Cannabis Industry Journal's Cannabis Quality Conference & Expo

IEC/ISO 17025 Accreditation: Preparing for Your Cannabis Testing Laboratory Audit Using a Cloud-based LIMS

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Chief Executive Officer, CloudLIMS.com

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Agenda

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What! is a Cannabis Lab Audit

A Cannabis Lab Audit is a systematic trace back through the cannabis lab's quality and testing standards.

Key Features and Advantages:

1. Audit : Quality Assurance
2. Integral Part of Regulatory Compliance Process
3. Increases Product Safety and Quality
4. Provides the laboratory an edge over its competitors

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What's New !!!- IEC/ISO 17025:2017

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What Continued Legalization Results- Pros and Cons

Positives

- Management of psychological disorders including depression, autism, seizures, cognitive performance, anxiety, Alzheimer's, etc.
- Relief in disorders like arthritis, multiple sclerosis, Parkinson's disease, etc.
- Helps patients suffering from PTSD

Negatives

- Public health disadvantages
- Vaping fear,
- Tainted product
- Fabrication of testing results

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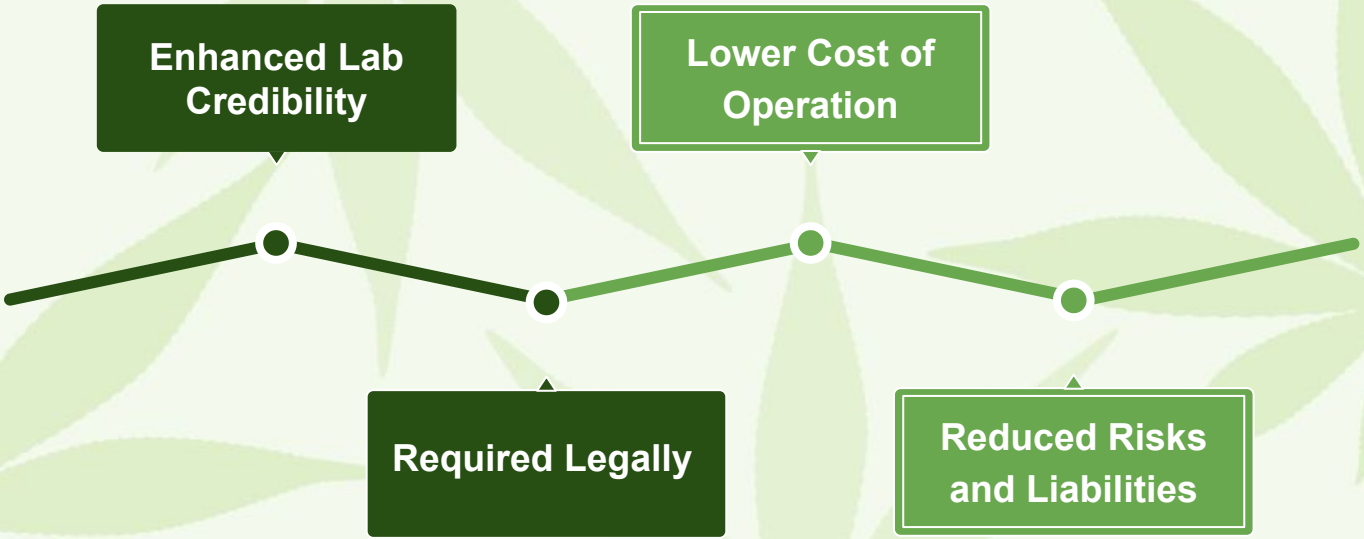
Why IEC/ISO 17025 Accreditation?



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How to Achieve IEC/ISO 17025 Accreditation?

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Auditing a Cannabis Testing Lab: A Checklist

Quality Manual / Quality Assurance documents

- Policy documents for accreditation
- Documents corresponding to your LIMS/QMS

Validation documents and Standard Operating Protocols

Test Calibration Methods and Validation Status

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Auditing a Cannabis Testing Lab: A Checklist

Documents for Corrective Action and Preventive Actions

Staff training records

Sample test calibration reports

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Auditing a Cannabis Testing Lab: A Checklist

Equipment Calibration and Maintenance reports and logs

Laboratory environmental condition reports

Proficiency testing results

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ISO/IEC 17025 Requirements

Management Requirements

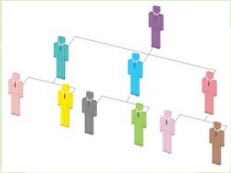
Pertain to the operation and effectiveness of the quality management system within the laboratory

Control of Records

Document Control

Internal Audits

Organizational Structure



Review of Requests, Tenders, & Contracts

Purchasing Services & Supplies

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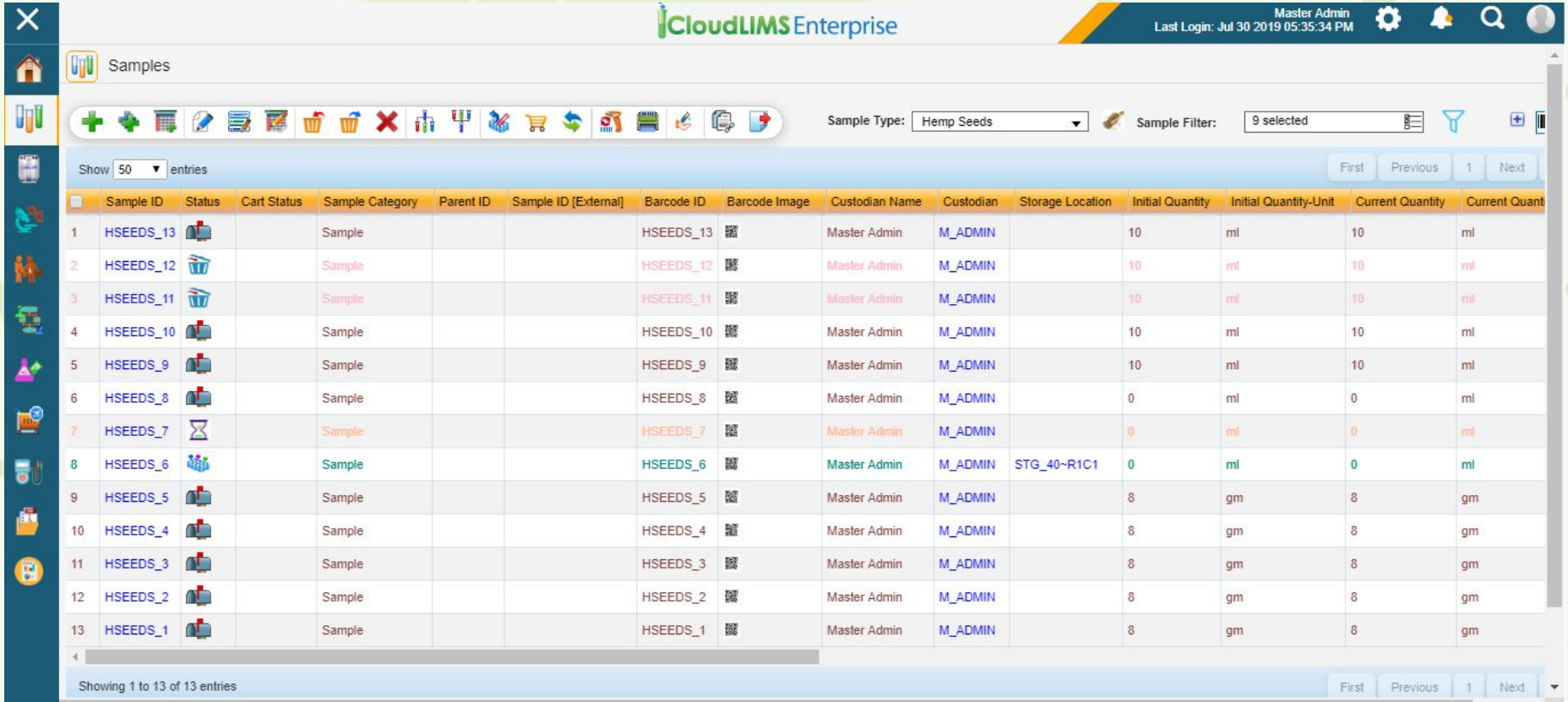
Control of Records: Barcoding

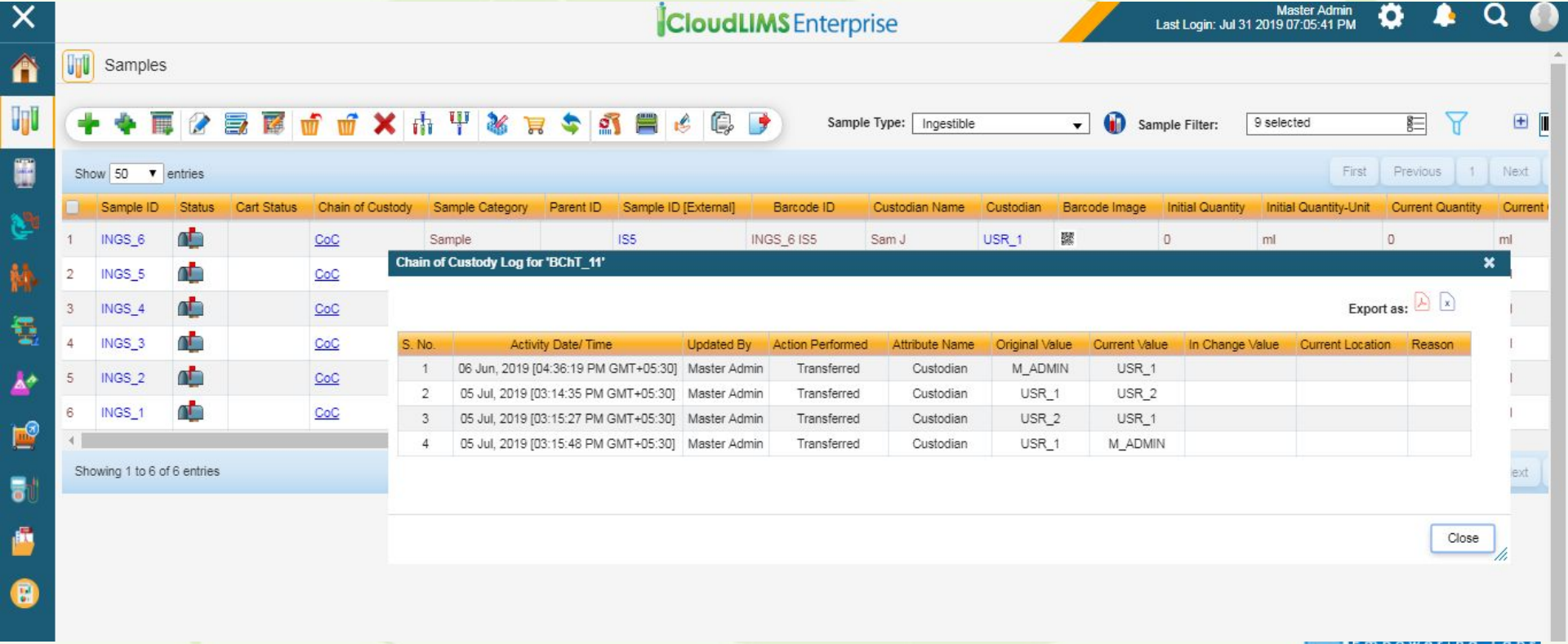
Sample accessioning with 1D, 2D barcoding or RFID to keep a track of sample throughout its life-cycle



