USDA's Hemp Testing Rules Have Changed: Accelerate Your Lab's Preparedness

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Cannabis IndustryJournal

CloudLIMS Empowering Labs

AGENDA

The value of the global hemp market in 2020 was $4.7 billion. With the legalization of hemp, the market is projected to increase at a CAGR of 22.5% and reach a value of $14.6 billion by 2026.

Source: Research and Markets Report 2021

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So, let’s delineate the USDA’s hemp testing framework

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The Journey of Hemp Legalization

- In 1937, hemp production was banned in the U.S. after the Marijuana Act was enacted.
- The Agricultural Act of 2014 reintroduced industrial hemp production in the U.S. through State pilot programs.
- Under the pilot programs, U.S. industrial hemp acreage increased from 0 in 2013 to over 90,000 acres in 2018.

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The Journey of Hemp Legalization

- The Agricultural Improvement Act of 2018 brought about significant changes in the agricultural sector.
- Hemp was legalized at the federal level in 2018.

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What was in the 2018 Farm Bill?

- The U.S. Farm Bill was signed on December 20, 2018.
- Hemp fell into the same class as other agricultural commodities.
- Due to its close relationship with cannabis (containing more than 0.3% THC), hemp production is heavily regulated.

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The USDA's Interim Final Rule (IFR)

The IFR gives guidelines on:

Sampling

Testing methods & THC level

Disposing of hot hemp

Licensing requirements

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The USDA's Final Rule

The USDA published the Final Rule that became effective from March 22, 2021.

Hemp testing labs need to get acquainted with these changes and be ready to implement them.

Several changes were introduced in the Final Rule that affects how hemp should be tested in the U.S.

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Wondering why the new hemp testing rules are so important?

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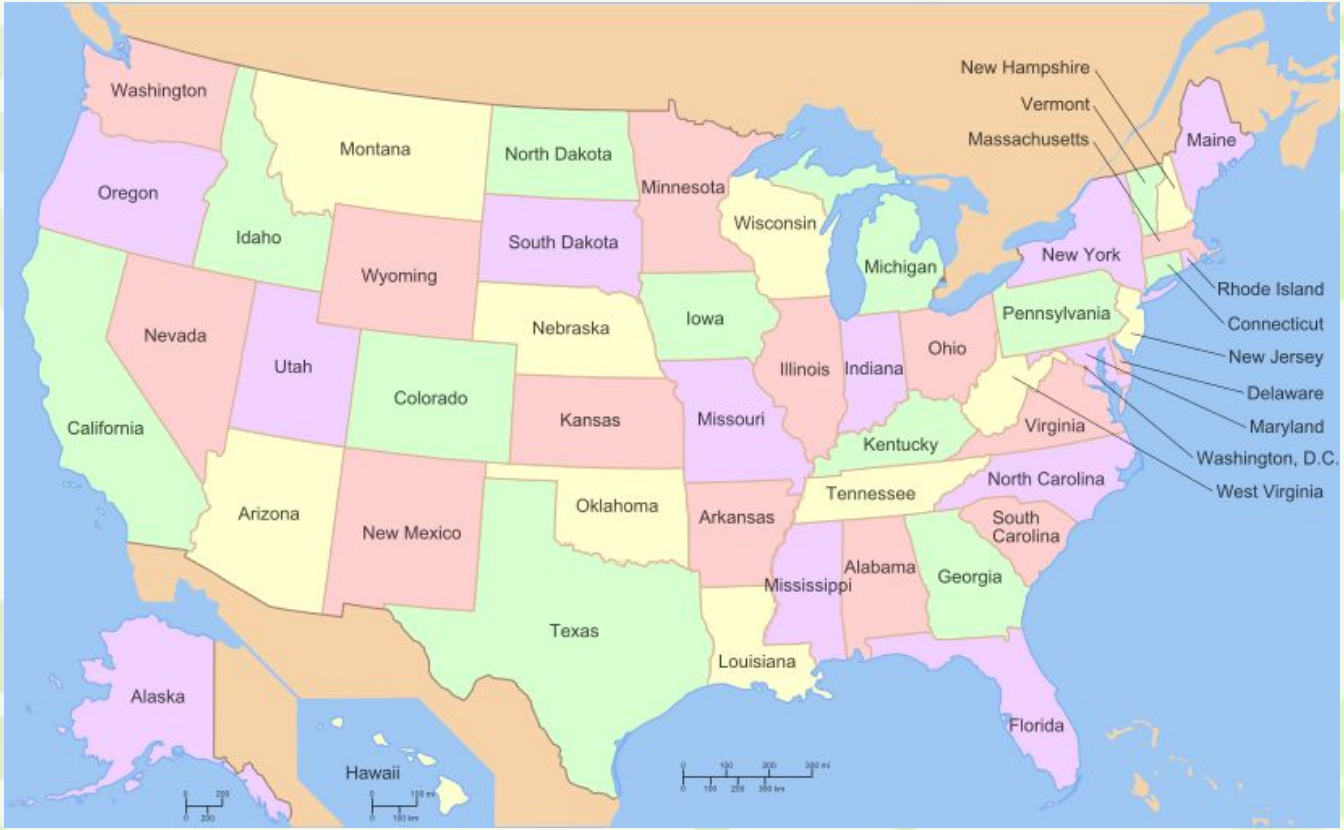
Why? Legally Required in All 50 States



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Why? Penalties for Hot Hemp

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So, let’s explore the USDA’s hemp testing rules and how to follow them with ease

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Sampling

- The plant parts to be tested were slightly modified in the Final Rule.
- Samples from the top 5-8 inches from the main stem, terminal bud, or central cola of the flowering top of the hemp plant should be collected.

