



# PROJECT SUMMARY

## SYSTEM INTEGRATION OF MES SOLUTIONS IN COMBINATION WITH SAP

### CLIENT

Our client is one of the leading European contract manufacturers for pharmaceutical products. Almost 5.000 employees at 20+ sites produce for more than 100 international companies, including 15 of the global Top 25. From purchasing to packaging, the CMO offers full service with tailor made solutions for nearly all dosage forms.

### PROJECT BACKGROUND

The existing weighing system at the clients' facility needed to be replaced at the end of its life cycle with a new system that met the current requirements of a pharmaceutical manufacturer. This meant that it also had to meet cGMP rules and comply with FDA 21 CFR Part 11: Electronic Records and Electronic Signatures, FDA CFR 21 Part 210 & 211 Current Good Manufacturing Practice, EU GMP Guidelines Annex 11, and GAMP 4 (Good Automated Manufacturing Practice) Guide for Validation of Automated Systems. The system also had to be documented and validated according to regulatory requirements. At the start of the project, the system deployment was to include one master PC that permitted the centralized management of the workstations and three weighing booths, which were each equipped with up to four scales. An interface was required to allow the weighing system to communicate with the SAP/R3 ERP system.

### PROJECT REALIZATION

The existing computer hardware and basic OS software were replaced by Systec & Services within the framework of the project. To meet explosion protection requirements, specialized hardware had to be deployed for one of the weighing booths. Where possible, order processing and processes from the current system were largely maintained.

Systec & Services implemented an industry leading weighing solution and tailored it to the various business processes of the client. Job orders are planned in SAP, and the dispensing system assumes controlled execution of job orders all the way from material identification to providing feedback to SAP on quantities consumed. This allows online batch checks by means of material information stored in SAP. Over the course of the project, it was also necessary to make the relevant SAP modifications that ensure reliable communication between the MES solution and SAP Business Connector. The solution was rolled out to 5 other sites so far.

**The clients is now equipped with an MES solution including SAP interfaces.**

### OUR SERVICES

- System integration of MES solutions in combination with SAP
- Business and Enterprise Manufacturing Intelligence Solutions
- QM, compliance management and e-Validation solutions
- Professional services for the optimization of production management
- Hardware platforms that meet the strictest requirements
- Roll out of Weighing solutions to 5 sites in 4 countries.