South Eastern 2019 Hemp & Medical Cannabis Convention

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Cobb Galleria Centre - Atlanta, GA

Addressing Regulatory Considerations of Cannabis Testing Laboratories Cost Effectively Using a Cloud-based LIMS

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Chief Executive Officer, CloudLIMS.com

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Agenda

- Setting up a cannabis testing laboratory
- Cannabis testing - regulations and compliance
- Challenges faced by cannabis testing labs for achieving compliance
- How a LIMS helps achieve regulatory requirements?
- Advantages of cloud-based LIMS
- Q & A

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Setting Up a Cannabis Testing Laboratory

- Operational requirements
- Quality Assurance & Quality Control requirements
- Regulatory requirements
- Data Management requirements

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Operational Requirements

- Layout of the premises
- Testing techniques and costs
- Instruments and equipment
- Stocks, standards and reagents
- Submission process
- Testing processes
- Reporting processes
- Legal requirements
- Staff
- Inventory
- Financial management
- Cleanliness and safety - a must!

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QA & QC Requirements

Quality Assurance

- Ensuring data integrity
- Following internal quality auditing practices

Quality Control

- Ensuring the quality of the cannabis sample
- Ensuring maintenance and calibration of testing equipment used
- Following good documentation and record-keeping practices by laboratory personnel
- Following Good Manufacturing Practices (GMP) to ensure products are consistently produced through controlled processes according to quality standards

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Regulatory Requirements

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Regulatory & Compliance Requirements

Integration with State Tracking Systems

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Data Management Requirements

- Accounting for the entire quantity of sample received, used, and disposed of
- Facilitating and organizing of laboratory data
- Automating complete laboratory work-flows
- Following fast-evolving regulatory requirements
- Enabling sharing of reports with your client in real-time, thereby, minimizing the turnaround time

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Challenges Faced While Complying with Regulations

- Requires thorough evaluation of the ISO 17025 standard, which is complex
- Adequate training is required to implement the standard
- Instrument integration and integration with seed-to-sale tracking systems does not happen seamlessly
- Conducting an internal audit to prepare for a third-party assessment is required
- Finding a dependable, unified solution instead of using multiple software to meet regulatory requirements is difficult

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Good Lab Practices Requirements

- Following SOPs (standard operating procedures)
- Proper labeling of reagents
- Assigning instruments and equipment to skilled analyst
- Instrument calibration and maintenance
- Reporting of experimental data and results and its secure archival

