# Achieve Quality Assurance in Cannabis Testing Laboratories using a LIMS

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Chief Executive Officer, CloudLIMS.com

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# Agenda

Need for cannabis analysis

What is quality assurance in cannabis testing?

Importance of quality assurance

Benefits of using LIMS

How a LIMS helps in achieving quality assurance?

What challenges are faced while achieving quality assurance?

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# Need for Cannabis Analysis

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# What is Quality Assurance in Cannabis Testing?

***"The improvement of processes that ensure quality cannabis is provided to consumers"***

Regular auditing processes

Conducting quality tests by adhering to validated methods

Managing the operations of a cannabis testing laboratory using established specifications, standards, and testing procedures

Complying with local and state regulations (like GLP, ISO 17025, and 21 CFR Part 11 Compliance)

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# Quality Assurance in Cannabis Testing

**Heavy Metals**
Plants can absorb heavy metals like nickel, mercury, and lead from the soil/fertilizer which are toxic to humans

**Microorganisms**
Salmonella, E.coli for example cause serious illness

**Mycotoxins**
Aflatoxins contribute to bone cancer

**Residual Solvents**
Chemicals from the processing laboratories can be harmful to sick patients using the extract

**Foreign Material**
Mold, organic materials, dust or anything that could adversely affect patients

**Pesticides**
Keeps cannabis free from insects but can cause illness in humans

**Potency**
Cannabinoid and terpenoid concentration

**Moisture Content**
Can be detrimental to the quality of cannabis. More than 12% is prone to mold growth

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# Importance of Quality Assurance

- To ensure data integrity
- To ensure consistent and accurate cannabis testing using validated test methods
- To minimize the source of variation in testing consistency and accuracy cause due to unavailability of actual sample
- To meet customer’s demands and expectations
- Saves time and costs by detecting and fixing issues before they become larger

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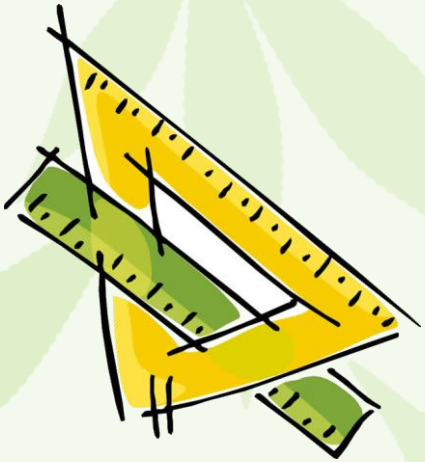
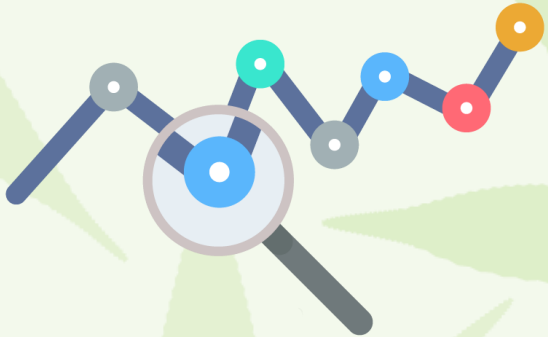
# QA & QC Good Lab Practices

## The Main Facets of GLP

Quality



Measurability



Traceability

Integrity

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# QA & QC Regulatory Requirements

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# ISO/IEC 17025 Requirements

## Management Requirements

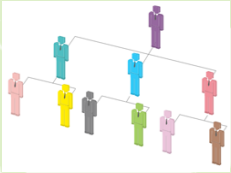
Pertain to the operation and effectiveness of the quality management system within the laboratory

### Control of Records

### Document Control

### Internal Audits

### Organizational Structure



### Review of Requests, Tenders, & Contracts

### Purchasing Services & Supplies

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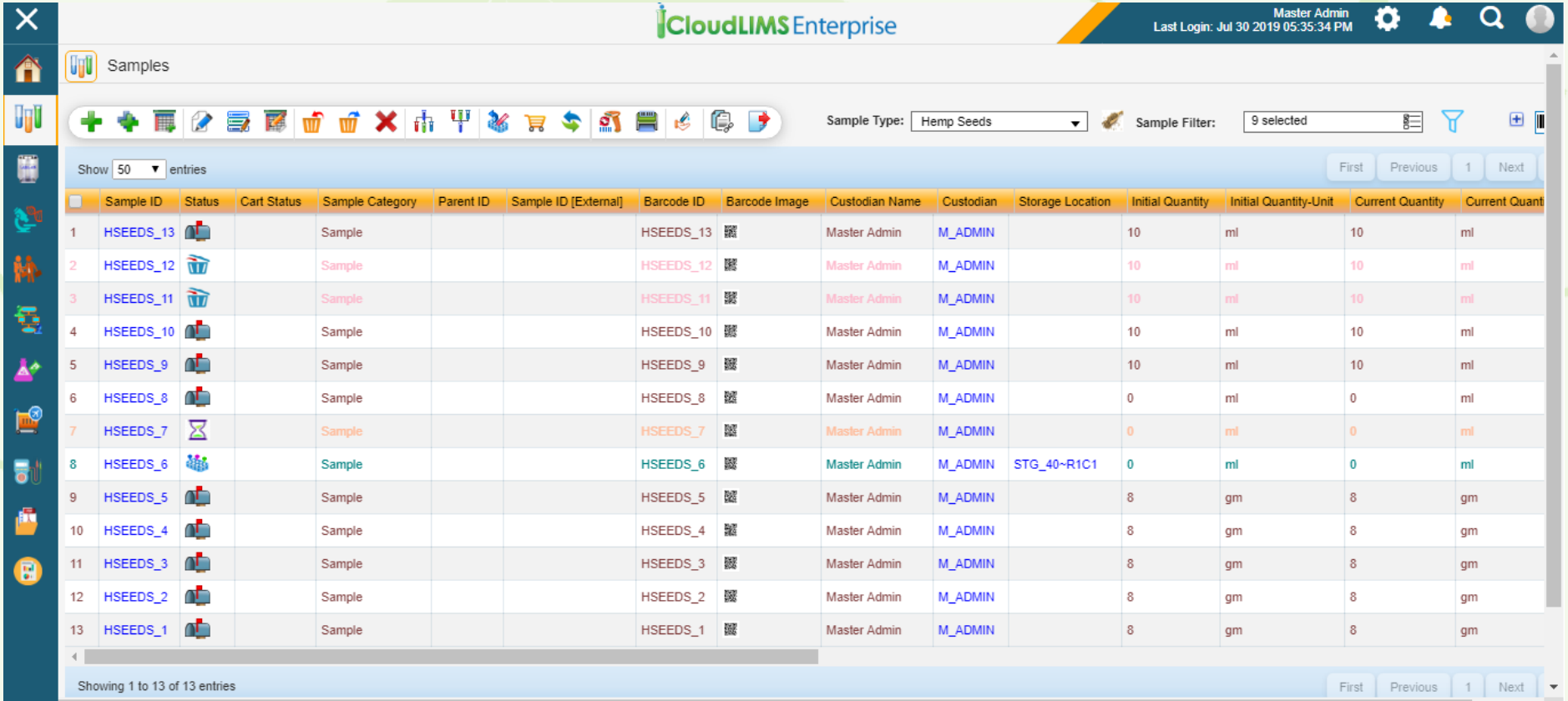
# Control of Records: Barcoding

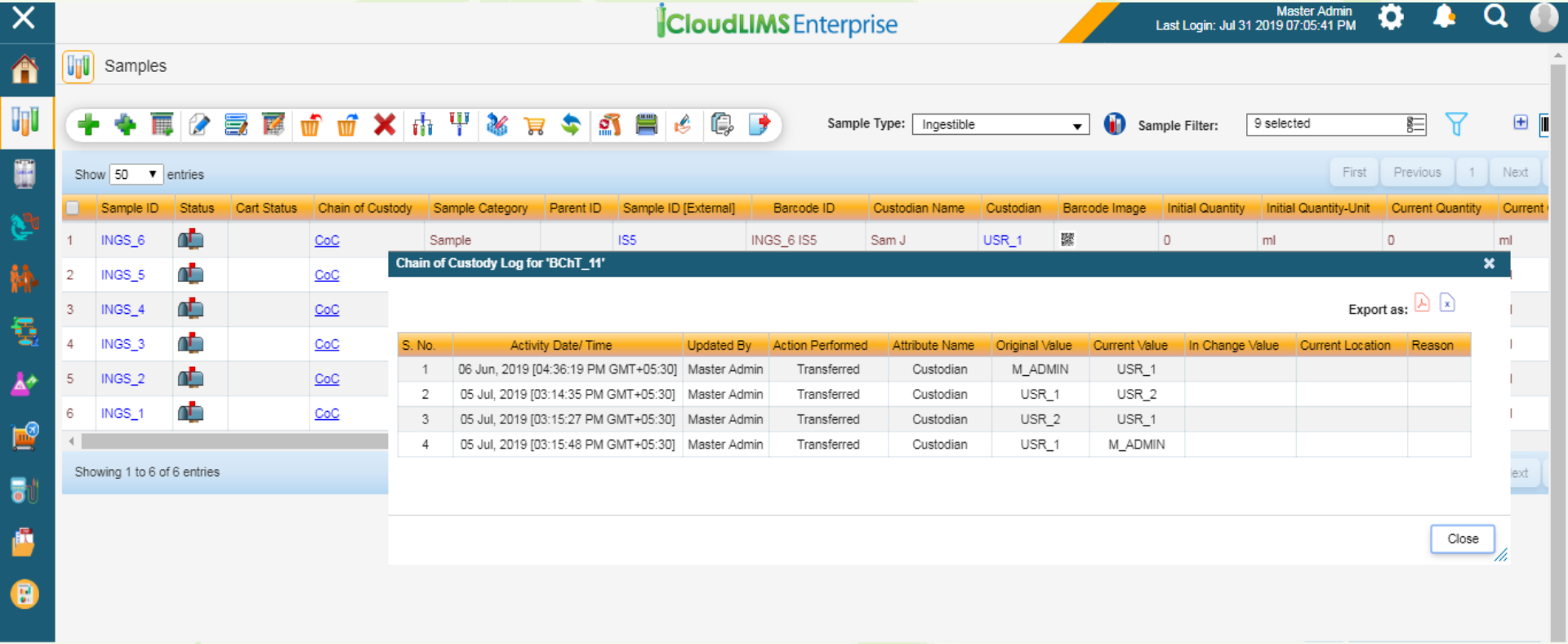
## Sample accessioning with 1D, 2D barcoding or RFID to keep a track of sample through-out its life-cycle