	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

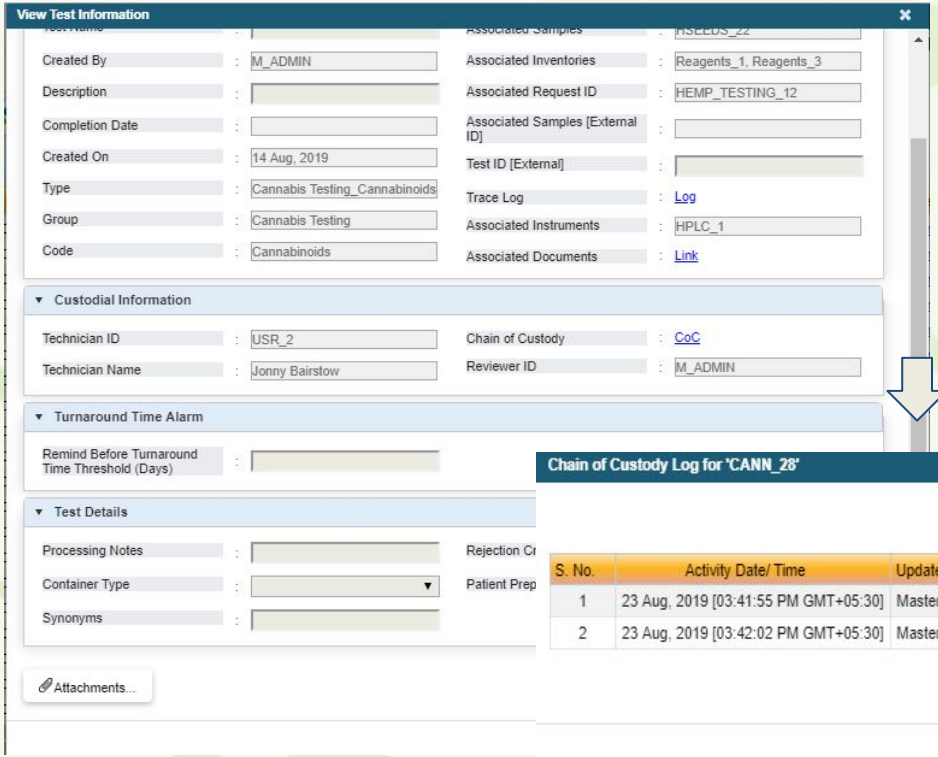
Control of Records: Chain of Custody

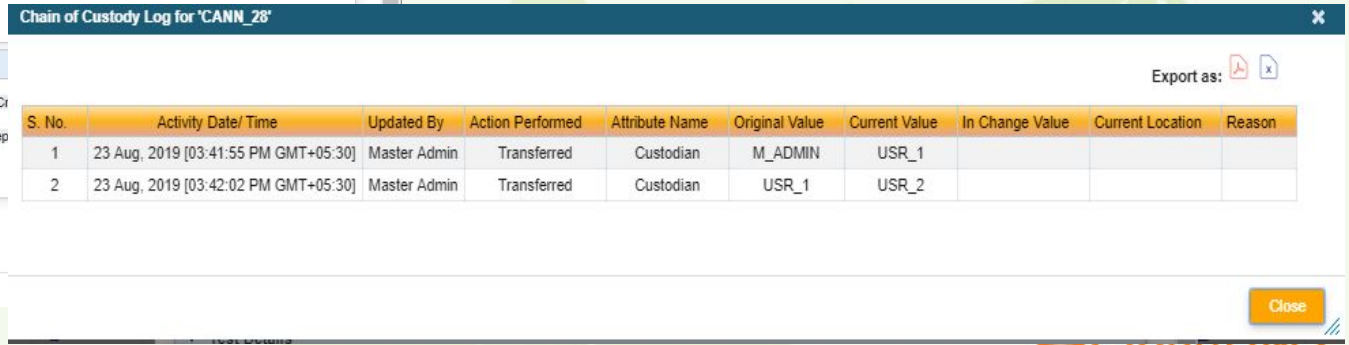
Track the entire chain of custody for all your samples



Control of Records: Chain of Custody

Track the entire chain of custody for all the Tests Performed





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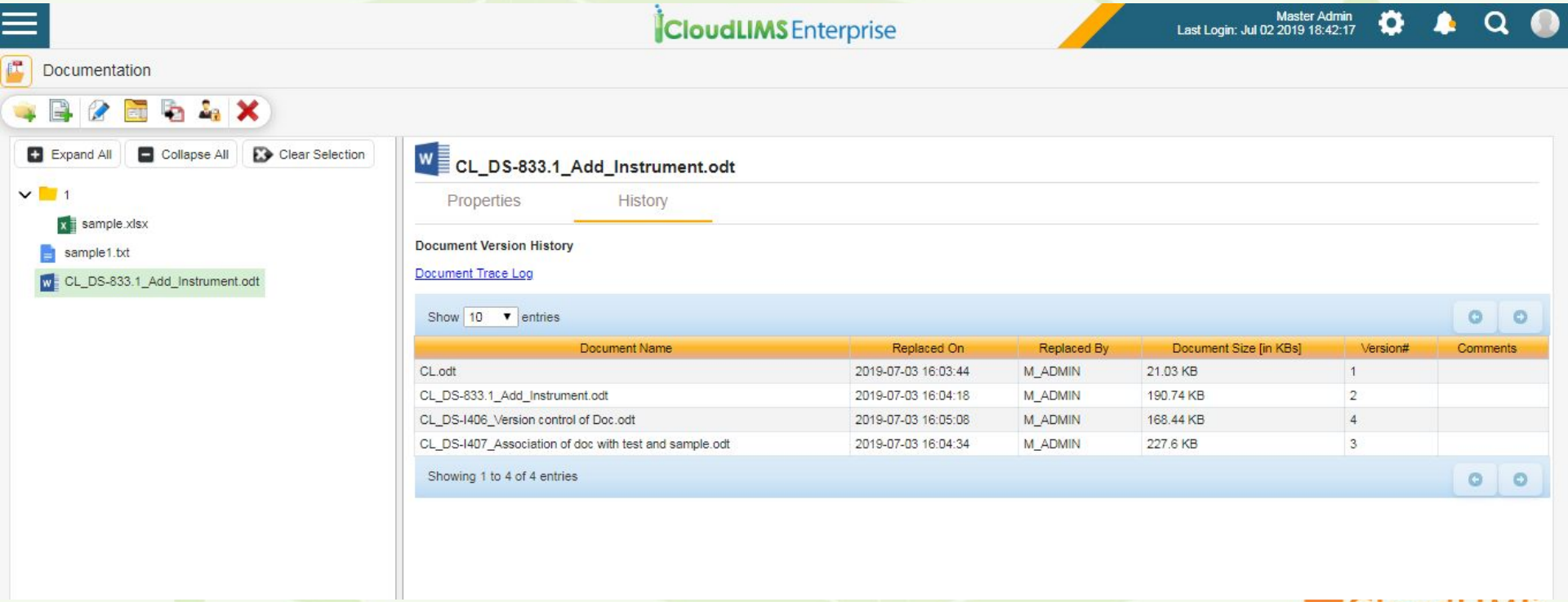
Document Control

