



CLIENT CASE STUDY

Computerised system validation for the facility & asset management digitalisation program

Expleo is ensuring one of the leading pharmaceutical groups in the world's IT systems for facility & asset management (FAM) and other systems are validated and consistent to comply with health regulations worldwide.



Pharmaceutical & Life Sciences



4 Expleo experts involved



Programme duration: 2021 to 2024



Around 20 sites worldwide benefiting from Expleo's services



Ensures no audit findings during inspections

Project background & challenge

Expleo has been working with one of the leading pharmaceutical groups in the world, since 2008 on various IT systems projects. In 2021, this client asked us to provide validation lead experts to ensure their IT systems for FAM and other systems are and remain compliant with the FDA and other health authorities regulations throughout sites worldwide. The global FAM program started in our customer's main facility in Germany and will be rolled out worldwide to about 20 sites, with several facilities to be maintained.



In the highly regulated pharmaceutical industry, ensuring consistent standards of compliance and safety in the company's global production sites is essential. With geographical variations based on different regulations (depending on local health authorities), our customer wanted to ensure worldwide transformation of business processes and data from local systems into one global ERP system, with correct data migration from source systems to target systems. Moreover, the customer needed some resources and expertise in validation and testing in some areas and we helped him to face this challenge. Raising awareness about the regulated patient-safety environment to all project members, as well as ensuring the digital facility & asset management system is compliant and does not fail inspections or external audits by health authorities and customers was key. We also had to create robust documentation to implement consistent standards throughout manufacturing sites.

Solution

Working with external consultants and contractors fully integrated within various customer's teams and organisations to fulfill the project demands, Expleo's diverse skills and experience of complex project management means we can offer a full array of services, from validation leads to test coordination, quality control, data migration experts, creation and execution of risk and data integrity assessments, documentation reviews (for URS / FS / TC / SOP), etc. As experts in computerised system validation (CSV) we provide consulting for software validation according to pharmaceutical standards (GxP, GAMP5, FDA). We also provide SAP Solution Manager trainings, tester trainings, data integrity trainings and the creation of regulatory operating procedures to be followed in production. Change management is a large part of the task, as well as creating systems for documentation relevant for health authorities and inspections of production systems.

Outcome

Digitalising and centralising facility & asset management can get more processes and systems implemented and reduce paper-based workflows. Expleo's deep knowledge of the internal customer processes in software development over the years is resulting in a uniform delivery of services and documents creation with continuity in the services and quality provided. Our validation leads ensure that the computerized systems get validated in time and on budget.



“I have been working in IT from the very beginning as Developer, Tester and Manager for almost 27 years in the pharmaceutical industry. Applying my knowledge to this industry is challenging and rewarding. The client is satisfied with the work that my team and I are delivering, and after several years working for them, there are good opportunities to extend the contract.”

Thomas Heimsath,
Quality Assurance Manager, Expleo

For further information, or if you have any other questions, please write an email to info@expleogroup.com

Think bold, act reliable
expleogroup.com

(expleo)