| | Sample ID | Status | Cart Status | Sample Category | Parent ID | Sample ID [External] | Barcode ID | Barcode Image | Custodian Name | Custodian | Storage Location | Initial Quantity | Initial Quantity-Unit | Current Quantity | Current Quant |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | HSEEDS_13 | | | Sample | | | HSEEDS_13 | | Master Admin | M_ADMIN | | 10 | ml | 10 | ml |
| 2 | HSEEDS_12 | | | Sample | | | HSEEDS_12 | | Master Admin | M_ADMIN | | 10 | ml | 10 | ml |
| 3 | HSEEDS_11 | | | Sample | | | HSEEDS_11 | | Master Admin | M_ADMIN | | 10 | ml | 10 | ml |
| 4 | HSEEDS_10 | | | Sample | | | HSEEDS_10 | | Master Admin | M_ADMIN | | 10 | ml | 10 | ml |
| 5 | HSEEDS_9 | | | Sample | | | HSEEDS_9 | | Master Admin | M_ADMIN | | 10 | ml | 10 | ml |
| 6 | HSEEDS_8 | | | Sample | | | HSEEDS_8 | | Master Admin | M_ADMIN | | 0 | ml | 0 | ml |
| 7 | HSEEDS_7 | | | Sample | | | HSEEDS_7 | | Master Admin | M_ADMIN | | 0 | ml | 0 | ml |
| 8 | HSEEDS_6 | | | Sample | | | HSEEDS_6 | | Master Admin | M_ADMIN | STG_40~R1C1 | 0 | ml | 0 | ml |
| 9 | HSEEDS_5 | | | Sample | | | HSEEDS_5 | | Master Admin | M_ADMIN | | 8 | gm | 8 | gm |
| 10 | HSEEDS_4 | | | Sample | | | HSEEDS_4 | | Master Admin | M_ADMIN | | 8 | gm | 8 | gm |
| 11 | HSEEDS_3 | | | Sample | | | HSEEDS_3 | | Master Admin | M_ADMIN | | 8 | gm | 8 | gm |
| 12 | HSEEDS_2 | | | Sample | | | HSEEDS_2 | | Master Admin | M_ADMIN | | 8 | gm | 8 | gm |
| 13 | HSEEDS_1 | | | Sample | | | HSEEDS_1 | | Master Admin | M_ADMIN | | 8 | gm | 8 | gm |

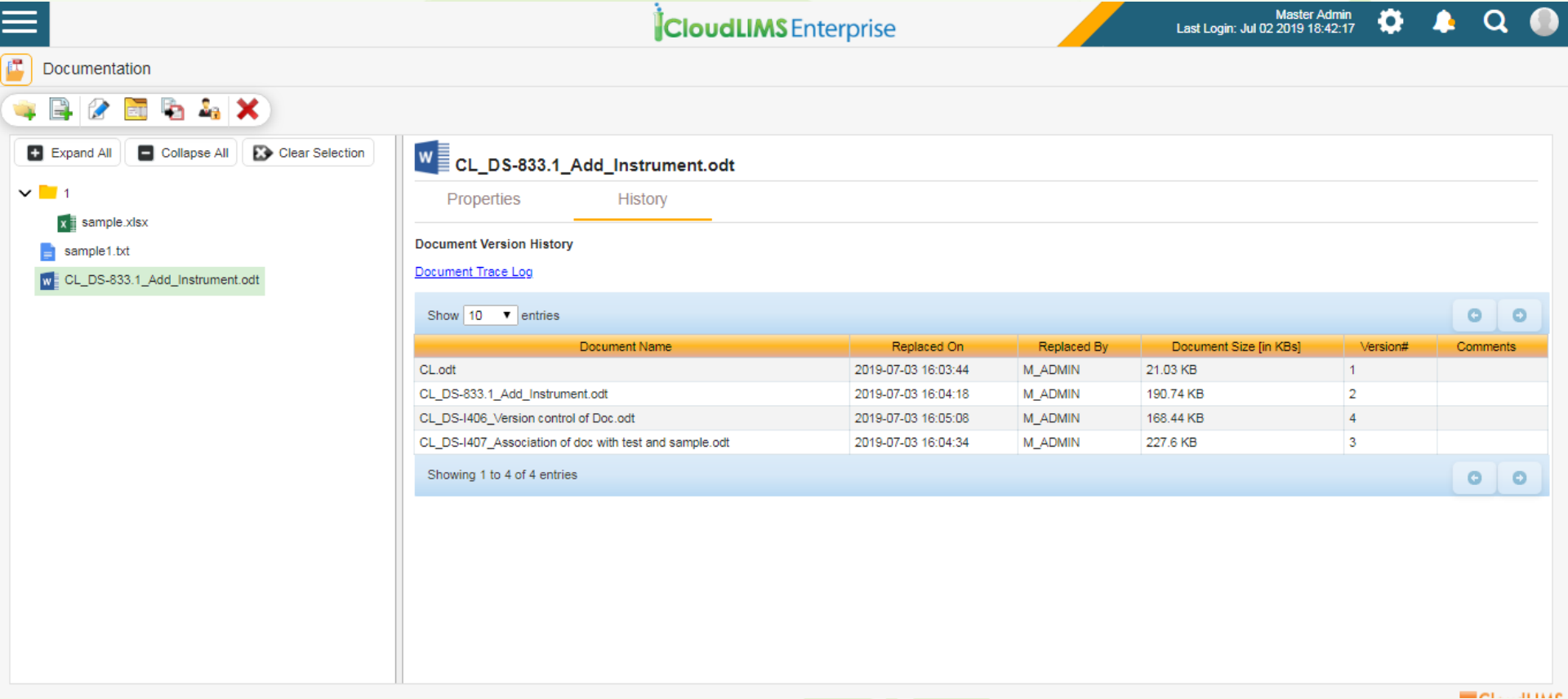
# Control of Records: Chain of Custody

## Track the entire chain of custody for all your samples



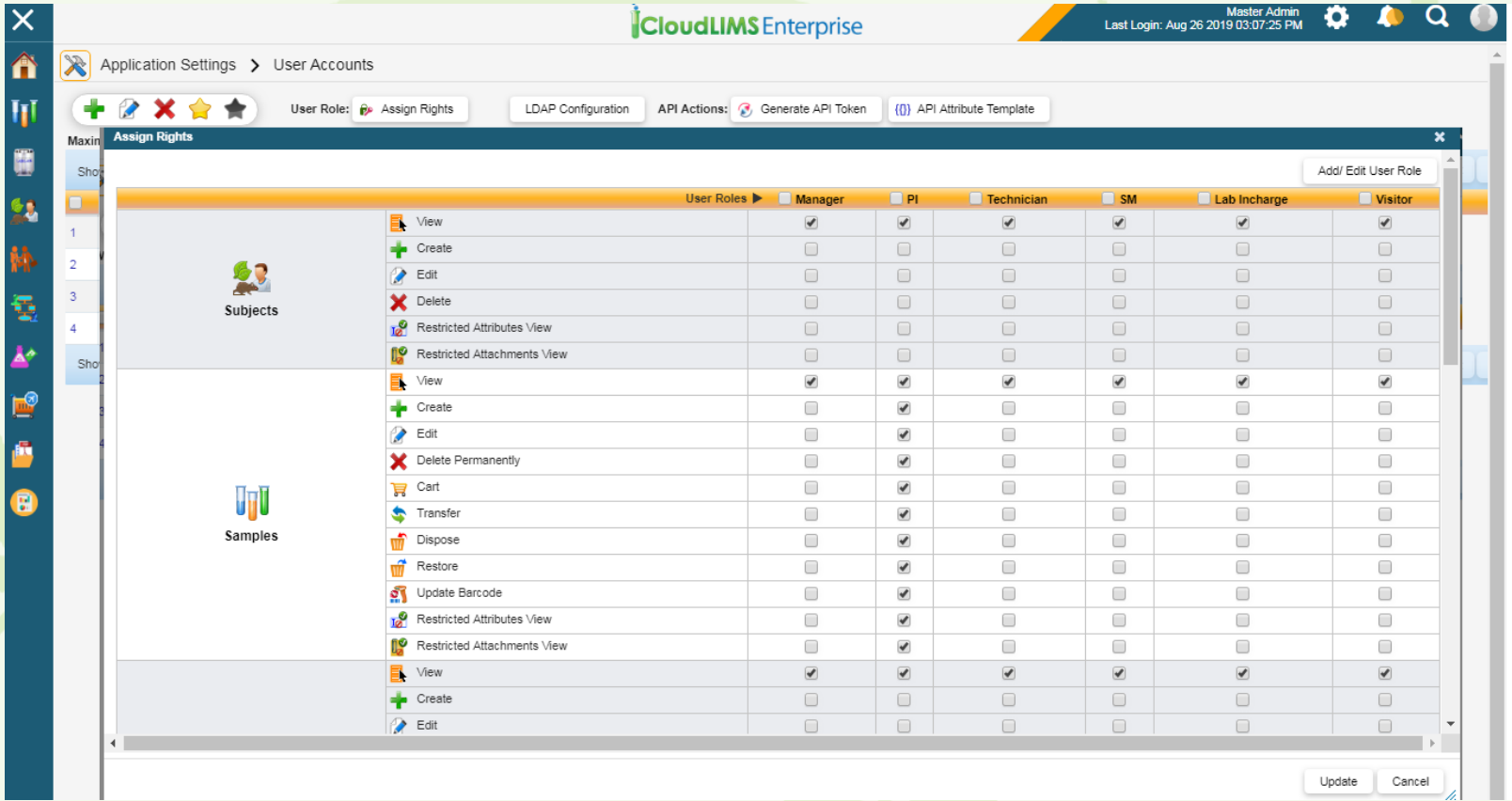
# Document Control

**Maintain and track all documents, and maintain version control, helps to meet ISO 9001 certification requirements as well**



