Is Your Food Testing Lab Ready for an FDA Inspection?

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LIMS Implementation Expert, CloudLIMS.com

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Agenda

- Food Safety and Challenges
- FSMA: Definition and Details
- How to Leverage Automation to Meet FSMA Requirements
- How a LIMS Helps?
- Q&A

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Food Safety

What is Food Safety?

Safe handling of food items through sampling, manufacturing, preparation, packaging, distribution, and storage of food to avoid foodborne illnesses.

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Food Safety: Challenges

Globalization of the food industry leads to changes in food production and supply, resulting in more imported foods.

Environmental changes leading to food contamination.

New and emerging bacteria, toxins, and antibiotic resistance. Point in case: COVID-19 and its effects on the global economy.

Changes in consumer preferences and dietary habits.

Changes in detection methods for foodborne illness and contagion.

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FSMA: An Overview

1. FSMA stands for Food Safety Modernization Act.
2. It came into existence in January 2011 and is governed and managed by the FDA.
3. FSMA enables FDA to scientifically evaluate food safety and preventive control measures implemented in a food manufacturing facility.
4. It focuses on preventing contamination during food manufacture.
5. Requires providing documentary evidence on the process of generating safer products.

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FSMA: FDA Requirements for Accredited Laboratories

1. Using appropriate analytical procedures and certifying its reports of analysis as true and accurate.
2. Establishing and maintaining internal quality systems.
3. Establishing procedures to evaluate and respond promptly to complaints regarding analyses and other activities pertaining to a laboratory's offerings.
4. Establish, control, and maintain records relating to food testing activities of a laboratory.
5. Compliance with ISO 17025:2017 guidelines.

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FSMA: FDA Requirements for Accredited Laboratories

Food Safety Management Plan

Complete Sample Traceability

Quality Assurance & Quality Management

Document Management

A Read-only Audit Trail

Adherence to ISO 17025:2017 Guidelines

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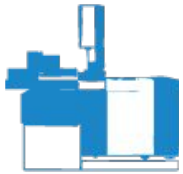
How a LIMS Helps in Meeting FSMA Requirements

A LIMS (Laboratory Information Management System) is a software solution to address the data management, automation, and regulatory challenges of food testing laboratories across the globe.



It can help schedule instrument calibration and maintenance,

It can maintain training records of personnel

It can automate testing workflows and integrate with analytical instruments for data transfer.

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How a LIMS Helps in Meeting FSMA Requirements

It ensures complete traceability from farm to fork, increases productivity, and enforces staff to follow food safety protocols.

It easily helps identify trends across the QC samples, assuring quality and maintaining proper quality control across the test procedures.

A LIMS helps manage documents and SOPs, establishes an easy to access audit, and helps meet compliance with ease. This decreases the overall turnaround time and enhances the efficacy of both food testing laboratories and food processing units.

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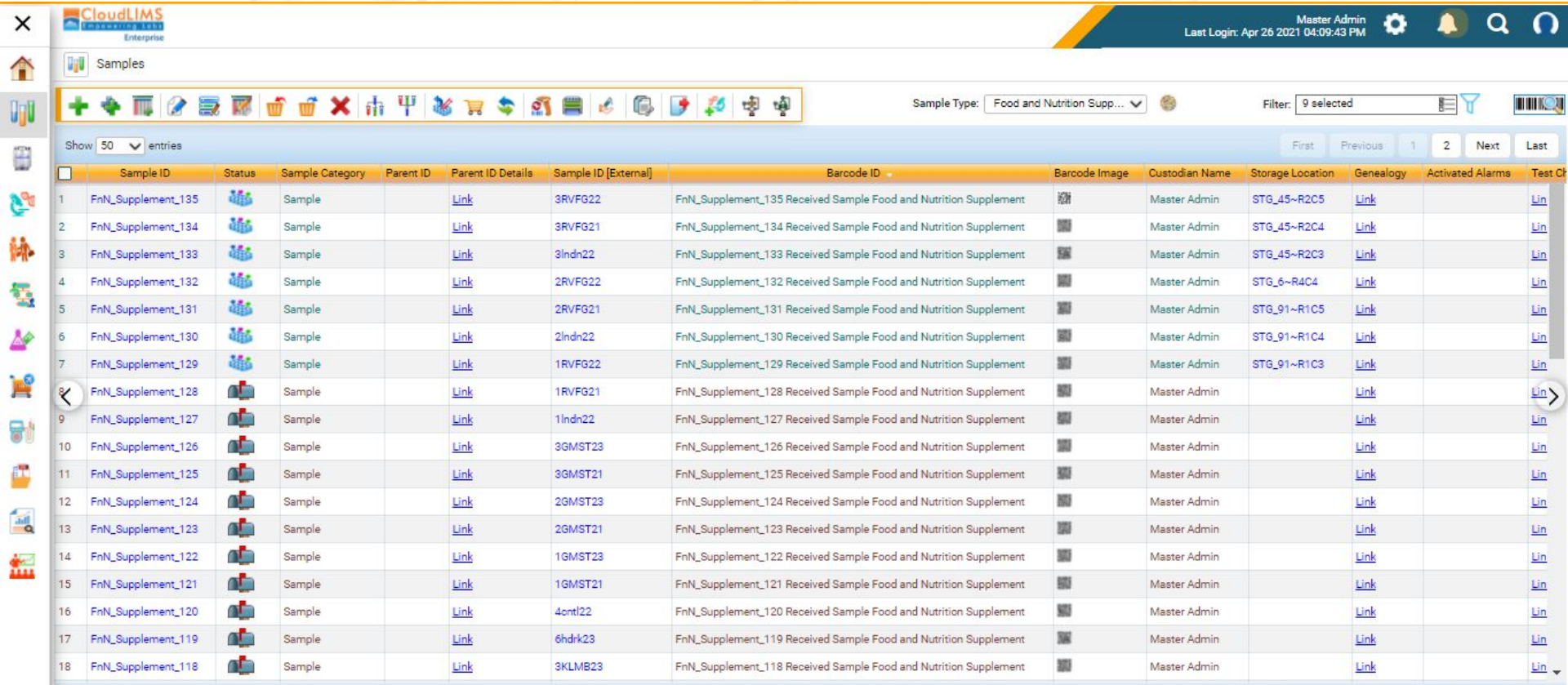
Sample Traceability and Barcoding

