GMP Compliance, Qualification and Validation

M+W Process Industries GmbH

GMP consulting  |  Process- and cleanroom qualification  |  Validation  |  Quality management
M+W Process Industries GmbH, a wholly owned subsidiary of the M+W Group, offers services covering the complete GMP value chain from a single source.

As a global engineering and construction company we offer complete process and facility solutions from design to construction.

Our clients include large and medium-sized enterprises as well as start-up companies in the following industries:

- Pharmaceutical
- Biotechnology
- Chemical and Fine Chemical
- Active Pharmaceutical Ingredients
- Pharmacy and Hospital
- Medical Devices
- Consumer und Beauty Care
- Food
- Laboratories
GMP Compliant Validation for Your Processes

Our Competences
- Active pharmaceutical ingredients (chemical, biotechnological)
- Solids
- Semi solids
- Parenteralia
- High potent substances
- Tissue engineering
- Advanced therapies
- In-vitro diagnostics
- Warehousing
- Laboratory techniques / Microbiology
- Die casting
- Extrusion

Competence Spectrum of Validation by M+W Process Industries

- Sampling
- Dispensing
- Air shower systems
- Solid-state handling
- Tablet pressing
- Compounding
- Filling
- Fermentation
- Sterilization
- Pure media
- Packaging
- Storage
- HVAC
- Cleanroom
- Die casting
Comprehensive Solutions for the GMP/FDA-regulated Industry

The requirements of the Life Science industry are complex. That’s why customers expect an expert partner to provide complete solutions – from consultancy, through offer preparation, to order processing with in-house and experienced employees. M+W Process Industries offers customer-specific solutions tailored to the requirements of the relevant industrial sector:

**GMP Consulting**
- GAP analysis/ GMP review
- Mock inspection
- Preparation and support for inspections of authorities

**Validation**
- Qualification master plan (QMP)
- Validation master plan (VMP)
- Risk analysis
- Qualification matrix
- Traceability

**Process- and Cleanroom Qualification**
- Detail risk analysis (FMEA, HACCP, ...)
- DQ, IQ, OQ, PQ
- Calibration
- Re-qualification

**Quality management**
- Audit
- SOP systems
- GMP training

- Scheduling
- Calibration
- Measuring
- Evaluation
- Documentation
The validation concepts of M+W Process Industries are derived from the relevant current legal framework, directives and internal standards. Our qualification and validation services are applied to complete procedures, machines, systems and installations.

M+W Process Industries is your expert partner when validation solutions are required.

**Process Equipment**
- Sampling systems
- Weighing systems
- Compounding systems
- Filling lines
- Packing installations
- Sterilization systems
- Air-shower systems
- Washing machines
- Isolators / RABS / Laminar Flow Units
- Freezing devices and incubators
- Laboratory equipment

**Qualification measures in conformity with "V Model"**

- **VMP incl. overall risk analysis**
- **User requirement specification**
- **Functional design specification**
- **Design qualification (DQ)**
- **Detailed risk analysis**
- **Brief URS**
- **OQ protocol**
- **PQ protocol**
- **Timeline**
- **GMP consulting | Design | Execution | Documentation | Project management**
- **Scheduling**
- **Calibration**
- **Measuring**
- **Evaluation**
- **Documentation**
Clean (ultraclean) media
- WFI, HPW, AP
- Compressed air
- Ultraclean steam gases (Nitrogen, Hydrogen, Helium, etc.)

Cleanrooms
- Classified rooms according to GMP (D,C,B) or ISO (8,7,6)
- Controlled rooms

HVAC
- Fresh air systems (with heat regeneration)
- Recirculation systems

Monitoring
Environmental parameters (particles, air speed, room differential pressures, temperature, humidity, etc. in rooms and process systems)

Computer Systems
- MSR process level
- Process Control System (PCS)
- Plant management level (MES)
- Enterprise management level (ERP)
- Special applications (Excel, logistics, etc.)
Apart from planning and realization of complex and highly technological process systems and buildings in the Life Science sector, GMP compliance as well as qualification and validation are also given top priority within the framework of quality assurance.

The interpretation and the professional implementation of international standards and directives, including EU GMP and FDA, are part of our routine work everyday. M+W Process Industries is your partner on all issues in the GMP environment.

**Our approach**

- Customer-specific procedure
- Cost-based procedure
- We qualify in conformity with customer specifications or in-house, standard operating procedures
- Qualification is only carried out where the risk analysis indicates this is necessary
- No “imposition” of unreasonably high requirements
- Prospective, concurrent or retrospective
- GMP training for the operator's personnel
- Establishment or expansion of the QM system
- Support after the end of the project

**Your benefits**

- Everything from a single source
- Work carried out by personnel with experience in the sector
- Track record of experience over 15 years
- Practice-oriented procedure
- 50 qualification engineers and technicians
- Comprehensive experience with authority inspections in Europe and the USA
- Execution of test and measurement procedures with in-house personnel and dedicated measurement systems
- Integrated approach: interdisciplinary project group from engineering and qualification including the user