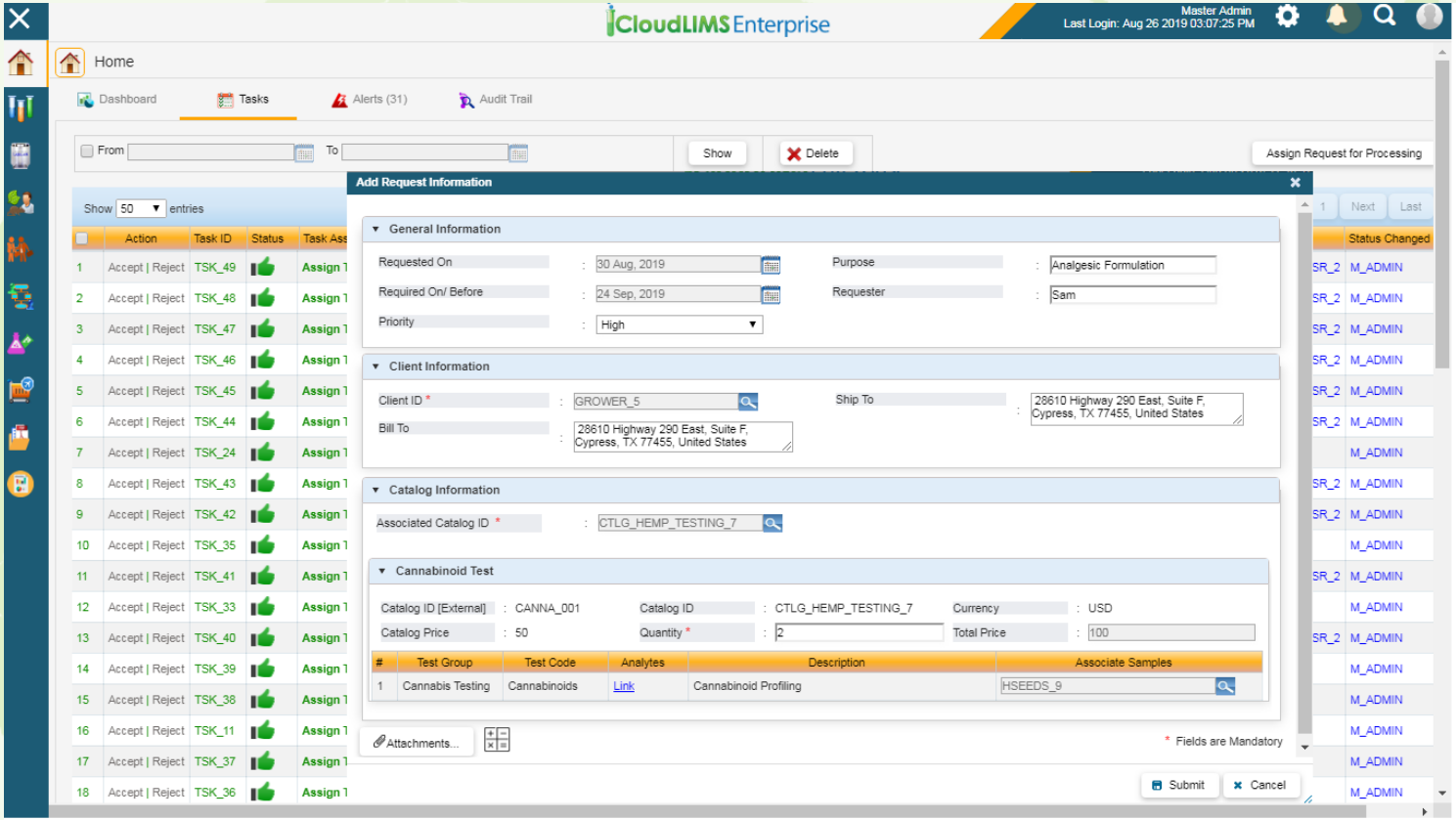
# Organizational Structure: Role Based Permission Level to Staff

## Users can be granted/revoked accesses to/from various functionalities based on their designation in the organization's hierarchy



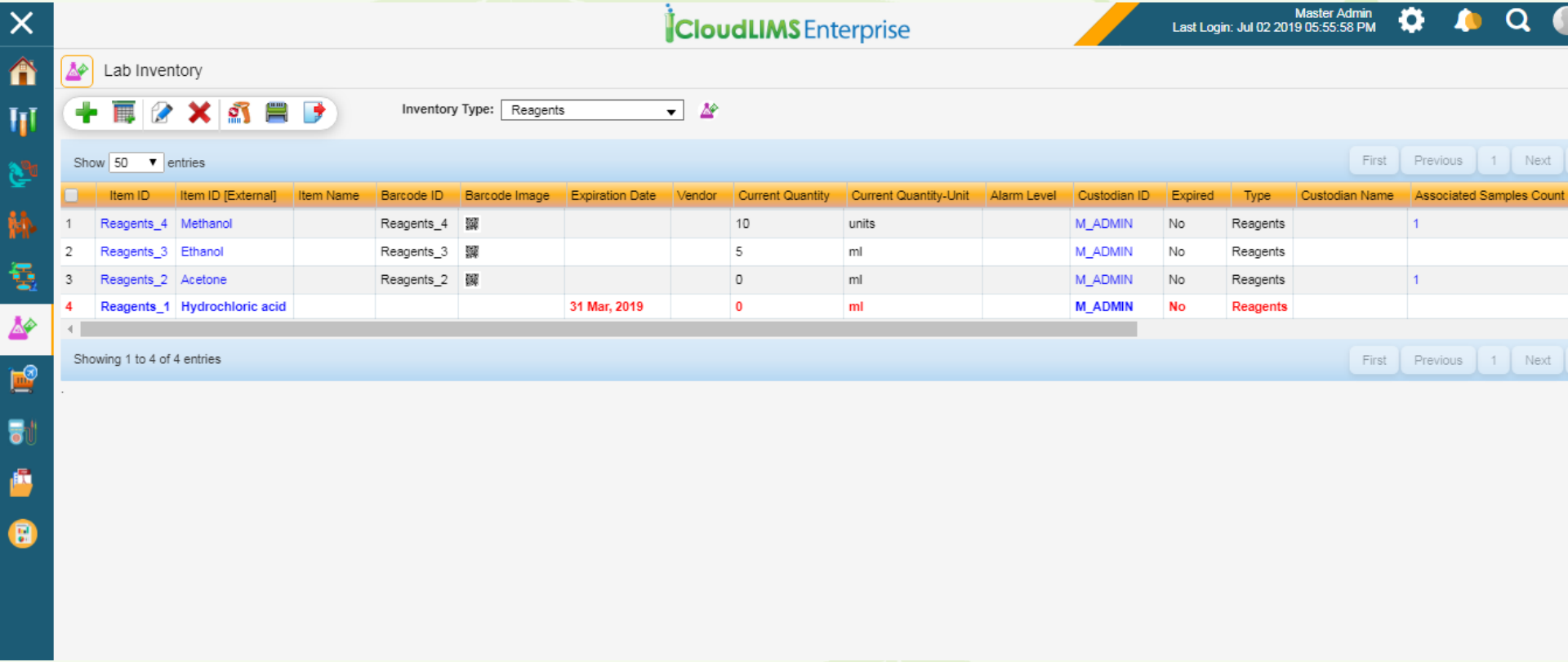
# Review of Requests, Tenders, & Contracts

**All details related to a service requested by a client can be seen along with the ability to accept, reject and assign the task pertaining to a request**



# Purchasing Services & Supplies

## Accurate barcode labeling of reagents and maintaining their stocks



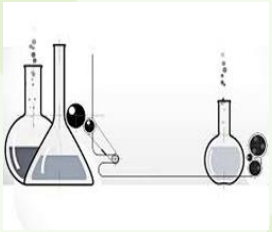
# ISO/IEC 17025 Requirements

## Technical Requirements

Address the competence of staff, sampling and testing methodology, equipment, and the quality and reporting of test and calibration results

### Personnel

### Equipment



### Reporting of Results

### Test and Calibration Methods & Method Validation

### Measurement Traceability

### Ensuring the Quality of Test and Calibration Results

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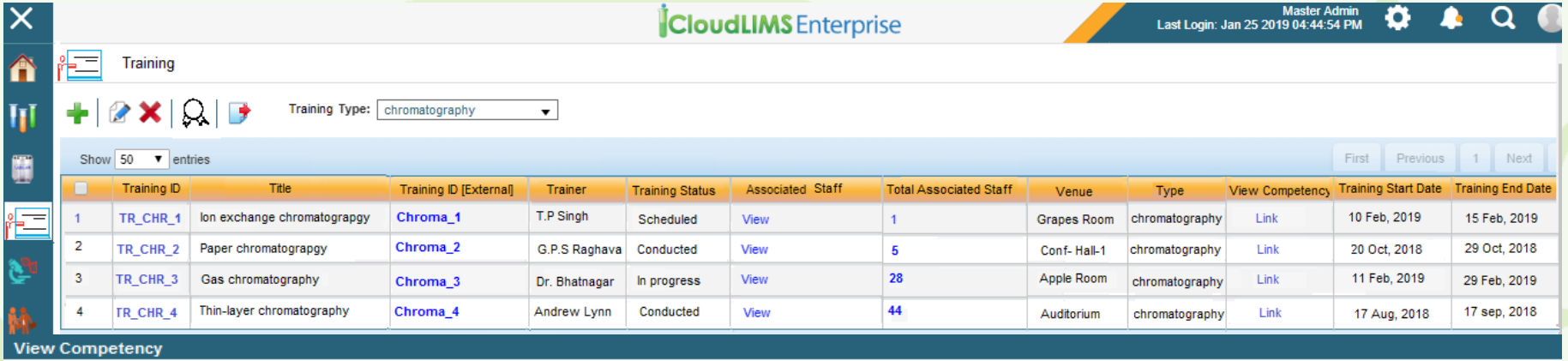
# Personnel: Staff &Training