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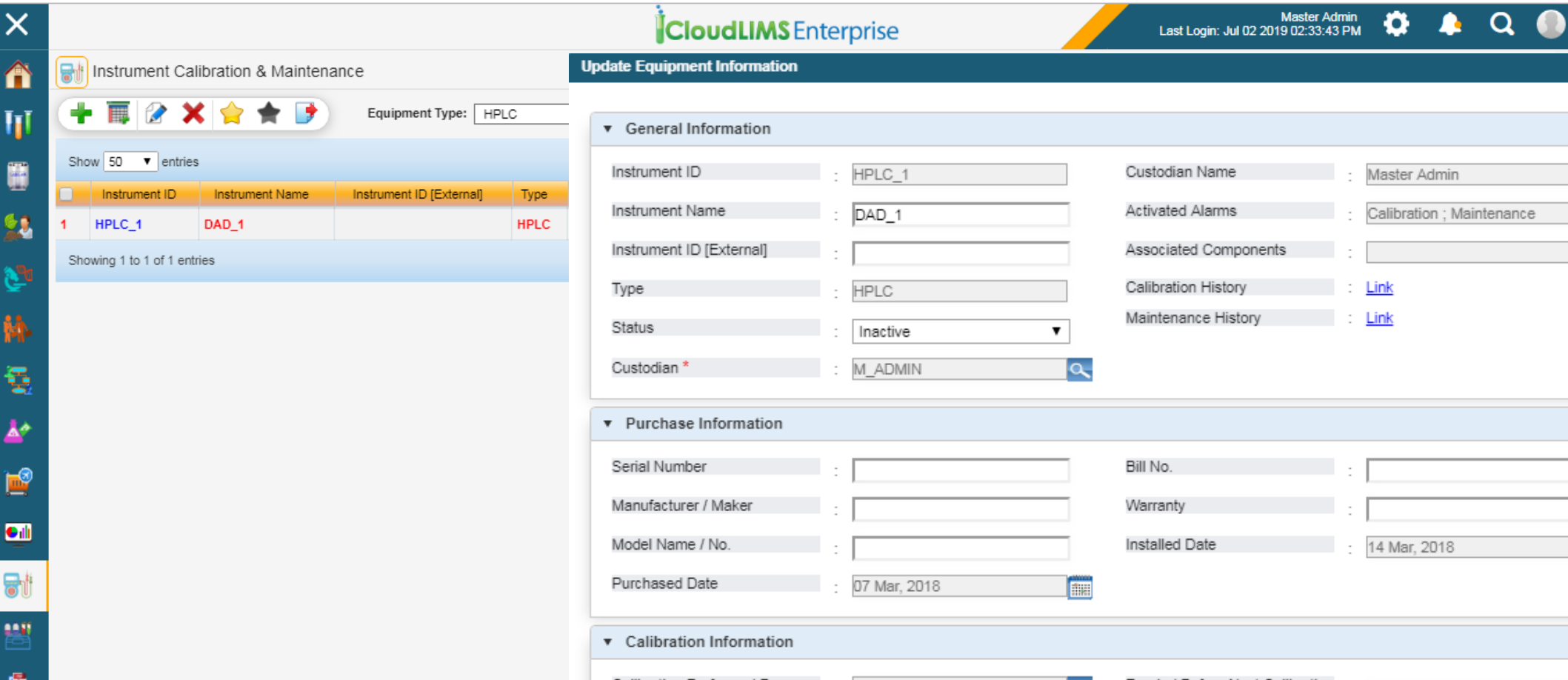
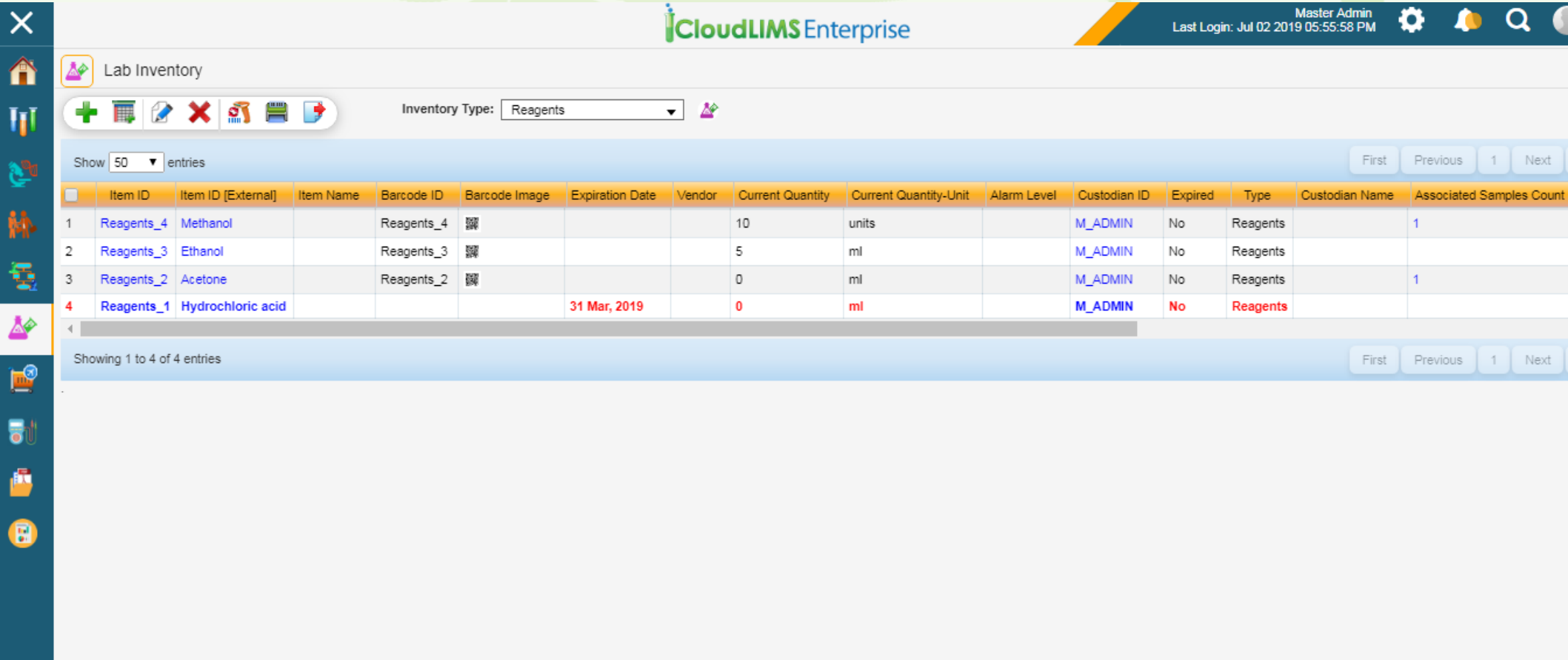
Good Lab Practices With LIMS

