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, ELN and SDMS software to drive quality, compliance and data integrity through their manufacturing QA/QC processes.

FASTER ROI
- Highly configurable, industry standard features
- 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 ensure successful adoption
- Complete solution comprises LIMS, LES, ELN and SDMS in one

LEADING TECHNOLOGY
- Integration to SAP™ and all leading Chromatography Data Systems
- Hosted in the cloud or on-premise
- Option to execute LES methods hands free, using Thermo Scientific™ SampleManager™ XR software and Microsoft Hololens

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, ELN and LES
- Dashboards
- Integration to SAP and PIMS
- Industry standard features and preconfigured LES methods
- Mobile and web access

**INSTRUMENT INTEGRATION**

- Balances, pH Meters, etc.
- Out of the Box CDS Interfaces (Thermo Scientific™ Chromatography Data System (CDS) software, Waters Empower™)

**VALIDATION KIT**

- OQ scripts and data
- IQ Scripts
- Trace matrix enabling risk based validation

**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 7 common analytical tests.

The LES methods can be used with or without Microsoft HoloLens connected to Thermo Scientific™ SampleManager™ XR software, for compliant, hands free operation. Enable analysts to review method instructions and record instrument readings and actions while they work.

<table>
<thead>
<tr>
<th>Preconfigured feature</th>
<th>Preconfigured LES method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retain samples</td>
<td>X</td>
</tr>
<tr>
<td>Reduced testing</td>
<td>X</td>
</tr>
<tr>
<td>Certificates</td>
<td>X</td>
</tr>
<tr>
<td>Statistical Quality Control</td>
<td>X</td>
</tr>
<tr>
<td>Review and approval</td>
<td>X</td>
</tr>
<tr>
<td>Environmental Monitoring</td>
<td>X</td>
</tr>
<tr>
<td>Stability</td>
<td>X</td>
</tr>
<tr>
<td>Media management</td>
<td>X</td>
</tr>
<tr>
<td>Content Uniformity</td>
<td>X</td>
</tr>
<tr>
<td>Dissolution</td>
<td>X</td>
</tr>
<tr>
<td>Inorganic impurities</td>
<td>X</td>
</tr>
<tr>
<td>Organic impurities</td>
<td>X</td>
</tr>
<tr>
<td>ID assay</td>
<td>X</td>
</tr>
<tr>
<td>Karl Fischer colorimetric titration</td>
<td>X</td>
</tr>
<tr>
<td>Karl Fischer volumetric titration</td>
<td>X</td>
</tr>
</tbody>
</table>
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.

Support for injectable drug and vaccine production
• Media management capabilities include support for ingredients, prepared media, containers, suppliers, stock batches and validation analysis
• Group samples within incubation locations and define and set alerts for parameters such as temperature, humidity, CO₂, and incubation time
• Manage microbial samples using a preconfigured microbiology library, with taxonomy and morphology information to enable grouping and automated name generation based on Genotype, Environment, and Microbiome interactions
• Clean room monitoring according to ISO standards with any actions based upon the clean room grade
**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:

![Implementation Diagram]

**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 and preconfigured LES methods, plus a 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 development and 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
- Directly record actions and instrument readings as you work using SampleManager XR software

**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
- Risk-based OQ process
- Pre-executed OQ scripts
- PQ guidelines and coaching

Find out more at [thermofisher.com/digitalscience](http://thermofisher.com/digitalscience)