## Manage staff and training records and mark their competency




**View Competency**

Training ID: TR_CHR_2 | Training ID [External]: Chroma_2 | Training Type: Chromatography | Title: Paper Chromatography

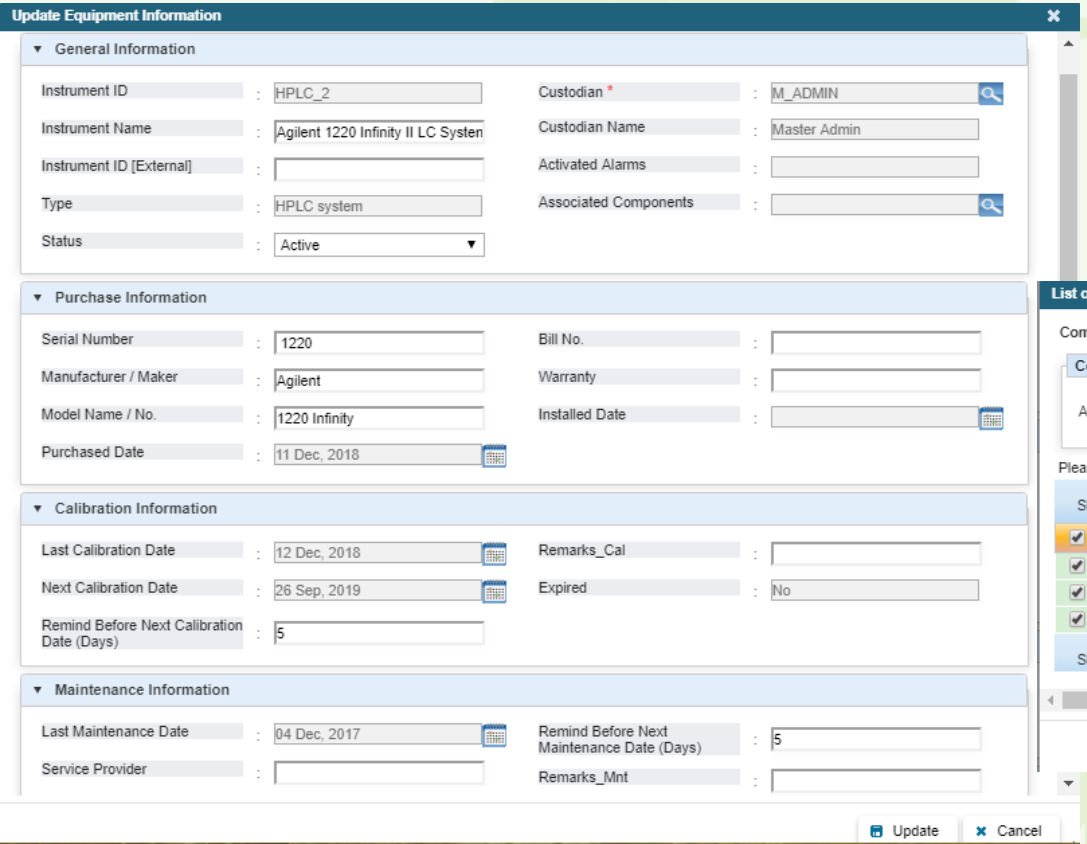
Competency Results for TR_CHR_2

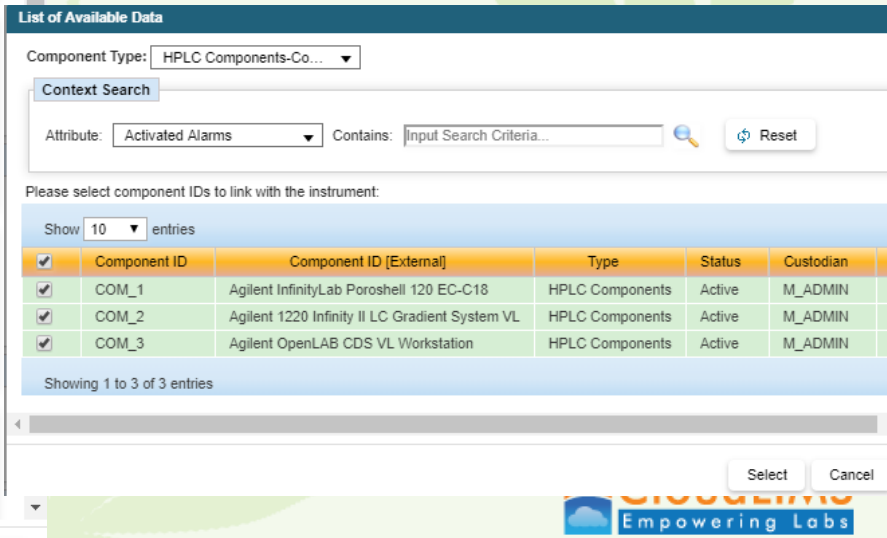
Participants

| # | Staff ID | First Name | Last Name | Attended | Certified | Competent |
|---|---|---|---|---|---|---|
| 1 | Stf_1 | Maxim | Gilbert | Yes | Yes | Yes |
| 2 | Stf_2 | Sania | Fernandis | Yes | Yes | Yes |
| 3 | Stf_7 | Christina | Paul | Yes | No | No |
| 4 | Stf_13 | Tim | Yan | No | No | No |
| 5 | Stf_15 | Jack | lynn | Yes | Yes | Yes |

# Equipment: Instrument Calibration and Maintenance

## Track your equipment and its components along with calibration status

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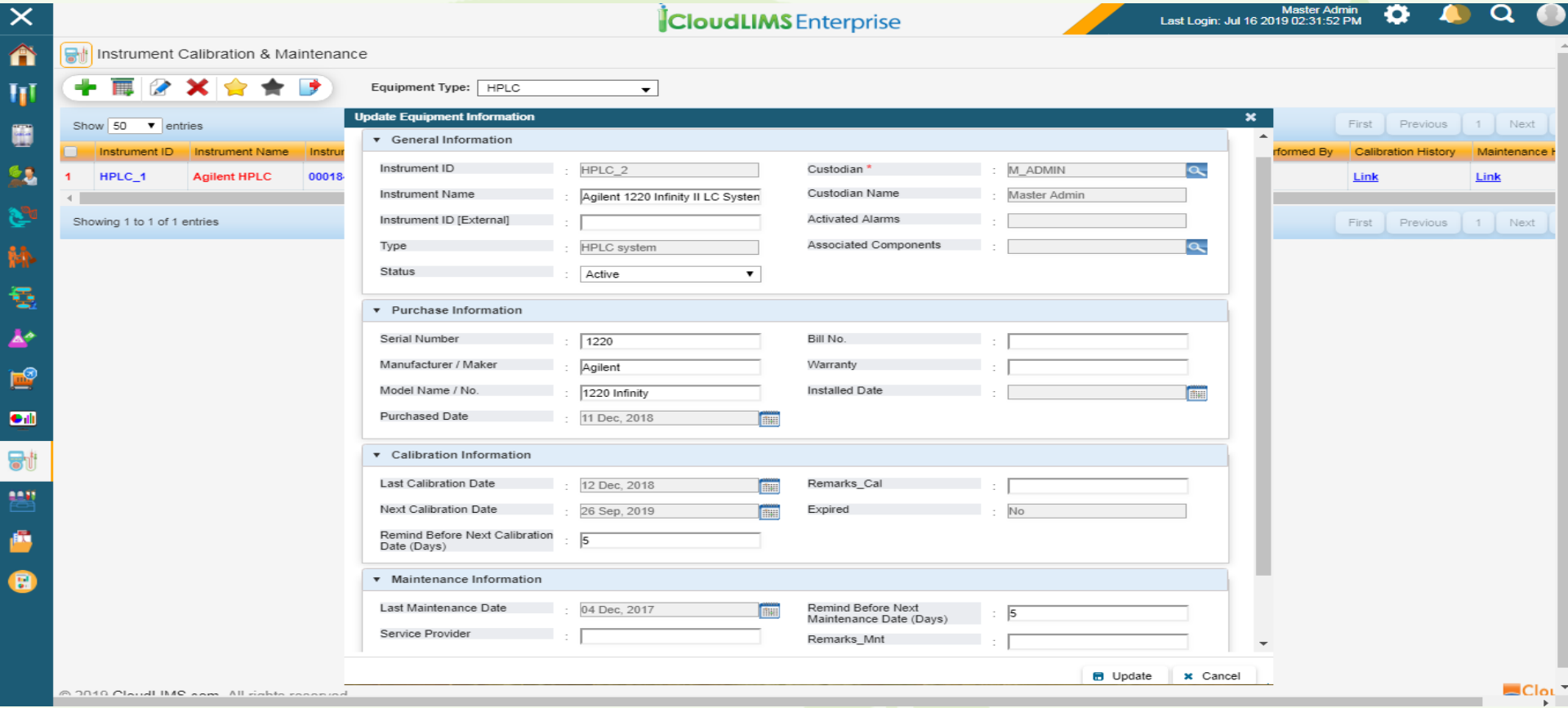
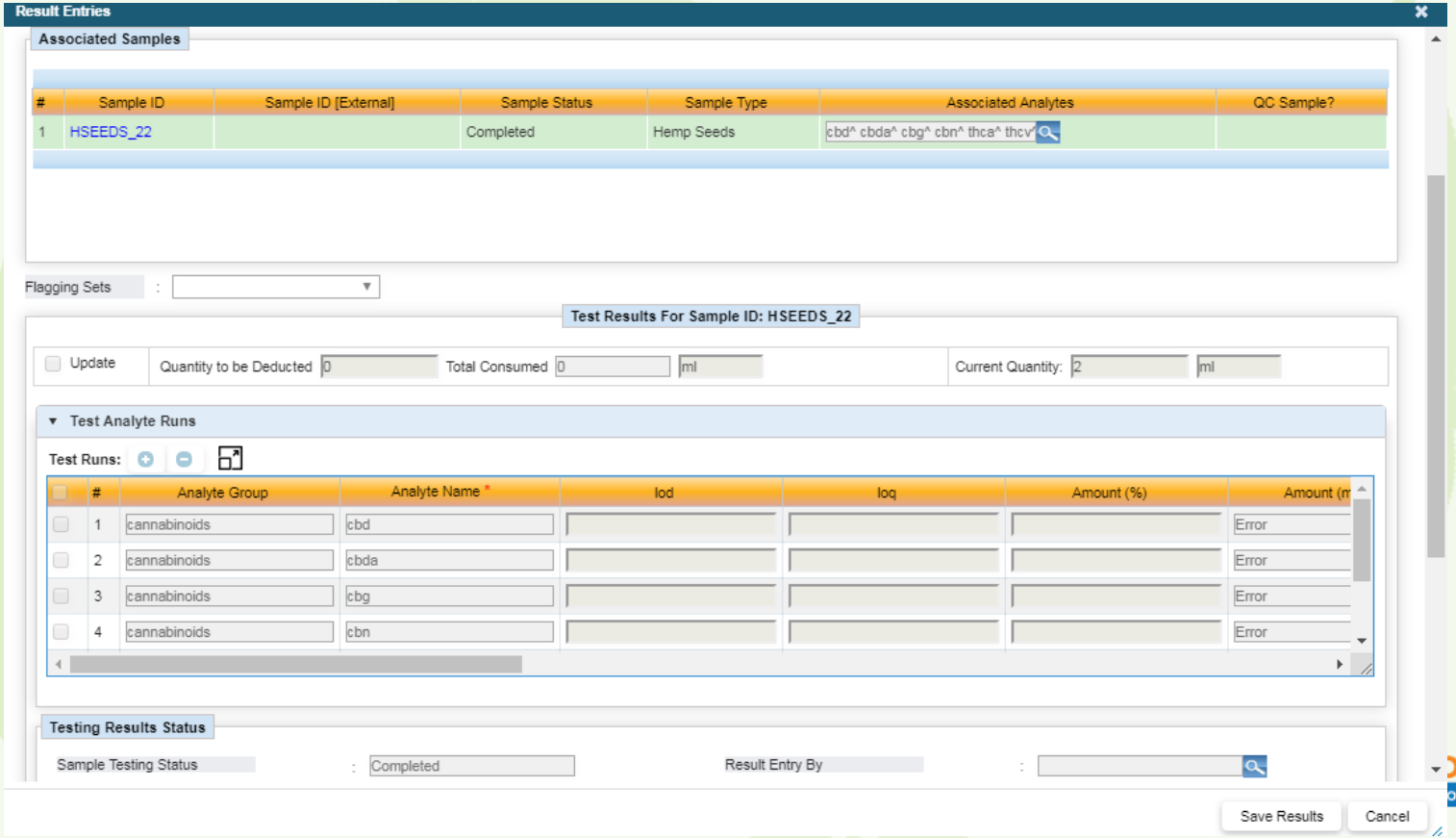
# Equipment: Assigning Competent Staff

