Carl Alletto, Senior QMS/Regulatory Consultant
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Carl Alletto, has a broad range of experience and expertise in the development and implementation of Quality Assurance Principles, Software Quality Processes, ISO Certification, and FDA Good Manufacturing Practices. He has firsthand knowledge of medical device regulations and software validation guidelines to satisfy USA Food and Drug Administration and European requirements, with over 30 years of experience in the medical device regulatory and quality assurance fields.

His qualifications include:

- Certified Professional Consultant by the International Guild of Professional Consultants.
- Certified Quality Manager, Certified Quality Auditor and Certified Software Quality Engineer by the American Society for Quality (ASQ)
- Experience with the development and implementation of FDA Medical Device Good Manufacturing Practices (GMP), Software Validation Processes, Regulatory Compliance, and ISO-13485 quality systems.
- Has served as Vice President of Quality/Regulatory for Kodak Health Imaging, and is currently a Senior Regulatory Consultant at OTech Inc.
- Has worked in the USA, Europe and Asia.
- Coordinated and implemented design processes and standard operating procedures for electro-mechanical and software products to meet ISO-13485, USA FDA Good Manufacturing Practice, and USA FDA Medical Device Regulations.
- Successfully developed strategies and submitted USA premarket notifications, (510(k) submissions), for ~ 70 devices (i.e. X-ray film handling equipment, medical laser printers, color imaging devices, and PACS devices, (Picture, Archiving, and Communication Systems).
- Implemented and managed quality system compliance programs for design and development, manufacturing, supplier qualification, and customer satisfaction.
- Partner with FDA district offices and other external regulatory agencies to develop relationships for improved communications and organizational effectiveness.
- Lead and managed medical device regulatory compliance audits.
- Managed medical device firm activities, to address unresolved quality system, FDA 483 and FDA Warning Letter issues to lift USA import detentions.

PROFESSIONAL MEMBERSHIPS

- American Society for Quality
- Regulatory Affairs Professional Society
- International Society of Speakers, Authors & Consultants
- IEEE