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



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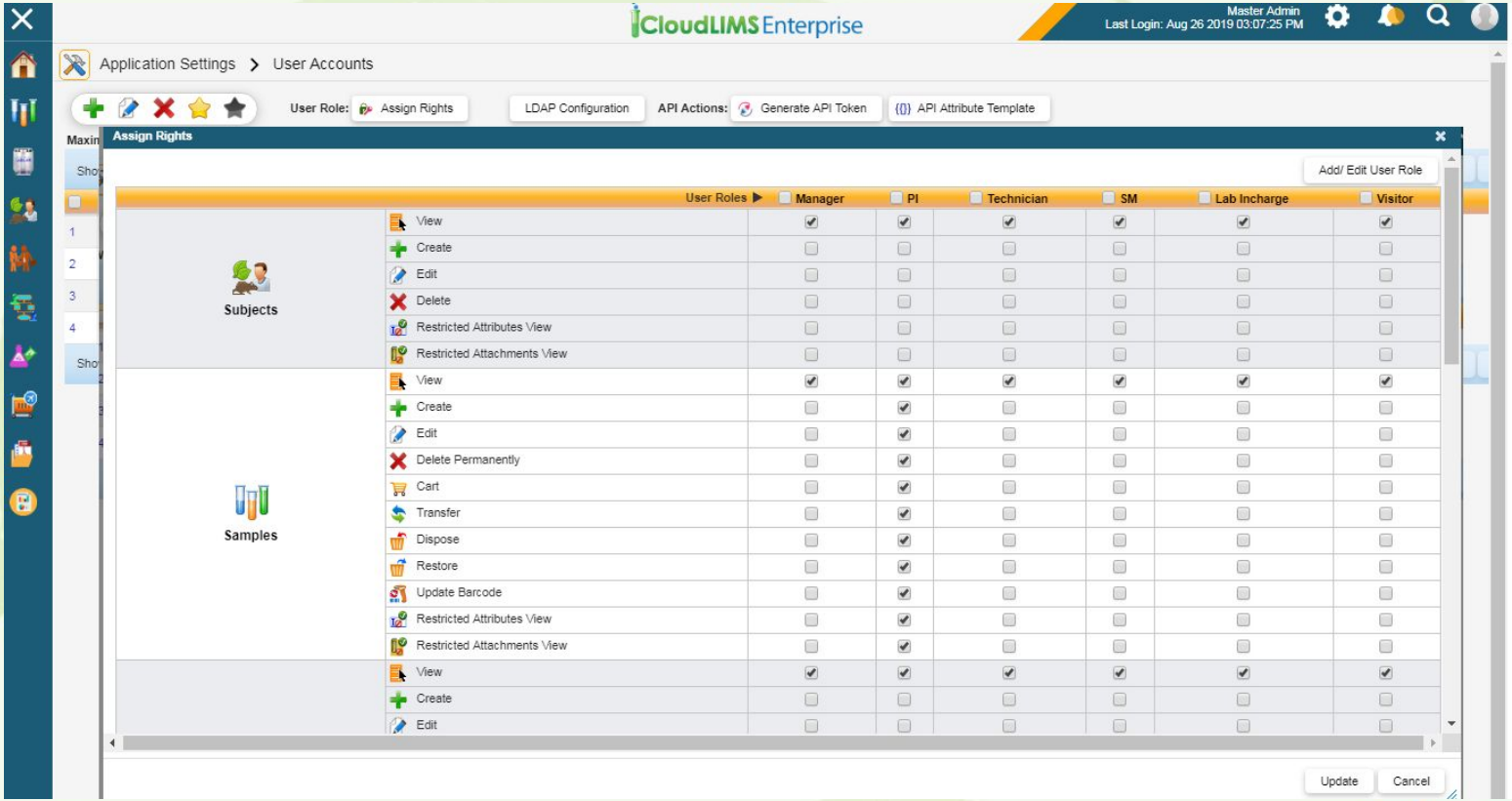
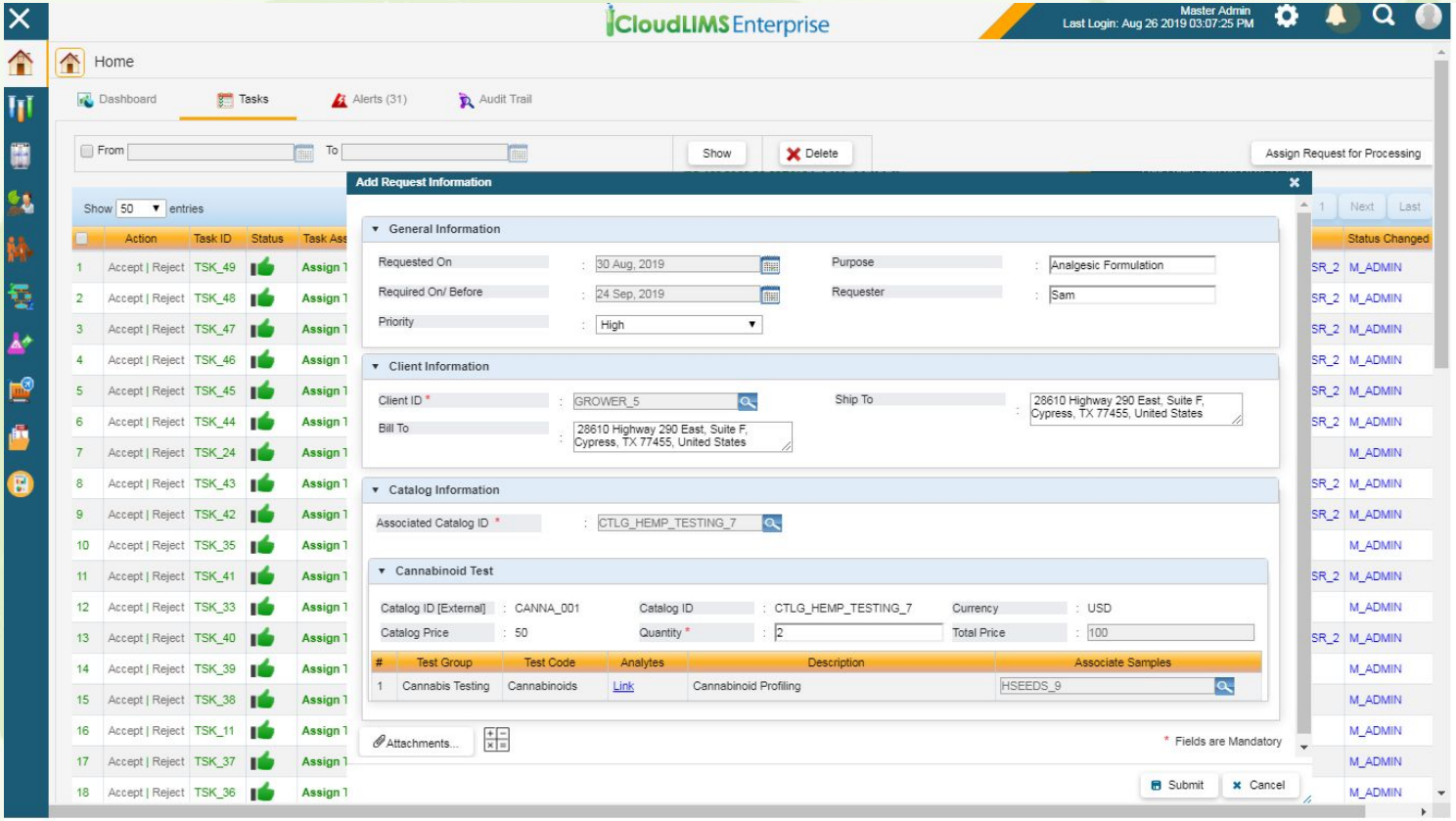
Organizational Structure: Role Based Permission Level to Staff

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



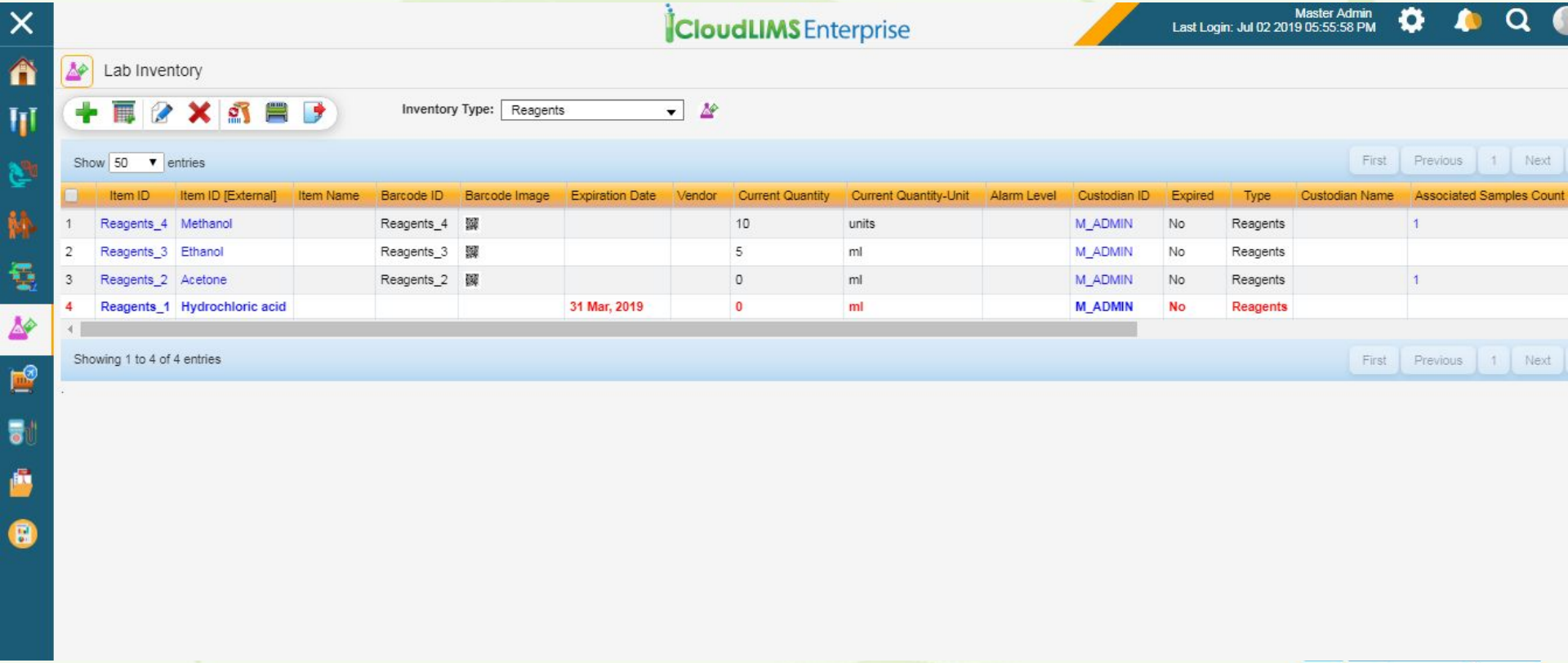
Review of Requests, Tenders, & Contracts

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



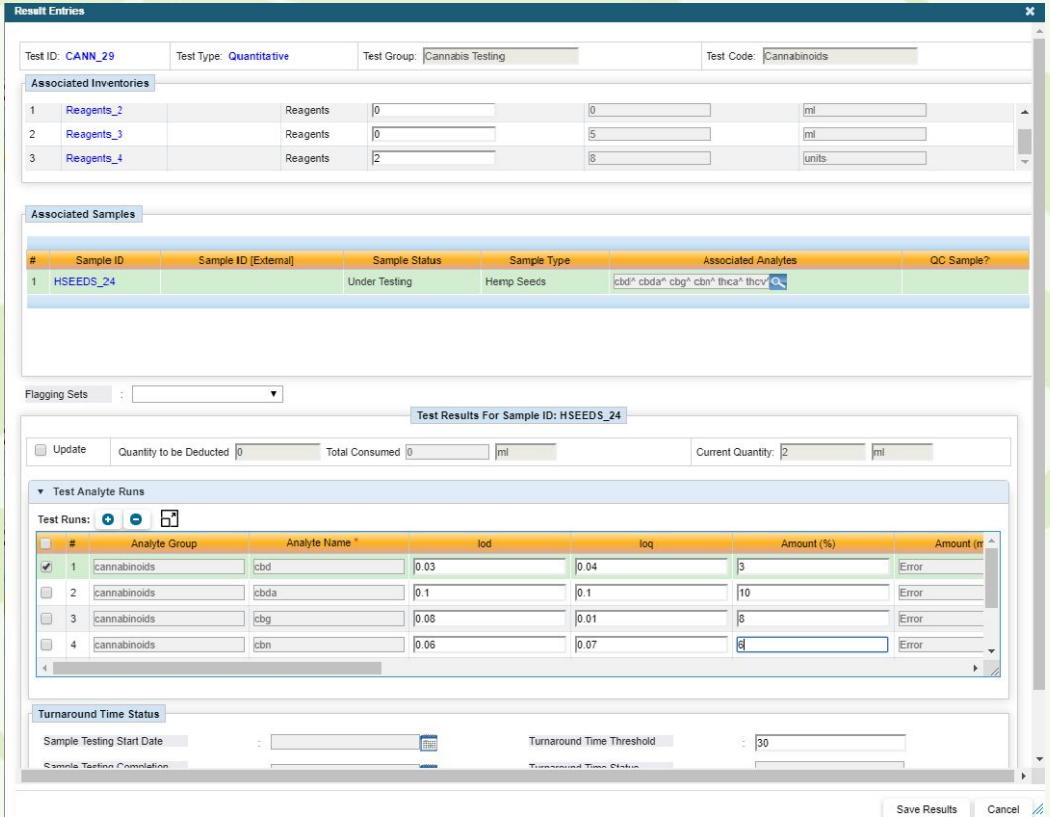
Purchasing Services & Supplies

Accurate barcode labeling of reagents and maintaining their stocks



Purchasing Services & Supplies

Ensure that services and supplies delivered by third parties do not adversely impact the quality and effectiveness of laboratory operations.



