

Consultant Profiles: [Kamm & Associates](#)



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](#). 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 Life 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. [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 quickly, accurately, and economically.



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 12 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



Carol J. Carlson

Carol J. Carlson is President of Technical Writing Services, Inc., a technical writing and communications firm she founded in 1987 specializing in technical publications, training, and special event planning for the medical device, pharmaceutical, financial, and related industries. She is skilled in the preparation of required FDA documentation including policies, procedures, specifications, research and clinical data reports, IDE's, PMA's, 510(k)'s, IND's, NDA's, ANDA's, product-use instructions/manuals, as well as other GMP compliance documentation. Previous positions include: Instructor at the Illinois Institute of Technology, Manager of Technical Publications and Training at Baxter Healthcare Corporation, Supervisor of the Editorial Research Department at Encyclopaedia Britannica and Research Assistant at the Argonne National Laboratory. Ms. Carlson has a B.A. in Chemistry and English Literature from the University of Minnesota, and an M.B.A. in Finance and International Business from the University of Chicago.



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.

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