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Hemp Testing Methods

- Hemp testing labs are required to use post-decarboxylation or other similar reliable methods to determine total THC concentration.

- THC is determined and reported on a dry-weight basis.

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Total THC Limit

The THC threshold was maintained at 0.3% in the USDA's final rule

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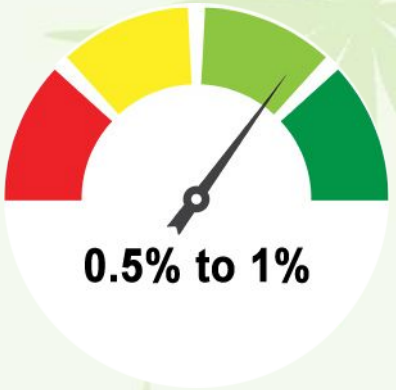
Negligent Violation

Hemp that tests above 0.3% THC but below 1 % THC can be remediated

This is not considered a violation of the law



This limit has been increased from 0.5% to 1%

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Measurement of Uncertainty (M.U.)

Labs should calculate the Measurement of Uncertainty (M.U.) when reporting THC concentration

The M.U. should be reported as a ± value; it is expressed in the same unit as the hemp THC threshold (e.g. +/- 0.05)

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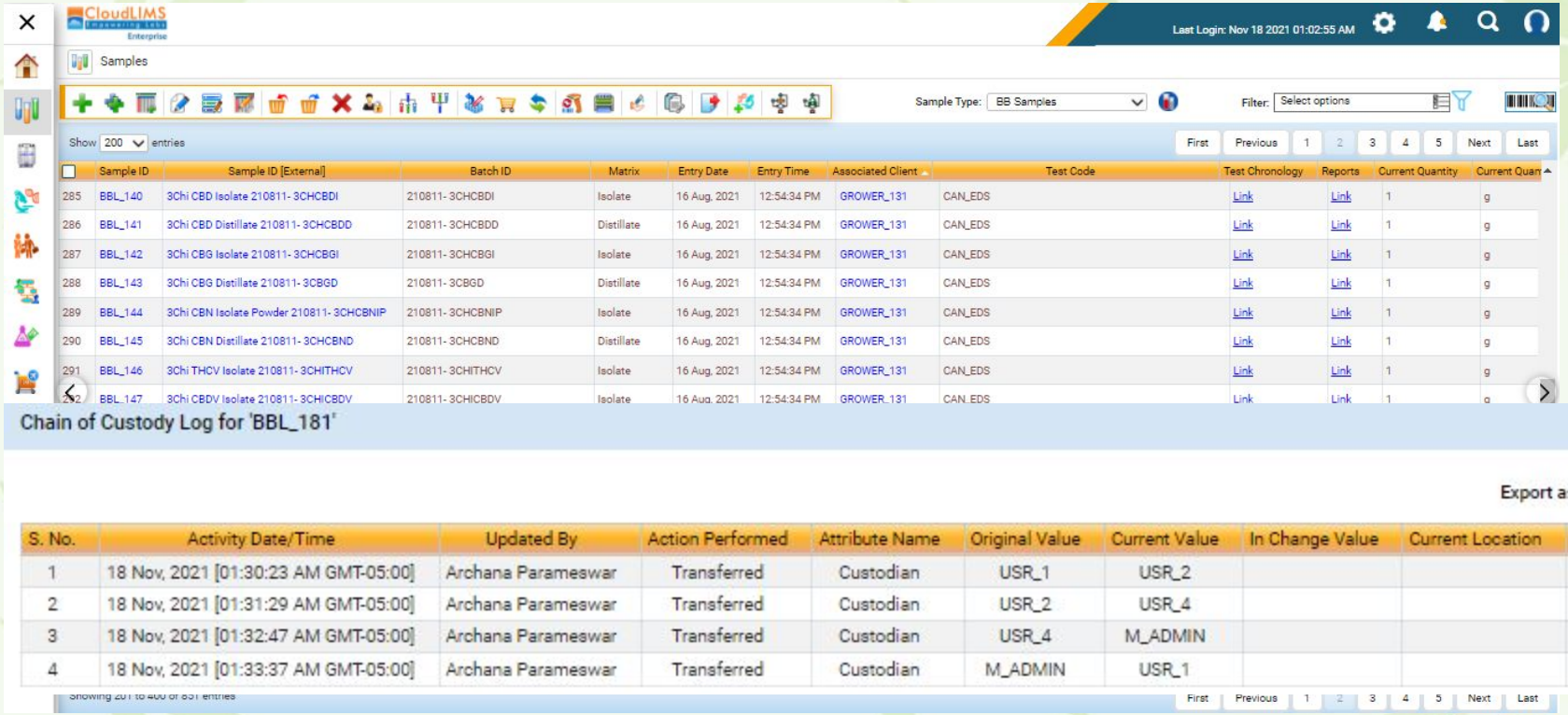
Manage Samples Through Their Lifecycle

Manage samples and maintain a chain of custody of all samples for complete traceability



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Configure Formula Expressions