Assigning of instruments and equipment to competent analyst



Good Lab Practices With LIMS

Accurate barcode labeling of reagents and maintaining their stocks



21 CFR Part 11 Compliance Requirements

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

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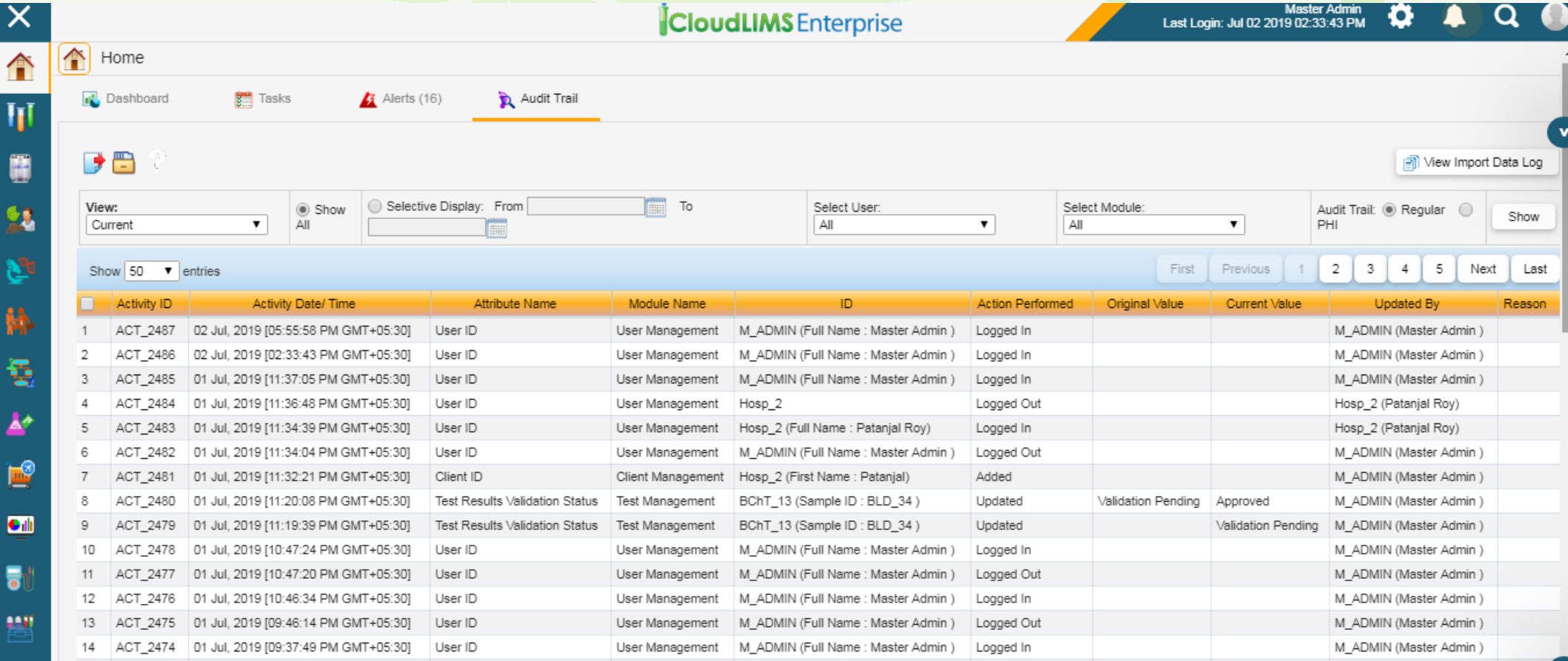
21 CFR Part 11 Compliance With LIMS

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



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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)	
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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)	
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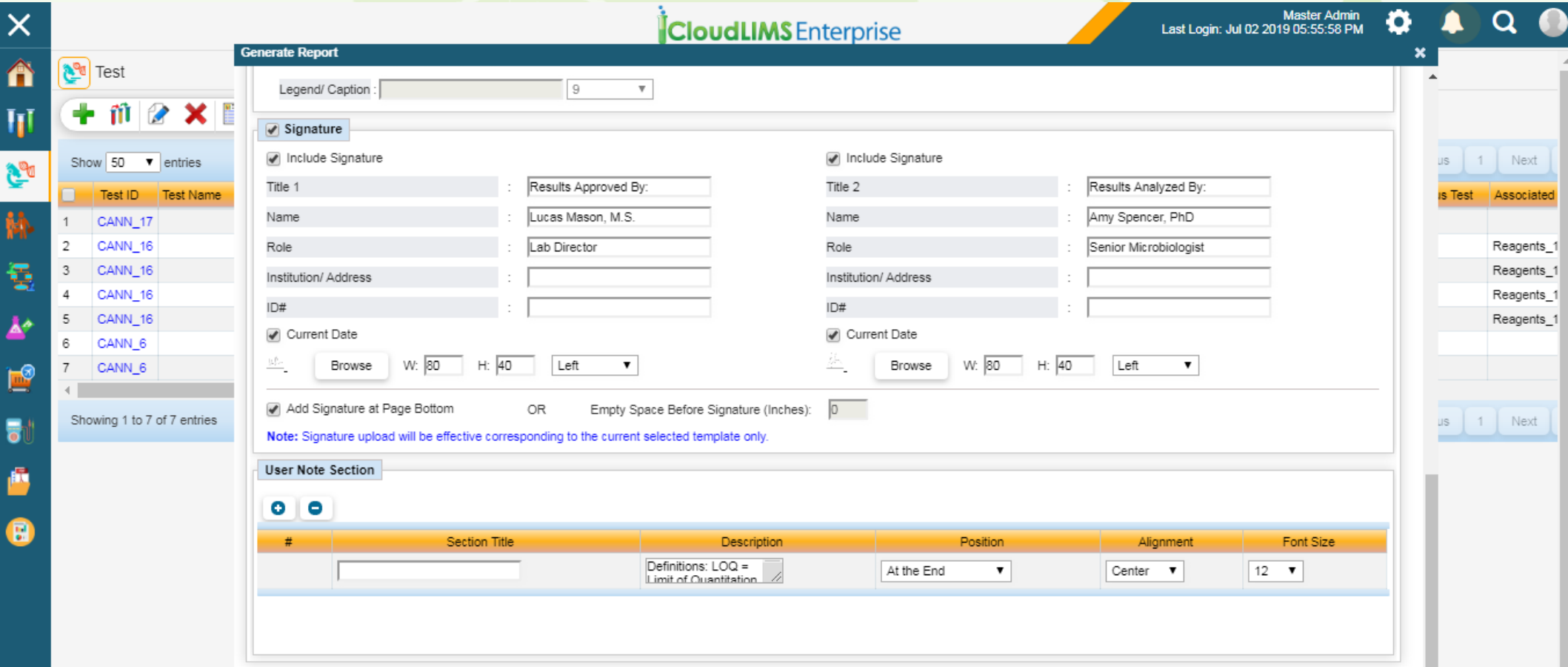
21 CFR Part 11 Compliance Requirements

