Agilent Case Study – Pharmaceuticals

Merck Pharmaceutical Site Accelerates Software Implementation and Validation

Using Agilent Validation Starter Kits

Agilent CrossLab
From Insight to Outcome

Merck enhances laboratory automation and speeds up software validation using the Agilent Validation Starter Kit and Consultancy Services

The regulatory focus on Data Integrity is driving many laboratories to upgrade their analytical technologies and software applications to ensure that they can:

- Benefit from new functionality/key features
- Decrease reliance on manual/paper-based workflows
- Enhance security, data integrity and increase automation

However, the regulatory requirements to validate software for intended use within the lab can represent a significant compliance workload. Unless addressed, this workload is a potential barrier to labs upgrading or implementing new software.

Business needs to upgrade software expansion of analytical capability

Merck Arklow provides expertise in the manufacture and delivery of over 55+ finished products and the development of new products for international clients. The on-site laboratory provides analytical support, in addition to a range of contract analytical services, including method development and validation, quality control and stability testing and testing to USP, PhEur, BP, and customer requirements-pharmacopendial certification[2].

This portfolio creates a very high workload in the analytical laboratory, which needed to expand its analytical capacity to:

- Continue to satisfy customer release deadlines
- Enhance support for New Product Development
- Meet growing analytical service requirements
- Support high demand finished product testing – for Covid 19 related vaccine materials

Analytical services are provided using a range of Agilent Technologies chromatography instruments, including HPLC, UHPLC, GC, and HS-GC based instruments.

Merck Arklow (Sigma Aldrich Ireland Limited) is an affiliate of Merck KGaA, Darmstadt, Germany. The site is FDA and HPRA inspected and approved to work to ICH Q7, supplying commercial and late-stage APIs.

The combined use of an Agilent Validation Starter Kit with Compliance Consultancy simplified the validation burden and reduced the implementation timeline by approximately 60% for a Chromatography Data System (CDS).

"The real-time support provided by Agilent consultants involved in deployment and CSV was superb and effective in delivering upon the expectations of the Merck Arklow site"

David Mythen[1]
Quality Engineer Technology Lead

Agilent

CSV resource challenge

Merck Arklow laboratories pro-actively identified the need to update their Chromatography Data System (CDS) to meet increased customer demand. The site targeted introduction of Agilent Technologies OpenLab CDS to facilitate the implementation of:

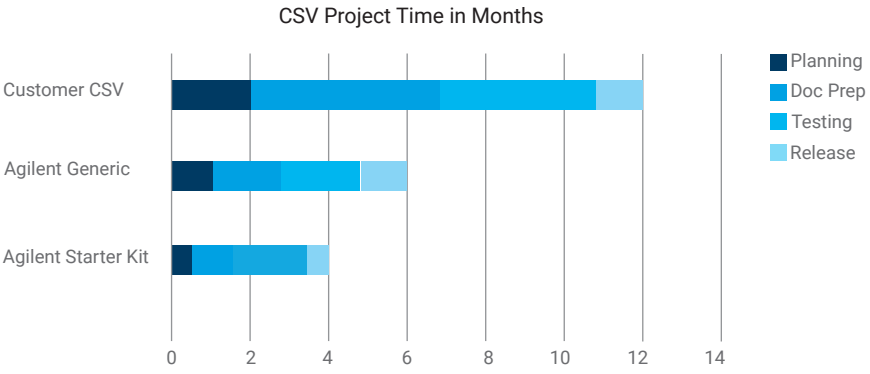
- Enhanced analytical capability
- OpenLab CDS functionality
- Newer, more robust hardware

However, because the site was already implementing several resources dependent GxP applications on-site, a dedicated site resource was not available to develop the suite of validation documents required.

Use of Agilent Validation Starter Kit

Merck Arklow wanted to know how Agilent could help reduce the CSV workload associated with validating software and workflows for intended use – an essential requirement to satisfy data integrity guidance[3, 4].

The site identified the need to utilize Agilent Validation Starter Kits, and Compliance Consulting Services, which can typically reduce the software validation timeline by 50 % or more[5]:



Advantages of Agilent CSV Services

The collaboration provided by working with Agilent ensured end-to-end execution of a CSV project against tight timelines, with minimal impact on a busy laboratory workload.

The project covered installation through to PQ testing and final system release, and included:

- Advice on data migration options
- Execution of user acceptance tests and finalizing IQ OQ protocols
- Hands-on support for PQ testing
- Project management support throughout
- Training, knowledge transfer and support to configure starter kit templates to specific site requirements

This collaboration delivered a CSV project which:

- Exceeded site and company expectations
- Provided long-lasting knowledge sharing
- Successfully deployment of OpenLab CDS, with full computerized system validation

1 Agilent CrossLab Ranked #1 in Compliance Services Again

Per independent surveys

References

1. David Mythen, Quality Engineer Technology Lead, Merck Arklow.
2. Arklow Facility Overview.
3. FDA Guidance for Industry, Data Integrity and Compliance With Drug CGMP, Final Guidance, December 2018.
4. MHRA 'GXP' Data Integrity Guidance and Definitions, March 2018.
5. Reducing Time to Achieve a Compliant Validation, Agilent publication 5991-9463EN, August 2021.

For further information on Agilent Compliance Services visit us at:
www.agilent.com/chem/crosslab-compliance-services

DE02695105

Published in the USA, March 07, 2022
5994-4407EN

Agilent
Trusted Answers