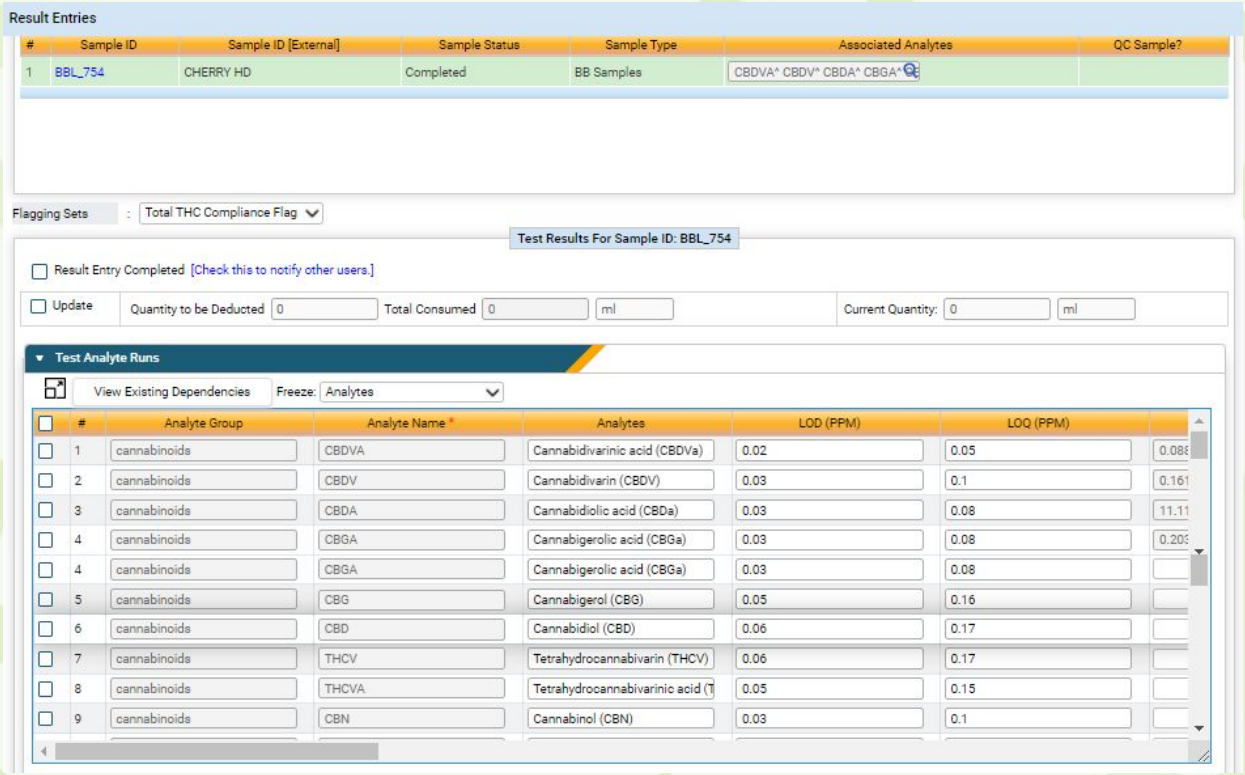
Configure formula expressions for calculation of total THC

View Existing Dependencies

32	Mapped Value & Replica	CBG~Result % From File	CBG~Result %	
33	Formula Expression		Total Cannabinoids~Result %	CBDVA~Result %+CBDV~Result %+CBDA~Result %+CBGA~Result %+CBG~Result %+CBD~Result %+THCV~Result %+THCVA~Result %+CBN~Result %+CBNA~Result %+D9-THC~Res
34	Formula Expression		Total CBG~Result %	CBGA~Result %*0.877+CBG~Result %
35	Formula Expression		CBGA~Result (mg/g)	CBGA~Result %*10
36	Formula Expression		CBL~Result (mg/g)	CBL~Result %*10
37	Formula Expression		CBN~Result (mg/g)	CBN~Result %*10
38	Formula Expression		CBNA~Result (mg/g)	CBNA~Result %*10
39	Formula Expression		D8-THC~Result (mg/g)	D8-THC~Result %*10
40	Formula Expression		CBC~Result (mg/g)	CBC~Result %*10
41	Formula Expression		Total THC~Result %	THCA~Result %*0.877+D9-THC~Result %
42	Formula Expression		D9-THC~Result (mg/g)	D9-THC~Result %*10
43	Formula Expression		THCA~Result (mg/g)	THCA~Result %*10
44	Formula Expression		THCV~Result (mg/g)	THCV~Result %*10
45	Formula Expression		THCVA~Result (mg/g)	THCVA~Result %*10
46	Formula Expression & Replica	THCA~Result %	Total THC~Result %	
47	Replica	Total THC~Result %	Total THC~Flag Based on this column	
48	Formula Expression & Replica	CBDA~Result %	Total CBD~Result %	
49	Formula Expression & Replica	CBDVA~Result %	Total Cannabinoids~Result %	
50	Formula Expression & Replica	CBGA~Result %	Total CBG~Result %	
51	Formula Expression		CBCA~Result (mg/g)	CBCA~Result %*10
52	Formula Expression		Total CBD~Result %	CBDA~Result %*0.877+CBD~Result %
53	Formula Expression		CBD~Result (mg/g)	CBD~Result %*10
54	Formula Expression		CBDA~Result (mg/g)	CBDA~Result %*10
55	Formula Expression		CBDV~Result (mg/g)	CBDV~Result %*10
56	Formula Expression		CBDVA~Result (mg/g)	CBDVA~Result %*10
57	Formula Expression		CBG~Result (mg/g)	CBG~Result %*10
58	Formula Expression & Replica	CBGA~Result %	CBGA~Result (mg/g)	
59	Formula Expression		Total Cannabinoids~Result (mg/g)	CBDVA~Result (mg/g)+CBDV~Result (mg/g)+CBDA~Result (mg/g)+CBGA~Result (mg/g)+CBG~Result (mg/g)+CBD~Result (mg/g)+THCV~Result (mg/g)+THCVA~Result (mg/g)+CB
60	Formula Expression		Total CBG~Result (mg/g)	CBGA~Result (mg/g)*0.877+CBG~Result (mg/g)
61	Formula Expression & Replica	CBL~Result %	CBL~Result (mg/g)	
62	Formula Expression & Replica	CBN~Result %	CBN~Result (mg/g)	

