

ASTM E2500

ASTM E2500 – 20 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment.

The ASTM E2500-20 is a standard guide for the specification, design, and verification of pharmaceutical and biopharmaceutical manufacturing systems and equipment. It aims to establish a risk-based approach to ensure the quality, safety, and efficacy of manufactured products.

The key aspects of the standard guide include

- **Lifecycle Approach:** The guide emphasizes the importance of a lifecycle approach for pharmaceutical and biopharmaceutical manufacturing systems, covering stages such as concept, design, fabrication, verification, and decommissioning. This holistic perspective ensures that quality and risk management principles are applied throughout the entire lifecycle of the manufacturing process.
- **Risk-based Approach:** The guide promotes a risk-based approach to the specification, design, and verification of manufacturing systems and equipment. By focusing on potential risks that could impact product quality, safety, or efficacy, companies can prioritize resources and efforts to address the most critical aspects of their manufacturing processes.
- **Specification Development:** ASTM E2500-20 provides guidance on developing clear and comprehensive specifications for manufacturing systems and equipment. These specifications should be based on product requirements, process understanding, and risk assessments, ensuring that the system and equipment are fit for their intended use.
- **Design and Verification:** The guide offers a framework for designing and verifying manufacturing systems and equipment. This involves ensuring that the design meets the established specifications, conducting thorough verification activities (such as Factory Acceptance Testing and Site Acceptance Testing), and confirming that the system operates as intended and complies with regulatory requirements.
- **Science- and Risk-based Commissioning and Qualification:** The guide encourages the integration of commissioning and qualification activities using a science- and risk-based approach. This approach focuses on critical aspects of the manufacturing process that may impact product quality, safety, or efficacy, and streamlines the overall verification process.
- **Documentation and Traceability:** ASTM E2500-20 emphasizes the importance of comprehensive documentation and traceability throughout the specification, design, and verification process. Proper documentation ensures that critical information is captured, and traceability is maintained, enabling a transparent and auditable record of the manufacturing system's lifecycle.

By following the guidance provided in ASTM E2500-20, companies in the pharmaceutical and biopharmaceutical industry can establish robust, risk-based processes for the specification, design, and verification of their manufacturing systems and equipment, ensuring product quality, safety, and regulatory compliance.