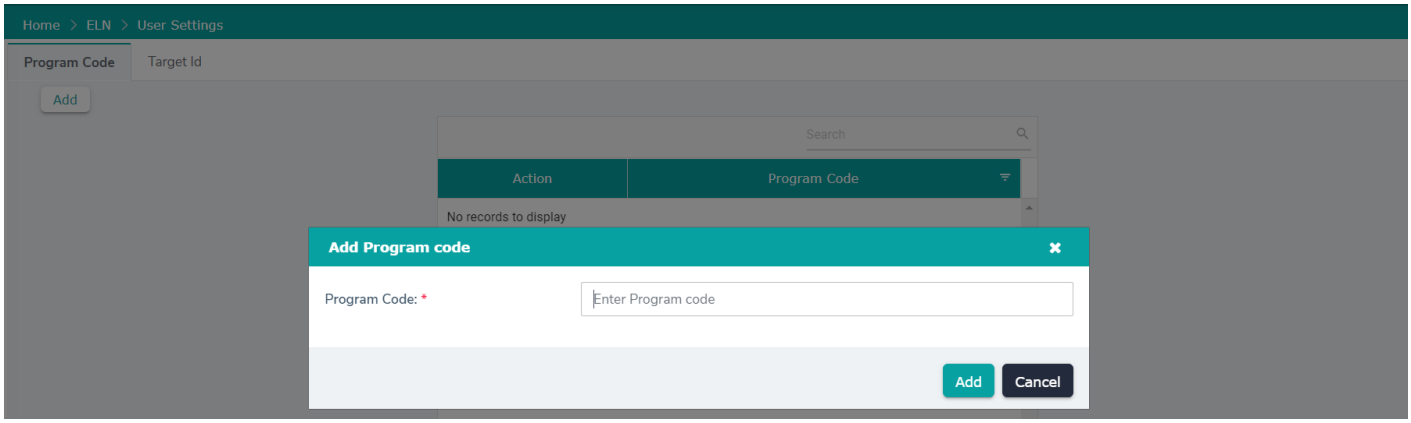
Sign & Submit section

4.4. Settings

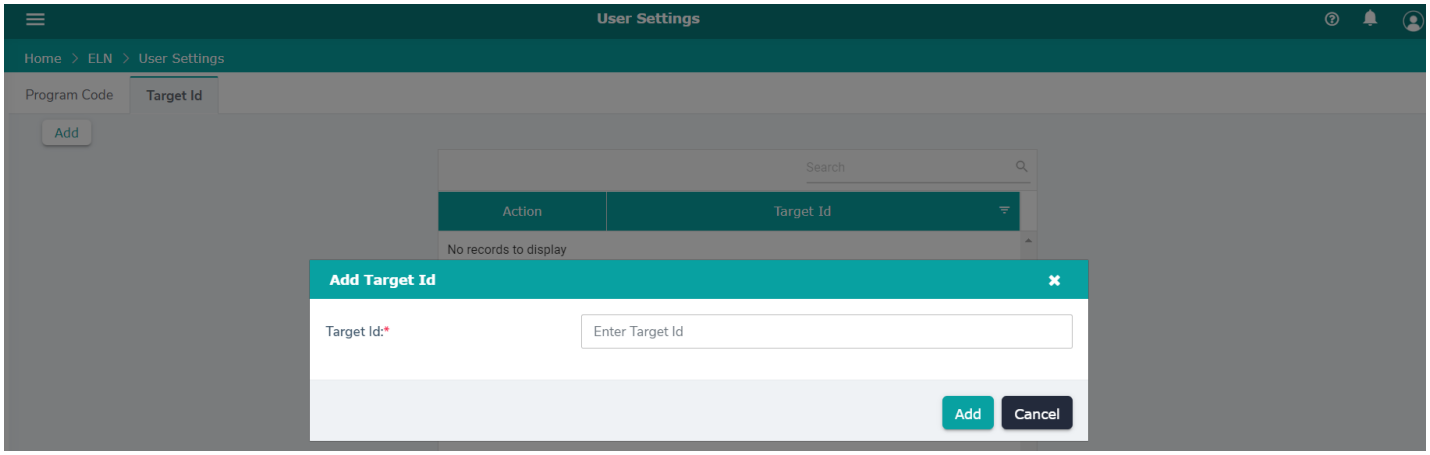
User Settings

As part of this phase, the following features will be provided in the module:

- *Program master:* Program codes created here will reflect in the drop-down for Program code in the header section of an experiment. Landing page of this section will list existing program codes which may be edited by clicking the corresponding (Pencil icon). A new program code may be created by clicking 'Add' button, typing the same name clicking 'add' here.



