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# Highlights of Qualifications

* **Twenty years’ experience in regulated industry**
* **Personnel and Project management**
* **Risk Management Strategy & Plans**
* **Continuous Improvement**
* **Global Quality Management System**
* **Successful FDA, ISO, JPAL compliance audits**
* **FDA and ROW Regulatory submissions**
* **Cross-functional team/ company initiatives**
* **CFRs, ICH, GMP, GLP, GDP, USP, ISO, MDD/MDR, HC, TGA, JPAL, Brazil, CFDA**

**SUMMARY OF EXPERIENCE**

**May 19 - CURRENT BIOGEN Durham, NC**

DIRECTOR, CORPORATE QUALITY AUDITS and COMPLIANCE

* Oversees the Internal and External GMP audit program for PO&T including risk management and audit program design. Responsibility for Annual compliance monitoring program development and execution.
* Primary responsibility for Annual Audit schedule development and execution for both Internal and External Audits. Develops and maintains the Affiliate audit schedule and maintains the Affiliate Audit program, including audit planning, execution and reporting.
* Manages and develops a team of Auditors with expertise across GMP regulations, including IT and Affiliates. Establishes clear goals and effective metrics that provide insight to industry benchmark and applicable trends with regard to cGMP compliance.
* Enables ongoing compliance and strategic application of Regulatory requirements by researching, collecting, organizing and maintaining files on regional and global quality/regulatory intelligence.
* Management Review QMS Business Process Owner
* Asset Lead for the Multiple Sclerosis Performance Test (MSPT).
* Provides inspection readiness preparation and guidance as needed. This includes participation in GMP inspections as applicable & supporting activities associated with inspections.
* Quality System Owner for the Science, Technology, and Development QMS
* Supports key innovation activities within Global Quality (GQ) and assures optimal approaches for project management on major initiatives.

ASSOCIATE DIRECTOR, CORPORATE QUALITY REGULATORY COMPLIANCE

STAFF ASSOCIATE, CORPORATE QUALITY

* Enables ongoing compliance and strategic application of Regulatory requirements by researching, collecting, organizing and maintaining files on regional and global quality/regulatory intelligence.
* Management Review QMS Business Process Owner
* Asset Lead for the Multiple Sclerosis Performance Test (MSPT).
* Development, oversight, implementation, and maintenance of PO&T Quality Management System (QMS) including Continuous improvement, Regulatory Intelligence implementation throughout the QMS, ensures global harmonization and provides strategic level support
* Provides inspection readiness preparation and guidance as needed. This includes participation in GMP inspections as applicable & supporting activities associated with inspections.
* Quality System Owner for the Science, Technology, and Development QMS
* Supports the development and maintenance of Core Quality Policies and Directives applicable at a global level and covering all aspects of GMP, GDP, and GLP performed within PO&T including biologics, small molecules, antisense oligonucleotides, gene therapy, combination products, and medical devices.
* Supports key innovation activities within Global Quality (GQ) and assures optimal approaches for project management on major initiatives.
* Supports Risk Management strategies and maintenance of the overall Risk Management plan.
* Provides ongoing Risk Management consulting to the PO&T operations.

**Apr 18 – May 19 BIOMEDOMICS, INC. Durham, NC**

BioMedomics, Inc. is an *in vitro* diagnostics medical device company dedicated to the creation of lifesaving diagnostic technologies.

SENIOR DIRECTOR OF QUALITY & REGULATORY AFFAIRS

* Updated Quality Management System to achieve compliance to ISO 13485:2016; successful ISO 13485 audit in achieving updated certificate.
* Successful FDA audit, Zero 483s identified by FDA Inspector
* Remediated the following key QMS processes to meet company goals/needs and achieve compliance: Complaint Handling, Non-Conforming Material, Product/Design Change, Document and Record Control, and Correction & Preventative Action
* Updated Design Control process to ensure outputs are in suitable form for verification against inputs
* Created and implemented a Risk Management process and SOP compliant to ISO 14971
* Provide guidance on complaints and product investigations to assess risk, determine testing to identify the root cause
* Responsible for company QMS including management review, document & record control, training, design controls, risk management, external & internal audits, CAPA, NCMR, and Complaints.
* Collaborates with manufacturing and R&D to troubleshoot manufacturing, production, and process non-conformances and CAPA
* Completed FDA Pre-submission negotiating clinical studies and non-clinical studies required for submission.

