M+W GROUP

Qualification and Validation

GMP Compliance for Life Science Production Facilities

M+W Group – plant design and construction
M+W Group is one of the leading global design, engineering and construction companies in the life science industry. With great teamwork our experienced specialists develop 'state-of-the-art' solutions for customers' facilities, maintaining GMP compliance throughout the entire lifecycle – from consulting, concept and design to full turnkey realisation along with qualification and validation.

Ensuring seemless GMP compliance
Regulatory requirements in the life science industry are becoming increasingly complex - with our thorough process and production understanding we offer seamless fullfillment of GMP and deliver ideal and holistic solutions to our customers' GMP investment projects. Our in-depth GMP knowledge and project management experience supports you from the scale-up of your laboratory throughout the commissioning and ongoing operation of your major production facility:

Pharmaceutical Industry | Industrial Biotechnology | Chemical and Fine Chemical | Active Pharmaceutical Ingredients | Pharmacy and Hospital | Medical Devices | Consumer and Beauty Care | Food & Nutrition | Laboratories |

How you benefit
Customer-specific and cost-based procedure |
Establishment or expansion of the QM system |
GMP training for the operator's systems |
Qualification based on risk analysis |
M+W standardised procedures |

Abbott | B. Braun | Baxter | Catalent | Charité | CSL Behring | GSK | MSD | Novartis | Pfizer | Roche | Sanofi | Sandoz |

Expertise for your project
We support you in developing your standards, enable the construction of your GMP compliant production plant and implement your production process:

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

Validation Approach
Qualification master plan | Validation master plan | Risk analysis |
Qualification matrix | Traceability matrix |

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

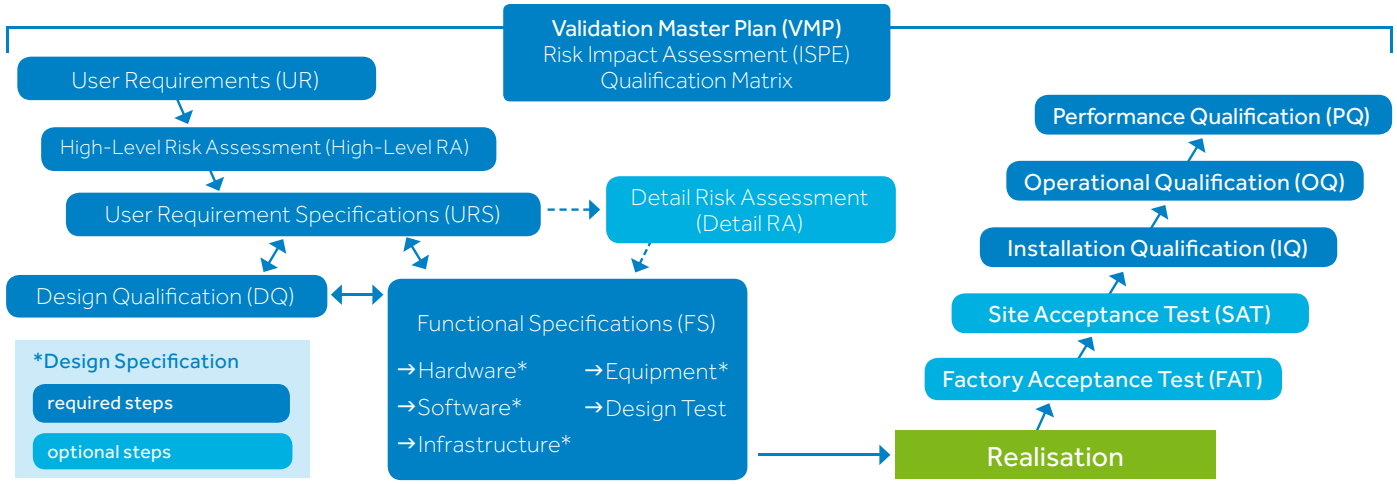
Validation
Process validation | Cleaning validation |
Method validation | Computer system validation |

Quality Management
Audit | SOP systems | GMP training |

Bringing the future of technology to life

GMP-/FDA-regulated Industry

Comprehensive Concepts



The V Model – basis for our validation concepts

GMP compliance is a core condition for the planning and design of complex high-tech process facilities and buildings within the life science industry. Along with these rules and interpretations also quality documentation and validation play an important role during the quality control process.

The interpretation and professional implementation of international standards and guidelines such as EU GMP, FDA or ANVISA shapes our day-to-day work – our team of professionals help you to achieve and maintain GMP compliance throughout the lifecycle of your product by delivering customised compliance services.

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 System Validation

MSR process level | Process Control System (PCS) |
Plant Management Level (MES) | Enterprise Management Level (ERP) |
Special applications (Excel, logistics, etc.) | Cyber Security |

Our expertise in qualification & validation

Sampling systems | Weighing | Fermentation (USP) | Purification (DSP) | Formulation |
Filling | Packing | Storage | HVAC | Lock system | Cleaning | Sterilisation |

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