- *Target ID master:* Target IDs created here will reflect in the drop-down for Target ID in the header section of an experiment. Landing page of this section will list existing target IDs which may be edited by clicking the corresponding (Pencil icon). A new target ID may be created by clicking 'Add' button, typing the same name clicking 'add' here.

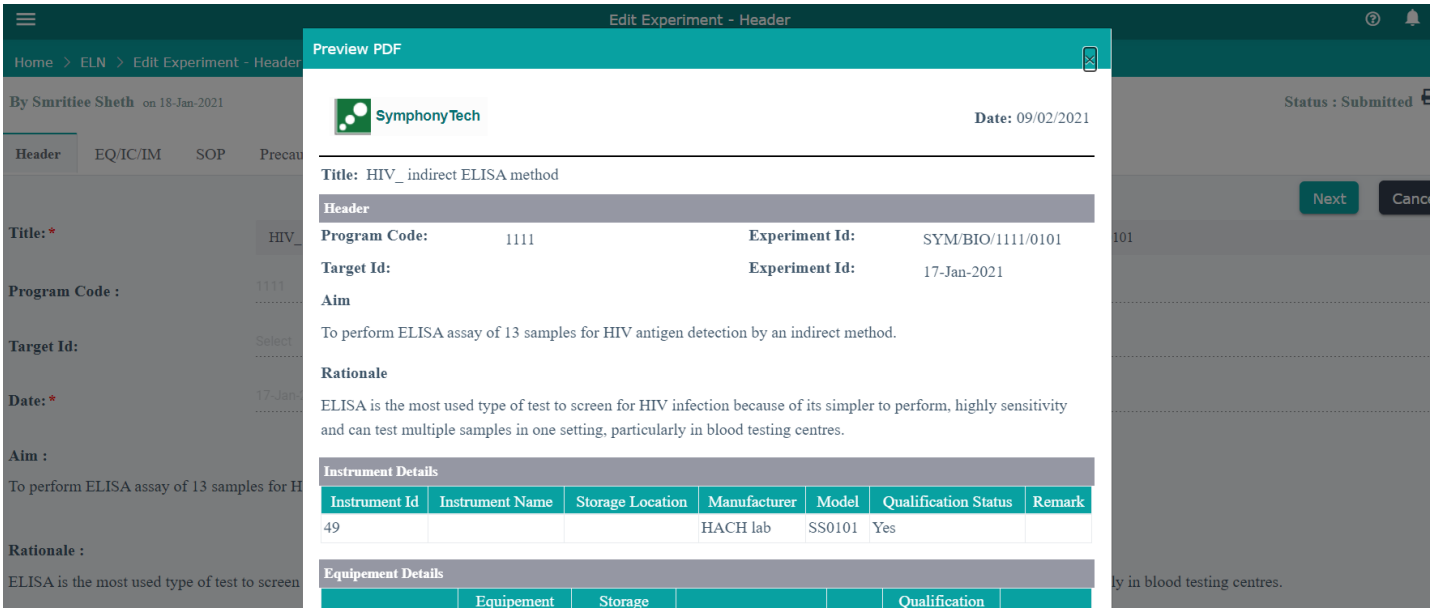


4.5. Reports

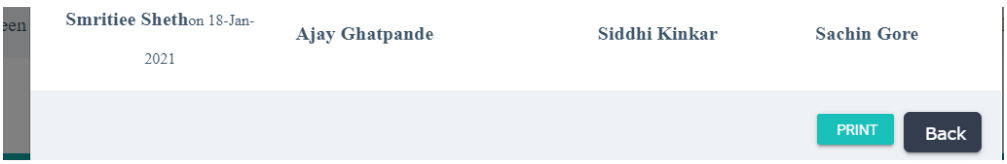
Reports

Experiment summary report can be generated by exporting individual experiments (in a PDF format) which are signed and approved. Please note that Attachments will not get exported while generating this report.

On clicking the icon, one can preview the summary in PDF format with all sections listed one after the other.



The report may be exported to the local machine at the end of the report preview window by clicking 'Print' and then 'download' ( ).