Manage Test Results

Manage multi-analyte test results using a LIMS



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Flag Out-of-Specification Results

#	Analytes	LOD (PPM)	LOQ (PPM)	Result %	Result (mg/g)	Flag	Minimum	Maximum
1	Cannabidivarinic acid (CBDVa)	0.02	0.05	0.0887	0.89			
2	Cannabidivarin (CBDV)	0.03	0.1	0.161	1.61			
3	Cannabidiolic acid (CBDa)	0.03	0.08	11.1199	111.2			
4	Cannabigerolic acid (CBGa)	0.03	0.08	0.2036	2.04			
5	Cannabigerol (CBG)	0.05	0.16	0.0533	0.53			
6	Cannabidiol (CBD)	0.06	0.17	1.2897	12.9			
7	Tetrahydrocannabivarin (THCV)	0.06	0.17	ND	ND			
8	Tetrahydrocannabivarinic acid (T	0.05	0.15	ND	ND			
9	Cannabinol (CBN)	0.03	0.1	ND	ND			
10	Cannabinolic acid (CBNa)	0.08	0.26	<LoQ	<LoQ			
11	D9-Tetrahydrocannabinol (D9-TH	0.12	0.36	0.1405	1.4			
12	D8-Tetrahydrocannabinol (D8-TH	0.15	0.45	ND	ND			
13	Cannabicyclol (CBL)	0.13	0.38	<LoQ	<LoQ			
14	D9-Tetrahydrocannabinolic acid	0.09	0.28	0.4017	4.02			
15	Cannabichromene (CBC)	0.06	0.19	0.1532	1.53			
16	Cannabichromenic acid (CBCa)	0.22	0.67	0.6013	6.01			
17	Total THC (THCa * 0.877 + THC)			0.49	4.93	Compliance Fail		0.3
18	Total CBD (CBDa * 0.877 + CBD)			11.04	110.42			
19	Total CBG (CBGa * 0.877 + CBG)			0.23	2.32			
20	Total Cannabinoids			14.21	142.13			

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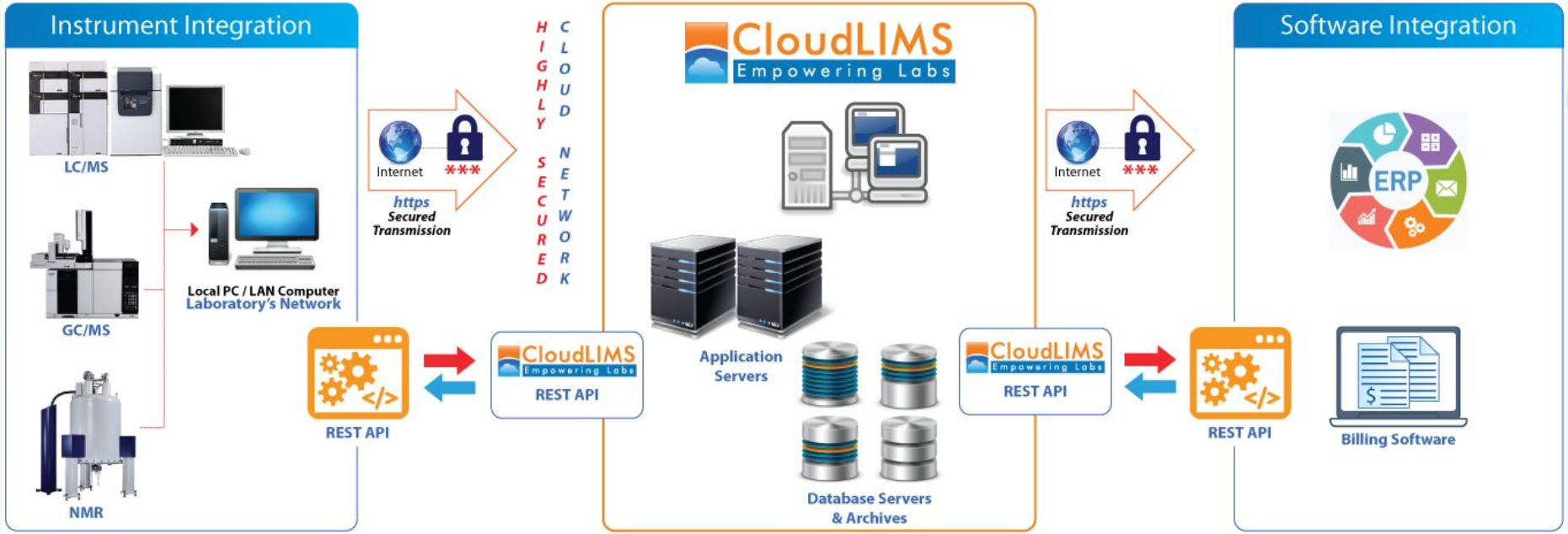
Instrument & Software Integration

Instrument and software integration assures data integrity, minimizes turnaround time, and enhances laboratory efficiency



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Operational Changes Introduced in the Final Rule

