MEDICAL DEVICE regulatory pathways



01. ISO 9001 Focuses on the Quality
Management Systems (QMS).
This provides a framework for
continual improvement and
consistent quality.

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

02. ISO 13485

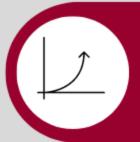




03. ISO 45001/ 50001 ISO 45001 ensures employee health and safety; ISO 50001 improves energy efficiency in manufacturing.

IATF standards include APQP, FMEA, and SPC tools to ensure early issue identification and consistent quality for medical devices. 04. IATF Core Tools





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

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

06.
Statistical
Process Control





07. Failure Mode & Effects Analysis FMEA identifies potential failures to mitigate risks proactively in products and processes.

MSA ensures measurement system accuracy and reliability for stable quality and compliance in medical device manufacturing.. 08.
Measurement
System Analysis



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.