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



ISO/IEC 17025 Requirements

Management Requirements

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

- **Organizational Structure**
- **Document Control**
- **Review of Requests, Tenders, and Contracts**
- **Control of Records**
- **Purchasing Services and Supplies**
- **Internal Audits**

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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**
- **Test and Calibration Methods & Method Validation**
- **Measurement Traceability**
- **Reporting of Results**
- **Ensuring the Quality of Test and Calibration Results**

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Advantage of ISO/IEC 17025 Accreditation For Cannabis Testing?

- Internationally recognized as THE laboratory QC standard
- Provides a framework for continuous improvement and self-correction
- Test results have greater comparability and reliability
- Provides defensibility
- Reduces the cost of doing business

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New Edition of ISO/IEC 17025

Latest Changes

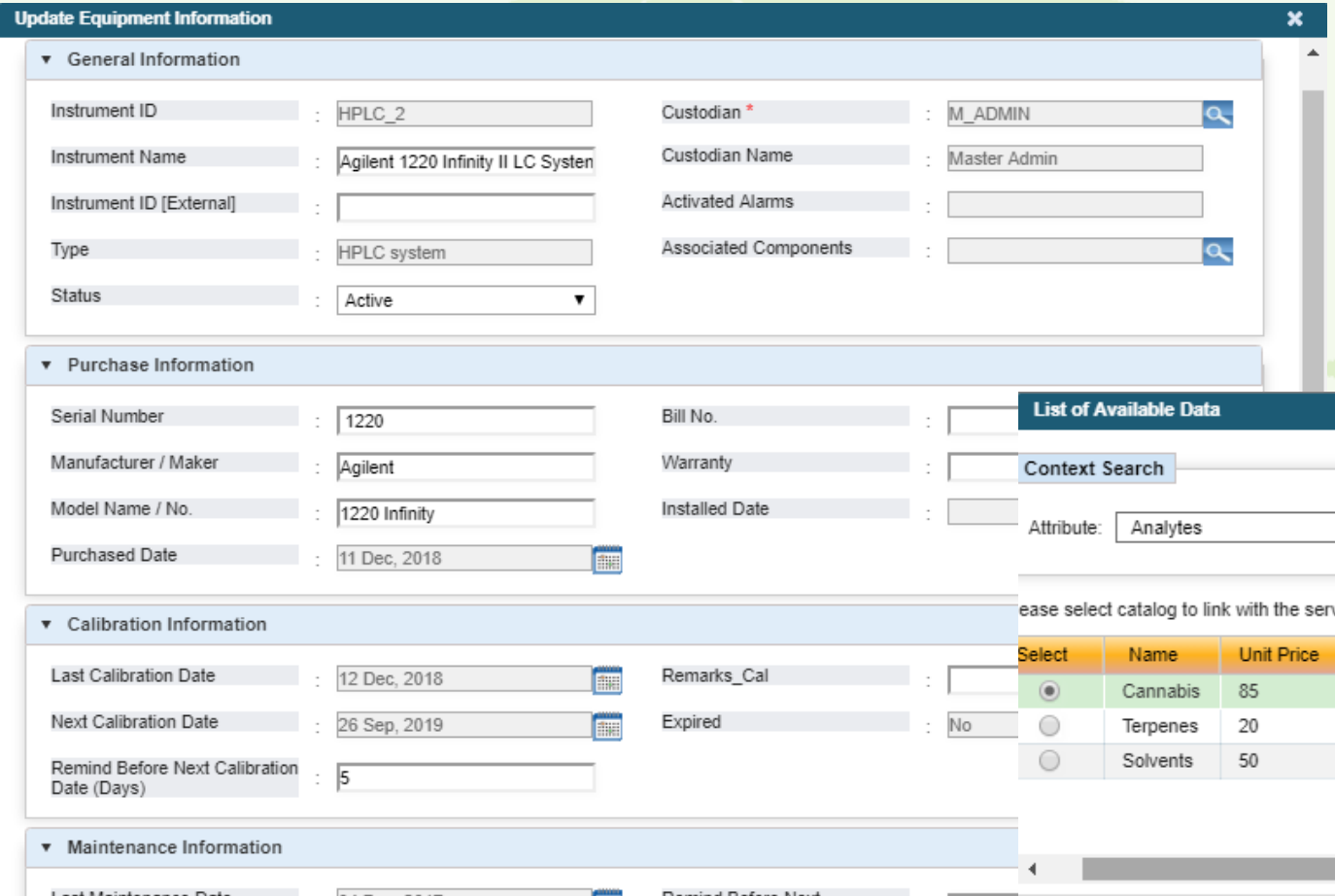
- **Risk-based Thinking**: Introduced a new chapter on risk-based thinking
- **Control of nonconforming testing and/or calibration work**: Has been made more general and flexible
- **Terminology Changes**: Terminology has been updated
- **Control of data and information management**: Use of computer systems, electronic records, and the production of electronic results and reports
- **Revision of scope**: The scope has been revised to cover all laboratory activities.

