

WARD

SCIENCES AND CONSULTING

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

WHO WE ARE



Jack Ward is a recognized quality assurance and regulatory affairs professional with over 40 year's experience in the medical device industry. Jack has held a broad range of corporate management, engineering and Quality/Regulatory positions with direct experience across a broad range of medical device types, technologies and applications. Jack's company, Ward Sciences and Consulting LLC, provides consulting expertise to medical device companies for regulatory submissions, Quality Management System implementations, remediations and training. His company can provide specific expertise for a broad range of medical device consulting services, including IVD, NGS and companion diagnostics, software (embedded, mobile apps and AI/ML), complex medical device types combining hardware and software, startup and small company considerations, and FDA medical device regulatory submissions.



Nick Ward is an accomplished and experienced international medical device professional with a Master's degree in Regulatory Affairs for Drugs, Biologics, and Medical Devices from Northeastern University in Boston. This is a well-regarded and highly rated advanced degree program for regulatory affairs professionals and provides a broad base of academic expertise and hands-on internships. Nick's areas of degree concentration and ongoing work experience include a focus on international medical device regulations and premarket regulatory submissions across a broad range of medical device types, technologies, and applications. Nick has recent hands-on experience with U.S. FDA Breakthrough Devices and FDA EUA submissions. Nick is an experienced medical device lead auditor with current international certifications in ISO 13485, MDSAP, EU MDR/ IVDR and has substantial expertise in providing guidance to firms in meeting the requirements of international regulations including U.S. FDA.



Jonathan Ward serves as a medical device cybersecurity consultant at Ward Sciences and Consulting. He holds a Master's degree in cybersecurity policy and governance from Boston College and a cybercrime and cybersecurity Graduate Certificate from Boston University. As a specialist in security risk management, coordinated vulnerability disclosure processes, SBOMs and threat modeling, Jonathan expertly guides companies through the complex and rapidly evolving regulatory landscape in both pre and post market medical device cybersecurity requirements. Additionally, John provides valuable training to organizations on how to develop their 510k/PMA submission cybersecurity documentation and QMS cybersecurity procedures. For longer term planning, John can provide a broad strategy roadmap to clients regarding future trends in medical device cybersecurity.

FOR MORE INFORMATION ABOUT WARD SCIENCES AND CONSULTING
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