

Our **Management Consulting** services range from business process and risk management, business process optimization to investment initiation. Our analyses provide a basis for sustainable and future-proof decisions.

Business Process and Risk Management

Production Strategy

- Production Optimization
- Site Master Planning
- Supply Chain Management
- Logistics Simulation
- Process Simulation

Process Analysis / URS Development

- Production Processes
- Company Quick Check
- Document Management Systems
- Archiving Systems
- Maintenance Management Systems
- Calibration Management Systems
- Business Process Management
- Lean and Six-Sigma Initiatives
- IT Integration Management

Risk Management

- GxP
- Structure and Organization
- Commercial and Project Risks
- HAZOP / FMEA

Technology Transfer

- Site to Site
- Client to Supplier

Investment Initiation

Capital Expenditure Analysis

- Product Cost Calculation
- Internal Rate of Return / Net Present Value

Quality and GxP Compliance

cGMP Consulting

- FDA Compliance Consulting
- Medical Devices (Part 820, ISO 13485)
- Zoning Concepts
- Cleaning Concepts incl. CIP
- Sanitisation/Sterilisation Concepts
- IS in Pharmacovigilance
- IS in GMP Maintenance
- Quality Systems
- GMP Change Control
- IS in Regulatory Affairs
- Variants Analysis
- Critical Systems
- Start-up Consulting

Qualification/Validation

- Validation Concepts CSV
- Master Validation Plan CSV
- IQ Protocols and Execution CSV
- OQ Protocols and Execution CSV
- ERP CSV (Planning)
- ERP Protocols and Execution
- Qualification/Validation Concepts (non-IS)
- IQ Protocols and Execution
- OQ Protocols and Execution
- PQ Protocols and Execution
- Cleaning Validation
- Cleaning Validation Protocols and Execution
- Process Validation Planning and Execution

SOPs

- SOP Structures
- SOP Development CSV
- SOP Development Non-CSV

Quality Audits/Mock Inspections

- In-house
- Suppliers

Gap Analysis

- Part 11
- cGxP

Quality and GxP Compliance

Consulting ensure that your systems and processes are compliant with the latest relevant regulations. Through Audits and Mock Inspections we prepare your business for inspections by authorities.

We have long experience in **Information System Consulting and Computerized System Validation** services that are key to an efficient and GxP compliant pharmaceutical business.