5. Help_ADMINISTRATION_V1.0

SYMPHONYTECH - ELECTRONIC LABORATORY NOTEBOOK
HELP SECTION
FOR
ADMINISTRATION

Document Number: Help-001

Version Number: 1.0

Version Date: December 28, 2020

VERSION HISTORY

Development and distribution of this Help Document will be controlled and tracked by SymphonyTech Biologics Pvt Ltd (SBx) based on changes approved by both parties. This document is being created for presenting details on how to use Administration module for SymphonyTech - ELN product.

Version Number	Implemented by	Revision date	Approved by	Approval date	Description of change
1	SBx	28-Dec-20			Help Section for Administration

5.1. Introduction

Introduction

Welcome to the Administration module. This module is designed to assist in managing Users, User Privileges, Departments and Audit Trails in a systematic and traceable manner. Data populated in this section is universal to all modules within the product and entries once added here will start reflecting in those modules too. This module may be used to track user activity and history throughout the lifespan of this system.

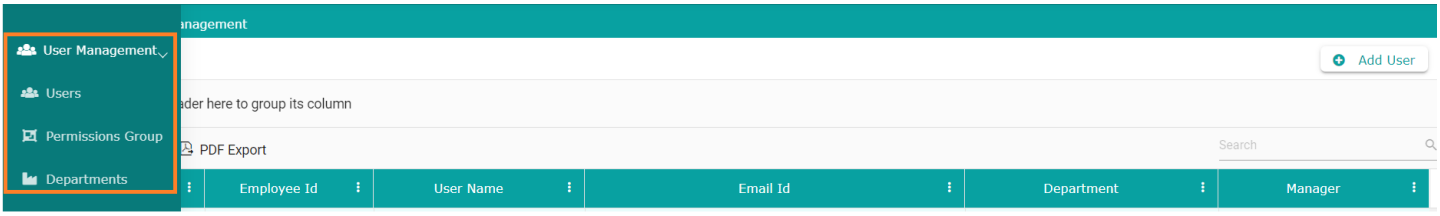
This guide will provide detailed information of the requested behavior and how the system will function.

5.2. User Management

Features of this section

User can perform the following actions:

- add new users or edit existing user details
- Create permission groups (which have a set of default read and write permissions) or edit existing permission groups. These permission groups can then be alloted to a user during user creation and may also be modified individually.
- Add new departments and corresponding heads or edit existing department details.



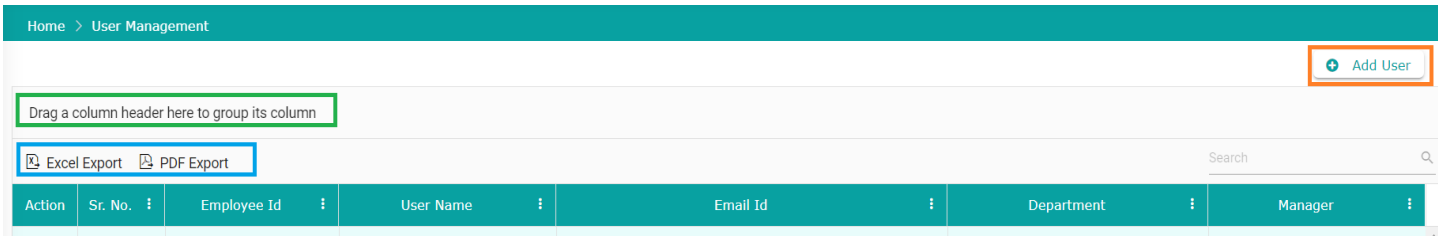
Landing page for User Management will be the User list

5.2.1. Users

Adding and managing users of ELN product:

The Landing page of the section will be a list of users which have already been added to the system. The logged in user may perform the following actions while on this page:

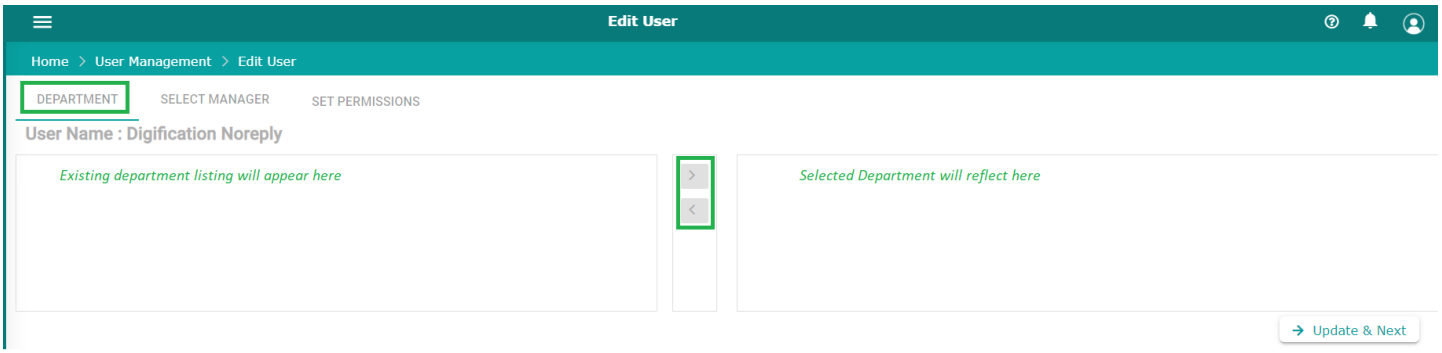
- User may view the list, arrange in any order by clicking on the title of the column or sort and group by column by dragging and dropping the column in the panel above the table (marked green in the screen shot below).
- User may download the user list in report format (marked blue in the below screen shot).
- User may add a new user by clicking on 'Add User' (marked orange in the below screen shot).
- User may edit an existing user by clicking on Edit action icon ( )
- Search a pattern by typing in the search bar



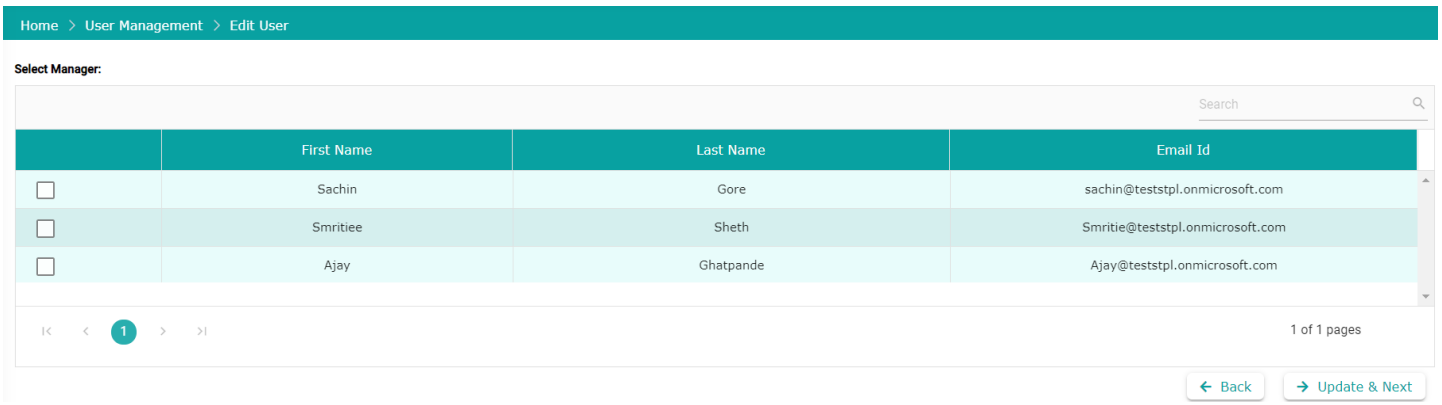
- **Adding a new user:**

'Add User', on click, will take the logged-in user to a pop-up where user details (User name, password, first name, last name, email ID) can be filled and saved. The new user is added on this click even if he/she isn't assigned to a department/manager or haven't been given any read-write permissions.