## Assigning of instruments to competent analyst



# Reporting Test Results to Clients

## Manage test results, generate CoA and send it to clients



# Advantages of Instrument Integration

**Why should you interface?**

- Increases data quality
- Increases accuracy
- Increases throughput
- Avoids duplication, saves $$$
- Enhances productivity
- ROI typically less than a year

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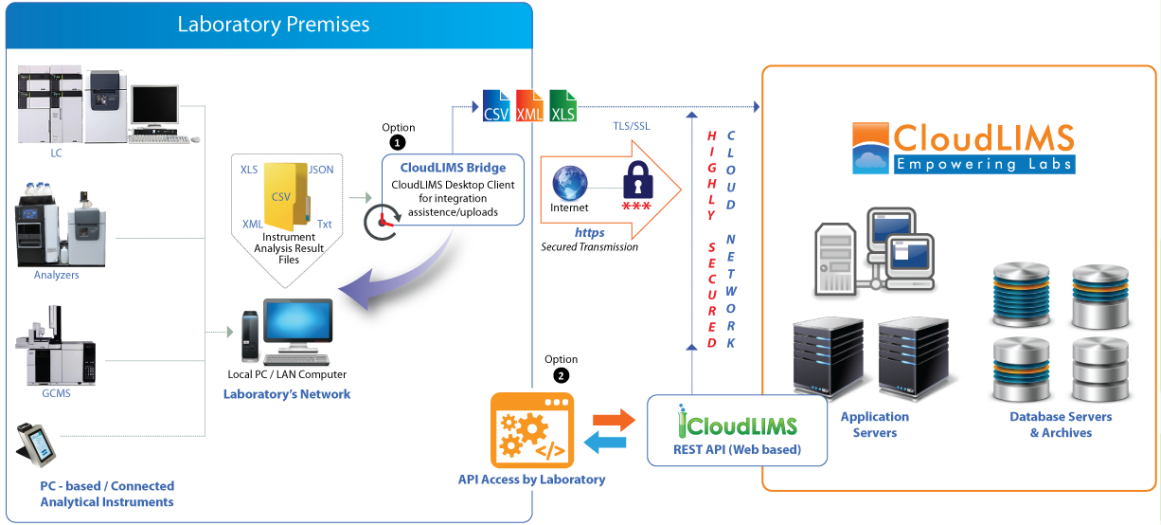
# Instrument Integration




**A LIMS Supports:**

- Automatic time scanned uploads of mapped CSV files
- Bidirectional data transfer using CloudLIMS web-based Rest API

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# Customized CoAs Per State Regulations

## CTL Certificate of Analysis

My Cannabis Lab, Plot No. 145, Sesame Street
Bridge-Highway Road, United States

### Client Information

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Client ID:** | GROWER_1 | **First Name:** | Mark | **Last Name:** | Jones | **Facility Name:** | Cannabis Growers Co. |
| **Type:** | Growers | **Entry Date:** | 01 Apr, 2019 | | | **License Number:** | C12-11984783-MY |
| **Address:** | 83, Park Avenue, CA | **Country:** | United States | **Email:** | mark@jones.com | | |

### Sample Information

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sample ID:** | HSEEDS_1 | **Sample ID [External]:** | AB-110101-##CZ | **Type:** | Hemp Seeds | **Current Quantity:** | 5 |
| **Batch ID:** | AB-1101 | **Current Quantity-Unit:** | gm | **Custodian:** | M_ADMIN | **Collection Date:** | 27 Mar, 2019 |
| **Entry Date:** | 01 Apr, 2019 | **Associated Client:** | GROWER_1 | **Entry Time:** | 05:27:24 PM | | |

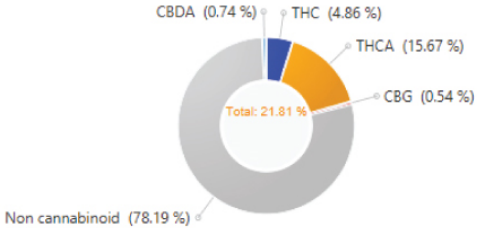
### Test Information: Cannabis Testing/ Cannabinoids

| Test ID | Completion Date | Type | Group | Code |
|---|---|---|---|---|
| CANN_1 | 2019-04-01 | Cannabis Testing_Cannabinoids | Cannabis Testing | Cannabinoids |

### Analytes and Results: Cannabis Testing/ Cannabinoids

| Analyte Name | LOD ppm | LOQ ppm | Amount (%) | Amount (mg/g) |
|---|---|---|---|---|
| Cannabidiol (CBD) | 0.01 | 0.04 | ND | ND |
| Cannabidiolic Acid (CBDA) | 0.29 | 0.67 | 0.7 | 7.1 |
| Tetrahydrocannabinol (THC) | 0.04 | 0.15 | 4.61 | 46.1 |
| Tetrahydrocannabinolic Acid (THCA) | 0.7 | 0.9 | 15.6 | 156 |
| Cannabinol (CBN) | 0.03 | 0.06 | ND | ND |
| Cannabigerol (CBG) | 0.04 | 0.12 | 0.54 | 5.4 |

### Cannabinoid Profile




### Analytes and Results: Cannabis Testing/ Terpenes

| Analyte Name | Amount (mg/g) | Amount (%) | Status |
|---|---|---|---|
| valencene | 0 | 0 | ND |
| terpinolene | 0 | 0 | ND |
| nerol | 0 | 0 | ND |
| menthol | 0 | 0 | ND |
| isoborneol | 0 | 0 | ND |
| camphor | 0 | 0 | ND |
| camphene | 0 | 0 | ND |
| beta_caryophyllene | 0 | 0 | ND |
| alpha_pinene | 0 | 0 | ND |

### Analytes and Results: Cannabis Testing/ Pesticides PASS

| Analyte Name | LOD (ug/g) | Amount (ug/g) | Status |
|---|---|---|---|
| spirotetramat | 0.04 | ND | Pass |
| spinosad | 0.04 | ND | Pass |
| pyrethrum | 0.38 | ND | Pass |
| paclobutrazol | 0.043 | ND | Pass |
| imidacloprid | 0.04 | ND | Pass |
| daminozide | 0.04 | ND | Pass |
| bifenazate | 0.04 | ND | Pass |
| acequinocyl | 0.04 | ND | Pass |

Disclaimer
All Tests are conducted by Cannabis Testing Laboratory and validated under proper administrative regulations. Please report any discrepancy in the report to: info.mylabe@address.com

