

Consultant Profiles:

[Kamm & Associates: fda-consultant.com](http://fda-consultant.com)



Daniel Kamm, P.E., C.Q.A.

Daniel Kamm, P.E., C.Q.A., is the Principal Engineer of Kamm & Associates. He is an electronics engineer and regulatory affairs executive with over thirty years' experience in the medical device business, specializes in Good Manufacturing Practices auditing, consulting, and training. He has made numerous successful [510\(k\) submissions](#). (More than 300) He also designs medical devices and thus has a unique grasp of the problems and

solutions to the GMP problems encountered by the device manufacturer. He has assisted the smallest to the largest device manufacturers on a world-wide basis to become GMP compliant and pass FDA inspection. He has directed R&D, regulatory affairs, and quality assurance efforts in companies such as Beckton-Dickinson, Picker International, and Fischer Imaging. He is a Registered Professional Engineer and a Certified Quality Auditor. International experience includes assignments in Canada, China, Finland, France, Germany, Italy, Japan, Korea, Netherlands, and Sweden. Member, Association for the Advancement of Medical Instrumentation, Regulatory Affairs Professional Society. Senior Member, Institute of Electrical and Electronics Engineers. Past participant in standards writing committees of AAMI: Electrical Safety; Diagnostic Electrocardiograph. Mr. Kamm has a B.S. in Electrical Engineering from Washington University.

- FDA Regulatory Auditing, Consulting, Training, Quality Assurance,
- ISO 13485 Compliance,
- CE Marking guidance,
- FDA submissions: 510(k), PMA, IDE.
- Process, Product, Software Validations.

- FDA-483 and Warning Letter responses.
- Senior Life Member, IEEE.

[Complete CV for Daniel Kamm, P.E.](#)

To help our clients to economize in the use of contract workers, a group of independent consultants has established a working affiliation. These highly motivated group members work either individually or collaborate in teams to serve your needs. We invite you to look at this list, which includes a summary of their services, contact any or all who might be able to assist you in your work. Contact us and we will be happy to facilitate the communication for you with any of our affiliated consultants. We will be pleased to assist you in assembling an appropriate, qualified consulting team equipped to handle your project expediently, accurately, and economically.



Jeff Kasoff, CMQ/OE, RAC, Lean Black Belt

Quality Assurance and Regulatory Compliance Professional with a strong record of introduction of and improvement to quality systems assuring streamlined, compliant processes. Collaborative leader in development of lean processes via use of operational excellence methodologies (e.g., kaizen, tiger team). Expert in

development of CAPA systems that feature data reporting and trending schemes that result in timely awareness of quality issues and prompt containment, root cause determination, and corrective actions. Extensive experience in establishment of cooperative supplier quality programs, resulting in establishment of quality metrics, excellent vendor relationships and reduction in inspection. Experienced in 510(k) preparation and submission. Effective communicator and compliance trainer at all organizational levels.

Speaker/presenter on quality system compliance topics for various organizations from 2005-present.

KEY COMPETENCIES

- Introducing lean principles into quality system processes
- CAPA
- Supplier Quality Management
- Implementing value stream-based system for trending of quality data
- Process Validation for medical device manufacturing
- QSR and ISO 13485 Auditing, Consulting and Training
- FDA-483 and Warning Letter Strategies
- 510(k) submissions



Kathleen Johnson, R.N., C.R.A.

Kathleen Johnson is the founder and owner of Medical Device Approvals, Inc., an independent regulatory and clinical research consultancy. Her skill set includes 15 years' experience as a regulatory submissions manager, CRA experience for all aspects of device studies, and excellent working knowledge of medical devices especially in the cardiovascular area..

Services offered:

- Regulatory strategy development for USA and Europe
- Extensive experience with 510(k) submissions.
- Experience with IDEs and combination products
- Submissions project planning, implementation and submission
- Implementation and management of Quality Systems compliant with FDA QSR and ISO 13485
- Document preparation to comply with Design Controls
- Software Validation documentation

- Conduct audits to assess compliance with FDA Quality Systems Regulations and ISO 13485
- Clinical study protocol development
- Case Report Form development
- Monitoring plan review
- CRA / Monitoring services



Donald P. Cox

Donald. P. Cox, Ph.D., M.B.A. is a scientist and business executive with over twenty-four years of diversified experience in the chemical, pharmaceutical, and biotechnology industries. He is academically qualified with scientific and business degrees and has published widely. For five years, he headed the regulatory affairs and science information functions at Janssen Pharmaceutica being responsible for numerous NDA, IND, and 510(k) submissions and

approvals. Since 1989, Dr. Cox has owned and managed a research biologicals distribution company servicing the biomedical reagents market with immunology products including antibody gold conjugates for research or diagnostics applications. Dr. Cox also consults to the pharmaceutical industry in areas of quality assurance, regulatory affairs, and new product development. He has worked individually and as part of team efforts. His recent projects include devoting over 85 on-site days to an FDA-organized integrity audit, creating a regulatory strategy for developing a topical prescription product, and researching technical documentation associated with silicone gel breast implant technology for a group of attorneys. Dr. Cox obtained master's and doctorate degrees in bacteriology at the University of Wisconsin, and his EMBA at Temple University.



John C. Hoffman

Creative and responsible professional with extensive worldwide V.P./Director level experience. Expertise in quality assurance and management and medical device regulatory affairs. Other areas of proficiency include all FDA regulations, ISO 9000/13485 international quality standards, sterilization, product safety and liability, SEI Capability

Maturity Model, and client satisfaction. Expertise in a wide range of products, including IVD, biologicals, pharmaceuticals, software, instrumentation, electronics and disposables. Effectively implemented and maintained compliance with regulations and standards through training and awareness initiatives. Utilized team building programs and strong working relations with the FDA and standards and industry associations.

- Thirty years of Medical Device, Pharmaceutical and Biologics Quality and Regulatory experience, including twenty years at the Director/Vice President level and over eight years in consulting.
- Experienced in start-ups and re-engineering quality systems.
- Twenty years' experience in medical software and information systems, including Medical Device Data Systems (MDDS), IEC-80001, HIPPA, GxP software, process control systems and software products regulated by the FDA. Expertise in all phases of the software development life-cycle, design controls, hazard analysis, validation, installation, support and PMAA, 510(k), pre-IDE and de novo submissions.
- Extensive, broad knowledge of US FDA quality & regulatory body regulations.