Sample accessioning with 1D, 2D barcodes or RFID to maintain sample traceability back to the original and finished product



	Sample ID	Status	Sample Category	Parent ID	Parent ID Details	Sample ID [External]	Barcode ID	Barcode Image	Custodian Name	Storage Location	Genealogy	Activated Alarms	Test Ch
1	FnN_Supplement_135		Sample		Link	3RVFG22	FnN_Supplement_135 Received Sample Food and Nutrition Supplement		Master Admin	STG_45~R2C5	Link		Lin
2	FnN_Supplement_134		Sample		Link	3RVFG21	FnN_Supplement_134 Received Sample Food and Nutrition Supplement		Master Admin	STG_45~R2C4	Link		Lin
3	FnN_Supplement_133		Sample		Link	3lndn22	FnN_Supplement_133 Received Sample Food and Nutrition Supplement		Master Admin	STG_45~R2C3	Link		Lin
4	FnN_Supplement_132		Sample		Link	2RVFG22	FnN_Supplement_132 Received Sample Food and Nutrition Supplement		Master Admin	STG_6~R4C4	Link		Lin
5	FnN_Supplement_131		Sample		Link	2RVFG21	FnN_Supplement_131 Received Sample Food and Nutrition Supplement		Master Admin	STG_91~R1C5	Link		Lin
6	FnN_Supplement_130		Sample		Link	2lndn22	FnN_Supplement_130 Received Sample Food and Nutrition Supplement		Master Admin	STG_91~R1C4	Link		Lin
7	FnN_Supplement_129		Sample		Link	1RVFG22	FnN_Supplement_129 Received Sample Food and Nutrition Supplement		Master Admin	STG_91~R1C3	Link		Lin
8	FnN_Supplement_128		Sample		Link	1RVFG21	FnN_Supplement_128 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
9	FnN_Supplement_127		Sample		Link	1lndn22	FnN_Supplement_127 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
10	FnN_Supplement_126		Sample		Link	3GMST23	FnN_Supplement_126 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
11	FnN_Supplement_125		Sample		Link	3GMST21	FnN_Supplement_125 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
12	FnN_Supplement_124		Sample		Link	2GMST23	FnN_Supplement_124 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
13	FnN_Supplement_123		Sample		Link	2GMST21	FnN_Supplement_123 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
14	FnN_Supplement_122		Sample		Link	1GMST23	FnN_Supplement_122 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
15	FnN_Supplement_121		Sample		Link	1GMST21	FnN_Supplement_121 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
16	FnN_Supplement_120		Sample		Link	4cntl22	FnN_Supplement_120 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
17	FnN_Supplement_119		Sample		Link	6hdrk23	FnN_Supplement_119 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin
18	FnN_Supplement_118		Sample		Link	3KLMB23	FnN_Supplement_118 Received Sample Food and Nutrition Supplement		Master Admin		Link		Lin

Chain of Custody

Maintain a chain-of-custody to track samples from accessioning to disposal

Chain of Custody Log for 'FnN_Supplement_143'

Export as:

S. No.	Activity Date/Time	Updated By	Action Performed	Attribute Name	Original Value	Current Value	In Change Value	Current Location	Reason
1	17 Mar, 2020 [09:10:36 AM GMT+05:30]	Master Admin	Transferred	Custodian	M_ADMIN	USR_2		STG_108~R1C1	
2	26 Apr, 2021 [04:46:31 PM GMT+05:30]	Master Admin	Transferred	Custodian	USR_2	M_ADMIN		STG_108~R1C1	
3	26 Apr, 2021 [04:46:42 PM GMT+05:30]	Master Admin	Transferred	Custodian	M_ADMIN	USR_5		STG_108~R1C1	
4	26 Apr, 2021 [04:46:53 PM GMT+05:30]	Master Admin	Transferred	Custodian	USR_5	USR_7		STG_108~R1C1	
5	26 Apr, 2021 [04:47:02 PM GMT+05:30]	Master Admin	Transferred	Custodian	USR_7	USR_2		STG_108~R1C1	