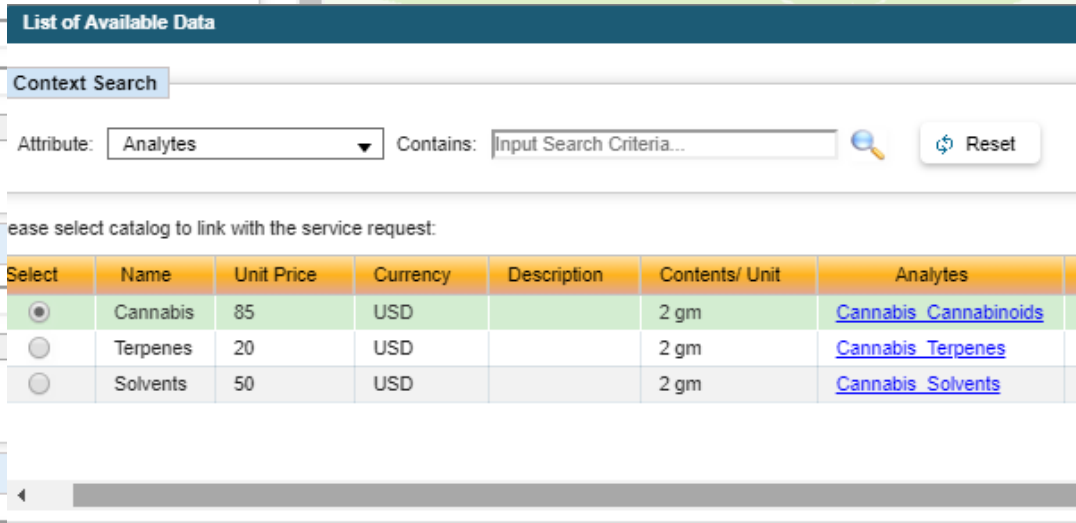
The three Convenors of CASCO working group 44 (CASCO/WG 44) that revised the standard tell us why the new version of ISO/IEC 17025 is so important for laboratories:

Discover the new ISO/IEC 17025:2017

Manage Instruments with LIMS

Track your equipment and its components along with calibration status





Manage Test Results with LIMS

Manage test results, generate CoA and send it to clients

Result Entries

Test ID: CANB_4	Test Type: Quantitative	Test Group: Cannabis	Test Code: Cannabinoids

Associated Samples

#	Sample ID	Sample ID [External]	Sample Status	Sample Type	Associated Analytes	QC Sample?
1	Flower_1	AFGFLW-2	Under Testing	Flower	CBC^ CBD^ CBDV^ CBL^ THCA	
2	Flower_2	AFGFLW-3	Under Testing	Flower	CBC^ CBD^ CBDV^ CBL^ THCA	
3	Flower_3	AFGFLW-4	Under Testing	Flower	CBC^ CBD^ CBDV^ CBL^ THCA	

Test Analyte Runs

Test Runs:

Analyte Name *	LOD ppm	LOQ ppm	Result %	Result mg/g	Test Ru

Test Chronology for 'Flower_8'

Test Chronology for : Flower_8

Test ID	Test ID [External]	Test Group	Test Code	Sample Testing Status	Sample-Test Runs	Turnaround Time	Turnaround Time Status	Test Type	Associated Instruments
CANB_1		Cannabis	Cannabinoids	Under Testing	Link			Quantitative	HPLC_2
CANB_2		Cannabis	Cannabinoids	Under Testing	Link			Quantitative	HPLC_2
CANB_3		Cannabis	Cannabinoids	Under Testing	Link			Quantitative	HPLC_2
CANB_4		Cannabis	Cannabinoids	Under Testing	Link	Error		Quantitative	HPLC_2

