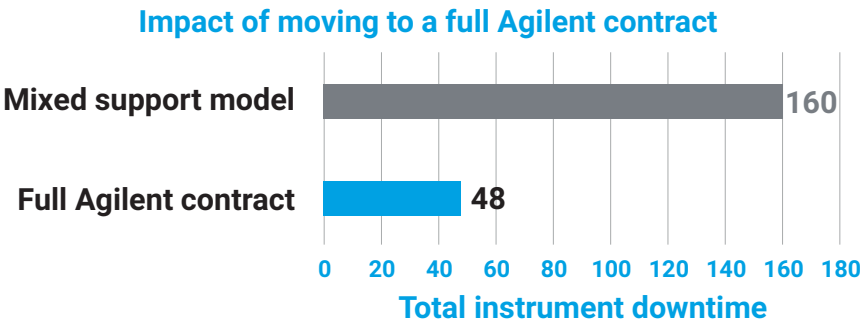
Agilent case study: Pharmaceutical

Move Away from Spreadsheets to Reduce Costs and Data Integrity Risk

Regulatory focus on data integrity is challenging laboratories to re-think their analytical workflow and question their use of Microsoft Excel spreadsheets for compliance work.

Use of spreadsheets for qualification work adds costs and data integrity risks,[1] at a time when laboratories are struggling to balance improving productivity with reducing risks. When a busy Contract Development and Manufacturing Organization (CDMO) contacted Agilent to see how we could help them reduce their costs and move away from Excel spreadsheets, we accepted the challenge.

The CDMO provided a range of bespoke services to small and mid-size pharmaceutical and biotechnology companies, from facilities in Europe and across the US, with approximately 1,000 employees. Historically, qualification work was performed in-house by the site metrology team, with the instrument vendor providing repairs and maintenance. This mixed support model created excessive instrument down-time, constraining laboratory productivity. The benefits of moving to a full Agilent support contract were significant for the 32 HPLC instruments in a European site:



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By moving to Agilent, the site gained over 100 additional days of instrument availability.

Laboratory management asked Agilent to compare the impact of moving to a full instrument service contract, with the current workflow. Agilent were able to compare the qualification work performed in-house with the Agilent Recommended qualification services. A key part of this initiative was for Agilent to compare workflows and perform a detailed cost comparison between the two options, including all the hidden costs associated with in-house qualification work.

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The customer challenge

Regulated laboratories such as those in the pharmaceutical industry must perform analytical instrument qualification to document that instruments remain suitable for intended use.

The CDMO company at the heart of this case study was having instrument qualification performed by an in-house metrology team. However, the in-house metrology team was not aware of the data integrity risks associated with the use of Microsoft Excel or the full hidden costs associated with performing qualification work in-house, such as the purchase, preparation, and management of reference solutions, keeping compliance tools calibrated, document management, and staff training to ensure that compliance and instrument knowledge remains current.

Because internal change is hard to implement, laboratory management asked Agilent to compare their current qualification with what Agilent would provide.

The Agilent solution

Agilent carried out a detailed review and comparison between the qualification being performed by the metrology team using Microsoft Excel and the Agilent-recommended qualification service that Agilent provides, using ACE. Note that the Agilent ACE qualification platform uses electronic qualification protocols, which support end-to-end data traceability and, when required, support protocol configuration to ensure that user requirements are satisfied. This facilitates compliance to the new USP general chapter <1058> on Analytical Instrument Qualification and ensures data integrity compliance.[1]

A core part of the review included a detailed cost comparison between the two approaches and was based on information provided by laboratory management.

The results

Working with Agilent as a compliance partner, the laboratory transitioned to Agilent for analytical instrument qualification, as well as repair and maintenance services.

This change resulted in several significant benefits for the laboratory:

- **Reduced costs by 13%** compared to in-house costs
- **Reduced instrument down-time by 70%** compared to the in-house model
- **Reduced data integrity risks** by moving away from use of Excel
- **Simplified workflows** with end-to-end data traceability and 21 CFR Part 11 compliance
- **Freed up the metrology team** to concentrate on other quality initiatives

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References

1. What Has Changed with the 2017 Version of USP <1058>, *Agilent Technologies white paper*, publication number 5991-9418EN, 15 November **2019**.
2. Analytical Instrument Qualification, Comparison of Qualification Approaches Across Electronic, Excel, or Paper-Based Protocols for HPLC, *Agilent Technologies technical overview*, publication number 5994-0506EN, 15 November **2019**.
3. Insights from Global Compliance Services Survey, *Agilent Technologies*, publication number 5994-1752EN, February **2020**.

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