Close

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Digital Signatures

Authenticate key laboratory activities through electronic signatures

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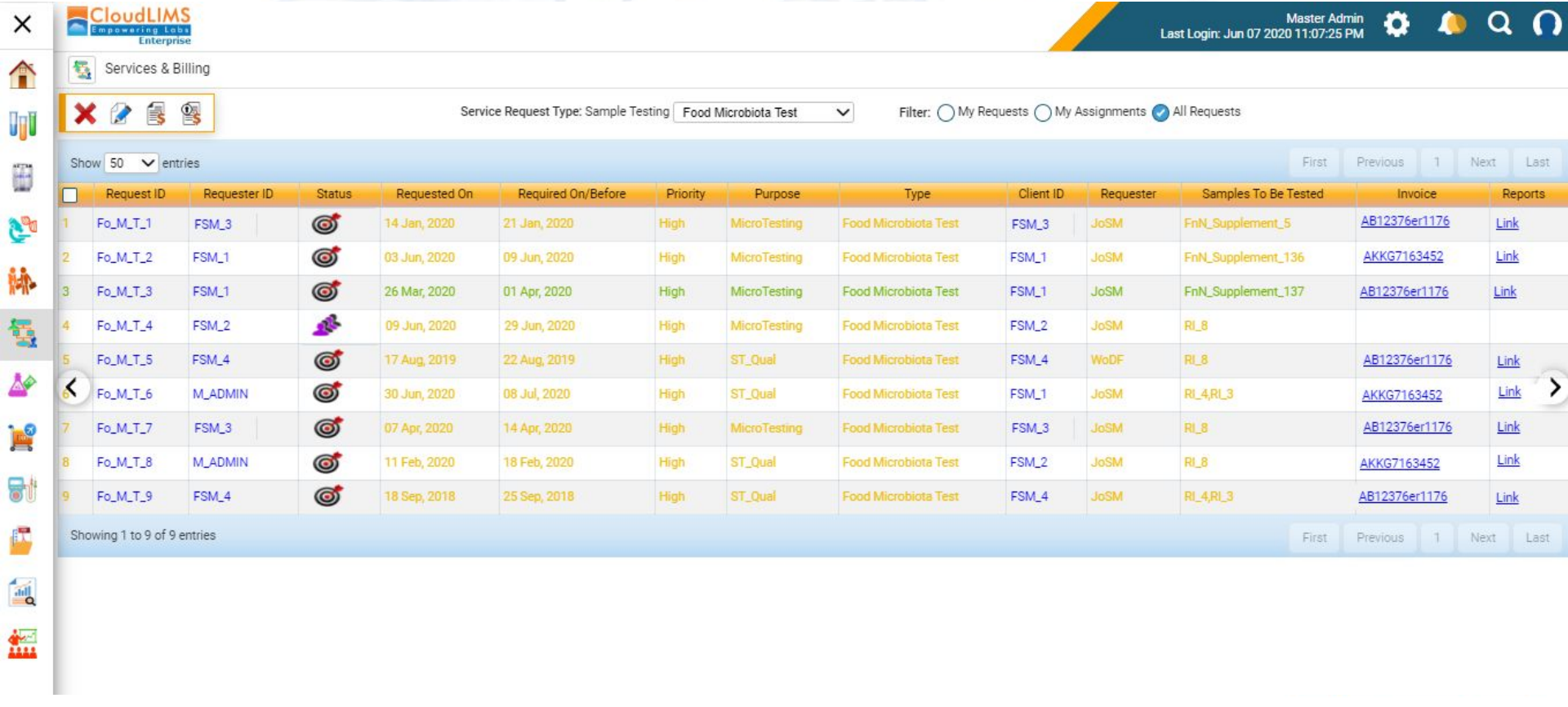
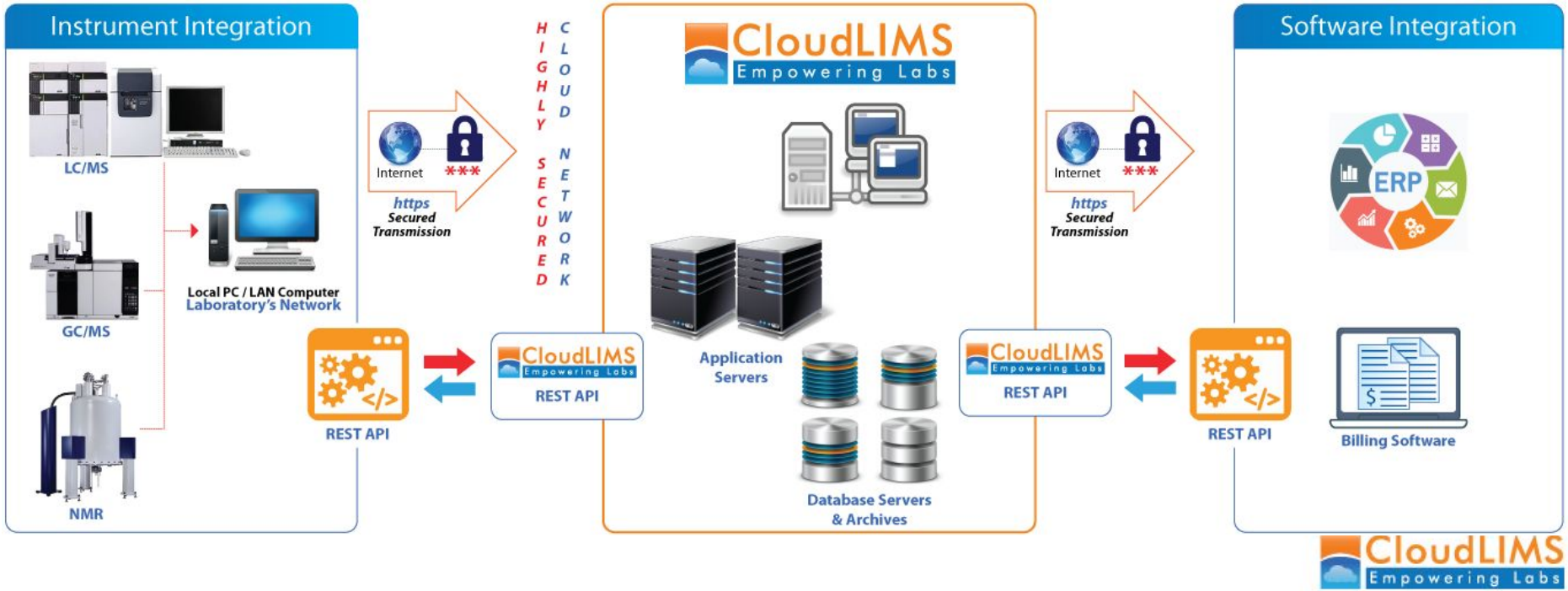
Manage Test Requests

