

Pharma Solution for manufacturing QA/QC

Our goal is to provide pharmaceutical customers with a leading, comprehensive informatics solution with a low cost of ownership and high return on investment

Thermo Scientific™ SampleManager LIMS™ software's Pharma Solution is an implementation and validation accelerator which uses industry-standard features, expertise and experience to help expedite return on investment and reduce project risk.

Half of the world's top 10 pharmaceutical companies as well as Thermo Fisher Scientific's own contract manufacturing business rely on SampleManager LIMS, LES and SDMS software to drive quality, compliance and data integrity through their manufacturing QA/QC processes.



FASTER ROI

- Highly configurable, industry standard features
- Accelerated implementation through industry experience and proven methodologies
- Efficient and effective validation tools



PROVEN SOLUTION

- Successful in global pharma for over 30 years
- Training, knowledge transfer and support to ensure successful adoption
- The only solution comprising LIMS, LES and SDMS in one



LEADING TECHNOLOGY

- Integration to SAP™ and all leading Chromatography Data Systems
- Web-enabled solution
- Hosted in the cloud or on-premise

Go-live can be achieved up to 50% faster using the Pharma Solution to expedite implementation.

The Pharma Solution is built on SampleManager LIMS, SDMS and LES software, with direct CDS integration providing a complete, streamlined QA/QC solution

SAMPLEMANAGER LIMS SOFTWARE PHARMA SOLUTION	LIMS, SDMS and LES	Dashboards	Integration to SAP and PIMS	Industry standard features	Mobile and web access
INSTRUMENT INTEGRATION	Balances, pH Meters, etc.	Out of the Box CDS Interfaces (Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) software, Waters Empower™)			
VALIDATION KIT	OQ scripts and data	IQ Scripts	Trace matrix enabling risk based validation		

Pre-configured industry standard features

 <p>RETAINS</p>	 <p>REDUCED TESTING</p>	 <p>CERTIFICATES</p>
 <p>SQC</p>	 <p>REVIEW AND APPROVAL</p>	 <p>ENVIRONMENTAL MONITORING</p>
 <p>CONTENT UNIFORMITY</p>	 <p>STABILITY</p>	 <p>DISSOLUTION</p>

Simplified review and approval

The Pharma Solution includes a specially designed module to ease the QC sample review and approval process.

The module provides authorized users with a clear overview of all samples awaiting review and leverages review by exception.

The screenshot shows a software window titled 'Review'. On the left is a tree view with folders for 'JOB_000154', 'PROD_XYZ_0008_006', 'pH/1', and 'Protein Content/1'. The main area contains a table with columns: JOB_HEADER, SAMPLE, TEST, RESULT, INSTRUMENT, STOCK_BATCH, and ESIG_DATA_VIEW. Below this is a detailed table with columns: TestNumber, ResultName, Text, Units, OutOfRange, EnteredBy, EnteredOn, and Reviewed. Two rows are visible, both with 'Reviewed' checkboxes checked. Below the table is an 'Audits' section with a table of transaction logs and a summary of audit dates and user information.

TestNumber	ResultName	Text	Units	OutOfRange	EnteredBy	EnteredOn	Reviewed
2778	pH	6.3		False	PHARMA1	13/01/2020 09:21	<input checked="" type="checkbox"/>
2779	Protein Content	18.4	mg/ml	False	PHARMA1	13/01/2020 09:21	<input checked="" type="checkbox"/>

Transaction	Date	Field	Old Value	New Value	User ID	Data Reason
2005	13/01/2020 09:...	VALUE	6.2	6.3	PHARMA1	retested
2005	13/01/2020 09:...	TEXT	6.2	6.3	PHARMA1	retested
2005	13/01/2020 09:...	ENTERED_ON	9-OCT-2019 1...	13-JAN-2020 0...	PHARMA1	
2005	13/01/2020 09:...	ENTERED_BY	PHARMA1	PHARMA1	PHARMA1	
2005	13/01/2020 09:...	COMMENTS			PHARMA1	