Hemp testing labs must use validated test methods

Labs should have appropriate quality assurance protocols in place

The USDA encourages hemp testing labs to be ISO/IEC 17025 accredited

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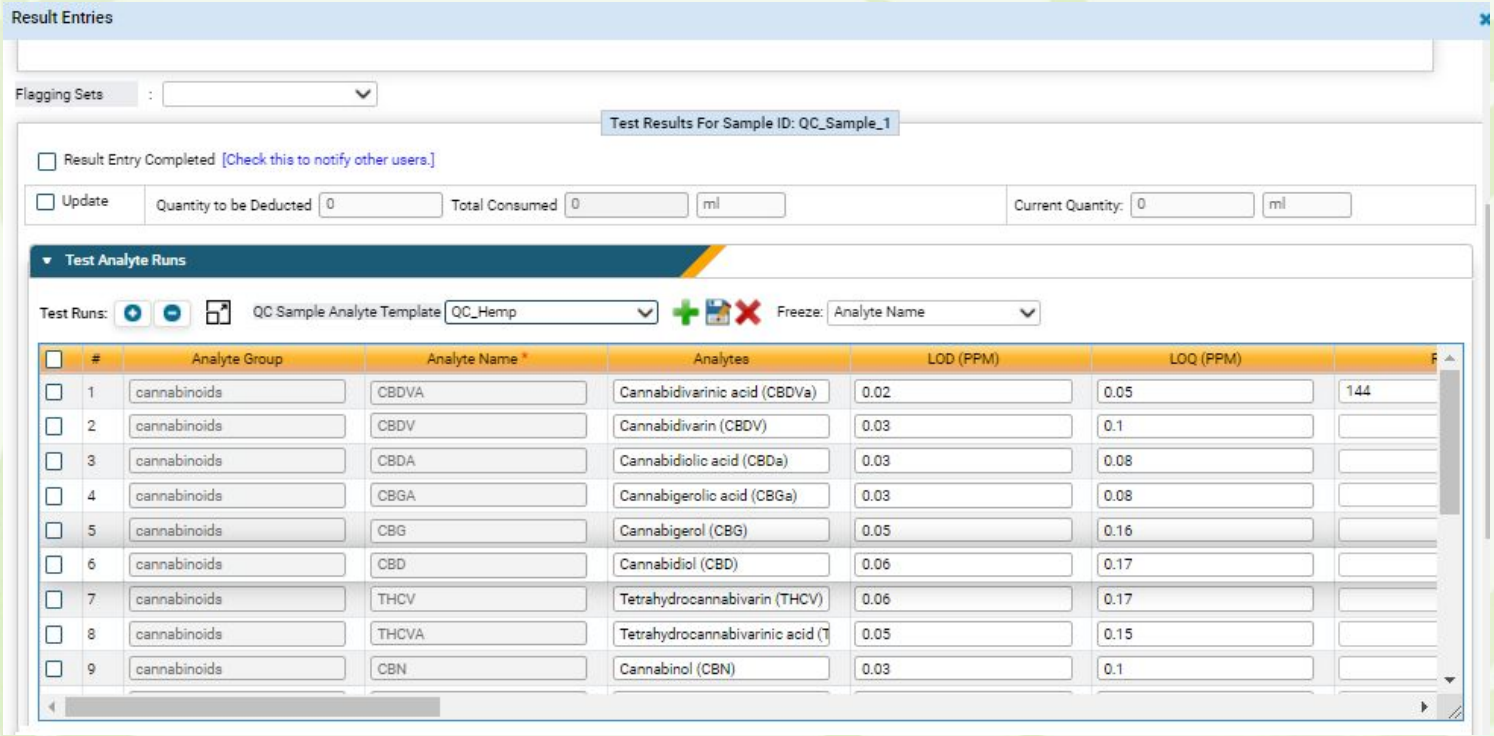
Manage QC Samples & Their Test Results

Manage quality control samples and monitor their results to detect anomalies



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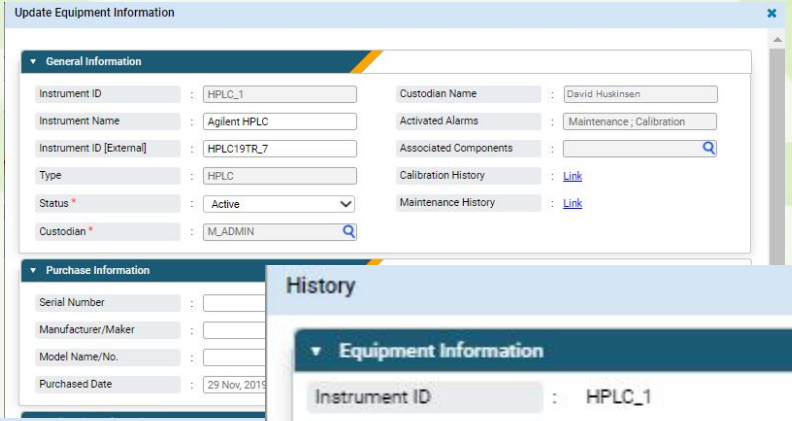
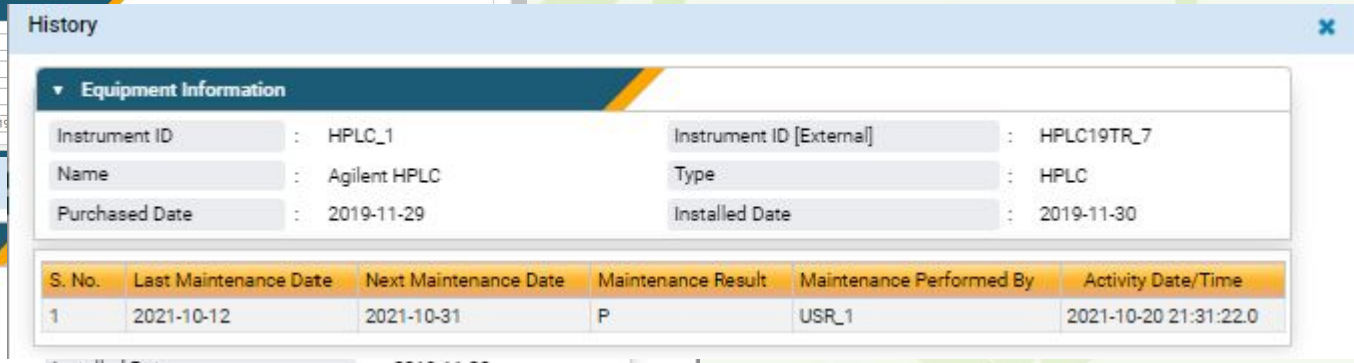
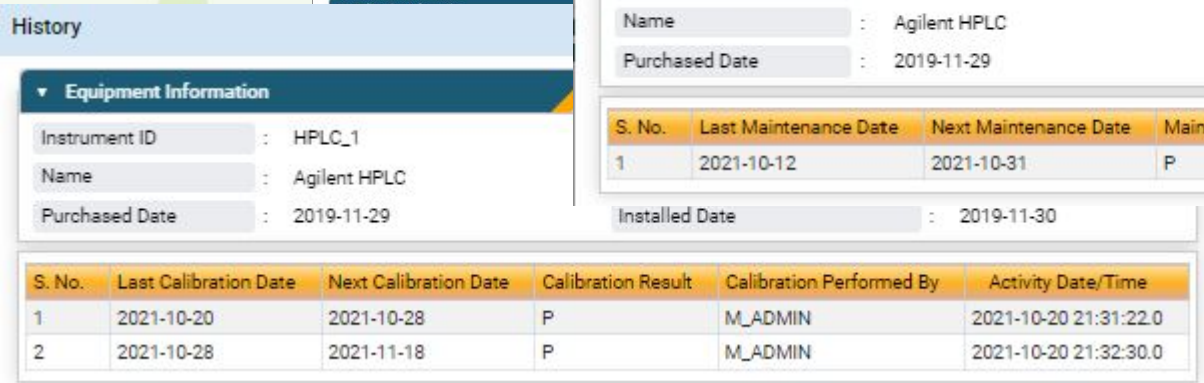
Instrument: Calibration and Maintenance