Review the test requests received from clients



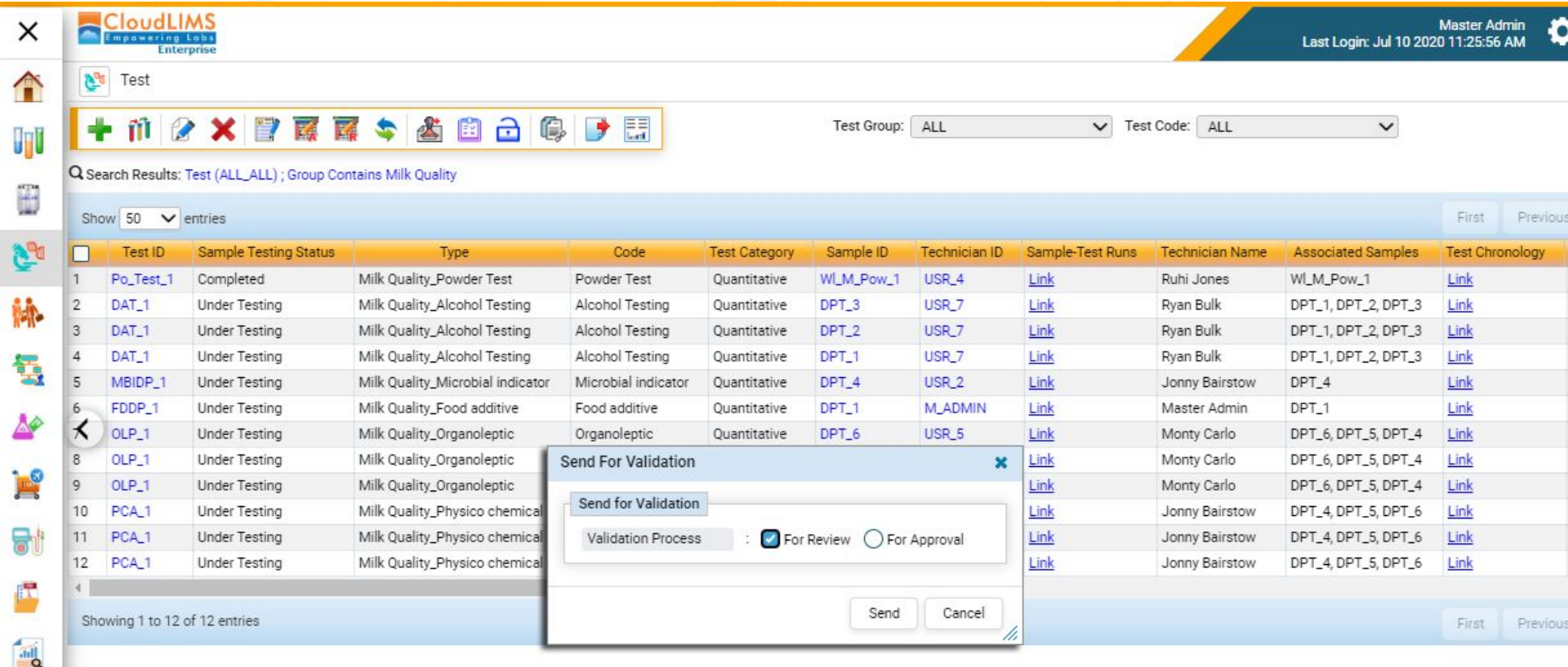
Instrument and Software Integration

Integrate with analytical instruments to automatically record analytical data, maintaining data integrity. Furthermore, a LIMS integrates with software, such as ERP, to manage day-to-day business activities.



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



Generate Custom CoAs with LIMS

MTL Certificate of Analysis

Milk Testing Lab, Plot 45, HWY 123, Leander, Texas, United States

Sample Information

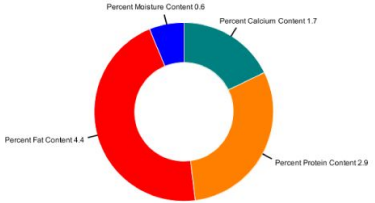
Sample ID	Status	Sample Lot ID	Type	Batch ID	Current Quantity	Current Quantity-Unit	Custodian
W_Mil_P_3	Received	EID00000030	Whl Milk Powder	WMP_012	28	ml	M_ADMIN

Test Information: Milk QC Test/ Powder Quality

Test ID	Created By	Type	Group	Code	Technician Name
Mil_P_Qua_3	M_ADMIN	Milk QC Test_Powder Quality	Milk QC Test	Powder Quality	Master Admin

Analytes and Results: Milk QC Test/ Powder Quality

Analyte Group	Analyte ID	Analyte Name	Test Run Number	Observed Value	Unit
Powder_Quality_Test	ARQNMil_P_Qua_2	Percent Moisture Content	1	0.6	%Volume
Powder_Quality_Test	ARQNMil_P_Qua_3	Percent Fat Content	1	4.4	%Volume
Powder_Quality_Test	ARQNMil_P_Qua_4	Percent Protein Content	1	2.9	%Volume
Powder_Quality_Test	ARQNMil_P_Qua_5	Percent Calcium Content	1	1.7	%Volume



Dr. Gerard Paul
Lab Director
07 Jun, 2020

Dr. Victoria Lee
Lab Manager
07 Jun, 2020

Disclaimer:
All tests are conducted by Milk Testing Laboratory and the results are duly validated.