Certificate of Analysis

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		

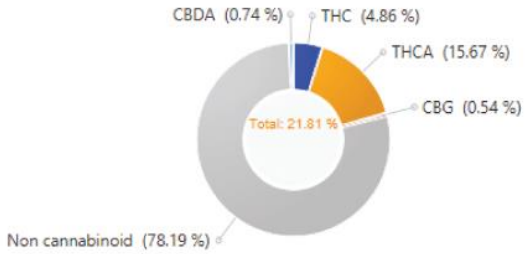
Test Information: Cannabis Testing/ Cannabinoids

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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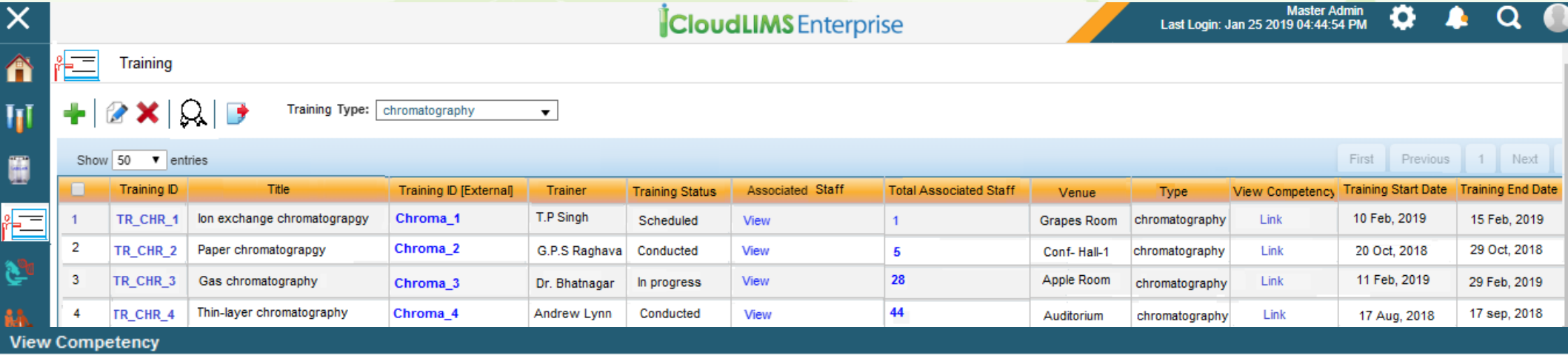
Manage Staff and Training with LIMS

Manage staff and training records, and mark their 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

QC & QA Requirements

- Ensuring proper validation of each test result
- Comparing the test results of QC samples with the test samples, to identify analytical errors
- Following Standard Operating Procedures
- Participation in proficiency-testing programs