Schedule instrument calibration, manage maintenance data & assign instrument handling to staff based on their competency







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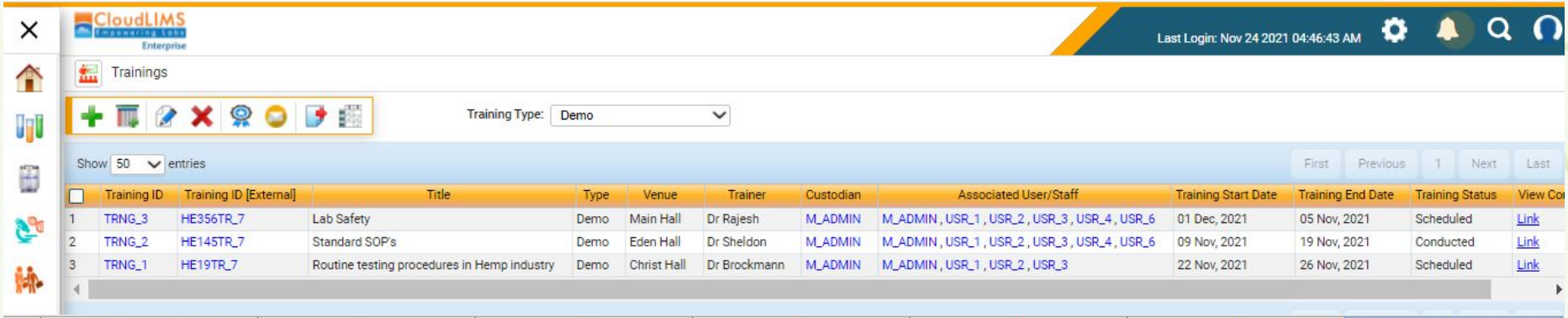
Personnel: Staff Training

Manage staff training & generate training competency matrix



	Training ID	Training ID [External]	Title	Type	Venue	Trainer	Custodian	Associated User/Staff	Training Start Date	Training End Date	Training Status	View Co
1	TRNG_3	HE356TR_7	Lab Safety	Demo	Main Hall	Dr Rajesh	M_ADMIN	M_ADMIN , USR_1 , USR_2 , USR_3 , USR_4 , USR_6	01 Dec, 2021	05 Nov, 2021	Scheduled	Link
2	TRNG_2	HE145TR_7	Standard SOP's	Demo	Eden Hall	Dr Sheldon	M_ADMIN	M_ADMIN , USR_1 , USR_2 , USR_3 , USR_4 , USR_6	09 Nov, 2021	19 Nov, 2021	Conducted	Link
3	TRNG_1	HE19TR_7	Routine testing procedures in Hemp industry	Demo	Christ Hall	Dr Brockmann	M_ADMIN	M_ADMIN , USR_1 , USR_2 , USR_3	22 Nov, 2021	26 Nov, 2021	Scheduled	Link

	A	B	C	D	E	F	G
1		M_ADMIN	Aaron Townsend	John Smith	Adam Lallana	Joe Gomez	John Smith
2	Lab Safety Training	5	4	0	3	4	1
3	Hemp Industry Standard S	0	0	0	0	0	0
4	Standard SOP's	4	4	0	3		

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DEA Registration

- All compliance hemp testing should be performed by labs that are registered with the DEA.
- However, labs were given up to December 31, 2022, to comply with this requirement.

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Reporting of Total THC is Maintained

- THC must be reported as total THC.
- This means “total THC on a dry weight basis”.
- This lumps up delta-9 tetrahydrocannabinolic acid (THCA) with THC.