Milk Testing Lab | www.milktesting.lab | info@mtesting.lab

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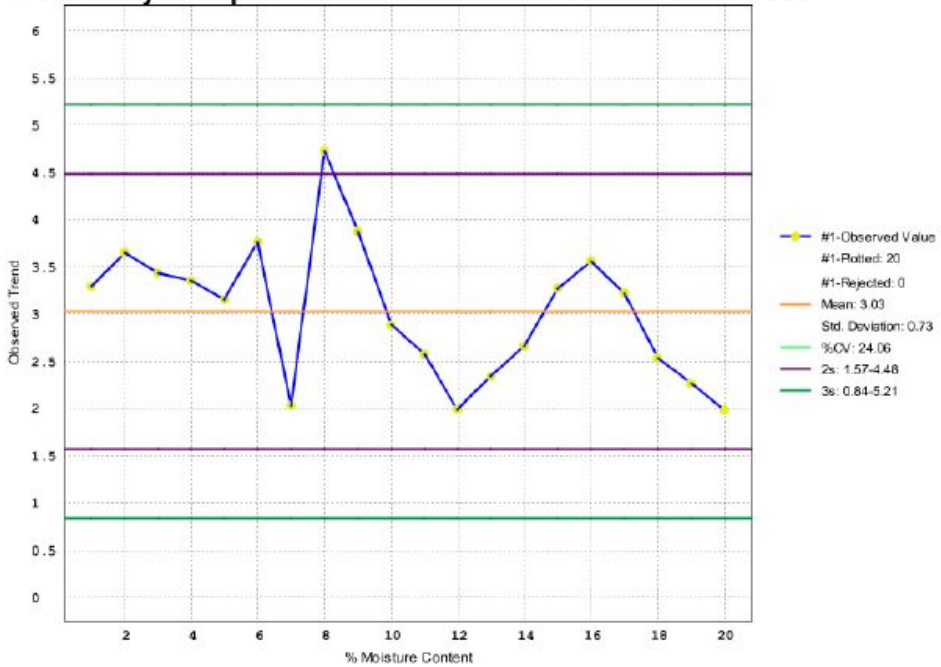
Quality Control and Trend Analysis

Manage quality control samples and their results to detect trends

Prepared By:	Dr. Hick Avantino	Printed:	18/08/2020
Analyses:	Moisture Content of Milk Powder	Client:	National Feed Test
Project:	Milk Powder QC	Matrices:	Protein-Moisture-fat
Equipment:	Chemical Analyzer, Effem Tech	Analyzed By:	Dr. Lina Sen