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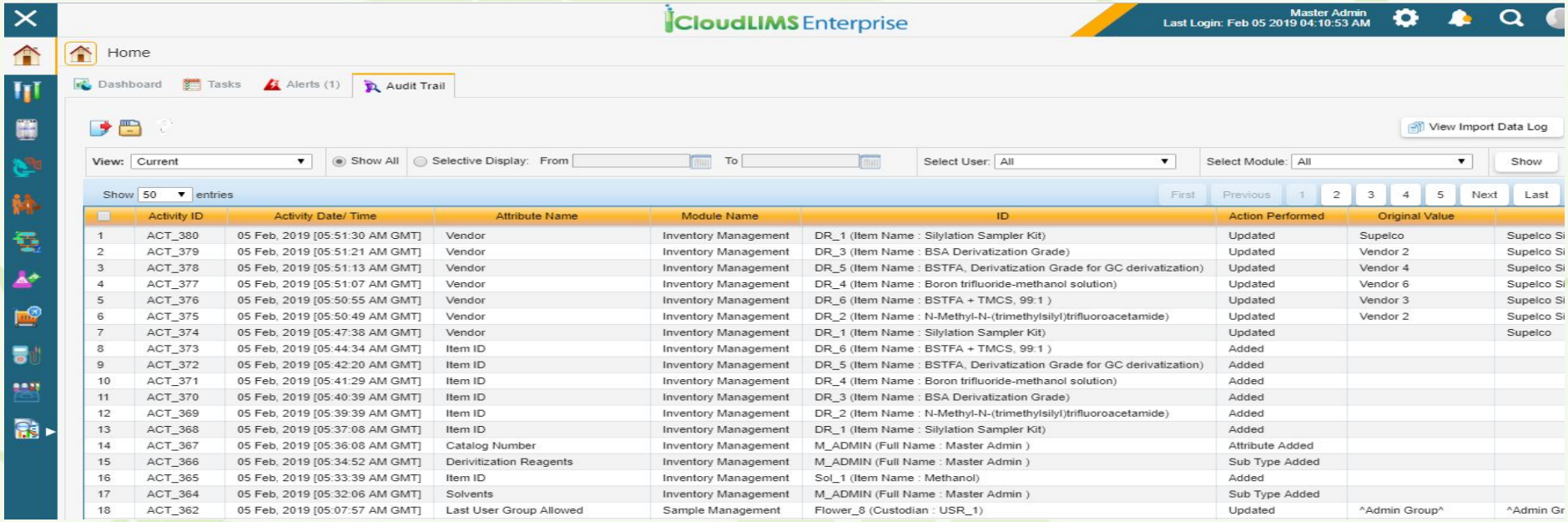
Internal Audit: Audit Trail

Maintaining internal audit of laboratory using a LIMS



	Activity ID	Activity Date/ Time	Attribute Name	Module Name	ID	Action Performed	Original Value	
1	ACT_380	05 Feb, 2019 [05:51:30 AM GMT]	Vendor	Inventory Management	DR_1 (Item Name : Silylation Sampler Kit)	Updated	Supelco	Supelco Si
2	ACT_379	05 Feb, 2019 [05:51:21 AM GMT]	Vendor	Inventory Management	DR_3 (Item Name : BSA Derivatization Grade)	Updated	Vendor 2	Supelco Si
3	ACT_378	05 Feb, 2019 [05:51:13 AM GMT]	Vendor	Inventory Management	DR_5 (Item Name : BSTFA, Derivatization Grade for GC derivatization)	Updated	Vendor 4	Supelco Si
4	ACT_377	05 Feb, 2019 [05:51:07 AM GMT]	Vendor	Inventory Management	DR_4 (Item Name : Boron trifluoride-methanol solution)	Updated	Vendor 6	Supelco Si
5	ACT_376	05 Feb, 2019 [05:50:55 AM GMT]	Vendor	Inventory Management	DR_6 (Item Name : BSTFA + TMCS, 99:1)	Updated	Vendor 3	Supelco Si
6	ACT_375	05 Feb, 2019 [05:50:49 AM GMT]	Vendor	Inventory Management	DR_2 (Item Name : N-Methyl-N-(trimethylsilyl)trifluoroacetamide)	Updated	Vendor 2	Supelco Si
7	ACT_374	05 Feb, 2019 [05:47:38 AM GMT]	Vendor	Inventory Management	DR_1 (Item Name : Silylation Sampler Kit)	Updated		Supelco
8	ACT_373	05 Feb, 2019 [05:44:34 AM GMT]	Item ID	Inventory Management	DR_6 (Item Name : BSTFA + TMCS, 99:1)	Added		
9	ACT_372	05 Feb, 2019 [05:42:20 AM GMT]	Item ID	Inventory Management	DR_5 (Item Name : BSTFA, Derivatization Grade for GC derivatization)	Added		
10	ACT_371	05 Feb, 2019 [05:41:29 AM GMT]	Item ID	Inventory Management	DR_4 (Item Name : Boron trifluoride-methanol solution)	Added		
11	ACT_370	05 Feb, 2019 [05:40:39 AM GMT]	Item ID	Inventory Management	DR_3 (Item Name : BSA Derivatization Grade)	Added		
12	ACT_369	05 Feb, 2019 [05:39:39 AM GMT]	Item ID	Inventory Management	DR_2 (Item Name : N-Methyl-N-(trimethylsilyl)trifluoroacetamide)	Added		
13	ACT_368	05 Feb, 2019 [05:37:08 AM GMT]	Item ID	Inventory Management	DR_1 (Item Name : Silylation Sampler Kit)	Added		
14	ACT_367	05 Feb, 2019 [05:36:08 AM GMT]	Catalog Number	Inventory Management	M_ADMIN (Full Name : Master Admin)	Attribute Added		
15	ACT_366	05 Feb, 2019 [05:34:52 AM GMT]	Derivitization Reagents	Inventory Management	M_ADMIN (Full Name : Master Admin)	Sub Type Added		
16	ACT_365	05 Feb, 2019 [05:33:39 AM GMT]	Item ID	Inventory Management	Sol_1 (Item Name : Methanol)	Added		
17	ACT_364	05 Feb, 2019 [05:32:06 AM GMT]	Solvents	Inventory Management	M_ADMIN (Full Name : Master Admin)	Sub Type Added		
18	ACT_362	05 Feb, 2019 [05:07:57 AM GMT]	Last User Group Allowed	Sample Management	Flower_8 (Custodian : USR_1)	Updated	^Admin Group^	^Admin Gr

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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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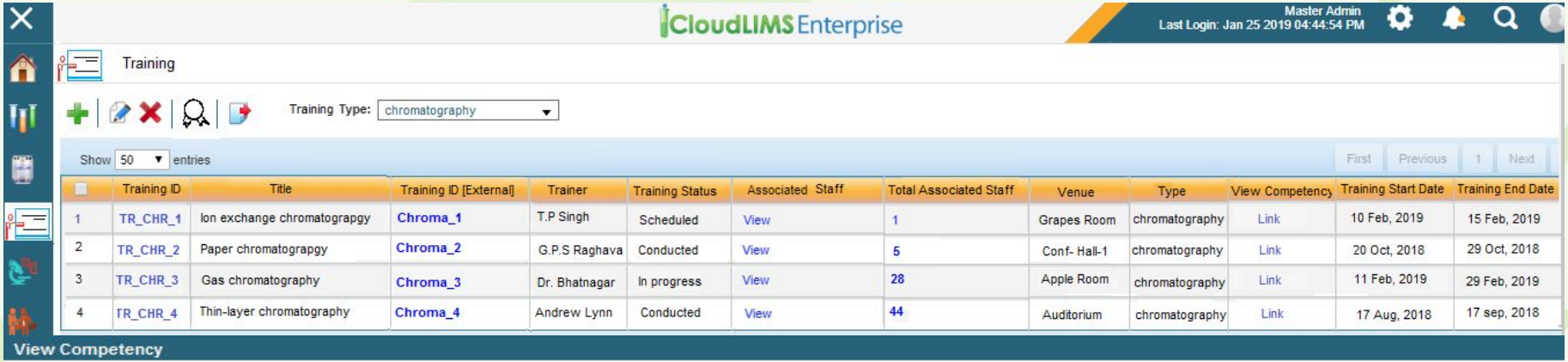
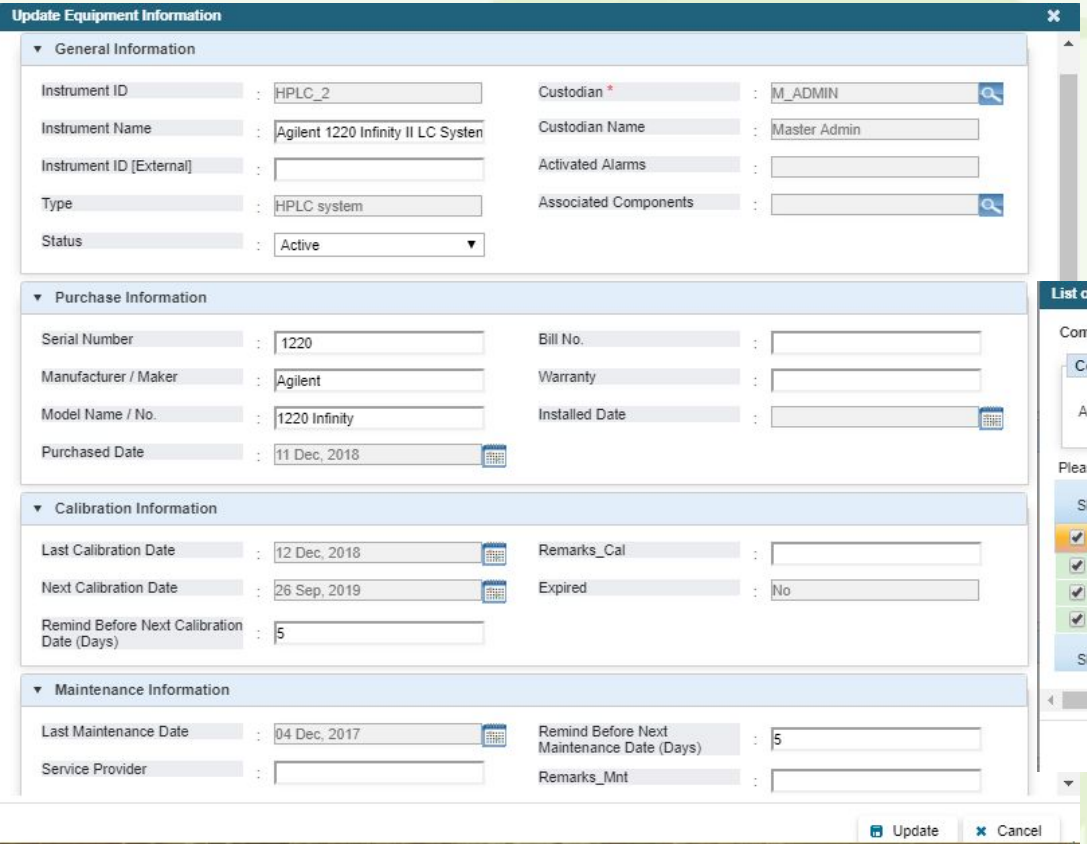
Personnel: Staff &Training