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Generate Custom CoAs

ABCL_170 page 1 of 1

ABC LABS

ABC Labs Certificate of Analysis

675 Valley View Ln, Dallas, TX 75234, United States | License: TL5220015

ISO/IEC 17025:2017 Certification L65-20-5 | Accreditation #

Sample 210621_2

Compliance Fail

Sample ID:	BBL_170	**Matrix:**	Tinctures	**Cultivar:**	ABC
Company:	Rps2	**Registration#:**		**Email:**	johan@cannabistech.com
Phone:	9187915521	**Sampler:**	Smith	**Sampled:**	12:30
Receiver:	Smith	**Received:**	21 Jun, 2021	**Reported:**	23 Jul, 2021
Address:	Address	**GPS:**	23:23	**Acreage:**	ARC
Description:	DES	**Lot Crop Permit ID:**		**Analyses Executed:**	NOTHC

Lab Notes:

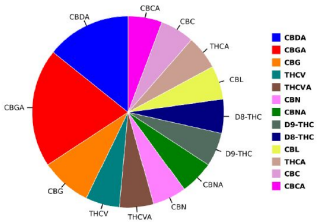
*NOTHC - Cannabinoid Profile Analysis

Analyzed 22 Jul, 2021 | Instrument HPLC-DAD | Method
Measurement Uncertainty at 95% confidence 10.0%

Analyte	LOD	LOQ	Result %	Result mg/g
Cannabidivarinic acid (CBDVa)	0.020	0.050	ND	ND
Cannabidivarin (CBDV)	0.030	0.100	NR	NR
Cannabidiolic acid (CBDa)	0.030	0.080	5	50.0
Cannabigerolic acid (CBGa)	0.030	0.080	7	70.0
Cannabigerol (CBG)	0.050	0.160	3	30.0
Cannabidiol (CBD)	0.060	0.170	>=99%	>=99%
Tetrahydrocannabivarin (THCV)	0.060	0.170	2	20.0
Tetrahydrocannabivarinic acid (THCVa)	0.050	0.150	2	20.0
Cannabinol (CBN)	0.030	0.100	2	20.0
Cannabinolic acid (CBNa)	0.080	0.260	2	20.0
D9-Tetrahydrocannabinol (D9-THC)	0.120	0.360	2	20.0
D8-Tetrahydrocannabinol (D8-THC)	0.150	0.450	2	20.0
Cannabicyclol (CBL)	0.130	0.380	2	20.0
D9-Tetrahydrocannabinolic acid (THCa)	0.090	0.280	2	20.0
Cannabichromene (CBC)	0.060	0.190	2	20.0
Cannabichromenic acid (CBCa)	0.220	0.670	2	20.0
Total THC			3.754	37.54
Total CBD			4.385	43.85
Total CBG			9.139	91.39
Total Cannabinoids			35.0	350.0

*Dry Weight

Sample Photography



ND Not Detected
N/A Not Applicable
NT Not Reported
LOD Limit of Detection
LOQ Limit of Quantification
<LOQ Detected
>ULOL Above upper limit of linearity
CFU/g Colony Forming Units per 1 gram
TNTC Too Numerous to Count

Accreditation #

Authorized Signature

Jack Spencer, PhD
Senior Technician
25 Jul, 2021 02:05:15 PM

"This report shall not be reproduced except in full, without the written approval of the lab. "This report is for informational purposes only and should not be used to diagnose, treat or prevent any disease. Results are only for samples and batches indicated. Results are reported on an "as received" basis, unless indicated otherwise. All required LQC (Laboratory Quality Control) samples were included in the performance of these analyses and met the acceptance criteria for ISO/IEC Regulations.

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Sharing of Test Results

- Labs may share test results with licensed producers in a manner that best aligns with their business practices.
- The producers must produce a legible copy of the test report upon request.

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Sharing of Test Results

Labs performing THC testing for compliance purposes must share test results with the following:

Licensed Producer

Appropriate State Department of Agriculture or Tribe

The USDA

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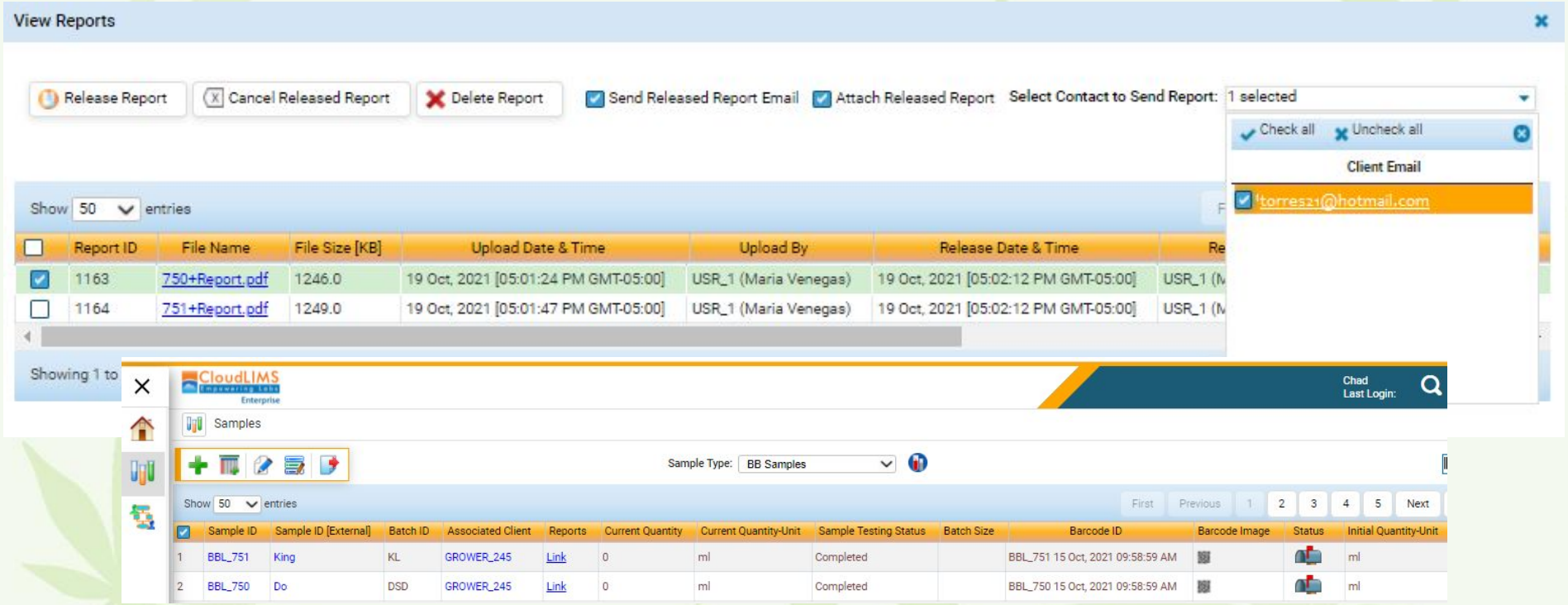
Client Portal: CoA Delivery in Real-Time



