QUALIFICATION & VALIDATION

ANALYSIS & CONSULTING
PLANNING & DOCUMENTATION

Qualification and validation aim at enhancing the safety of drugs and patients in the pharmaceutical industry. Every quality management system based on regulatory requirements serves to guarantee the reproducibility of manufacturing processes as well as the proper operation of machines and installations, and therefore the quality of the pharmaceutical product. The applicable specifications and acceptance criteria must be compliantly and verifiably observed for equipment and processes.

Our extensive qualification and validation activities provide you with fundamental expertise during your plant's entire lifecycle and your established processes, too.

Qualification: Equipment and plants

Validation: Processes and systems

Documentation

Qualification

- Risk analysis with consideration of GxP
- Validation master plan as governing document of qualification and validation
- Design qualification (DQ): current status analysis, creation of requirement profiles (URSs), requirements and specifications, requests for bids and bid comparison, selection of suppliers
- Installation qualification (IQ): on-site inspection with IQ tests, technical acceptance tests
- Operational qualification (OQ): assessment of functionality according to test plan and generation of test reports
- Performance qualification (PQ): performance test of complete installations including the original product under realistic conditions
- FAT, SAT and handover

Validierung

- Prospective and retrospective validation
- Process validation: process analysis using Process Analytical Technology (PAT) and statistical process control
- Cleaning validation: definition of acceptability criteria and sampling procedures
- Validation of computerized systems (computer systems and processes) taking GAMP into account

Engineering & Maintenance

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