Dr. John Smith
Lab Director

01 Apr, 2019

Dr. Joanna Black
Chief Technician
CTL
01 Apr, 2019



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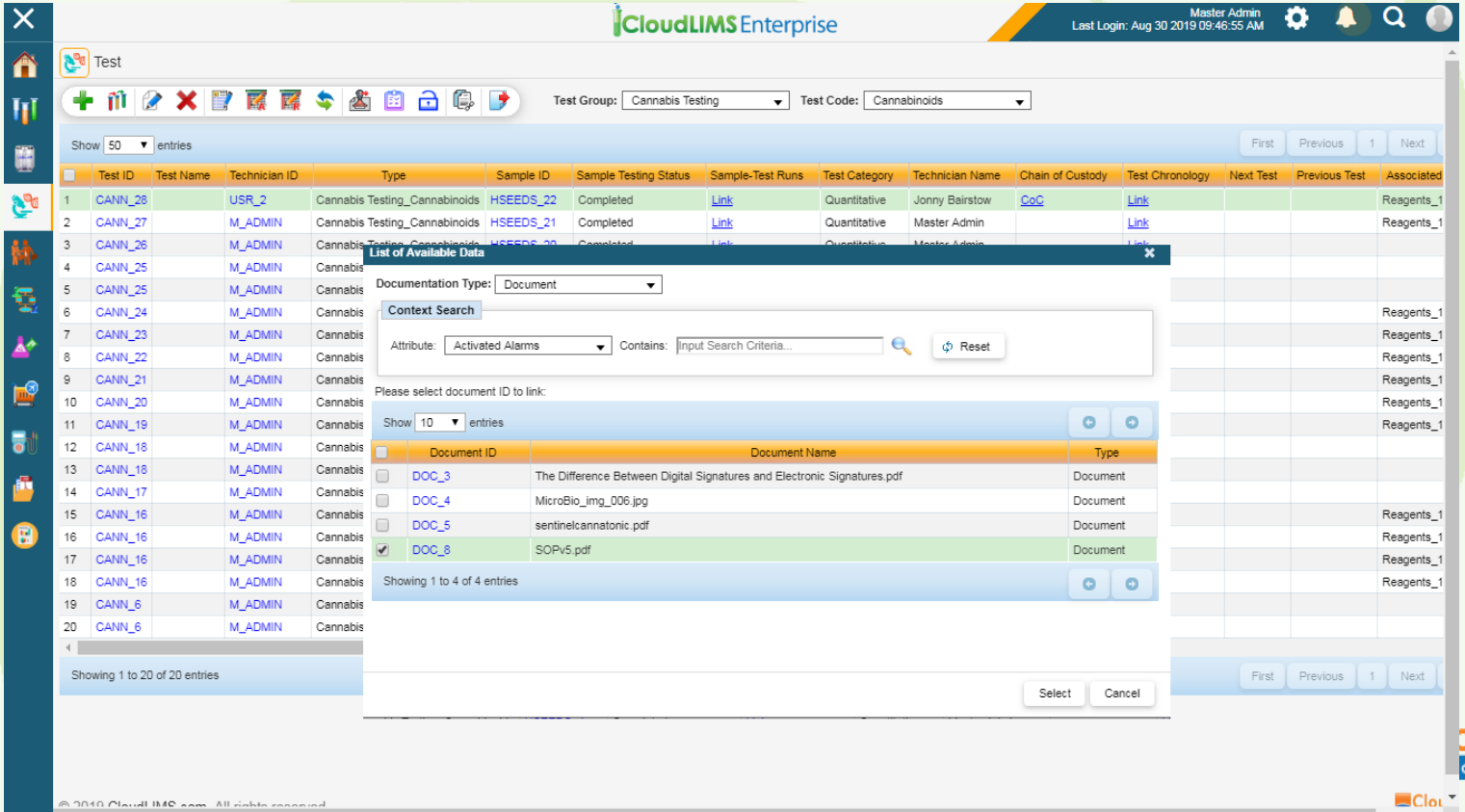
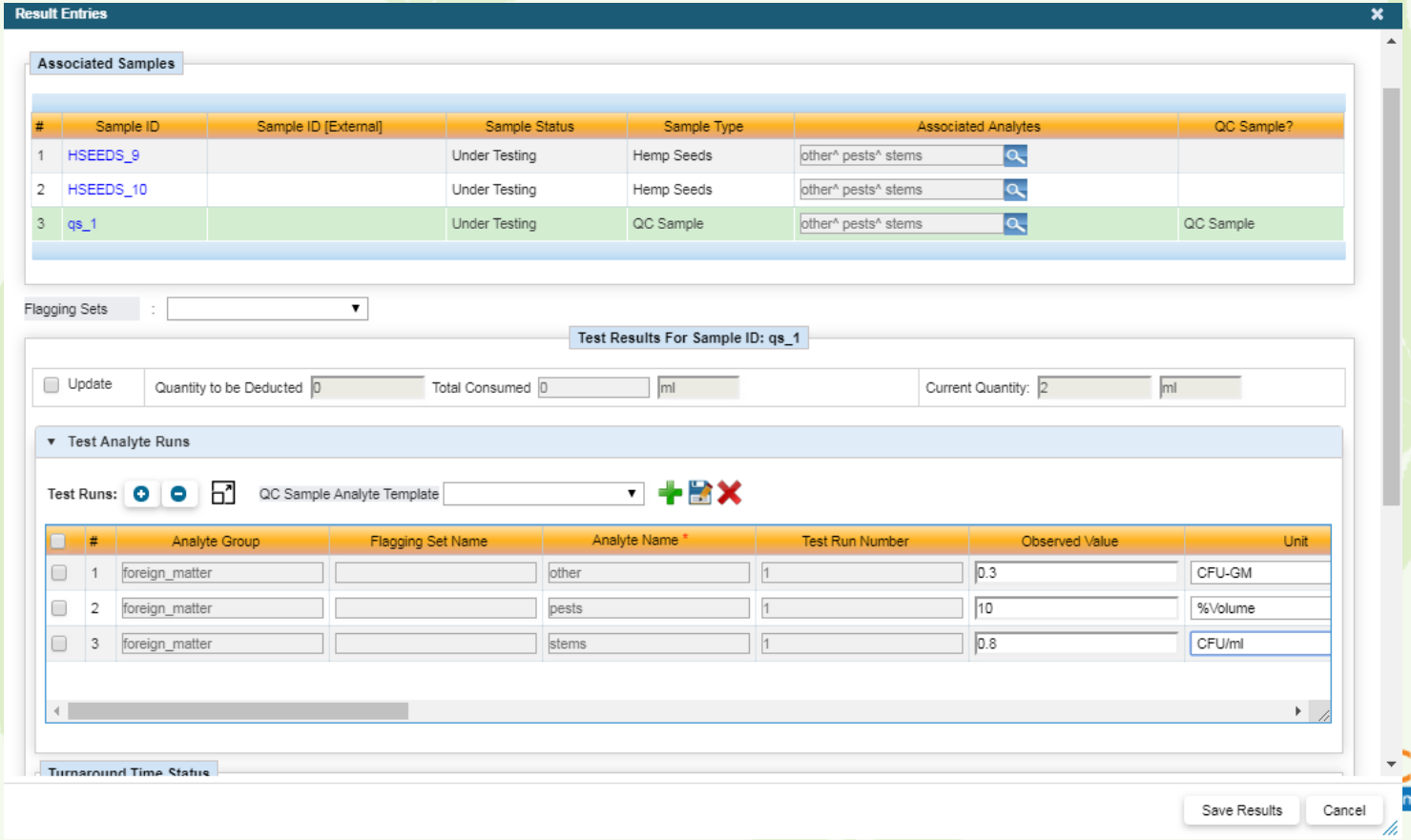
# Test and Calibration Methods: Associating Docs

**Easily access the appropriate instructions for operation, handling of instruments and testing samples to ensure the personnel is using only latest/compliant methods**