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Sharing of Test Results

Appropriate State Department of Agriculture or Tribe

Test Results

The USDA

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Other Significant Changes to Hemp Testing

- The samples must be homogenous.

- A lab should have an internal SOP for testing and retesting hemp.

- Testing protocols should specify a disposal procedure for hot hemp.

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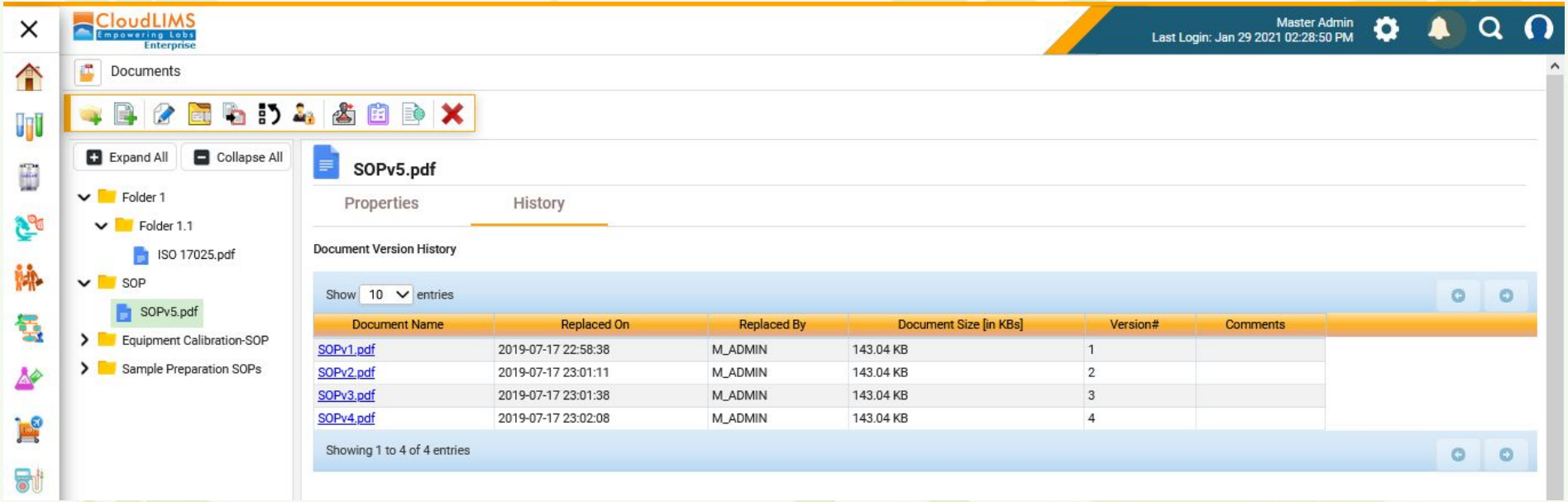
Document Control

Manage SOPs and confidential documents and provide access to all authorized users while tracking the full version history of the folders, subfolders, and each document within them



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How to Choose the Right LIMS for Your Lab

Here's a Checklist of Essential Functionality:

- Integrate with the reporting system of the USDA & the state department of agriculture
- Streamline and automate QA/QC processes
- Generate custom Certificates of Analysis (CoA)

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How to Choose the Right LIMS for Your Lab

Here's a Checklist of Essential Functionality:

- Manage staff training and their competency
- Manage documents, SOPs, and track their version history
- Schedule instrument calibration & manage maintenance data
- Maintain a chain of custody of all samples through their lifecycle

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Benefits of Deploying a Hemp LIMS

TEST RESULT ACCURACY

PRODUCTIVITY

QUALITY

LOWER COSTS

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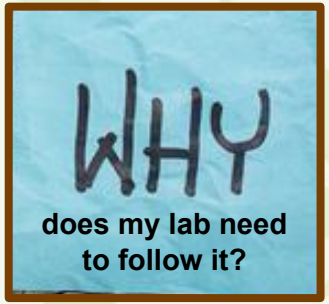
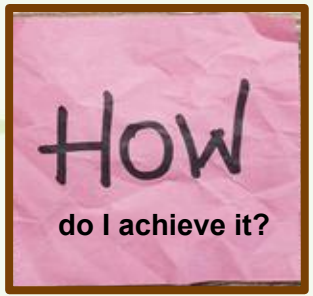
In Conclusion...

Important Federal Rules



Legally Required



Deploy a LIMS

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Thank You For Your Attention!

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