WARD
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.

- Our client list includes premier U.S and international medical device companies, as well as smaller technology driven startups and mid-size established firms and technologies.

- We are experienced and qualified medical device cybersecurity consultants with substantial recent and ongoing FDA 510k cybersecurity submission development and support for our clients.

- We have also 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:

  - FDA Cybersecurity 510k submission planning, development, and implementation.
  - Cybersecurity remediation consulting for 510k AINN/deficiency responses.
  - Complete regulatory and quality medical device consulting coverage.
  - Gap assessments and Mock audits to assess current regulatory and compliance status and suggested remediation plans. (ISO 13485, MDSAP, EU MDR, EU MDR and FDA QS regulation).

  - 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.

  - 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.