

# Equipment Qualification – Routine Support

Zamann Pharma Support GmbH offers comprehensive support for equipment qualification in pharmaceutical manufacturing facilities. Our services ensure that equipment used in production processes meets regulatory requirements and industry standards, contributing to product quality, safety, and compliance

## User Requirement Specification (URS) and Equipment Selection

We support on URS to identify critical equipment and potential risks to product quality and patient safety. Our experts assist in selecting appropriate equipment based on intended use, process requirements, and regulatory expectations, ensuring suitability for intended applications.

## Installation and Operational Qualification (IQ/OQ)

Our team provides support for the installation and operational qualification of equipment, including the development and execution of IQ and OQ protocols. We verify proper installation, functionality, and performance of equipment to ensure it operates within specified parameters and meets predefined acceptance criteria.

## Performance Qualification (PQ) and Continued Monitoring

We conduct performance qualification studies to assess the ability of equipment to consistently produce product meeting quality attributes. Additionally, we establish monitoring programs to ensure ongoing compliance with qualification status and regulatory expectations, including periodic requalification and performance monitoring.

