Qualification and Validation - Routine Support

We offer support for the execution of all activities related to Qualification and Validation routines, including Computerized Systems Validation, Equipment Qualification, Cleaning Validation, Process Validation, Validation of Water Systems

Equipment Qualification

Our team specializes in qualifying equipment to ensure its suitability for pharmaceutical manufacturing processes. We conduct thorough assessments, testing, and documentation to verify that equipment meets regulatory standards and operational requirements.

Computerized System Validation (CSV)

We offer end-to-end solutions regarding CSV, including document creation (according to GAMP5), test execution, third-parties management, access control, trainings, and data management. Our experts ensure that these systems meet regulatory requirements and industry standards, covering aspects such as data integrity, security, and functionality.

Cleaning Validation

Support for Cleaning Validation activities to ensure that equipment and facilities are effectively cleaned and free from contamination. Our services include protocol development, and sampling plans, to demonstrate the effectiveness of cleaning processes.

Process Validation

Our team assists in Process Validation to ensure consistent product Quality and compliance with regulatory requirements. We develop validation protocols, and execute validation studies, to confirm the robustness and reliability of manufacturing processes.

Validation of Water Systems

We provide support related to strategy and document creation to Water Systems Validation, to ensure the quality and purity of water for various applications.

Reckitt | BIONTECH | ratiopharm | SANOFI | Boehringer Ingelheim | Biotest | Heraeus | Takeda

- Quality Consulting and Risk Management
- Qualification and Validation
- Personnel Qualification
- Customer-specific provision of QMS

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