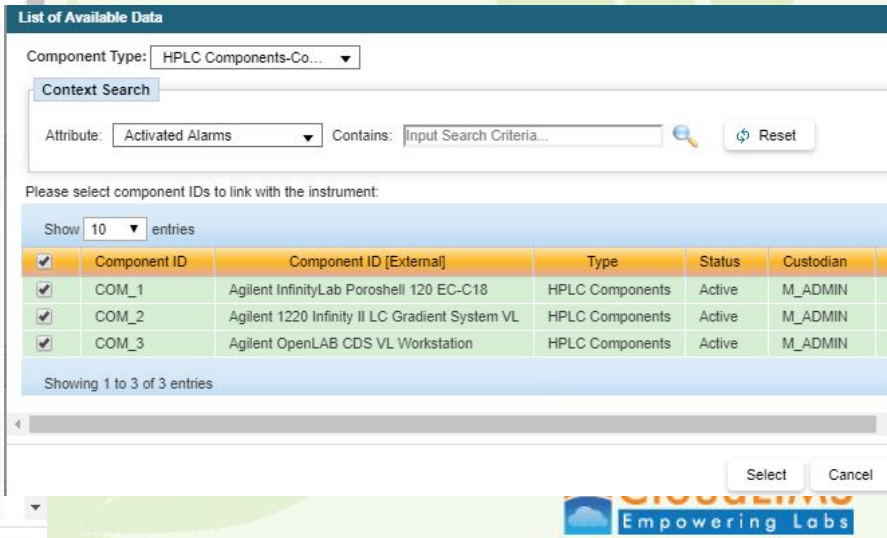
Manage staff and training records and mark their competency



Equipment: Instrument Calibration and Maintenance

Track your equipment and its components along with calibration status





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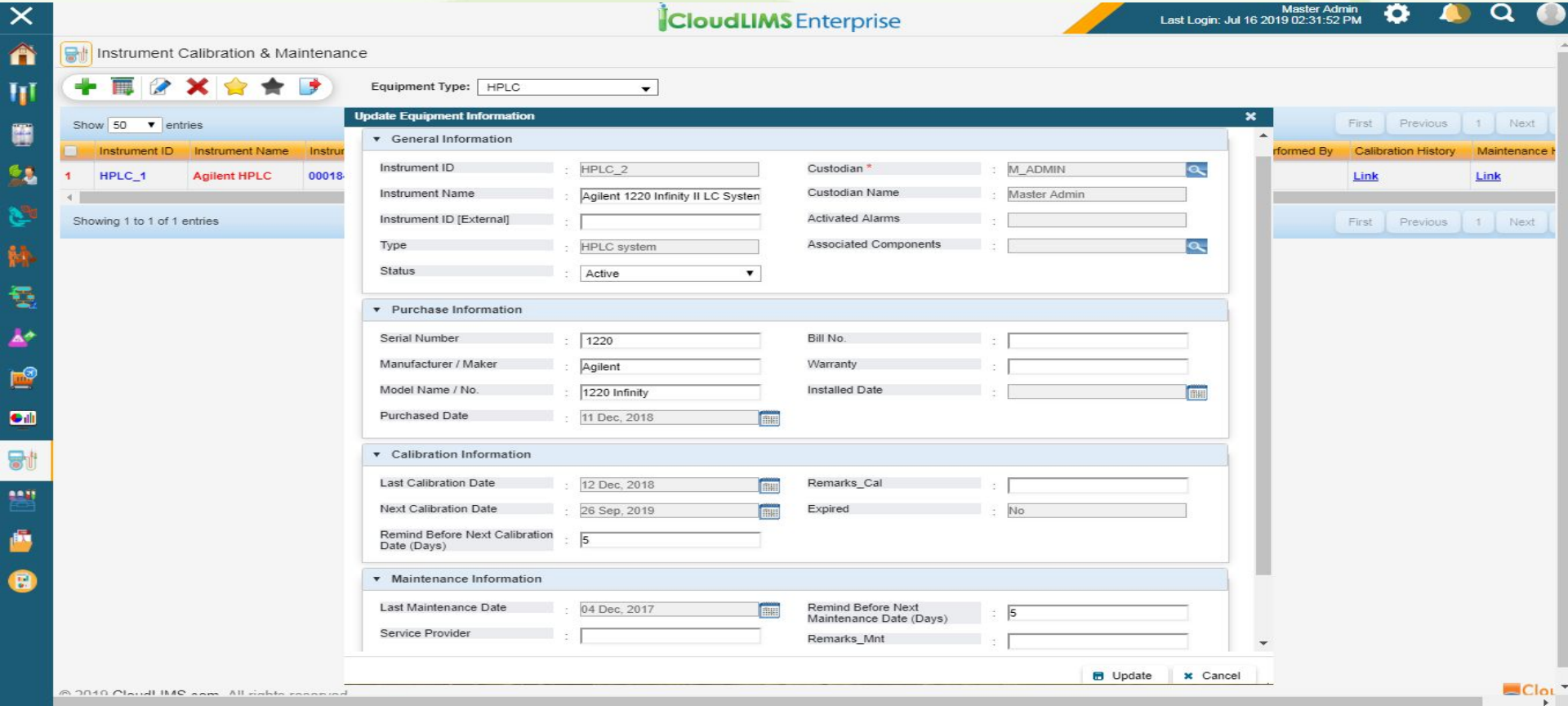
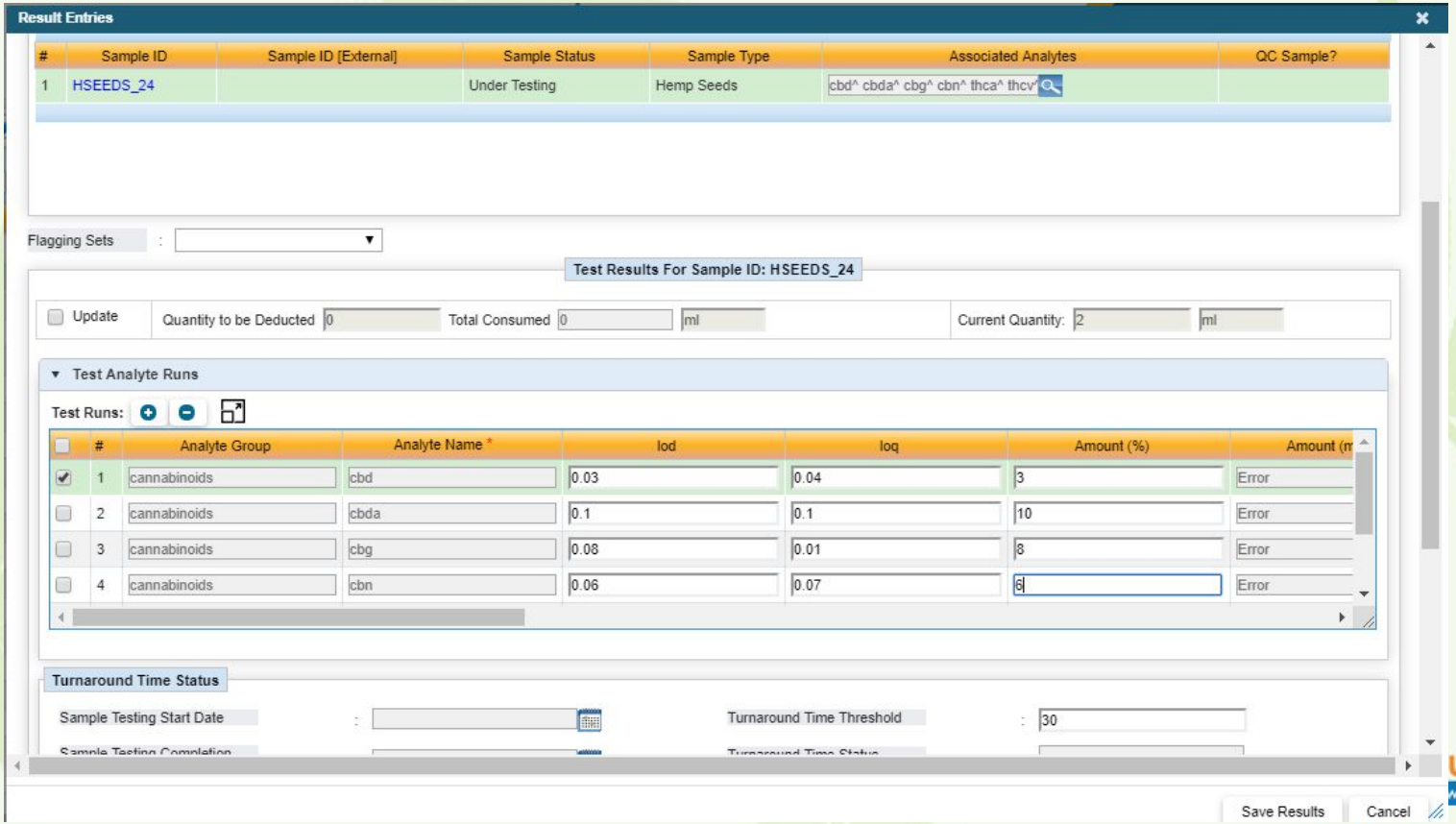
Equipment: Assigning Competent Staff

Assigning of instruments to competent analyst



Reporting Test Results to Clients

Manage test results, generate CoA and send it to clients



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Advantages of Instrument Integration

