

Pharma IT Offerings

• 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

Dipl.-Ing. Dr. Siegfried Proyer

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.



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 and materials science. Development of experimental apparatuses. Systematic process optimization.