Agilent Case Study: Pharmaceutical

Harmonized Qualification Protocols Minimize Compliance Risk and Instrument Downtime

The global regulatory focus on data integrity means that pharmaceutical companies are making improvements in the data integrity of laboratory operations a high priority. Against this, many companies are unsure how to interpret and implement compliance to the new United States Pharmacopeia (USP) general chapter on AIQ, <1058>. The 2017 version of <1058> integrates AIQ with Computer System Validation (CSV) requirements, which are aligned to GAMP Guide "A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems" (second-edition, ISBN 978-1-936379-48-4).

As uncertainty increases, it becomes harder to maintain calibrated tools, certified reference materials, and the specialist knowledge to use them correctly. Many companies are turning to trusted compliance partners with whom they can collaborate efficiently and effectively.

Agilent compliance services use Agilent Automated Compliance Engine (ACE) software to satisfy the most stringent regulatory requirements. Agilent engineers deliver instrument qualification services using ACE to some of the most demanding pharmaceutical customers, including laboratories that are regulated by the US Food and Drug Administration (FDA), USP, Environmental Protection Agency (EPA), and even directly to many laboratories within regulatory agencies. The reliable, efficient, and confident qualification services provide minimized regulatory risk and enable faster time-to-market.

In this case study, we will discuss how **Agilent's Compliance solution facilitates streamlined regulatory reporting which in turn enables pharmaceutical products to reach the market faster.**

"Agilent compliance services minimize instrument downtime, while the expertise of the Agilent customer service engineers brings trust, confidence, and the competence to discuss instrument applications and best practices. The high quality of the Operational Qualification protocols influences the purchase of our new instruments."

- QC Manager at an independent, family-run pharmaceutical firm

Old	with Agilent
Multiple Service Providers	Single Compliance Partner
Vendor Specific Compliance	Harmonized Compliance
Individual System/ OEM Protocols	Harmonized Protocols

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Trusted Answers

The Challenge

Most pharmaceutical companies perform analytical development work and Quality Control (QC) analysis to test products for sale.

For their HPLC and GC instruments, the pharmaceutical company at the heart of this case study relied on Original Equipment Manufacturers (OEM) for support with maintenance, repair, and qualification. **Their laboratories contained instruments from various manufacturers, the OEM qualification protocols and reports had different formats, content and even contrasting scientific rationale for the test performed.**

The time required to understand, review, and approve these different qualification documents meant it took longer to return instruments to production use after qualification, repair or maintenance. Without "spare" equipment, instrument downtime placed a strain on laboratory services. They had to do extra qualification work to ensure instruments are qualified for their full range of laboratory use. This increased downtime further and wasted valuable laboratory resources.

The Solution

The pharmaceutical company developed trust and confidence in the range of support services Agilent can provide as a compliance partner. Agilent has significant experience in laboratory compliance and in applying ACE qualification protocols across instruments from different manufacturers. This harmonizes the diverse OEM approaches.

Additionally, Agilent continues to focus on customer needs and is closely involved in supporting compliance harmonization through active involvement in GAMP and USP <1058> updates. **At the laboratory, Agilent compliance services using ACE software increased reliability and reduced downtime during instrument qualification.**

A **full electronic report** is immediately available after the Operational Qualification (OQ) work is completed. This is ideal for the rapid sample turnaround the lab needs and its customers demand. **Agilent personnel manage all qualification testing to enable laboratory staff to focus on science, project execution, and customer satisfaction.**

When the pharmaceutical company needed to relocate its laboratory systems, it turned to Agilent to serve as project manager and provide qualification services upon re-installation. Analysts in the lab rely on the experience and expertise of Agilent customer service engineers for advice on instrument applications, and to augment HPLC and GC training courses.

The Results

Working with Agilent as a trusted compliance partner brings significant benefits to the pharmaceutical company.

- **Reduced downtime** for qualification of GC and HPLC instruments
- **Faster compliance approvals** using Agilent all-electronic qualification reports
- **More resources focused on science** with Agilent experts performing qualification tests
- **Faster turnaround** of customer samples with unmatched confidence in results
- **Hassle-free laboratory relocation** that relies on Agilent project management, installation, and qualification expertise
- **HPLC and GC training** that increases laboratory analyst competence and efficiency
- **Harmonized approach to streamline qualification** across all HPLC and GC instruments, regardless of manufacturer
- **Meeting regulatory requirements** and regulations

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