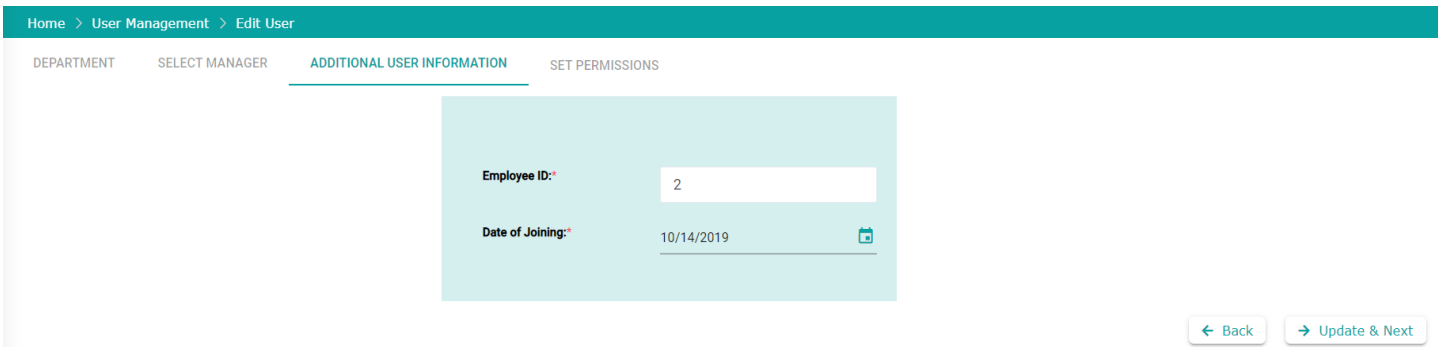
On clicking next, a department from the existing list of departments (refer page User Management > Departments for more details on this section) may be assigned to the user by selecting a department and clicking arrow '>' (To remove the department from the user's profile, arrow '<' may be clicked after selecting the department name if needed). The department gets linked to the user's profile on clicking 'Update and Next'.



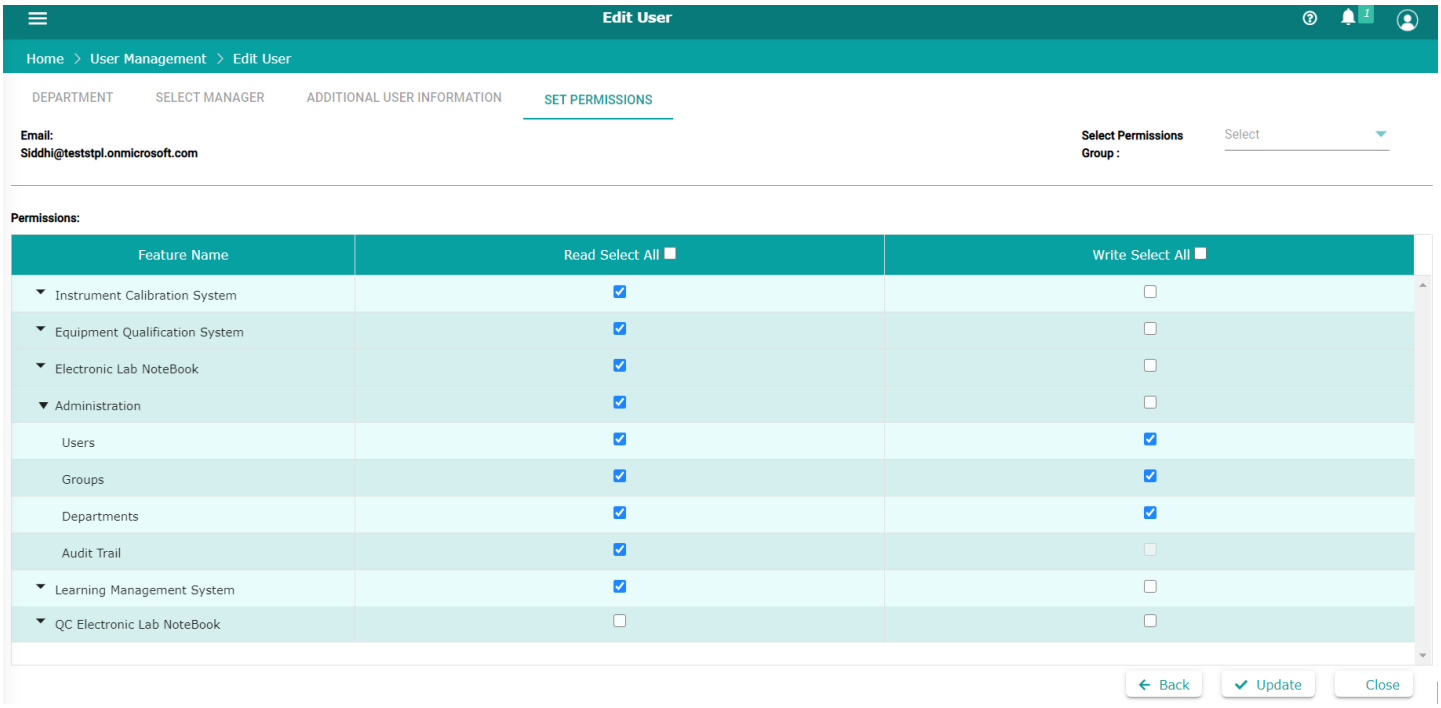
A manager can be set for the user on the next page by checking the name of the manager from the list and clicking 'Update and Next'.



