9 MEDICAL DEVICE regulatory pathways

01. ISO 9001

Focuses on the Quality Management Systems (QMS). This provides a framework for continual improvement and consistent quality.

02. ISO 13485

A specific standard for medical devices with stringent QMS, risk management, and design control requirements.

03. ISO 45001/ 50001

ISO 45001 ensures employee health and safety; ISO 50001 improves energy efficiency in manufacturing.

04. IATF Core Tools

IATF standards include APQP, FMEA, and SPC tools to ensure early issue identification and consistent quality for medical devices.

05. Design of Experiments

DOE is a statistical method that helps manufacturers understand production variables for reliable design practices.

06. Statistical Process Control

SPC ensures processes operate at full potential, crucial for consistent quality in healthcare equipment manufacturing..

07. Failure Mode & Effects Analysis

FMEA identifies potential failures to mitigate risks proactively in products and processes.

08. Measurement System Analysis

MSA ensures measurement system accuracy and reliability for stable quality and compliance in medical device manufacturing..

09. Problem Solving

LA3, DMAIC, RCA, and 8D methods identify root causes, implement corrective actions, and prevent recurrence

Partner with GENEDGE to join Virginia's initiative to improve medical device quality and supply chain resiliency.

GENEDGE alliance

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