# Measurement Traceability: Manage QC Samples

## Manage quality control samples and their results to detect trends

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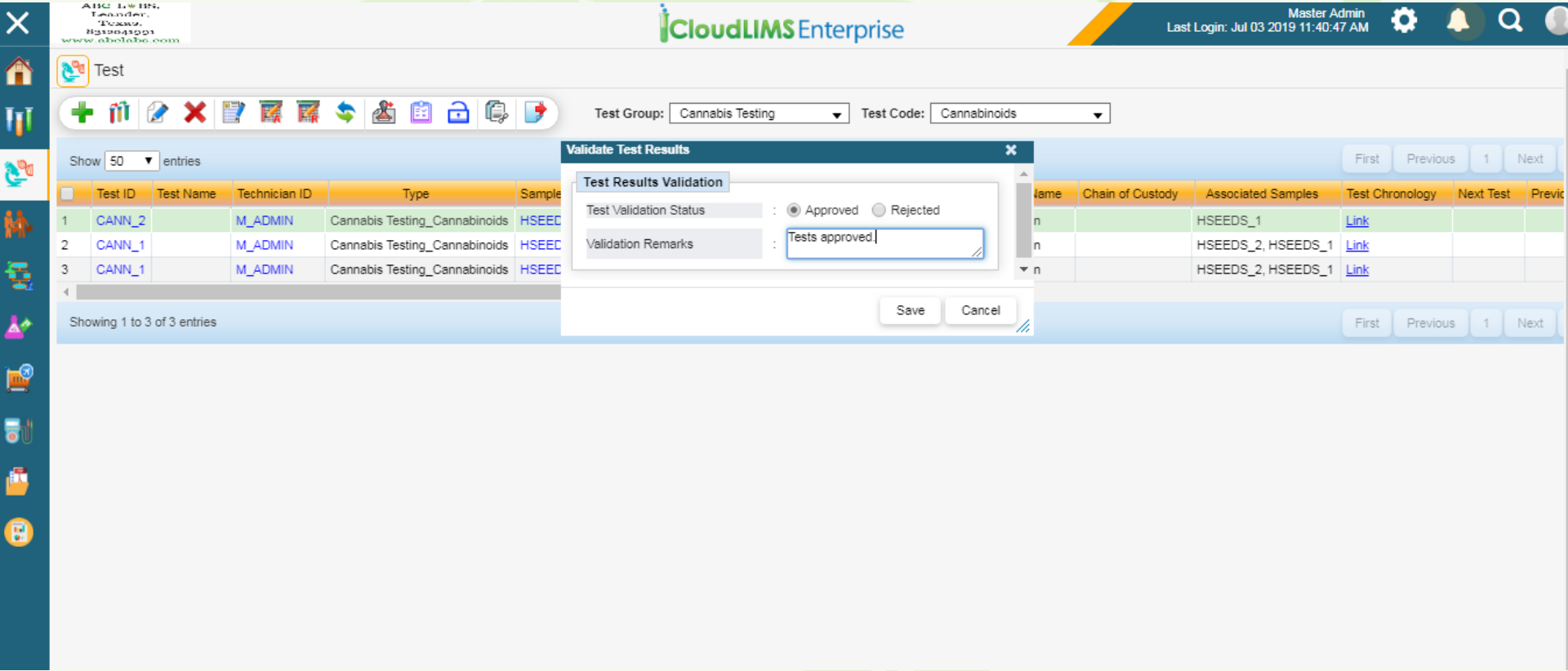
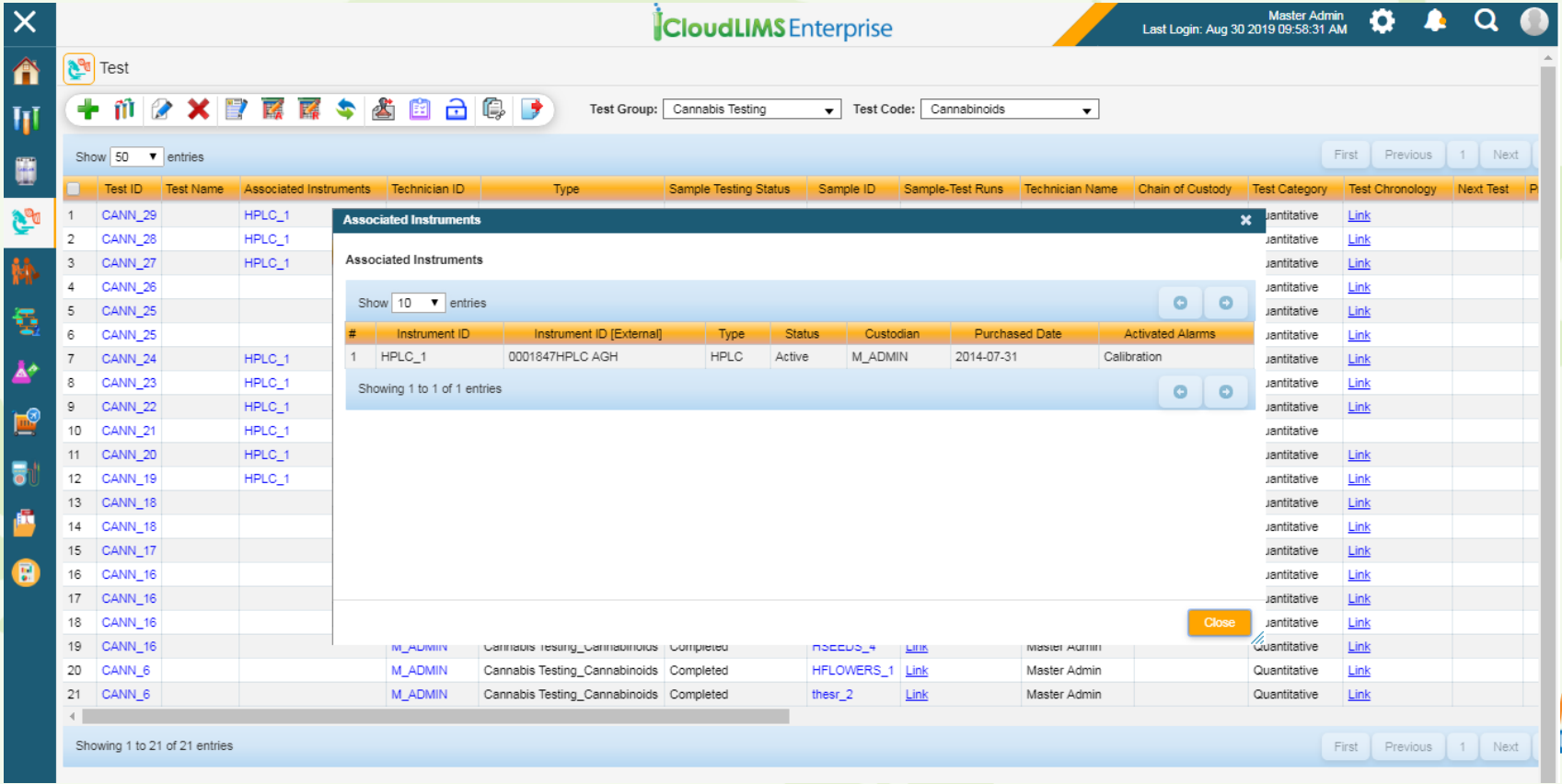
# Validate Test Results

**Configure a test validation process, send multiple results for validation, select a verifier, track the validation status, thereby assuring the final test results**



# Associated Instruments: Testing the Quality of Results

## At the time of association of an instrument with a test, indicate that the instrument was properly calibrated before test was conducted



# 21 CFR Part 11 Compliance

- Confidentiality of electronic records
- Digital signature on electronic records
- Audit trail compliance

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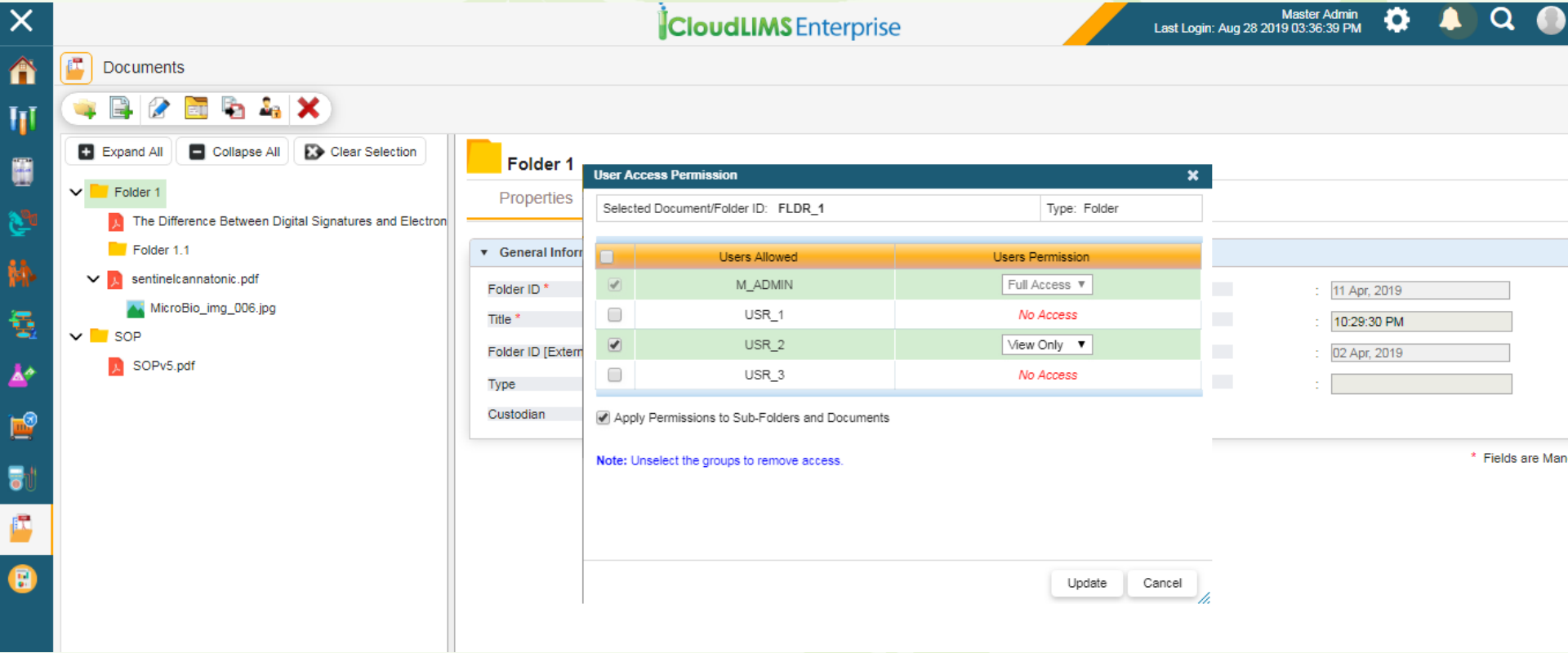
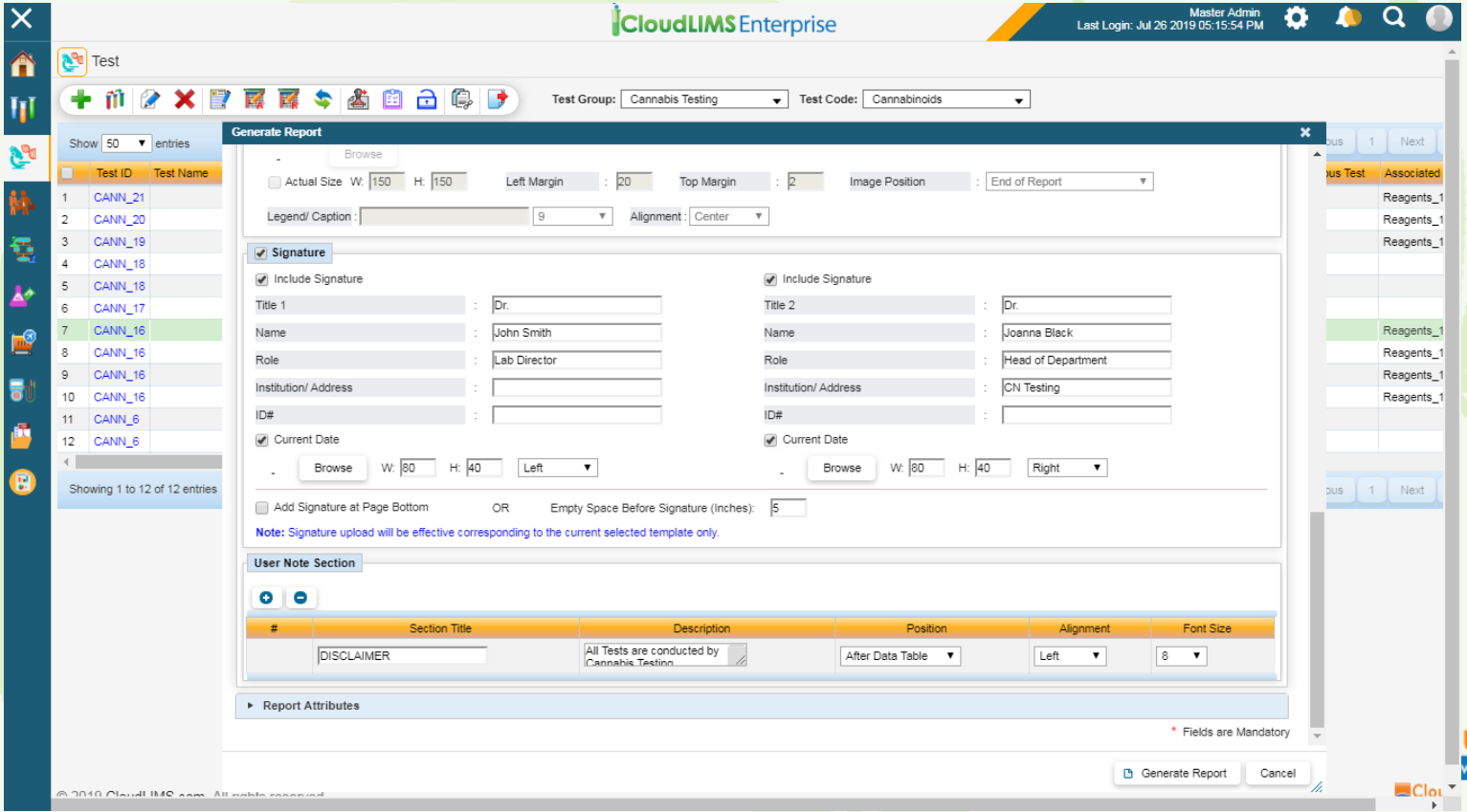
# User Access: Secure Confidential Data