Additional information of Employee ID (Numeric value) and Date of Joining (From the date picker till today) may be set on the next page (This information will be useful for the Learning management system module as of now) and clicking 'update and next'.



User read/write permissions may be set on the next page. Here, a list of all features per module will be listed. A user may be assigned any of these permissions or a permission group (detailed in permission groups section). Permissions may be changed for individuals even after assigning a permission group. On clicking 'update', the said user will now be able to view/write in the corresponding sections of modules for which he/she has been granted permissions to.



❖ **Editing an existing user:**

User details may be edited by clicking on the pen icon ( ) in actions against the user name in the User management section.

Notes:

o Users once created will not be permitted to be deleted from the system.

5.2.2. Permission groups

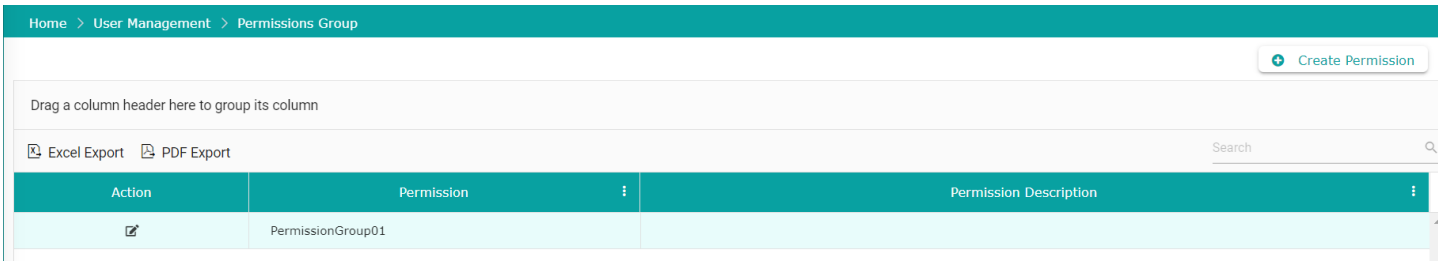
ELN Platform is designed based on features (processes) rather than user roles. This will enable each user accessing the system to have individualistic access and only his/her access permissions need to be modified in case the role of that individual in the company changes. In addition to this, new joinees can be given limited access as per need.

Adding and managing Permission Group in the Product:

Permission group is a set of permissions which can be assigned together to users with just one click. These permissions (read/write permissions to features of every module in the product), once assigned, may be edited individually for each user.

Landing page for the Permission groups section will display a list of existing permission groups set within the product. Functionality on the page:

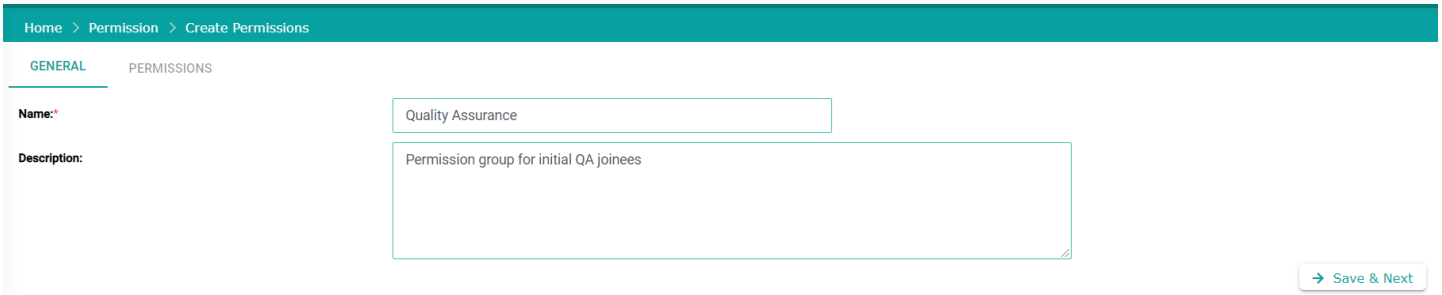
- ❖ Create new permission groups by clicking on the 'create permission' button
- ❖ Edit existing permission groups by clicking Edit icon ( ) in action tab against the group.
- ❖ Export a report of permission group names by clicking on Excel/PDF export
- ❖ Sort, filter, group by headers in the list by clicking on the header names (here: permission, permission description)
- ❖ Search panel to search for patterns on the page