Trend Analysis Report - Moisture Content in Pediatric Grade Food



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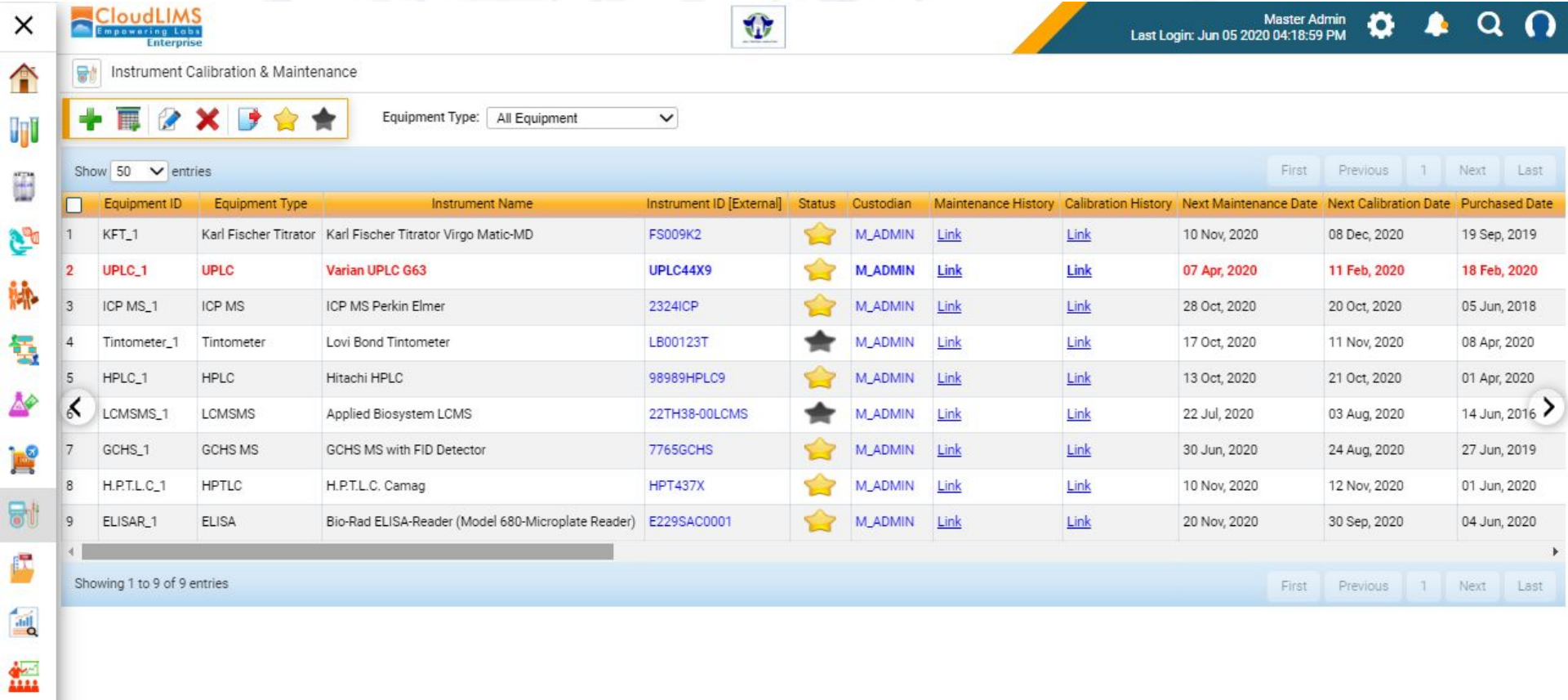
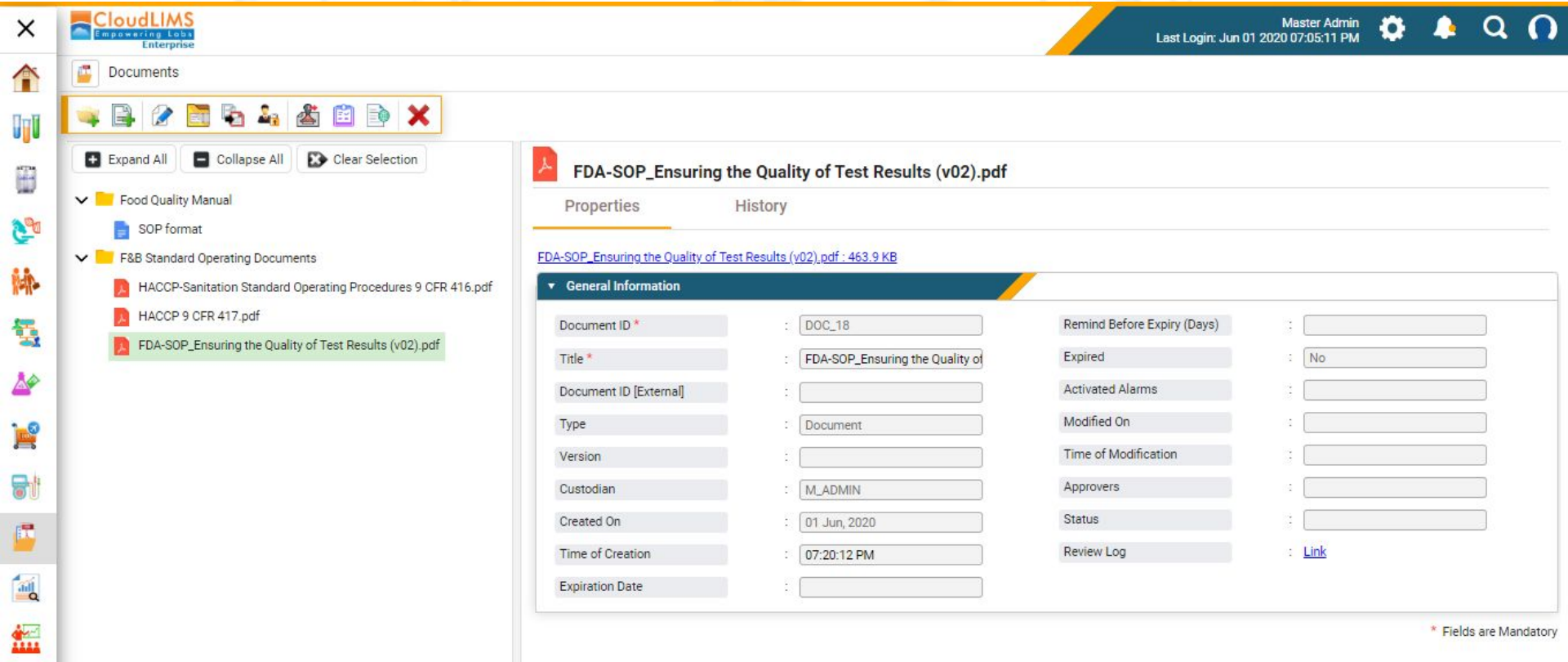
Instrument Calibration and Maintenance

