STREAMLINING QUALIFICATION PROTOCOLS IMPROVES LABORATORY EFFICIENCIES AND GREATLY REDUCES COMPLIANCE RISK

The Measure of Confidence

Pharmaceutical

Labs are filled with various instruments from an array of manufacturers. Each instrument carries its own equipment qualification protocols, which can mean tedious management of multiple compliance vendors and valuable time spent approving, completing, and reviewing handwritten reports.

Agilent Enterprise Edition streamlines compliance procedures across a lab, site, or company to save time and money with a solution that’s compatible with instruments from all leading vendors. It’s the world’s most advanced equipment qualification product with a proven track record for improving consistency, accuracy and efficiency. Agilent Enterprise Edition provides a harmonized approach to compliance, with a single protocol across laboratory systems. For MSD, located in Swords, Ireland, the implementation of Enterprise Edition has allowed the company to consolidate qualification protocols for a more audit-ready laboratory.

CHALLENGE

Historically, MSD in Swords utilized a highly intensive, manual process as their approach to laboratory compliance. Like many pharmaceutical companies, chromatography compliance was typically delivered by the Original Equipment Manufacturer (OEM). This involved reviewing and pre-approving paper-based documents — over 30 for the chromatography systems. All documents were completed manually, consuming numerous hours of highly qualified laboratory time. Additionally, compliance was greatly compromised by the increased possibility of transcription errors and data integrity concerns inherent in a manual-based approach.

“With Agilent, we have now designed a compliance package that is perfect for our laboratories’ requirements — a customized approach that reflects our unique needs. Agilent has provided us with the flexibility to align with FDA guidelines regarding range or use. Auditors have been very impressed with the approach we have taken to compliance with Agilent.”

— Clair Mannion, QC Manager, MSD in Swords, Ireland

Old with Agilent

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<td>Multiple Service Providers</td>
<td>Single Compliance Partner</td>
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MSD in Swords recognized these impressive benefits from creating a harmonized approach to compliance with Agilent.
SOLUTION

By working with Agilent as a consultative compliance partner, MSD engaged in a collaborative exploration to find a better way of ensuring laboratory compliance. Instead of considering chromatography compliance requirements on a system-by-system basis, MSD took a holistic approach by instituting Enterprise Edition from Agilent. The solution enabled MSD to use a single protocol to cover their entire QC chromatography compliance needs — streamlining the previously arduous process.

One of the clear differentiators of Agilent Enterprise Edition was the Automated Compliance Engine (ACE). This fully automated software platform enabled full system-level qualification in a simple, comprehensive service. Benefits of the software platform and process included:

• A MSD specific compliance package developed to incorporate the full range of use across all methods used in MSD.
• Time saving compliance procedures and qualification protocols across many manufacturers.
• Flexibility to use any data system allowing for chromatography data capture with complete traceability.
• Increased consistency and accuracy that simplified qualification, minimized risk, and saved money.

RESULTS

Implementing the Agilent Enterprise Edition Compliance produced significant benefits for MSD in Swords:

• Streamlined Protocols – from 30 to 2 Equipment Qualification Protocols (one for HPLC; the other for GC)
• Data System Compatibility – calculating test results from the original digital data regardless of the laboratory CDS
• Reduced Costs – fewer hours of costly downtime from faster, more efficient review and approval processes
• Harmonized Approach to Compliance – single protocol across laboratory systems