

PROJECT REFERENCE
IT QUALITY DURING LOGISTICS DIGITAL
PROCESS TRANSFORMATIONS

RESULTS & BENEFITS

Reduction of personnel costs with improvement of processing and allocation of incorrect deliveries.
Increased transparency for logistics management.
Improvement of validation strategies for new innovative CSV projects to ensure compliance with applicable EU/FDA and global intercompany requirements as part of the transition to digital logistics processes during the overarching company merger.



CUSTOMER

Medical device company



CHALLENGES

The logistics department was striving to transform from manual to digital processes including management cockpits for e.g., product labelling, warehouse management, quality controls in the delivery of country-specific (non-)registered products, cold chain processes (data logger) and delivery error management. Compliance with GxP regulatory requirements was required.



APPROACH

Define validation strategies and consult on strategic application landscape designs from a GxP records, data and validation management perspective. Discuss and agree validation approach with Business, IT, CSV and suppliers. Development and QA review of deliverables over the whole system development life cycle. Execution of Change Management requests for CSV projects.



FACTS & FIGURES

3 years | Logistic centers & distributors affected worldwide | Global GxP standards



QUDITS ROLE

Digital Compliance and CSV Expert | Project Lead for Sub-Project "Validation"