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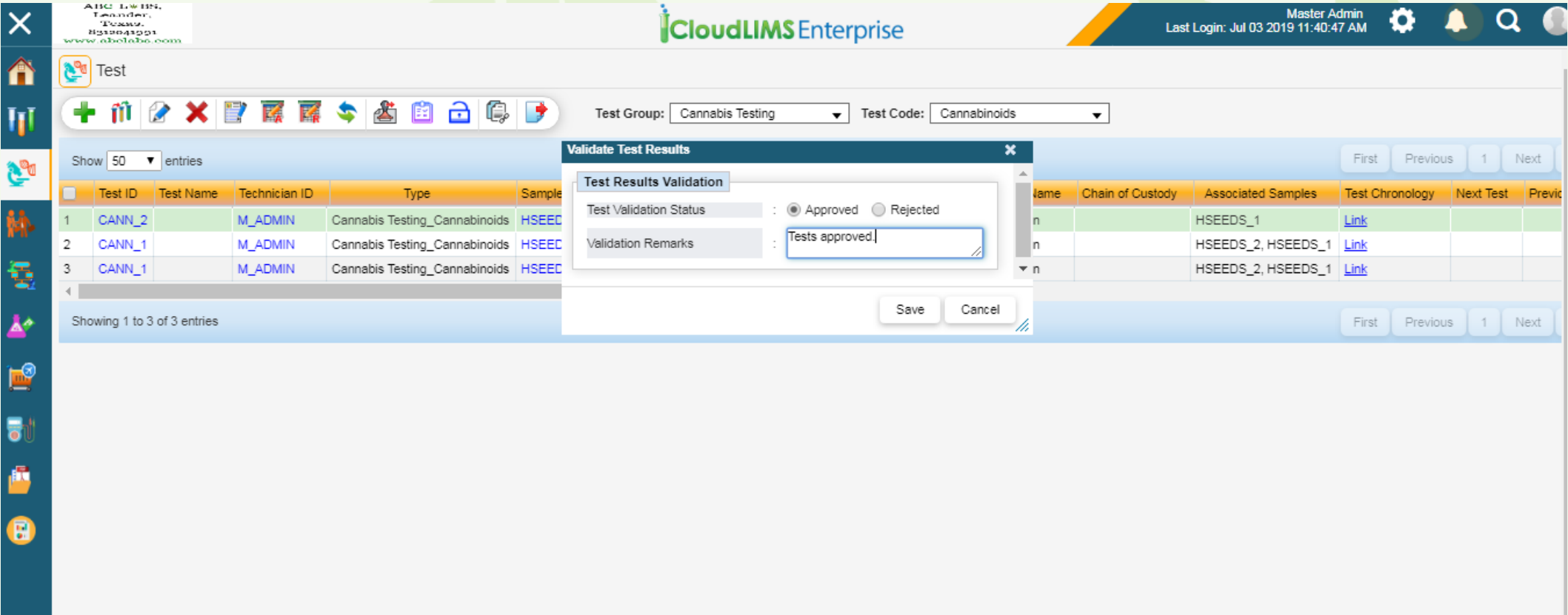
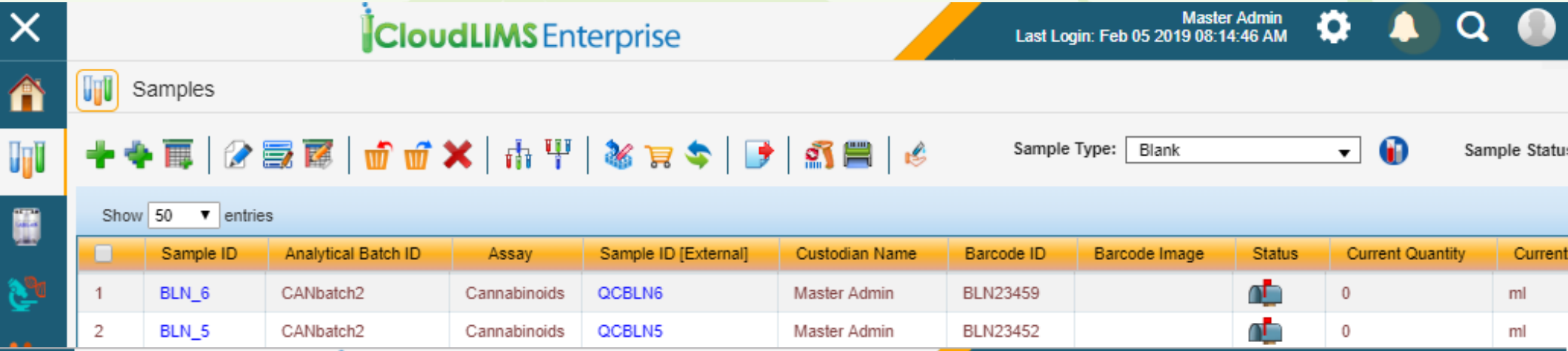
Validate Test Results With LIMS

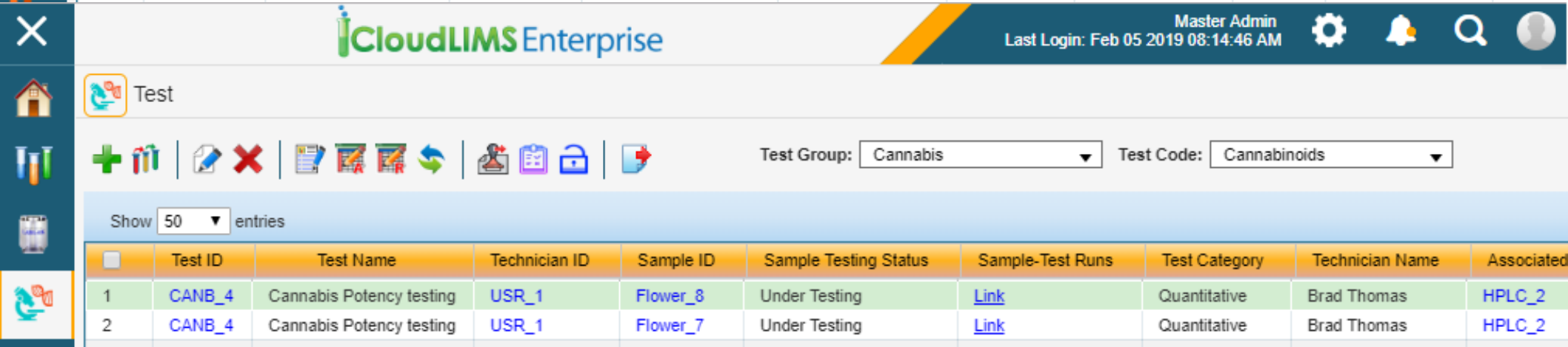
Configure a test validation process, send multiple results for validation, select a verifier, track the validation status, thereby assuring the final test results



