

These services are only offered to long-term clients.

Implementation Support for Manufacturing Execution Systems [MES]

Analysis of IT-enabled business processes in warehouse management, manufacturing control, material flow and logistics. Modelling of business processes in MES considering: usability, flexibility and traceability. Establishing and employing industry proven best practices and standards. User Requirement Specification, Functional Specification. Logical design of interfaces, connecting MES to other systems [ERP, LIMS] considering business processes and validation aspects. Process-oriented training of key users. Development of go-live strategy, go-live support.

Project punktwissen, Project Coaching

Support of the internal project manager as Trusted Advisor with pragmatic hints and suggestions [Notes from the field]. Know-how transfer on the job, joint development of project plans, documentation and reports. Support with communication of project strategy, status and methodology to internal stakeholders.

Pragmatic Compliance

Pragmatic design of policies, guidelines and standard operating procedures for the implementation, operation, change management and retirement of IT systems. Tailored to legal requirements, EU and FDA guidelines and management frameworks. Compliant with industry standards, applicable to pharmaceutical manufacturing. Based on the analysis of risks and technical and organizational feasibility.

Computer Systems Validation

Validation support for the implementation of pharma IT systems [Automation, database systems]. Generation and review of key documents such as validation plan, specifications, documentation of business processes, risk analysis, validation report. Minimizing investments in validation using a risk-based approach. Pragmatic suggestions for efficient validation strategies.

Engagements and Approach

Customers:

European pharmaceutical companies with sites in AT, CH, DE, FR, SE, and IE. By order of clients or MES software vendors.

Typical engagements:

Remote or onsite support in all stages of a project. Focus on integration of IT system with production and logistics processes.

Ongoing project support, 2 days a week maximum. Intensive support during critical phases, especially go-live.

Products and standards:

MES software Werum PAS-X, GMP, GAMP, FDA 21 CFR Part 11, Computer Systems Validation.

Methodology:

Support of the internal project manager as trusted advisor. Intermediator between supplier and customer. Intensive know-how transfer for key users.

Dipl.-Ing. Dr. Siegfried Proyer



Experience in pharmaceutical manufacturing since 1998:

Since 2006 self-employed consultant 1998-2005 with Octapharma Vienna as IT Manager in the production division and QM IT Manager.

Manufacturing Execution Systems: Specialized on the implementation of MES in regulated industry and their interfaces with ERP systems.

Experimental physicist: Laser physics, materials science, heat pump systems. Development of experimental apparatuses, Systematic process optimization, monitoring and control.