Track your equipment and its components along with calibration status



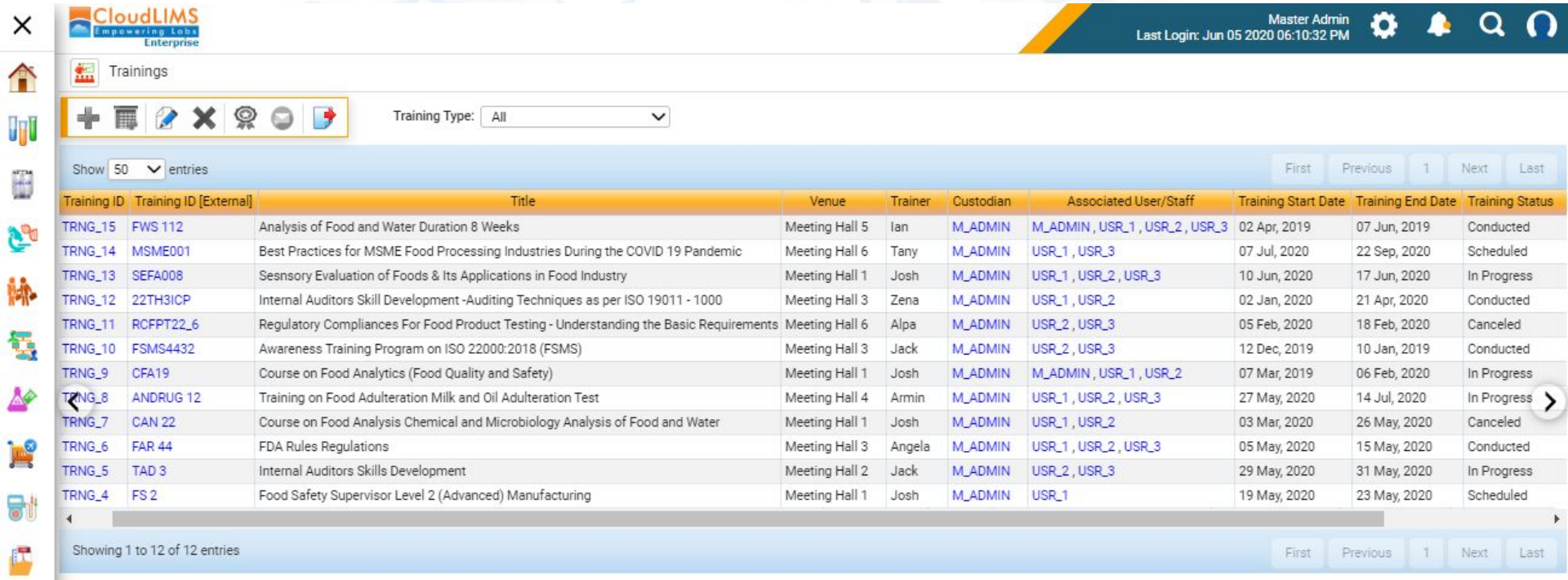
Document Management

Manage documents, such as Standard Operating Procedures (SOPs), and provide quick access of documents to all authorized users



Training Management

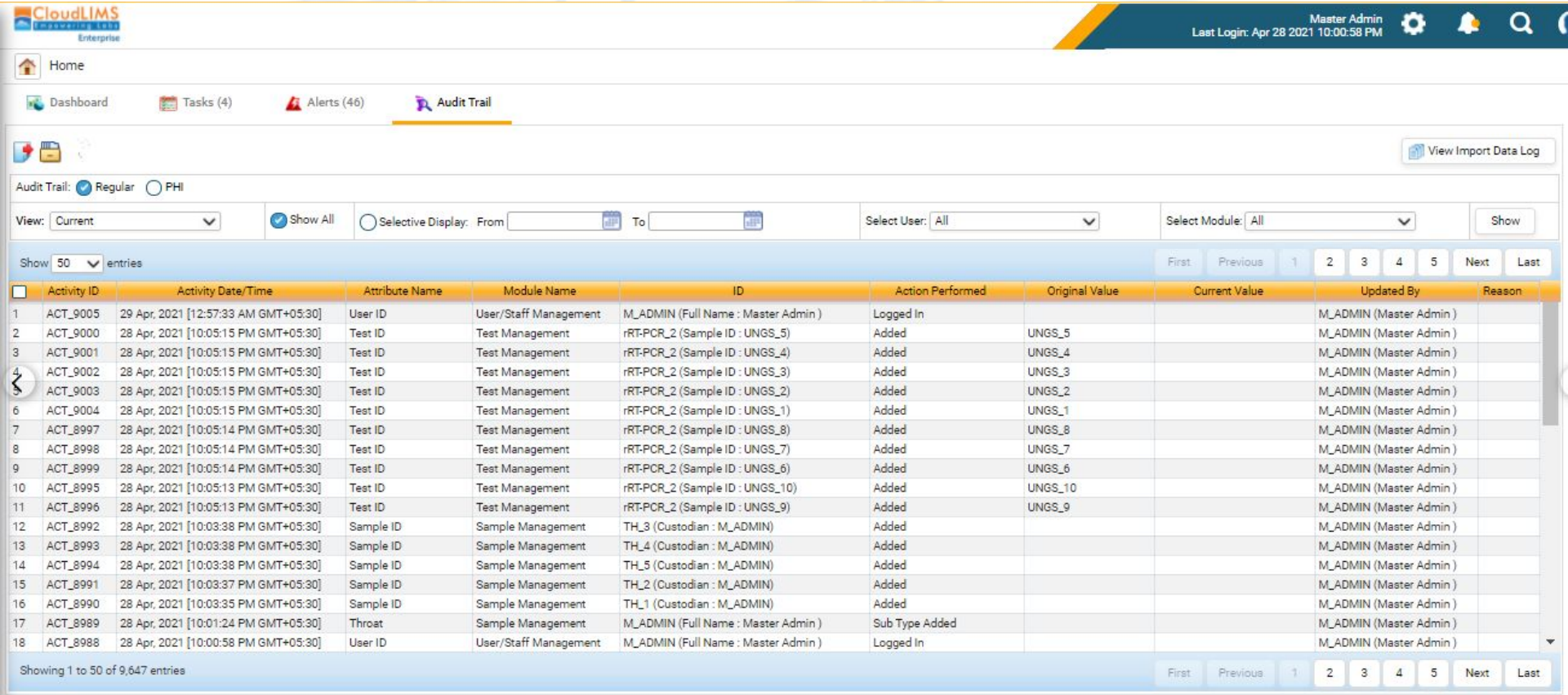
Manage staff and training records and mark their competency