Manage Quality Control Samples With LIMS

Manage quality control samples and their results to detect trends





ISO 9001 Certification Requirements

- The lab must have a qualified, trained and experienced staff
- Usage of equipment which is appropriately calibrated and maintained
- Adequate quality assurance and quality control procedures
- Implementation of appropriate sampling practices
- Sound testing/inspection procedures should be in place
- Accurate recording and reporting of data is a must
- Appropriate testing environment

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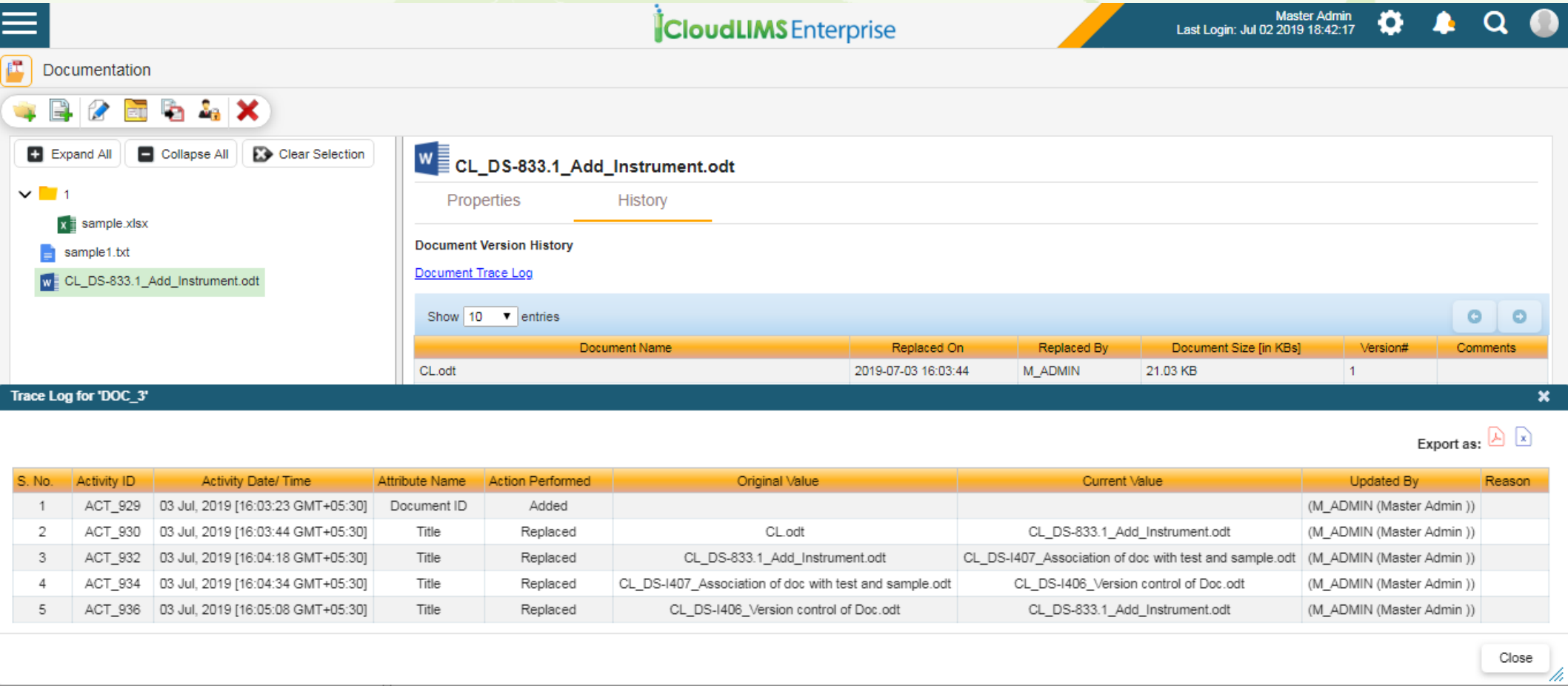
Manage Documents with LIMS

Maintain and track all documents, and maintain version control



Regulatory Compliance with State Tracking Systems

The state tracking systems are critical for state regulation of the cannabis products

- To have inventory-control and reporting systems in place
- To monitor legalized cannabis products through every step in the supply chain by state regulators
- To make legalized cannabis industries safe and accountable

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States Using State Tracking Systems

METRC™	Alaska, California, Colorado, Ohio, Oregon, Nevada, Montana, Michigan, Maryland, Louisiana, Massachusetts
BioTrackTHC™	In 34 states across DC, Puerto Rico, Jamaica, Canada, Colombia, Australia, and New Zealand
Leaf by MJ Freeway	Washington (and 11 more countries globally)

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Integration with Tracking Systems Using LIMS

LIMS enables a cannabis testing lab to integrate with seed-to-sale tracking systems via:

- **CSV file-based integration**
- **API-based integration**

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Benefits of Using a LIMS

- Enhance reputation, gain a competitive advantage
- Ensuring strong commitment to quality, operational efficiency & management practices, to your prospective clients
- Improved quality and productivity
- Reduce operational costs

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Advantages Offered by Cloud-based LIMS

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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