

Pharmaceutical Compliance Consulting Services

Helping Business Resolve Regulatory Issues

Thermo Electron now offers the experience and expertise of the LMSi consulting group for a wide range of compliance services. The LMSi team has extensive expertise in laboratory and manufacturing compliance consulting coupled with broad industry experience in identifying and solving the compliance problems in FDA-regulated environments.



Consulting Capabilities

- Laboratory audits and corrective action plans addressing cGMP/cGLP deficiencies
- Laboratory conversion (to cGMP status) and relocation
- Technology transfer
- Root cause analysis and tools
- Current FDA operational compliance thinking (cGMPs, cGLPs, methods validation, documentation, inspectional approaches)
- Review corporate quality and operational organizational structures
- Prepare and review Chemistry, Manufacturing and Controls sections of New Drug Applications
- Assist in preparing responses to deficiency letters
- Expert opinion

Information Technology Capabilities

- IS validation systems development
- Data system operations audits and recommendations
- Risk-based 21 CFR Part 11 validation
- Network qualification
- SOPs, procedures, validation policies
- Bench top laboratory data systems validation
- Personnel placement through development and implementation phases

Compliance Services for Laboratory Instruments

A flexible Approach to Meet Customer Needs

Thermo Electron Corporation now offers the experience and expertise of LMSi (Laboratory Management Systems Inc.) to perform a full range of compliance services for most makes, models and types of equipment in the typical lab. The LMSi team has built a reputation for customizing programs to meet unique customer requirement with a flexible approach that provides field-tested procedures or utilizes the customer's own internal procedures. LMSi operations are built around stringent adherence to GMP compliance processes and procedures - just like a regulated pharmaceutical lab. In fact, customers are encouraged to perform periodic quality assurance audits to document that the highest standards are being met. LMSi's root cause committee tracks, trends and identifies all out of specification and deviation events.



Instrument Services Offered

- Instrument Qualification (IQ/OQ/PQ)
- Preventive Maintenance (PM)
- Repair
- Demand Service
- Relocation Services
- Metrology

Major Instruments and Equipment Supported

- HPLC systems
- Dissolution
- GCs/Headspace
- UV/Vis Spectrophotometers
- FTIRs
- TGA/DSC
- Robotics
- Other

The Thermo Advantage

Partnering with Thermo provides the security of working with a global, financially stable instruments company committed to serving life and analytical science customers. The Thermo advantage includes providing a "single source" for the compliance needs of your multiple-technique laboratory. With expertise in laboratory sciences and regulatory compliance, Thermo's professional services staff is one of the largest in the industry working from field locations around the globe.



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