Increased Data Accuracy

Decreased Cost of Business

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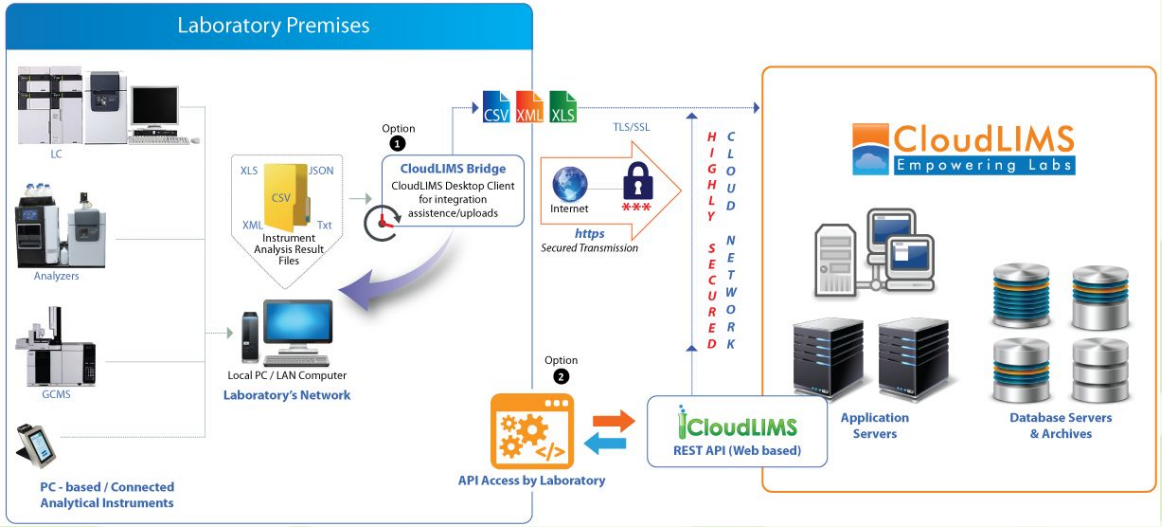
Instrument Integration



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		

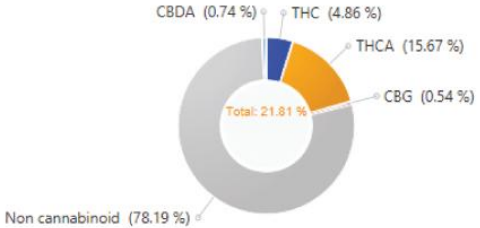
Test Information: Cannabis Testing/ Cannabinoids

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



CTL

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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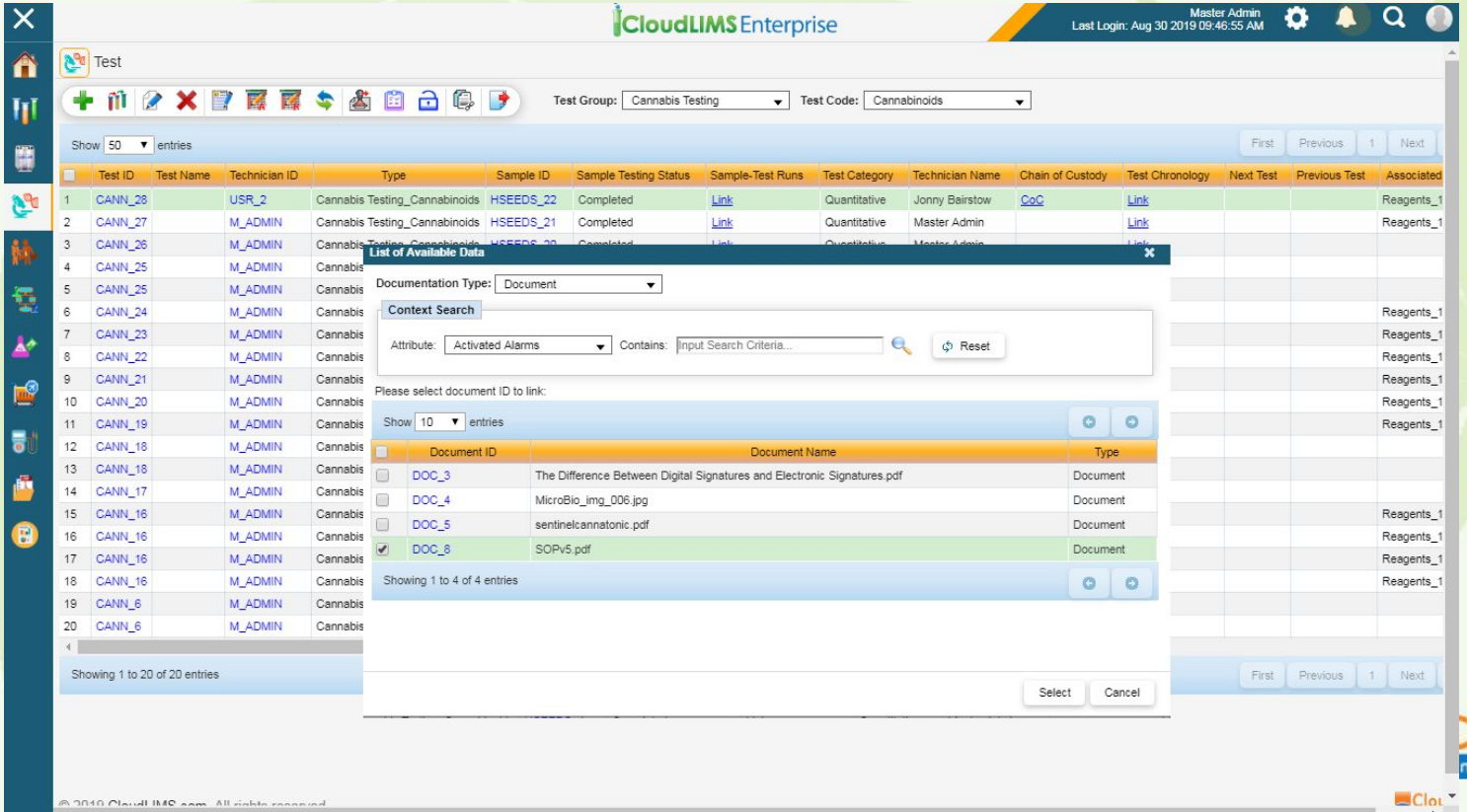
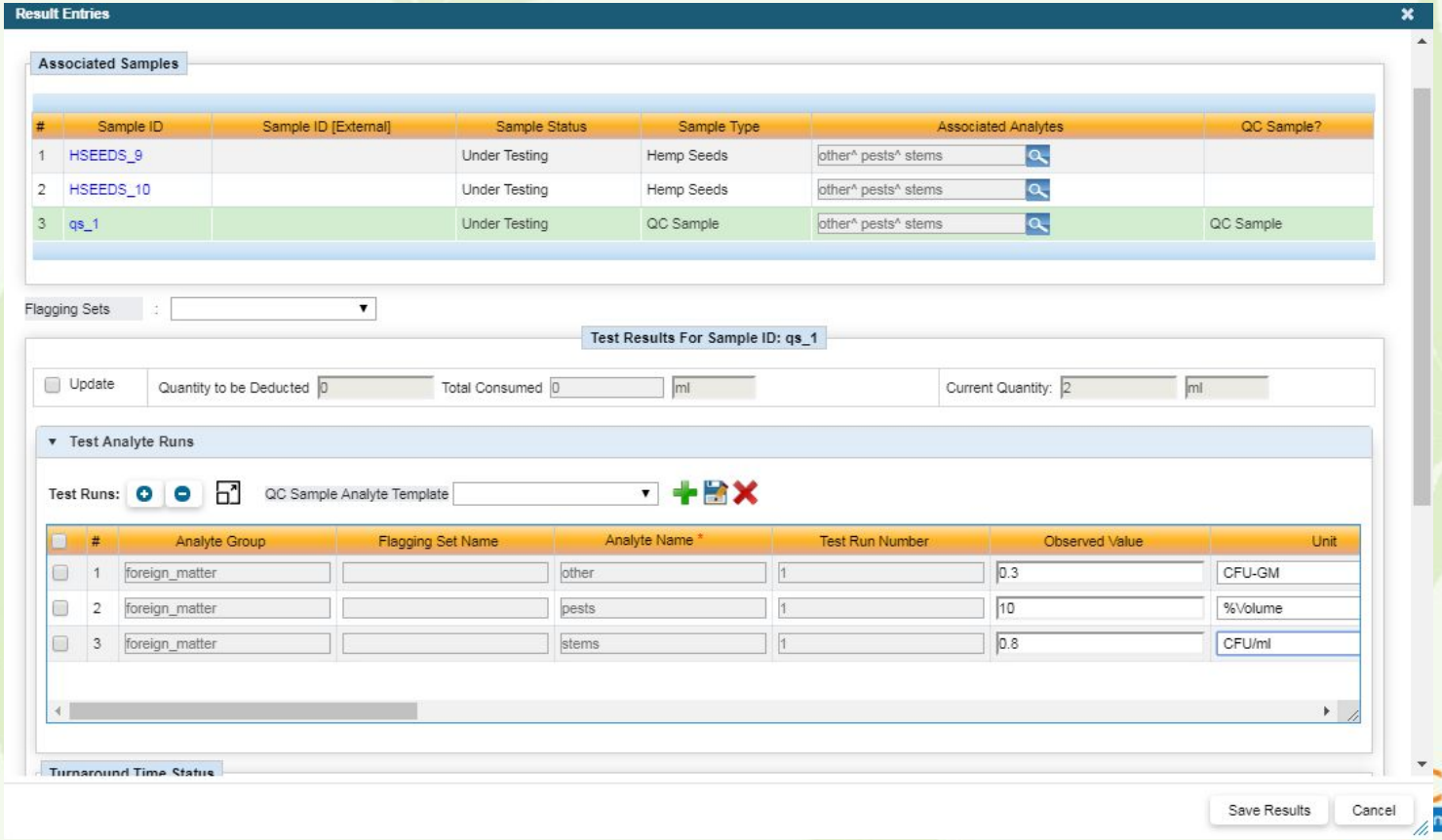
Test and Calibration Methods: Associating Docs

