



Carl T. Alletto

Carl Alletto, offers clients 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 first hand knowledge of medical device regulations and software validation guidelines to satisfy FDA requirements. With over 20 years experience in the quality assurance and the medical device fields, he understands quality standards and regulations that can effect your business, in the area of regulatory compliance and customer satisfaction.

His qualifications include:

- Certified Professional Consultant by the International Guild of Professional Consultants. American Society for Quality Control (ASQC) Certified Quality Manager, Certified Quality Auditor and Certified Software Quality Engineer.
- Experience with the development and implementation of FDA Medical Device Good Manufacturing Practices (GMP), Software Validation Processes, Regulatory Compliance, and ISO 9001 and ISO 9002 certified quality systems.
- Has served as a Quality Assurance Manager, Regulatory Affairs Manager, Director of Regulatory Affairs, and Vice President of Quality. Has worked in both the USA and Europe.
- Coordinated and implemented design processes and standard operating procedures for hardware and software products to meet ISO 9001, FDA GMPs and FDA Medical Device Regulations.
- Successfully developed strategies for premarket notifications, (510(k) submissions), for X-ray film handling equipment, medical laser printers, color imaging devices, and PACS devices, (Picture, Archiving, and Communication Systems).
- Developed comprehensive corrective and preventative action plans to meet Medical Device Regulations and have instituted quality system audit programs to verify continued compliance to ISO and FDA regulations.
- Implemented and managed quality system compliance programs for 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



PROFESSIONAL EXPERIENCE

OTECH, INC. Dallas TX, (a medical device consulting firm) 1997- Present

Senior Consultant - Quality Compliance & Regulatory Affairs

- Responsible to assess quality system compliance to ISO 9001, FDA Quality System Regulation, EN-46001, and European Medical Device Directorate.
- Managed German medical device firm activities, to address unresolved quality system and FDA Warning Letter issues. US import detention lifted after corrective actions were successfully implementation. Zero finding on the next FDA site inspection.
- Developed and implemented an ISO 9001/FDA based quality system in 3 US medical device companies.
- Wrote 510(k) submissions for electronic imaging and software medical device companies: Olicon Imaging Inc., Konica Medical Imaging, Sectra AG in Sweden, C.M.A. srl in Italy, Seiko in Japan, Soering GmbH in Germany, and Samsung in Korea.
- Developed and presented monthly quality compliance and quality system training classes

AMTECH SYSTEMS CORPORATION, Dallas TX, 1996 -1997

Corporate Quality Manager, Reporting to the President.

- Implemented an ISO 9001 based quality management system for the corporate office and design activities.
- Championed 2 teams to re-engineer business processes (order administration, servicing, system design and integration, software design, systems engineering) which saved an estimated \$2M.

EASTMAN KODAK COMPANY 1972 -1996

KODAK MEDICAL IMAGING SYSTEMS INC., Dallas, Texas 1993 -1996

Director of Quality Systems & Regulatory Affairs. Responsible for quality assurance at two company facilities

- Managed a group of 30 quality, software quality, and regulatory professionals
- Ensured compliance to UL/CSA Safety Regulations, European CE Marking, FDA Regulations.
- Prepared submission of seven 510(k) pre-market notifications for software/firmware products.
- Implemented an ISO 9001 Quality System in two facilities, certified in February 1994.
- Implemented Software Quality Engineering measures that reduced customer problems by 30%.
- Initiated a software/hardware "Product Commercialization Process" to meet agency regulations, reduced development time and increased quality.
- Directed a "Supplier Certification Team" for the evaluation and pre-approval of suppliers. This improved product quality and reduced supplier audit costs by 30% or \$1M.

Quality Assurance/Regulatory Manager, Health Sciences & Clinical Divisions 1988 -1993

On loan to Kodak Germany in Stuttgart reporting to the General Manager

- Developed & implemented the first ISO-9001 Quality System within Kodak, certified in 1990.



- Developed and implemented a product "Quality Improvement Plan" which reduced field service by 50% and saved \$2.5 million in warranty costs.
- Improved "out of box quality" of finished product by 35% from two European device suppliers.

Senior QA Engineer Professional Products Group. Rochester, New York 1980 - 1988

- Designed and performed verification and product validation tests for in-vitro diagnostic medical devices.
- Coordinated validation testing between German and USA that reduced overall test time by 25%.
- Developed a manufacturing in-line quality process that reduced end of line quality costs by 75%.

Systems Development Engineer, Clinical Products Division 1972 -1980
Developed and tested in-vitro diagnostic medical device feasibility systems for R&D.

EDUCATION - Bachelor of Science - 1974 Digital Computer Design
Rochester Institute of Technology, Rochester, New York

RECENT PROFESSIONAL TRAINING

Design of Experiments, Fail Safe Problem Solving Techniques, EN 46001 European Directorate, Document Control Systems, Software Quality Engineering, People Skills for Managers, Finance for Non-Financial Managers

CERTIFICATIONS

Certified Quality Manager, cert # 1418 America Society for Quality
Certified Quality Auditor, cert # 13936 America Society for Quality
Certified Software Quality Engineer, cert # 178 America Society for Quality
ISO 9000 Lead Auditor
Certified Professional Consultant (CPC) by International Society of Speakers, Authors & Consultants

PROFESSIONAL MEMBERSHIPS

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