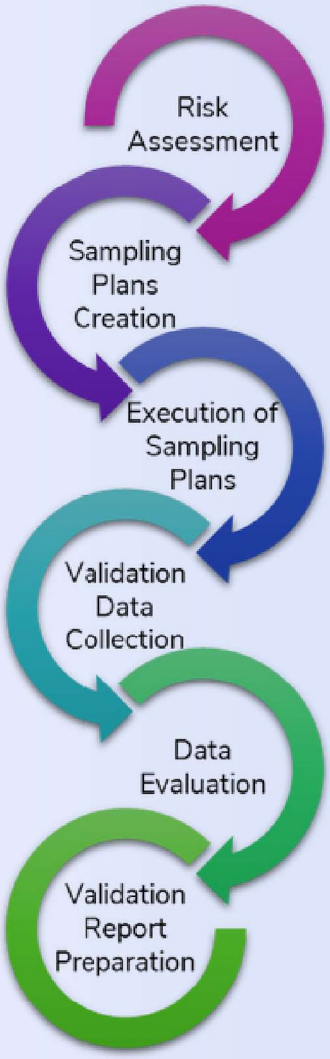
Process Validation – Routine Support

Zamann Pharma Support GmbH offers services to pharmaceutical companies, providing hands-on assistance in the execution of Cleaning Validation activities. Our expert consultants work closely with clients to execute the Cleaning Validation tasks

Protocols Development and Execution

Our experts can support the development of robust protocols, created to their specific processes and products. This includes conducting risk assessments to identify critical process parameters and defining sampling plans to ensure representative data collection. We execute Validation Protocols studies, providing guidance on protocol implementation and ensuring adherence to established procedures and regulatory standards.



Data Collection and Analysis

We support companies in the systematic collection of validation data, including process parameters, product characteristics, and performance indicators. Our experts employ statistical analysis techniques to evaluate the collected data, assess process variability, and determine the robustness of the manufacturing process. By analyzing validation data comprehensively, we identify trends, deviations, and potential areas for process improvement.

Validation Report Preparation

Our team assists in the preparation of comprehensive Validation Reports that document the entire process, from protocol development to data analysis and conclusions. We ensure that validation reports are clear, concise, and compliant with regulatory requirements, including FDA and EMA guidelines. Our reports provide a detailed overview of the validation activities performed, the results obtained, and the conclusions drawn, facilitating regulatory submissions and audits.

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

Contact:
quality-services@zamann-pharma.com
www.zamann-pharma.com