BMC MEDICAL MANUFACTURING

where vertical integration **meets excellence.**

At BMC Medical Manufacturing, we prioritize rigorous qualification of our equipment to ensure optimal performance and high reliability across all our manufacturing processes. Our approach is divided into four key stages:

1 Design Qualification (DQ)

We assess whether the equipment design meets the specified requirements and regulations, ensuring its suitability and compliance with established standards.

2 Installation Qualification (IQ)

We verify that the equipment is correctly installed according to the manufacturer's specifications and regulatory requirements, ensuring a solid foundation for its operation.

3 Operational Qualification (OQ)

We confirm that the equipment operates according to the established specifications and performance criteria through functional and calibration testing.

4 Performance Qualification (PQ)

We evaluate the equipment's performance under real or simulated operating conditions, demonstrating its ability to produce consistent results and meet predefined acceptance criteria.

Stability Studies

We conduct thorough studies to ensure the reliability and longevity of our medical devices:

Accelerated Aging Studies

We assess product performance and durability by exposing them to extreme temperature and humidity conditions in our climate chamber, ensuring long-term reliability.

Real-Time Aging Studies

In addition to accelerated aging, we monitor products under normal storage conditions to evaluate their stability and performance, allowing for proactive quality management.

ISO 11135 and ISO 10993 standards are updated every 3 to 5 years to reflect the latest advances in safety and efficacy.

Product Line Validation

Ensuring the integrity and reliability of our product line is crucial at BMC Medical Manufacturing. Our comprehensive validation process covers various aspects to ensure consistency, safety, and efficacy across our range of medical devices.

High-Volume Production

We rigorously validate our production processes to ensure scalability and maintain product quality in large volumes, meeting strict regulatory standards and customer demands.

ETO Sterilization

Our ethylene oxide (ETO) sterilization methods undergo rigorous validation to ensure effectiveness, preserving device sterility and safety throughout its lifecycle. We comply with ISO 11135 and ISO 10993 standards

Design Validation

We thoroughly review our product designs to ensure they meet intended use requirements and function reliably, aligning with industry standards and regulatory guidelines for safety and efficacy.

Clinical Studies

We collaborate with institutions and healthcare professionals to conduct rigorous trials that validate the safety, efficacy, and performance of our products in real-world settings, ensuring regulatory compliance and providing tangible benefits to patients and healthcare providers.