

Laboratory software

# Pharma Solution for manufacturing QA/QC

Providing a leading,  
comprehensive informatics  
solution to expedite  
implementation

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.

75% of the world's top 20 largest pharmaceutical companies as well as Thermo Fisher Scientific's own contract manufacturing business rely on SampleManager LIMS, LES, ELN and SDMS software to drive quality, compliance and data integrity through their manufacturing QA/QC processes.

With years of experience implementing pharmaceutical LIMS around the globe, we have collaboratively developed the Pharma Solution with our team of seasoned LIMS professionals. This comprehensive solution aims to increase efficiency and encompass all the required features for both present and future requirements. The various modules within the Pharma Solution effectively address the complete pharmaceutical workflow, eliminating the need for additional customization.

**With standard industry capabilities,  
your lab can be up and running in  
less than 5 months.**

*\*Additional capabilities can be added in future*



## FASTER ROI

- Highly configurable, industry standard features and preconfigured LES methods
- Efficient and effective validation tools



## PROVEN SOLUTION

- Successful in global pharma for over 30 years
- Training, knowledge transfer and support to help ensure successful adoption
- Complete solution comprises LIMS, LES, ELN and SDMS in one

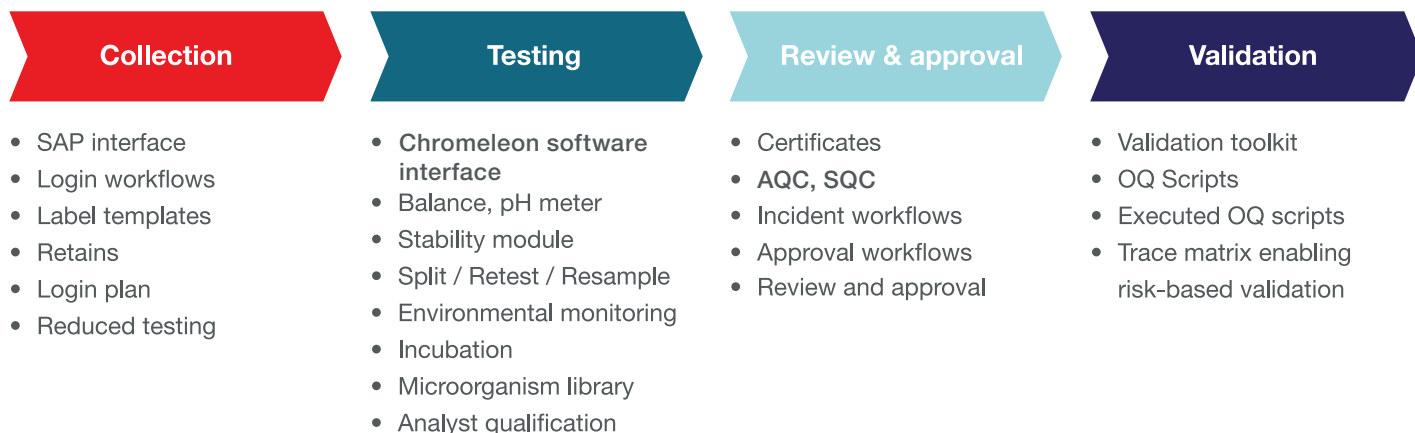


## LEADING TECHNOLOGY

- Integration to SAP™ software and all leading chromatography data systems
- Hosted in the cloud or on-premise

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

Achieve the following LIMS capabilities designed to support your pharma workflows:



**Speed implementation and drive process compliance using extended reality technology**

To expedite implementation and LES method setup, the Pharma Solution includes a set of industry standard features out of the box, as well as a set of preconfigured LES methods for common analytical tests.

	Preconfigured feature	Preconfigured LES method
Reduced testing	X	
Environmental monitoring	X	
Media management	X	
Login plans	X	
Analyst qualification	X	
Content uniformity		X
Dissolution		X
Inorganic impurities		X
Organic impurities		X
ID assay		X
Karl Fischer coulometric titration		X
Karl Fischer volumetric titration		X
Detection of impurities using HPLC		X
Loss on drying		X
Monthly balance calibration		X
Sulphated ash method		X
Volumetric water content		X

## Simplified review and approval

The Pharma Solution is designed to simplify the review and approval process. It provides authorized users with a clear overview of all samples awaiting review and leverages review by exception.