Training ID	Training ID [External]	Title	Venue	Trainer	Custodian	Associated User/Staff	Training Start Date	Training End Date	Training Status
TRNG_15	FWS 112	Analysis of Food and Water Duration 8 Weeks	Meeting Hall 5	Ian	M_ADMIN	M_ADMIN , USR_1 , USR_2 , USR_3	02 Apr, 2019	07 Jun, 2019	Conducted
TRNG_14	MSME001	Best Practices for MSME Food Processing Industries During the COVID 19 Pandemic	Meeting Hall 6	Tany	M_ADMIN	USR_1 , USR_3	07 Jul, 2020	22 Sep, 2020	Scheduled
TRNG_13	SEFA008	Sesnsory Evaluation of Foods & Its Applications in Food Industry	Meeting Hall 1	Josh	M_ADMIN	USR_1 , USR_2 , USR_3	10 Jun, 2020	17 Jun, 2020	In Progress
TRNG_12	22TH3ICP	Internal Auditors Skill Development -Auditing Techniques as per ISO 19011 - 1000	Meeting Hall 3	Zena	M_ADMIN	USR_1 , USR_2	02 Jan, 2020	21 Apr, 2020	Conducted
TRNG_11	RCFPT22_6	Regulatory Compliances For Food Product Testing - Understanding the Basic Requirements	Meeting Hall 6	Alpa	M_ADMIN	USR_2 , USR_3	05 Feb, 2020	18 Feb, 2020	Canceled
TRNG_10	FSMS4432	Awareness Training Program on ISO 22000:2018 (FSMS)	Meeting Hall 3	Jack	M_ADMIN	USR_2 , USR_3	12 Dec, 2019	10 Jan, 2019	Conducted
TRNG_9	CFA19	Course on Food Analytics (Food Quality and Safety)	Meeting Hall 1	Josh	M_ADMIN	M_ADMIN , USR_1 , USR_2	07 Mar, 2019	06 Feb, 2020	In Progress
TRNG_8	ANDRUG 12	Training on Food Adulteration Milk and Oil Adulteration Test	Meeting Hall 4	Armin	M_ADMIN	USR_1 , USR_2 , USR_3	27 May, 2020	14 Jul, 2020	In Progress
TRNG_7	CAN 22	Course on Food Analysis Chemical and Microbiology Analysis of Food and Water	Meeting Hall 1	Josh	M_ADMIN	USR_1 , USR_2	03 Mar, 2020	26 May, 2020	Canceled
TRNG_6	FAR 44	FDA Rules Regulations	Meeting Hall 3	Angela	M_ADMIN	USR_1 , USR_2 , USR_3	05 May, 2020	15 May, 2020	Conducted
TRNG_5	TAD 3	Internal Auditors Skills Development	Meeting Hall 2	Jack	M_ADMIN	USR_2 , USR_3	29 May, 2020	31 May, 2020	In Progress
TRNG_4	FS 2	Food Safety Supervisor Level 2 (Advanced) Manufacturing	Meeting Hall 1	Josh	M_ADMIN	USR_1	19 May, 2020	23 May, 2020	Scheduled

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_9005	29 Apr, 2021 [12:57:33 AM GMT+05:30]	User ID	User/Staff Management	M_ADMIN (Full Name : Master Admin)	Logged In			M_ADMIN (Master Admin)	
2	ACT_9000	28 Apr, 2021 [10:05:15 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_5)	Added	UNGS_5		M_ADMIN (Master Admin)	
3	ACT_9001	28 Apr, 2021 [10:05:15 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_4)	Added	UNGS_4		M_ADMIN (Master Admin)	
4	ACT_9002	28 Apr, 2021 [10:05:15 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_3)	Added	UNGS_3		M_ADMIN (Master Admin)	
5	ACT_9003	28 Apr, 2021 [10:05:15 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_2)	Added	UNGS_2		M_ADMIN (Master Admin)	
6	ACT_9004	28 Apr, 2021 [10:05:15 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_1)	Added	UNGS_1		M_ADMIN (Master Admin)	
7	ACT_8997	28 Apr, 2021 [10:05:14 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_8)	Added	UNGS_8		M_ADMIN (Master Admin)	
8	ACT_8998	28 Apr, 2021 [10:05:14 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_7)	Added	UNGS_7		M_ADMIN (Master Admin)	
9	ACT_8999	28 Apr, 2021 [10:05:14 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_6)	Added	UNGS_6		M_ADMIN (Master Admin)	
10	ACT_8995	28 Apr, 2021 [10:05:13 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_10)	Added	UNGS_10		M_ADMIN (Master Admin)	
11	ACT_8996	28 Apr, 2021 [10:05:13 PM GMT+05:30]	Test ID	Test Management	rRT-PCR_2 (Sample ID : UNGS_9)	Added	UNGS_9		M_ADMIN (Master Admin)	
12	ACT_8992	28 Apr, 2021 [10:03:38 PM GMT+05:30]	Sample ID	Sample Management	TH_3 (Custodian : M_ADMIN)	Added			M_ADMIN (Master Admin)	
13	ACT_8993	28 Apr, 2021 [10:03:38 PM GMT+05:30]	Sample ID	Sample Management	TH_4 (Custodian : M_ADMIN)	Added			M_ADMIN (Master Admin)	
14	ACT_8994	28 Apr, 2021 [10:03:38 PM GMT+05:30]	Sample ID	Sample Management	TH_5 (Custodian : M_ADMIN)	Added			M_ADMIN (Master Admin)	
15	ACT_8991	28 Apr, 2021 [10:03:37 PM GMT+05:30]	Sample ID	Sample Management	TH_2 (Custodian : M_ADMIN)	Added			M_ADMIN (Master Admin)	
16	ACT_8990	28 Apr, 2021 [10:03:35 PM GMT+05:30]	Sample ID	Sample Management	TH_1 (Custodian : M_ADMIN)	Added			M_ADMIN (Master Admin)	
17	ACT_8989	28 Apr, 2021 [10:01:24 PM GMT+05:30]	Throat	Sample Management	M_ADMIN (Full Name : Master Admin)	Sub Type Added			M_ADMIN (Master Admin)	
18	ACT_8988	28 Apr, 2021 [10:00:58 PM GMT+05:30]	User ID	User/Staff Management	M_ADMIN (Full Name : Master Admin)	Logged In			M_ADMIN (Master Admin)	

Key Learnings

1. An overview of FSMA requirements for food testing laboratories for food safety
2. Discovering how automation enables easy retrieval/visibility of data and enhances data security
3. Learning how a LIMS drives automation & enables food testing laboratories to meet FSMA requirements with ease

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