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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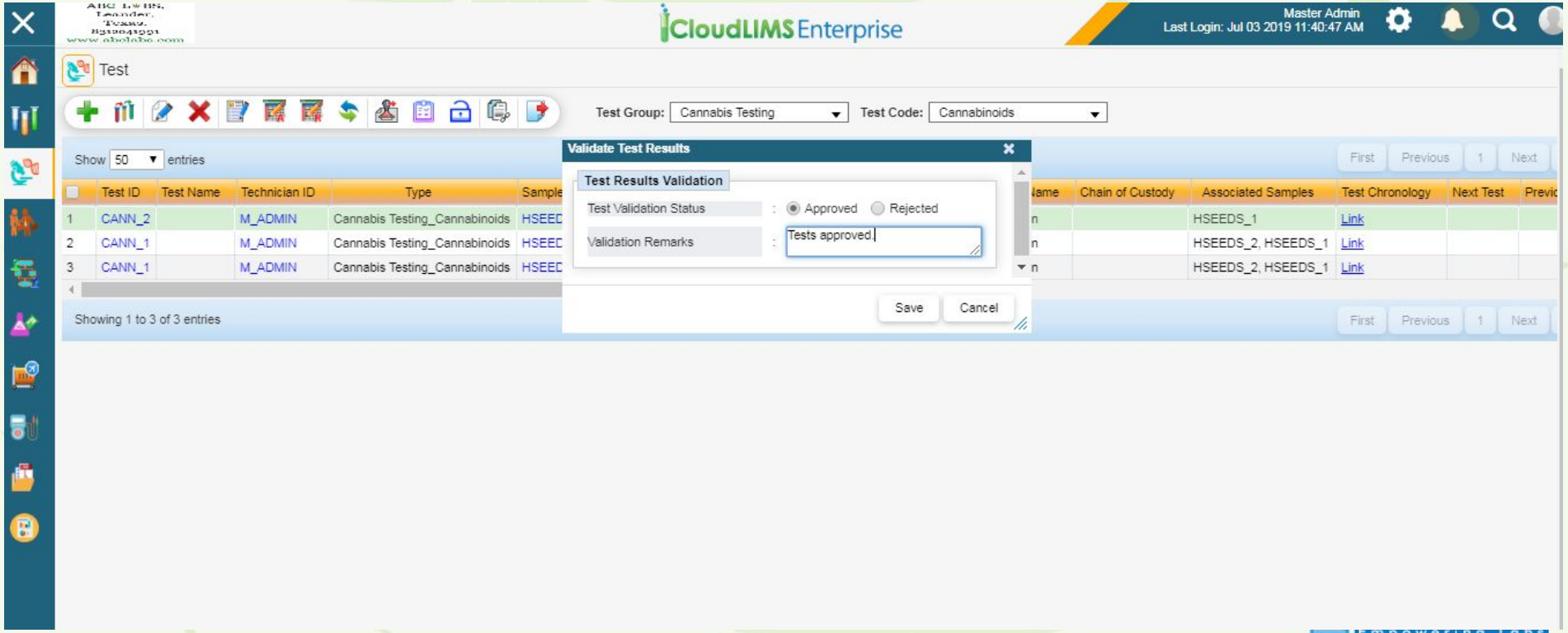
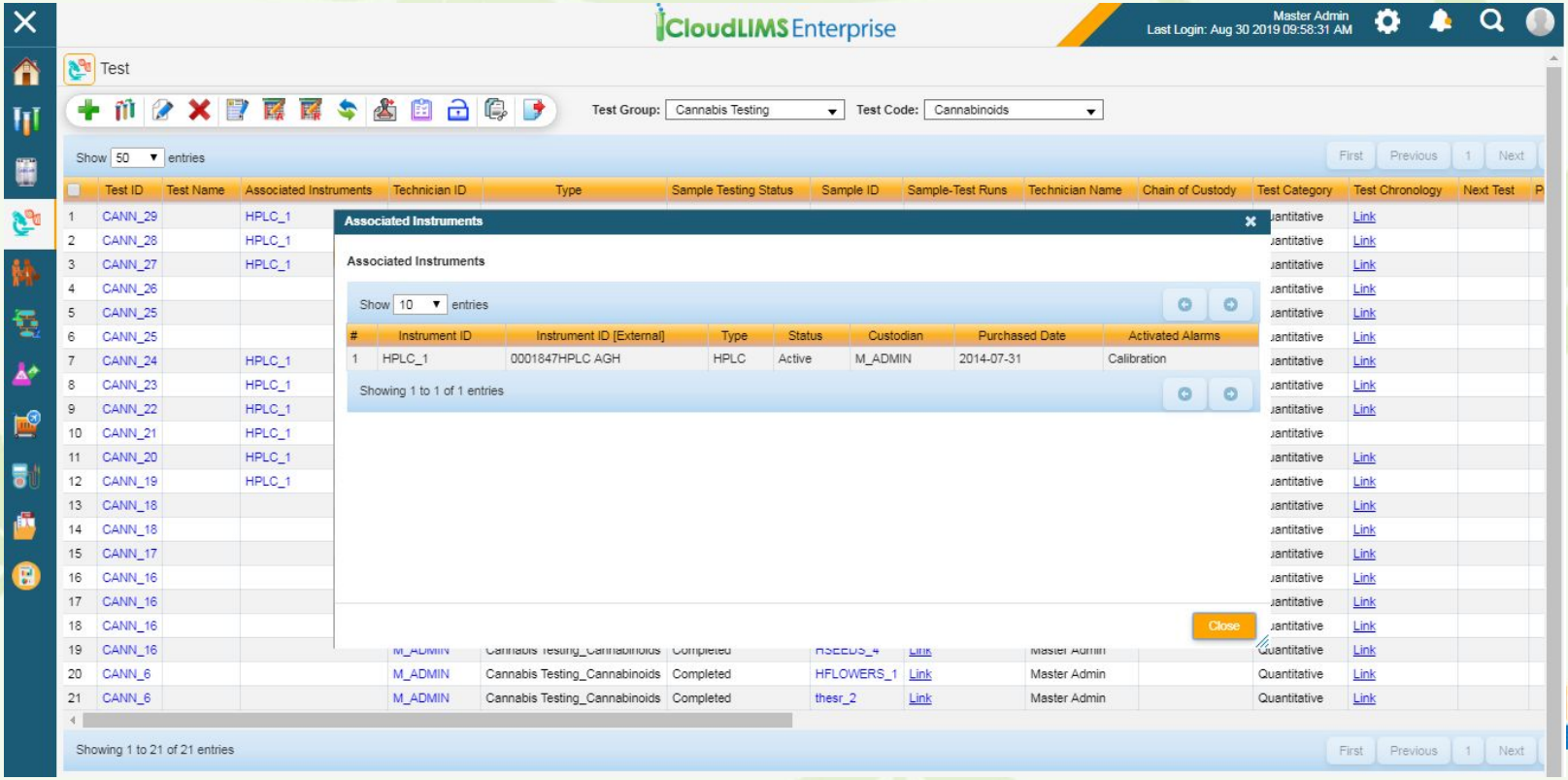
Validate Test Results

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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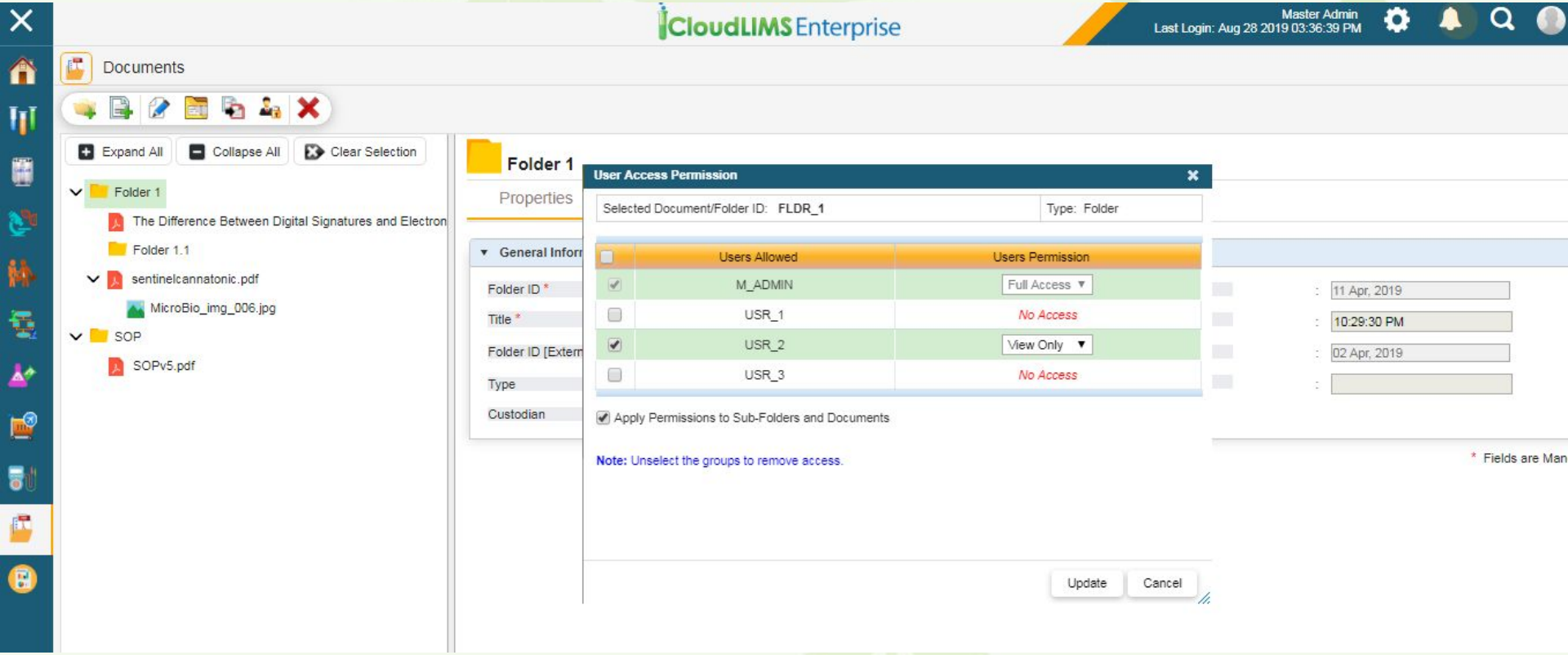
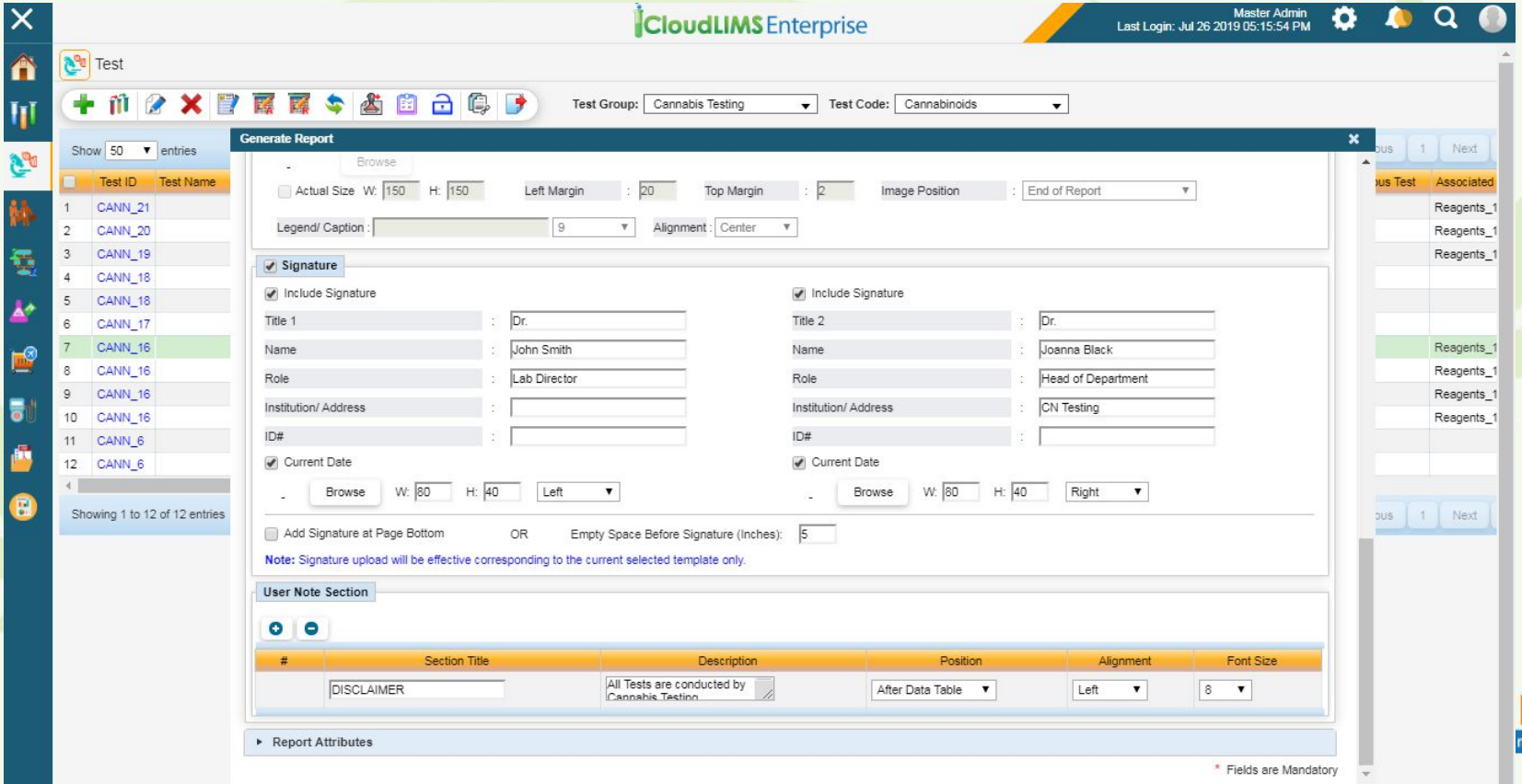
User Access: Secure Confidential Data

