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Informatics

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Thermo Fisher Scientific Demonstrates new SampleManager LIMS functionality for ISO 17025 at Analytica 2008

PHILADELPHIA, Penn., March 25 2008 – Thermo Fisher Scientific Inc., the world leader in serving science, will introduce new functionality to its flagship SampleManager LIMS that facilitates compliance with the requirements of ISO 17025: 2005. Thermo Scientific SampleManager LIMS may be seen on booths 104 and 105/204, Hall B1 at Analytica 2008, Messegelände Munich, from April 1 – 4, 2008. SampleManager LIMS (Laboratory Information Management System) is Thermo Fisher's premier product for industrial laboratories that increases productivity, improves access to data, and ensures compliance with regulatory requirements.

The 2005 release of ISO 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*, covers laboratories using standard, non-standard, and laboratory-developed methods. It is applicable to all organizations performing tests and/or calibrations, and laboratories where testing and/or calibration forms part of inspection and product certification. This international standard is the accepted standard for analytical laboratories in developing their management system for quality, administrative and technical operations. Thermo Scientific SampleManager LIMS benefits management by providing them with a centralized system to access data and extract information, allowing them to more effectively manage their laboratory operations. SampleManager LIMS provides evidence and documentation that organizations are in compliance with ISO 17025.

Thermo Scientific SampleManager facilitates compliance in two principle areas of ISO 17025 (Section 4 Management Requirements, and Section 5 Technical Requirements). SampleManager's enhanced functionality covers a broad range of requirements, including validation of methods, instrument calibration; sampling, control of non-conformance testing and reporting of results.

To respond to the **Management Requirements** of ISO 17025, SampleManager addresses the security required for laboratories conducting testing in their "permanent facilities, at sites away from permanent facilities, or in associated temporary or mobile facilities", by providing for full security controls, including "group security" which can be used to segregate work from different clients or in different laboratory areas.

In addition, the laboratory's Quality System procedures are easily stored in SampleManager LIMS for reference at any time by relevant personnel, meeting requirements of ISO 17025 that each laboratory "establish, implement and maintain a quality system", including a documentation of the scope of activities, all policies and procedures, as well as results.

To properly meet ISO 17025 requirements regarding the “control of non-conforming testing and/or calibration work”, SampleManager has built-in functionality for incident management and statistical analysis of both calibration standards and sample results. SampleManager also automatically maintains all electronic records and makes them available for either reviewing or reporting, and has built-in archiving, which allows for the removal of older records once their retention period has expired. Full audit trail facilities are standard for SampleManager, allowing full traceability of the personnel and the procedures that were entered. These built-in capabilities for SampleManager allow laboratories to more easily review the lab’s quality system by having ready access to all incidents, corrective actions, non-conforming results and other events.

To address the **Technical Requirements**, SampleManager has built-in functionality to handle environmental monitoring, a critical component of laboratory compliance with ISO 17025. Within SampleManager, environmental monitoring of key areas of the laboratory can be scheduled on a routine basis. Certain instrumentation can be connected via SampleManager’s Instrument Manager, and data collected and logged at periodic intervals.

Validation of methods is a critical ISO 17025 requirement, for which SampleManager has built-in functionality to allow lab managers to be in continuous compliance. SampleManager’s Batch Management functionality provides analytical QA/QC support, including automatic and interactive sample assignment according to pre-defined templates.

Equipment and Instrument calibration, also an important part of ISO 17025, is managed by SampleManager through Instrument Calibration Scheduling, allowing the LIMS to prevent the use of any instrument that is past its calibration due date. SampleManager provides reporting that indicates instruments out of compliance or needing calibration.

Finally, to comply with ISO 17025 Reporting requirements, SampleManager’s existing functionality includes a powerful and flexible report writing, making it possible to create any report format required by the laboratory, and including any data stored within the SampleManager database.

For more information about Thermo Scientific informatics solutions, please visit **booth 105/204**, hall B1 at Analytica 2008 in Munich. Alternatively, please call +1-866-463-6522, e-mail marketing.informatics@thermofisher.com or visit www.thermo.com/informatics.

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