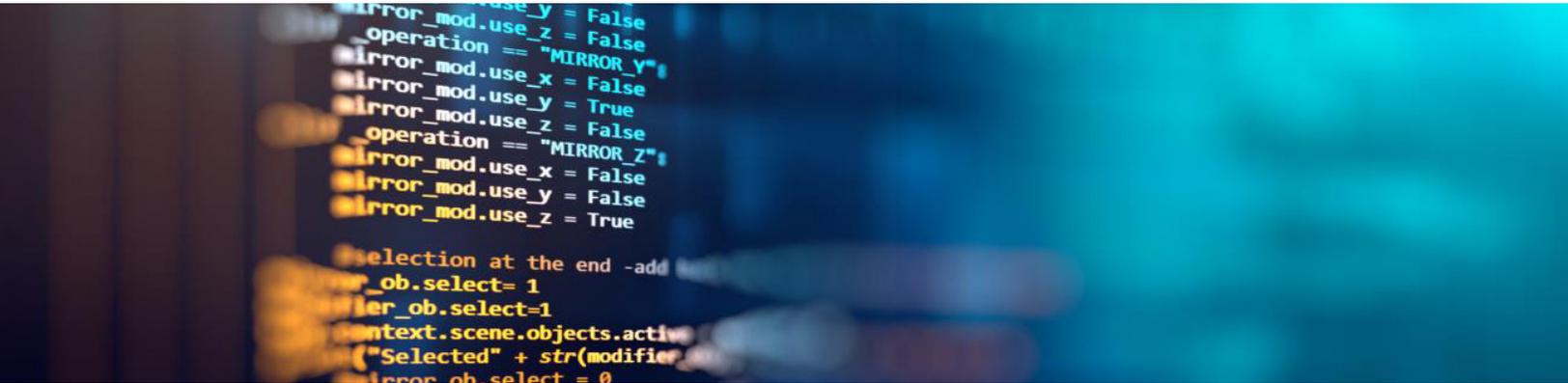


KELA Relies on CTG to Perform Validation Activities for its SAP Implementation



Reliability Matters



The Client

KELA is a Belgium-based company that specializes in the manufacturing and worldwide sale of pharmaceutical products.

The company is a long-established, leading producer of both veterinary and human pharmaceuticals, as well as nutritional supplements, that are distributed to more than 100 countries across the world. Throughout its rich history of more than 70 years, KELA's success has been built on the high quality of its products, its long-lasting and highly regarded customer service, and overall operational reliability.

Challenges and Objectives

KELA decided to replace its legacy, mainframe-oriented system with SAP ECC 6.0. Situated in a Good Manufacturing Practice (GMP)-critical environment, KELA requested that CTG provide our SAP validation service and expertise in order to implement the SAP system in a compliant way. The primary business objectives of the project were to implement a software quality product while successfully meeting compliance and validation requirements and passing applicable regulatory agency inspections.

The CTG Solution

The applied validation approach, which CTG tailored to KELA's needs, was scalable and risk-based in order to steer and focus the validation effort using the outcome of the GxP Criticality and Risk Assessment, software categorization according to GAMP5, and supplier documentation. In addition, a lean and Agile approach was taken; deliverables were combined and review and approval cycles were shortened by organizing workshops.

Results

KELA realized a significant reduction of the validation effort, and thus cost savings for validation, by applying this risk-based approach. A ready-to-use validation kit (framework, templates) was made available for KELA where necessary. CTG provided best practices regarding SAP compliance, including GxP Criticality and Risk Assessment, authorization approach, EU Annex 11 controls, and supporting procedures.

“CTG has proven to be a helpful and reliable partner, at critical times, for the “CERBO” SAP implementation and validation by identifying and mitigating risks that could have had a negative impact on the project.”
– Bart Lavrysen, CFO



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