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



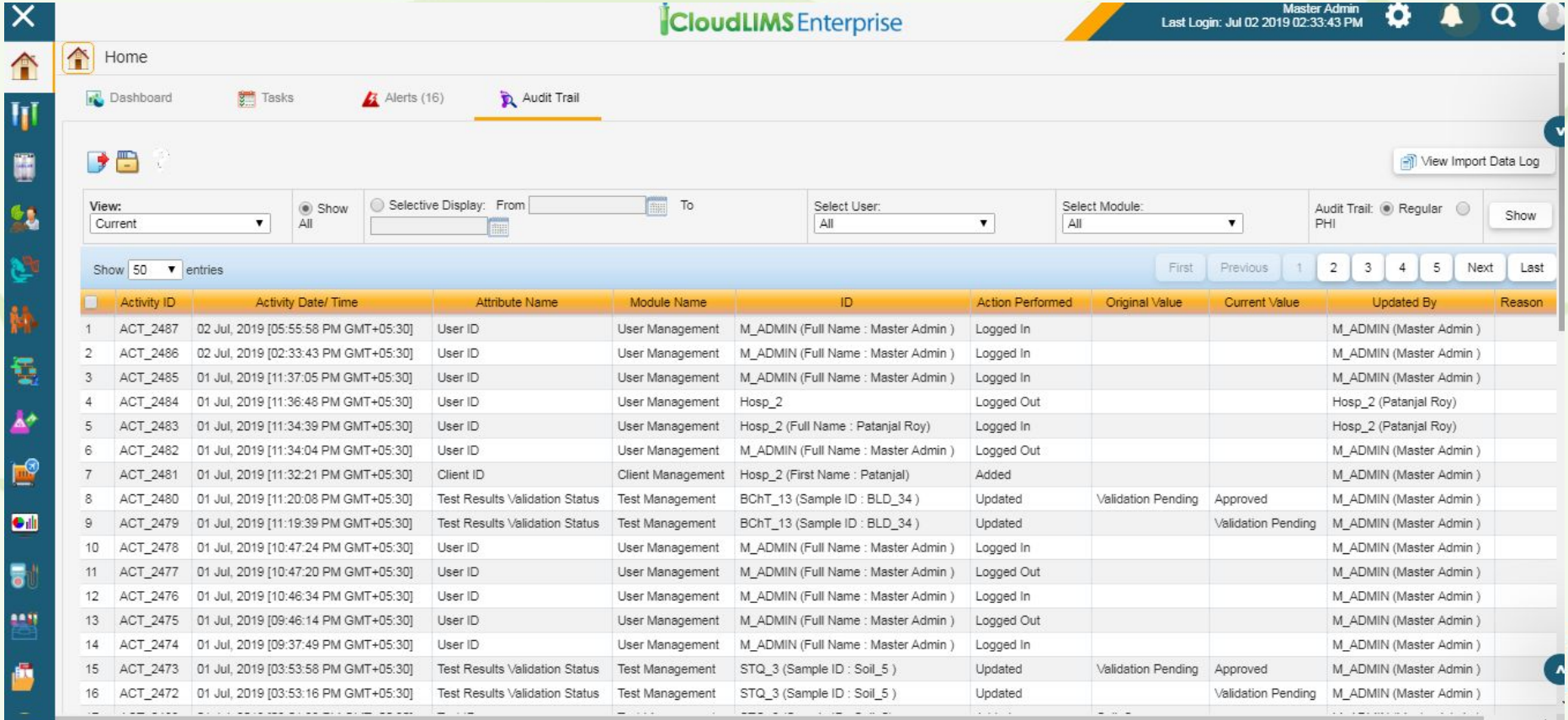
Generate Reports with Authorized Signatures

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)	

Where Do You Get Accredited?

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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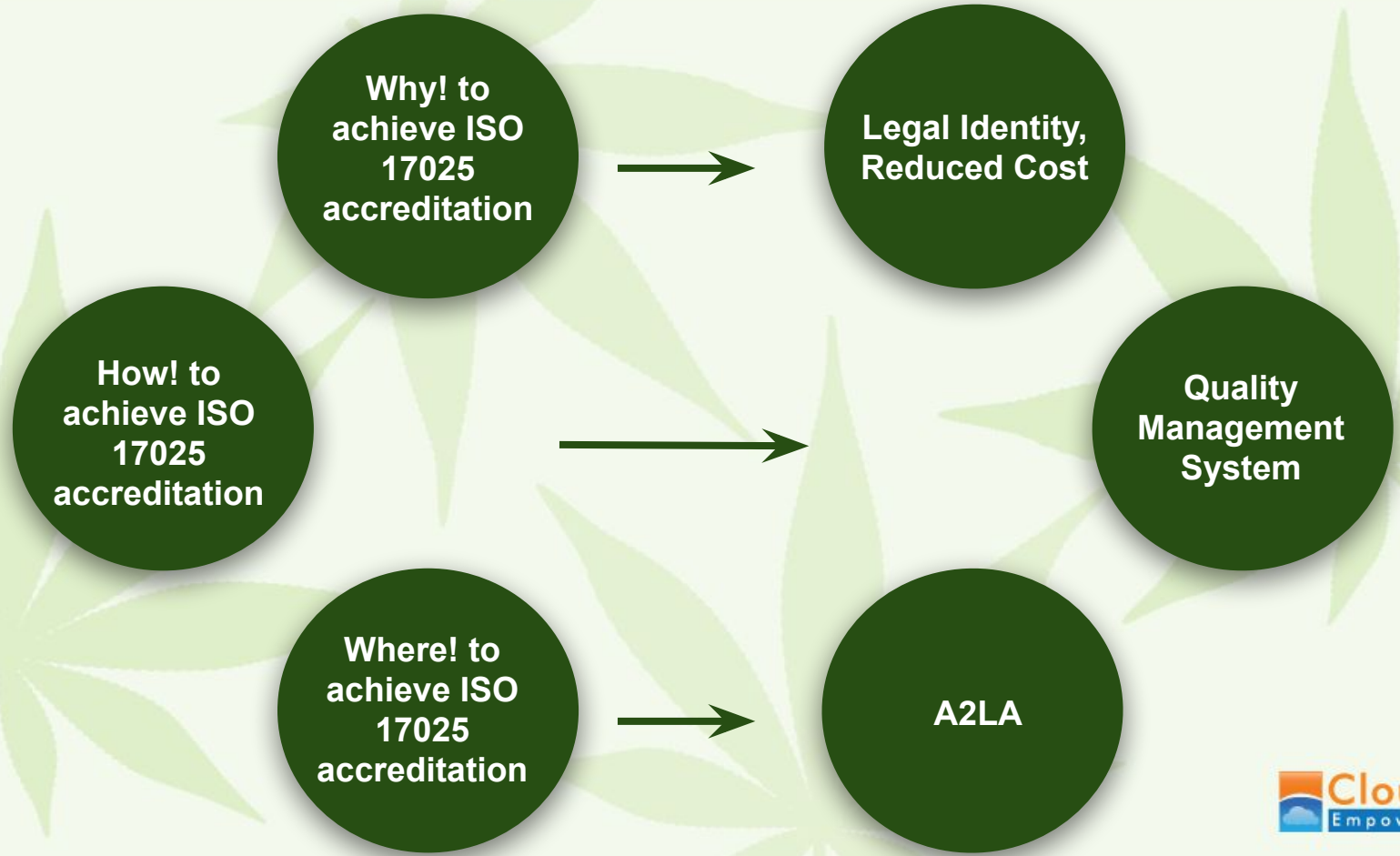
In Conclusion...



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Thank You

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