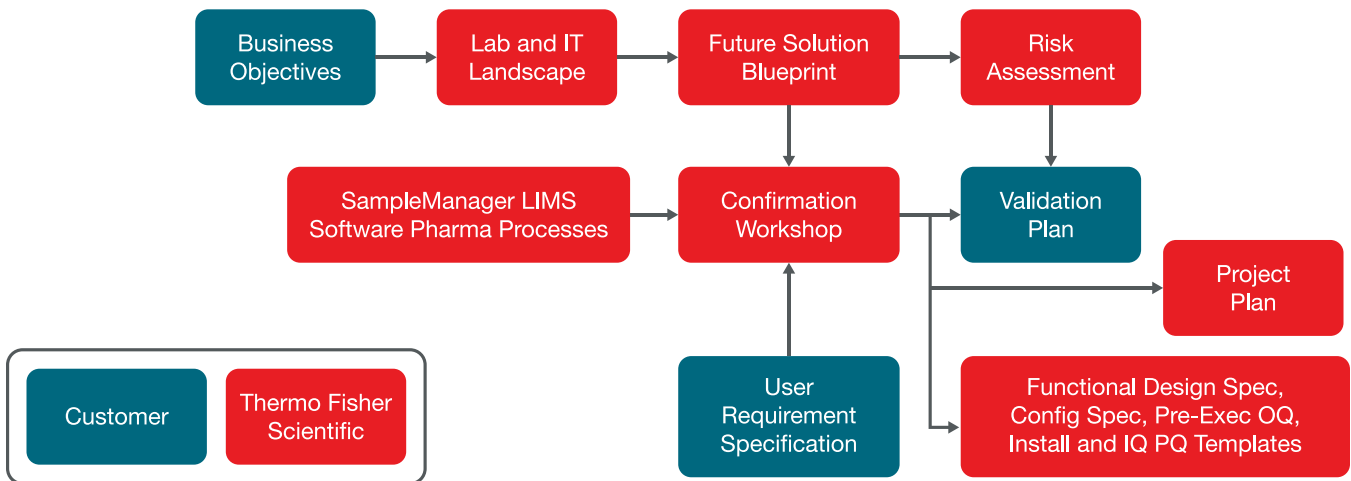
Audits Summary:
 Audit Date Start: 01/01/2019 00:00
 Audit Date End: 13/01/2020 09:25
 Reviewed by: Pharma1
 Reviewed on: 09/10/2019 12:06:48
 Review comment:

Buttons: Review, Reject, Approve

Low risk implementation

The long-established use of SampleManager LIMS software and our vast experience in pharmaceutical implementations secures project success from the outset. From requirements gathering to team selection, project management to system training, go-live and beyond,

our implementation experts have the knowledge and expertise to drive project success. Thermo Fisher's LIMS implementation experts work alongside your project team to define a project plan tailored to the needs of your organization:



Expedited validation

Thermo Fisher supply standard OQ scripts for SampleManager LIMS software, pre-executed OQ scripts for pharmaceutical features, script templates for OQ and PQ and a configured system installation kit and IQ script. Organizations can expect to reduce OQ time by 90% and PQ by up to 50%.

Validation is essential and unavoidable, but represents the greatest time-savings opportunity.

SampleManager LIMS software Pharma Solution

- Delivers industry-standard capabilities including dissolution, retains sample management and stability testing as well as a unique review module built to expedite review and approval
- Streamlines operations to help ensure consistency, efficiency & productivity across laboratories
- Has been deployed globally across 25 sites of Thermo Fisher's own contract manufacturing organization

Thermo Fisher Scientific invests significantly in digital innovation to accelerate science and improve laboratory productivity.

DATA INTEGRITY COMPLIANCE

- Review & approval module
- Pre-configured workflows control data entry and management
- Drives adherence to SOPs
- LES enforces method and analyst qualification
- Fully configurable audit trail



EXPEDITES IMPLEMENTATION

- Project work minimized
- Workflows map business processes
- Master data build toolkit
- Tailored training courses

EASES VALIDATION

- Pre-configured industry standard capabilities
- Full documentation from URS to OQ scripts
- Risk-based OQ process
- Pre-executed OQ scripts
- PQ guidelines and coaching

Find out more at thermofisher.com/digitalscience