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EXPERIENCE

7/13 – Present **QUALMED SOLUTIONS, LLC,** West Newbury, MA
PRINCIPAL

- Providing Quality Assurance, Regulatory Affairs and HIPAA/GDPR expertise and guidance to medical device and life science firms including startup, entrepreneurial and large, well-established companies.
- Projects include gap assessments, continual improvement efforts and creating total Quality Management Systems compliant with the FDA's Quality System Regulation (QSR), ISO 13485, ISO 9001, MDR and IVDR.

1/13 – 1/21 **N-of-ONE, a QIAGEN Company,** Concord, MA
VICE PRESIDENT, QUALITY and REGULATORY OPERATIONS (Consultant 2/19 – 1/21)
(Part-time Permanent Employee 9/17 – 2/19)
Director, Quality and Regulatory Operations (Part-time Permanent Employee 2/15 – 9/17)
(Consultant 1/13 – 2/15)
Specializing in Personalized Cancer: Molecular Diagnostics and Therapeutic Strategies

- Providing Quality Assurance, Regulatory Affairs and HIPAA/GDPR expertise and guidance.
- Creating, implementing and maintaining an ISO/QSR compliant quality system.

2/06 – 11/12 **PICIS, INC.,** Wakefield, MA
VICE PRESIDENT, QUALITY ASSURANCE AND REGULATORY AFFAIRS (05/10 – 11/12)
Senior Director, Quality Assurance and Regulatory Affairs (09/09 – 05/10)
Director, Quality Assurance and Regulatory Affairs (09/06 - 09/09)
Director, Quality Systems (R & D) (02/06 – 09/06)

- Led a global, cross functional team in the development and continuous improvement of a Quality System Regulation, ISO 9001, ISO 13485, MDD and CMDCAS compliant Quality Management System for all locations including Wakefield MA, Rosemont IL, Spain and England. Obtained ISO 9001 and 13485 Certification in 2011 and ability to CE mark in 2012.
- Established and then improved the Quality Assurance and Regulatory Affairs functions including Regulatory Global Strategies, Documentation Control, Complaint Handling, CAPA and Auditing.
- Supervised all Quality Engineering activities for a Software Only Medical Device.
- Submitted a 513g requesting FDA classification of Picis' product. Subsequently, submitted a 510(k) requesting and receiving clearance as a Class II medical device for one piece of functionality.
- Assessed product lines at the Corporate Level for appropriate Medical Device Classifications.
- Oversight of the development of Picis' HIPAA program covering the confidentiality, integrity, availability, security and privacy of personally identifiable information including protected health information in compliance with global, federal and state laws.

8/04 – 2/06 **DRAEGER MEDICAL SYSTEMS, INC.,** Danvers, MA
DIRECTOR, QUALITY ASSURANCE AND REGULATORY AFFAIRS (8/04 – 2/06)

- Executive responsibility for all quality and regulatory affairs personnel, budgetary planning and activities including quality engineering, internal audits, customer complaints, medical device reporting, promotional and technical literature approval and all domestic and international product regulatory strategies, submissions and approvals.
- Member of the division's Executive Management team driving achievement of the business' goals.
- Transitioned the Quality System to comply with ISO 13485:2003 and Corporate's Management System within 6 months. Led division through Registration audit with zero nonconformances.

2/01 – 8/04 **MILLIPORE, INC.,** Bedford, MA
QUALITY SYSTEMS PRINCIPAL ENGINEER (BioPharmaceutical Division) (2/03 – 8/04)

- Provided Divisional Quality Engineering support for new product development, plant quality and change management and notifications both internally and externally.
- Member of Corporate and Divisional teams that implemented the systems needed to obtain a single, North American ISO 9001:2000 Registration including a corporate CAPA database system.

QUALITY MANAGER (Life Science Division) (11/01 – 1/03)

- Managed all aspects of the Quality function including quality engineering, internal audits, documentation control, quality control, customer complaints, external audits including the FDA and TuV, quality systems, metrics and departmental budgets.
- Led a cross functional team of 10 in the total redesign of the Product Development Protocol.
- Supported the transfer of new products into Pilot Manufacturing responsible for validation planning, Gamma Sterilization, QA/QC expertise and document control support as a Core Team member.
- Supported a successful ISO 9002 surveillance audit with zero nonconformances.

