SCIENCES AND CONSULTING

PROVIDING INTERNATIONAL MEDICAL DEVICE REGULATORY, QUALITY SYSTEM AND CYBERSECURITY CONSULTING SERVICES

WHAT WE DO

- We are an established leading edge medical device consulting company.
- Client list includes premier U.S and international medical device companies, ranging from small startups to large multi-national corporations.
- We have worked directly with the FDA as a recognized Quality System Expert Witness in the review of FDA site inspectional results to assess compliance.
- Services provided:

  - Complete regulatory and quality medical device consulting coverage.
  - Focus on international requirements, including U.S., EU and China.
  - Consulting on Quality Management Systems including review and "fine-tuning" of existing QMS structure and documentation as well as a complete rewrite or first implementation.
  - Development of specific medical device technologies, including IVDs, active implantables, wound care products, catheters, patient monitors, imaging systems, software, Next Gen Sequencing, and other complex hardware and software device technologies.
  - Training on all aspects of U.S./World-Wide medical device regulations.
  - Gap assessments and Mock audits to assess current regulatory and compliance status and suggested remediation plans. (ISO 13485, MDSAP, EU MDR, EU INDR and FDA QS regulation).
  - Integration of current and pending FDA and international "best practices" and standards to support "best in class" medical device development.
  - Implementing regulatory and quality requirements for medical device software, including embedded device software, mobile apps and AI/ML.
  - Process validation planning and implementation.
  - Complete regulatory planning and implementation to support PMA/510(k) submissions, with recent focus on FDA Emergency Use Authorizations and Breakthrough Device Designation.

FOR MORE IMFORMATION ABOUT WARD SCIENCES AND CONSULTLING
CONTACT US AT JACKWARDQUALITY@GMAIL.COM