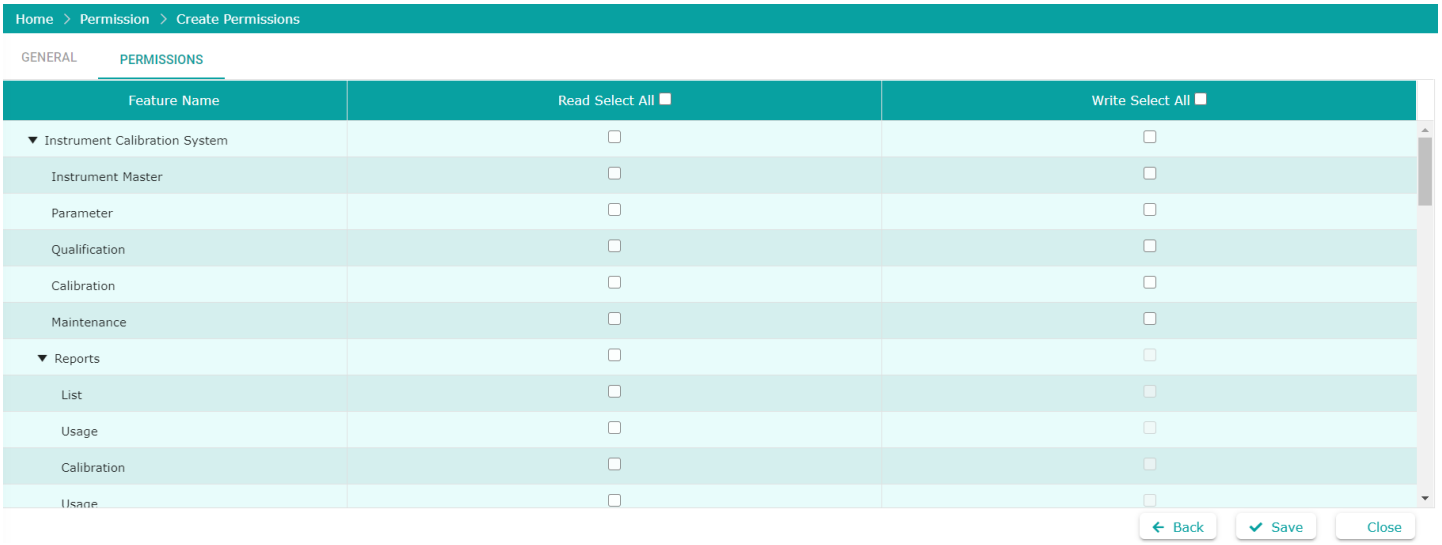
Creating a new permission group:

New permission groups may be created by clicking 'create permission' button to view the below pop-up.

- General: Here, Permission group may be saved by filling Name (mandatory field to save a group) and Description (optional field) and clicking 'Save & Next' button.



- Permissions: Read and Write Permissions are listed for features of all modules on this page. A combination of permissions may be saved for the said permission group by checking the box against each feature and clicking 'Save'.



Editing permission groups:

Existing permission groups may be edited by clicking icon (✎) in action tab against the group in the permission group list.

Notes of caution:

- ❖ Permission group cannot be assigned to users permanently. These are to be used initially to assign a group of permissions in one go.
- ❖ Permissions initially assigned for a user will be overwritten on assignment of a permission group to the said user.
- ❖ Permission groups are not to be mistaken with user groups in the LMS module. These are created solely for the purpose of bulk assignment of read/write permissions for modules of the product.

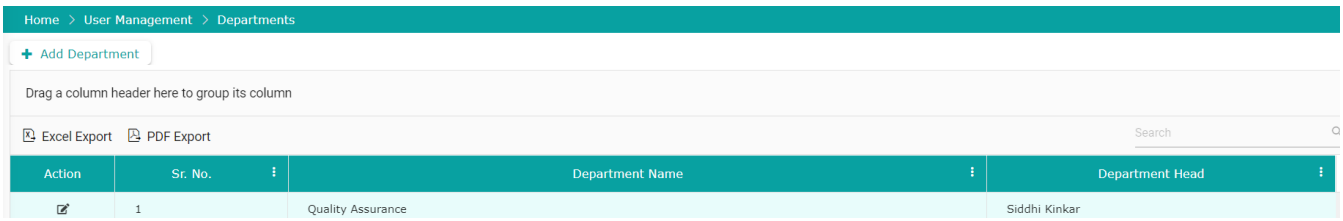
5.2.3. Departments

Listing Company's departments:

Departments used throughout the product may be created in this section. The landing page will list all existing

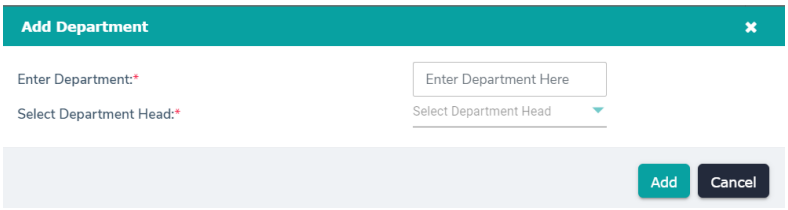
departments along with the department heads. Functionality on the page:

- Add new Departments by clicking on the 'Add Department' button
- Edit existing Departments by clicking Edit icon ( ) in action tab against the department.
- Export a report of department names and heads by clicking on Excel/PDF export.
- Sorting, filtering, searching headers in the list by clicking on the header names (here: Department Name, Department Head)



Adding a new department:

'Add Department', on click, will open a pop up where a new department may be added. Logged in user needs to fill 'Enter Department' (Mandatory field with manual entry) and 'Select department Head' (mandatory field with drop down of user list) and click 'Add' button to create an entry in the department list.



Editing an existing Department:

Existing Department may be edited by clicking icon ( ) in action tab against the group in the Department list.

Note:

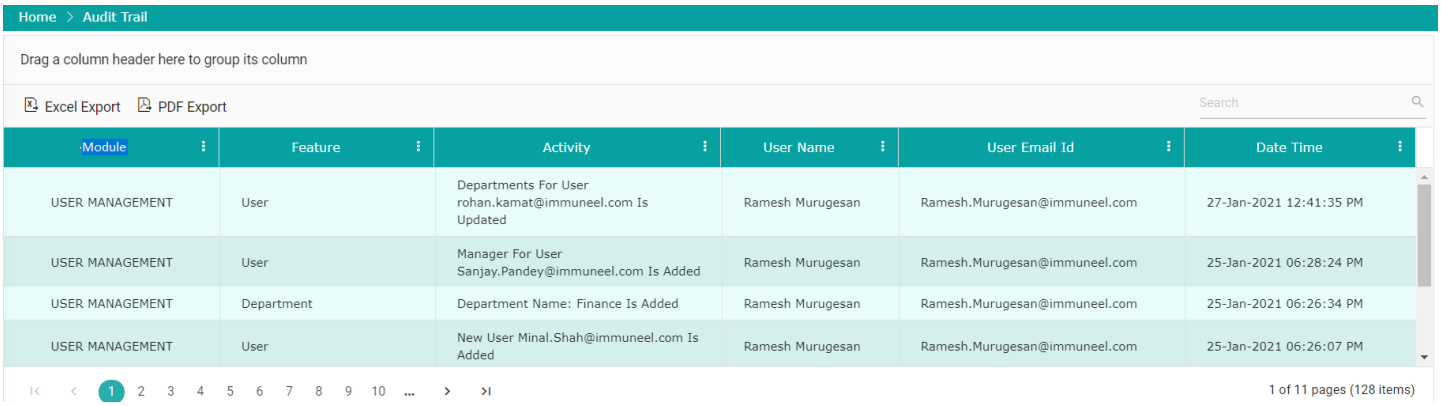
- To add a department, Department head needs to be present in the user list (check user section to know how to add a user).

5.3. Audit Trail

Audit Trail:

This section will list the activity of all logged in users in descending order of performing the action. The section will list the below details:

- *Module*: Module name in which the user performed the action
- *Feature*: Section within the module in which the user performed the action
- *Activity*: Action performed by the user
- *User name*: Name of the user who performed the activity
- *User Email ID*: Email ID of the user who performed the activity
- *Date Time*: Time stamp of the activity



Features on the page:

- Search panel to search a pattern on the page
- Sort, filter, group by headers in the list by clicking on the header names (here: Module, Feature, Activity, User name, User Email ID, Date Time)
- Export a report of audit trail (With filters applied) by clicking on Excel/PDF export