VALIDATION ENGINEER (Life Science Division) (2/01– 11/01)

EXPERIENCE (continued)

9/99 – 2/01 **CELESTICA,** formerly Hewlett-Packard Co., Andover, MA
QUALITY MANAGER

- Member of the division's leadership team formulating the business plan for this newly acquired Celestica division.
- Developed the Quality function, system and department.
- Managed all Quality Assurance Engineering Activities and the Documentation/Data Control Group.
- Created an ISO 9002 & QSR compliant quality system while managing a cross functional team of 15 members each responsible for creating procedures and processes for their respective elements.
- Interacted with customers to resolve Supplier Action Requests and customer issues.

7/98 – 9/99 **HEWLETT-PACKARD CO.,** Medical Products Group, Andover, MA
REGULATORY AFFAIRS ENGINEER

- Responsible for global registration and PTT (Post, Telephone and Telegraphy) licensing for the Telemetry product line along with performing all other regulatory tasks.
- Performed a mock FDA Audit for the Group Quality Organization in preparation for an FDA Inspection for the clearance of a warning letter and a general QSR inspection.

9/97 – 7/98 **ALLERGAN, INC.,** North Andover, MA
QUALITY SYSTEMS MANAGER

- Key contributor in final preparation of the Quality System resulting in ISO 9001/EN46001 Certification with zero observations.
- Responsible for quality system development, training and continuous improvement including the internal audit and corrective action systems.
- Assumed responsibility for the Documentation Services system and personnel in October, 1997.
- Assured compliance to ISO 9001, EN46001 and MDD CE Mark labeling requirements.

12/90 – 9/97 **MEDTRONIC INTERVENTIONAL VASCULAR, INC.,** Danvers, MA
STERILIZATION and TEST SERVICES TEAM LEADER (6/97 – 9/97)

- Supervised daily activities of an Associate QAE responsible for EtO sterilization validation activities, daily sterilization issues and biocompatibility requirements.
- Supervised daily activities of a QA Technician and R&D Test Technician responsible for test method development and validation testing. Began the establishment of an on-site LAL Testing Lab.
- Began Gamma Radiation validation activities until determined the method to be cost prohibitive.

SENIOR QUALITY ASSURANCE ENGINEER (1/92 – 5/97)

- Supervised daily activities of a QAE responsible for sterilization and biocompatibility requirements.
- Led MIV to ISO 9001/EN46001 Registration.
- Key interface with the FDA during inspections and in response to a Medical Device Safety Alert.
- Reviewed MDRs and 510(k)s.
- Led a cross functional team in the complete rewrite of the Product Development Process.
- Member of product development teams that introduced new technologies including continuous extrusion and braiding, injection molding and lumenal coating reducing FAPC by 50%.
- Supplier Certification program development and certification of two suppliers in first year.
- Member of a team that received Medtronic's Star of Excellence Award

QUALITY ASSURANCE ENGINEER (12/90 – 12/91)

OTHER RELEVANT EXPERIENCE

BARD CRITICAL CARE, Tewksbury, MA
HONEYWELL ELECTRO-OPTICS DIVISION, Lexington, MA

EDUCATION **UNIVERSITY OF VERMONT,** Burlington, Vermont
Bachelor of Science Degree in Mathematics

CERTIFICATIONS
RAPS Regulatory Affairs Certificate: Medical Devices and Pharmaceuticals (dual) (2023)
A.S.Q. Certified Quality Auditor
Certified Lean Six Sigma Green Belt
Exemplar Global Certified ISO 9001:2015 QMS Lead Auditor
Quality & Productivity Solutions, Inc., Certified ISO 13485:2016 Lead Auditor

PROFESSIONAL AFFILIATIONS
American Society for Quality – Senior Member
Regulatory Affairs Professional Society