**Provide full/limited/no access to different user groups to maintain confidentiality of information**



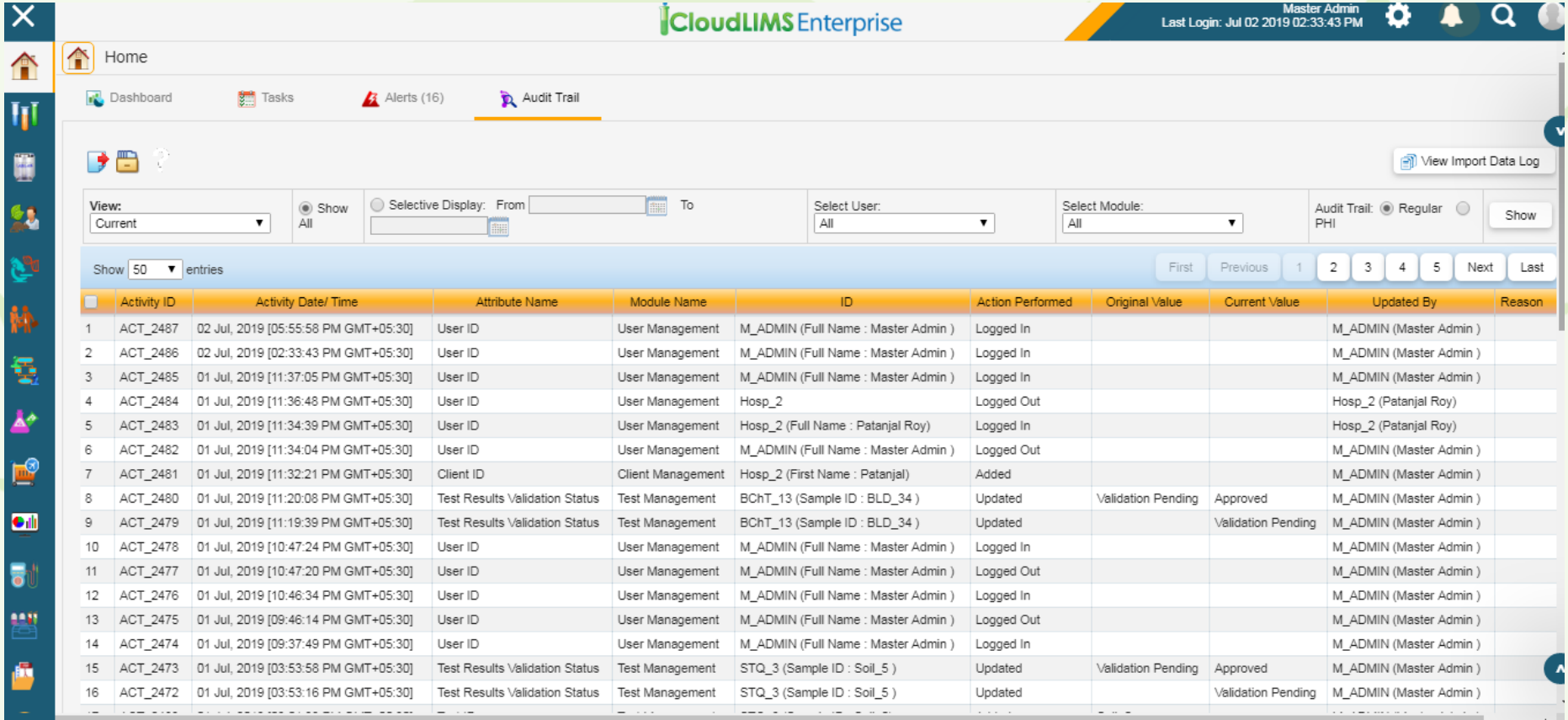
# Generate Reports with Authorized Signatures

## Digital signature with the name, designation and the date of signing



# Dedicated Section for Audit Trail

## Manage complete audit trail of each activity along with a date & time stamp




| | Activity ID | Activity Date/ Time | Attribute Name | Module Name | ID | Action Performed | Original Value | Current Value | Updated By | Reason |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ACT_2487 | 02 Jul, 2019 [05:55:58 PM GMT+05:30] | User ID | User Management | M_ADMIN (Full Name : Master Admin ) | Logged In | | | M_ADMIN (Master Admin ) | |
| 2 | ACT_2486 | 02 Jul, 2019 [02:33:43 PM GMT+05:30] | User ID | User Management | M_ADMIN (Full Name : Master Admin ) | Logged In | | | M_ADMIN (Master Admin ) | |
| 3 | ACT_2485 | 01 Jul, 2019 [11:37:05 PM GMT+05:30] | User ID | User Management | M_ADMIN (Full Name : Master Admin ) | Logged In | | | M_ADMIN (Master Admin ) | |
| 4 | ACT_2484 | 01 Jul, 2019 [11:36:48 PM GMT+05:30] | User ID | User Management | Hosp_2 | Logged Out | | | Hosp_2 (Patanjal Roy) | |
| 5 | ACT_2483 | 01 Jul, 2019 [11:34:39 PM GMT+05:30] | User ID | User Management | Hosp_2 (Full Name : Patanjal Roy) | Logged In | | | Hosp_2 (Patanjal Roy) | |
| 6 | ACT_2482 | 01 Jul, 2019 [11:34:04 PM GMT+05:30] | User ID | User Management | M_ADMIN (Full Name : Master Admin ) | Logged Out | | | M_ADMIN (Master Admin ) | |
| 7 | ACT_2481 | 01 Jul, 2019 [11:32:21 PM GMT+05:30] | Client ID | Client Management | Hosp_2 (First Name : Patanjal) | Added | | | M_ADMIN (Master Admin ) | |
| 8 | ACT_2480 | 01 Jul, 2019 [11:20:08 PM GMT+05:30] | Test Results Validation Status | Test Management | BChT_13 (Sample ID : BLD_34 ) | Updated | Validation Pending | Approved | M_ADMIN (Master Admin ) | |
| 9 | ACT_2479 | 01 Jul, 2019 [11:19:39 PM GMT+05:30] | Test Results Validation Status | Test Management | BChT_13 (Sample ID : BLD_34 ) | Updated | | Validation Pending | M_ADMIN (Master Admin ) | |
| 10 | ACT_2478 | 01 Jul, 2019 [10:47:24 PM GMT+05:30] | User ID | User Management | M_ADMIN (Full Name : Master Admin ) | Logged In | | | M_ADMIN (Master Admin ) | |
| 11 | ACT_2477 | 01 Jul, 2019 [10:47:20 PM GMT+05:30] | User ID | User Management | M_ADMIN (Full Name : Master Admin ) | Logged Out | | | M_ADMIN (Master Admin ) | |
| 12 | ACT_2476 | 01 Jul, 2019 [10:46:34 PM GMT+05:30] | User ID | User Management | M_ADMIN (Full Name : Master Admin ) | Logged In | | | M_ADMIN (Master Admin ) | |
| 13 | ACT_2475 | 01 Jul, 2019 [09:46:14 PM GMT+05:30] | User ID | User Management | M_ADMIN (Full Name : Master Admin ) | Logged Out | | | M_ADMIN (Master Admin ) | |
| 14 | ACT_2474 | 01 Jul, 2019 [09:37:49 PM GMT+05:30] | User ID | User Management | M_ADMIN (Full Name : Master Admin ) | Logged In | | | M_ADMIN (Master Admin ) | |
| 15 | ACT_2473 | 01 Jul, 2019 [03:53:58 PM GMT+05:30] | Test Results Validation Status | Test Management | STQ_3 (Sample ID : Soil_5 ) | Updated | Validation Pending | Approved | M_ADMIN (Master Admin ) | |
| 16 | ACT_2472 | 01 Jul, 2019 [03:53:16 PM GMT+05:30] | Test Results Validation Status | Test Management | STQ_3 (Sample ID : Soil_5 ) | Updated | | Validation Pending | M_ADMIN (Master Admin ) | |

# A2LA or Other Accreditors for Cannabis Testing Accreditation

A2LA offers accreditation to laboratories performing analytical testing of cannabis and cannabis-derived products, such as flowers, concentrates, butters/waxes, drinks, tinctures, oils and edibles, as well as hemp and hemp-derived products.

**Benefits of A2LA:**

- Labs can focus on improvements rather than rectifications
- Provide a cost-effective way to get accredited
- Provide professional, knowledgeable assessors, and make the entire process right from initial contact to assessments simple
- Provides a dependable calibration program that makes labs well equipped for a scenario of micro-level scrutiny

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# Benefits of Automation Using LIMS

- Eases data transfer and maintenance
- Simplifies data traceability and eases data accessibility
- Reduces manual intervention leading to improved quality and productivity
- Reduces operational and implementation costs
- Reduces human errors and time taken to follow protocols

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# Cloud-based LIMS Benefits

No Upfront Cost

No IT Personnel

Configurable

Quick to Deploy

Light on Pocket

Scalable

Global Accessibility

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**Thank You!**

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