Qualification and Validation

GMP Compliance for Life Science Production Facilities

Exyte – plant design and construction

Exyte is a global leader in design, engineering and construction in the life sciences industry with a special expertise in controlled and regulated environments, maintaining GMP compliance throughout the entire lifecycle – from consulting, concept and design to full turnkey realisation along with qualification and validation.

Ensuring seamless 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 regulations and deliver ideal and holistic solutions to our customers' 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 for all LSC industries:

Pharmaceutical Industry I Biotech Industry I Chemical and Fine Chemical Industry I Medical Devices I Laboratories I Food & Nutrition I Pharmacy and Hospital I Consumer and Beauty Care Industry

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 | Requalification

Validation

Process validation | Cleaning validation
Method validation | Computer system validation

Quality Management

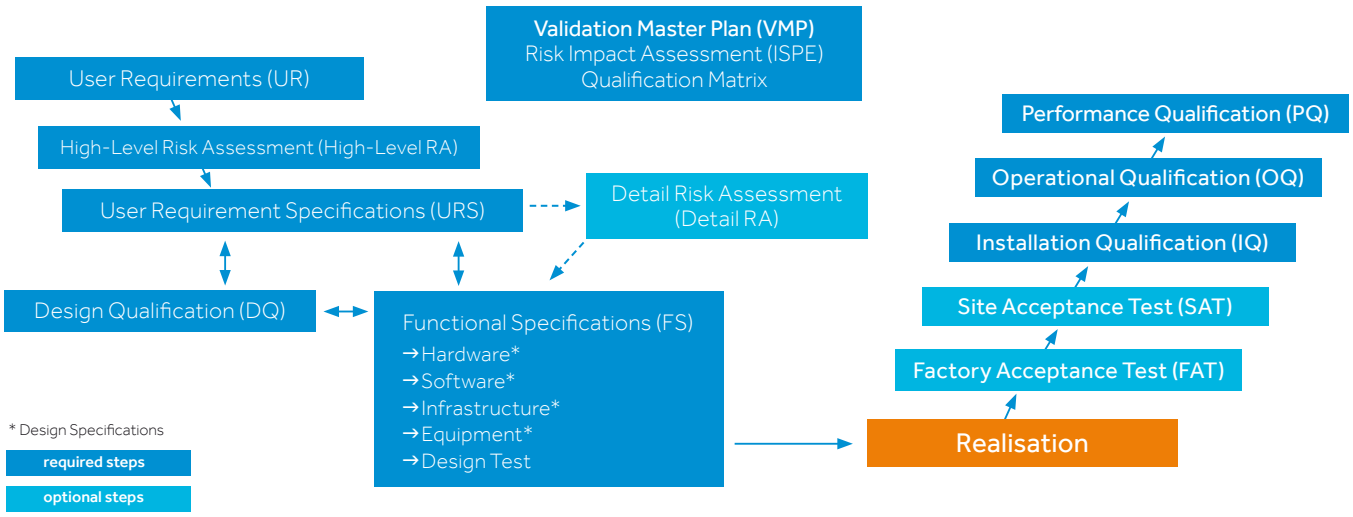
Audit | SOP systems | GMP training

Reference Clients

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

Qualification and Validation

Comprehensive Concepts for the GMP/FDA Regulated Industry



The V Model – basis for our validation concepts

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.

Our expertise in qualification & validation

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

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
- Exyte standardised procedures
- GMP-trainings for operators

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

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