Display Name	ID Text	Analysis	Component Name	Type	Value	Units	Status
EM-LINE_1_J-04-MAR-2024-1	EM-LINE_1_J-04-MAR-202...	Listeria/1	Listeria spp.	B	Absence		E
		Salmonella/2	Salmonella	B	Absence		E
		Aerobic Plate Count/3	Aerobic Plate Count	N	0	CFU...	E
EM-LINE_1_J-03-MAR-2024-1	EM-LINE_1_J-03-MAR-202...	Listeria/1	Listeria spp.	B	Absence		E
		Salmonella/1	Salmonella	B	Absence		E
		Aerobic Plate Count/1	Aerobic Plate Count	N	0	CFU...	E
EM-LINE_1_J-02-MAR-2024-1	EM-LINE_1_J-02-MAR-202...	Listeria/1	Listeria spp.	B	Absence		E
		Salmonella/1	Salmonella	B	Absence		E
		Aerobic Plate Count/1	Aerobic Plate Count	N	0	CFU...	E
EM-LINE_1_J-01-MAR-202...	EM-LINE_1_J-01-MAR-202...	Listeria/1	Listeria spp.	B	Absence		E
		Salmonella/1	Salmonella	B	Absence		E
		Aerobic Plate Count/1	Aerobic Plate Count	N	0	CFU...	E

## Support for production of in-house media

- Produce your own in-house media and keep full traceability of samples in the lab
- Media management capabilities include support for ingredients, prepared media, containers, suppliers, stock batches and validation organisms

## Low-risk implementation

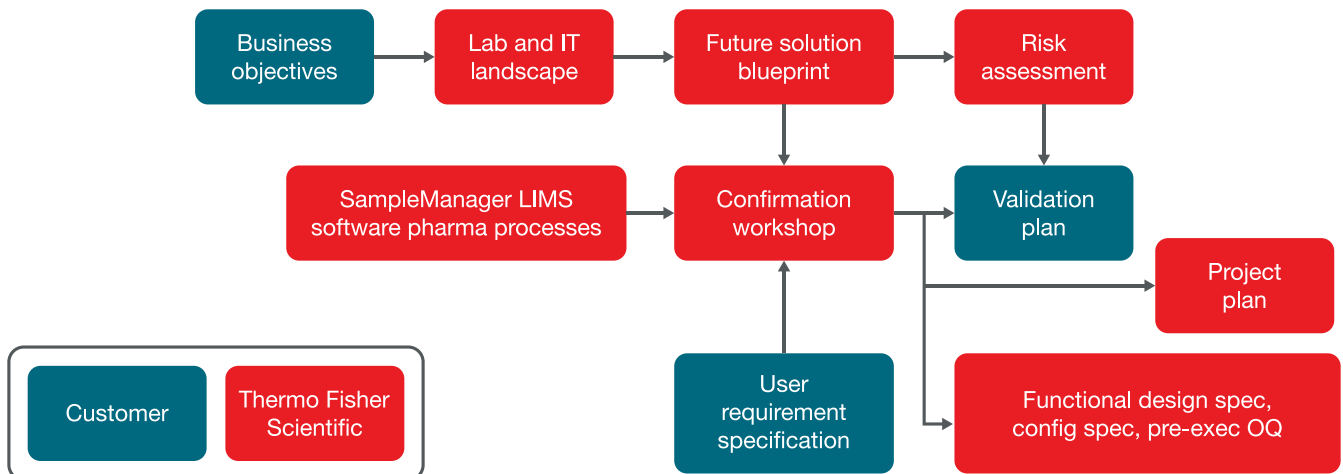
The long-established use of SampleManager LIMS software and our vast experience in pharmaceutical implementations secures project success from the outset. From requirements gathering to team selection, project management to system training, go-live

## Environmental monitoring

- Clean room monitoring support
  - Critical for pharmaceutical manufacturing to ensure ISO/EU compliance
- Personnel monitoring
- Pre-loaded ISO / EU specifications for clean room applications
- Multi-stage incubation for microbiological analysis
  - Library of common microbiological organisms
- Visualization dashboards for samples that don't meet compliance guidelines



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:



## DATA INTEGRITY COMPLIANCE

- 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
- Preconfigured LES methods

## EASES VALIDATION

- Pre-configured industry standard capabilities
- Full documentation from URS to OQ scripts
- Trace Matrix enables risk-based validation
- Pre-executed OQ scripts

### Expedited validation

Thermo Fisher supplies standard IQ and OQ scripts for SampleManager LIMS software, pre-executed OQ scripts and templates for pharmaceutical features. As a result, organizations can expect a significant reduction of OQ and PQ time with the adoption of this accelerator.

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

### Pharma Solution for SampleManager LIMS software

- Delivers industry standard capabilities on a preconfigured solution
- Streamlines operations to help ensure consistency, efficiency and productivity across laboratories
- Has been deployed globally across 25 sites of Thermo Fisher's own contract development and manufacturing organization

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

Learn more at [thermofisher.com/samplemanager](https://thermofisher.com/samplemanager)