**Nov 15 – Apr 18 NOVAERUS, INC. Raleigh, NC**

Novaerus, Inc. is a start-up indoor air quality company. Novaerus Air Purifiers are considered a Class II medical device by the FDA.

VP OF QUALITY & REGULATORY AFFAIRS

* Created and implemented a Quality Management System compliant to ISO 13485 & 21CFR820.
* Created and implemented a Design Control process to develop and verify products classified as a medical device for the US and European Union.
* Responsible for company QMS including management review, document & record control, training, design controls, risk management, supplier & internal audits, CAPA, NCMR, and Complaints.
* Responsible for Quality Control, Quality Engineering, and Quality assurance.
* Completed Technical file for a MDD CE Mark for registration in the EU.
* Plasma Air Acquisition team: conducted technical evaluation of Plasma Air, completed integration planning and execution

**Feb 15 – Jan 16 REGULATORY AND QUALITY CONSULTANT RTP, NC**

An independent quality and regulatory consultant for the medical device, biotechnology, and pharmaceutical industries.

* 40hr/wk. contract for Bioptigen acquired by Leica Biosystems: to develop DHF nomenclature, remediate design control and QMS, author Technical File, and complete 510k response.
* Develop Quality Management Systems in compliance with government regulations and standards (FDA CFRs/GMP, ICH, CMDCAS, MDD,TGA, JPAL and ISO 13485).
* Provides expertise in method development and validation and software validation.
* Complete risk assessment and risk management file in compliance with ISO 14971.
* Research and identify appropriate device classification and regulatory pathway for device clearance.
* Complete FDA (Pre-submission, 510(k), DeNovo) and International regulatory applications.

**Nov 07 – May 15 TEARSCIENCE, INC. Morrisville, NC**

TearScience, Inc. was a start-up ophthalmology medical device company. TearScience grew from 15 employees to over 200 employees while consistently achieving excellent compliance audits over my tenure at TearScience. We received one FDA DeNovo clearance, two original 510k clearances, two design change 510k clearances, three CE Certificates, and regulatory approvals in Canada, Australia, New Zealand, Japan, South Korea, Taiwan, and Thailand. TearScience was acquired by Abbott Medical Optics, the surgical operating company of Johnson & Johnson Vison.

SR. DIRECTOR OF QUALITY & REGULATORY COMPLIANCE Apr 12 – May 15

* Hosted successful FDA, ISO 13485, ISO 13485 “Micro”, and CE Certificate audits achieving Zero 483s for FDA audit, Zero nonconformances for ISO 13485 and one nonconformance for CE audit).
* Expanded Quality metrics and KPIs: increased content, increased frequency from quarterly to monthly, and expanded distribution to include continuously present on TV. This effort contributed to the improved complaint, NCMR, and CAPA closure rates, reduction in number of NCMRs, and to the internal audit on-time % and nonconformances.
* Implemented electronic labeling, which streamlined manufacturing process & reduced product cost.
* Streamlined the electronic complaint process reducing closure time by 60%.
* Updated the CAPA process and implemented a review board to ensure continued timely completion of each stage: initiation, root cause investigation, implementation, and effectiveness review.
* Responsible for company QMS including: management review, document & record control, training, design controls, risk management, supplier & internal audits, CAPA, NCMR, and Complaints.
* Completed audits of our contract manufacturing partners and critical/key suppliers.
* Responsible for quality engineering, quality management system, quality assurance and control.
* Ensured products are developed, manufactured, tested and delivered according to established procedures that will assure that they meet all quality requirements.
* Implemented strategic development, modification, and streamlining of the Quality management system to achieve compliance and meet the needs of an expanding company
* Responsible for company regulatory compliance including Technical Files, vigilance, medical device reporting, correction & removals, device listings and registration.
* Responsibility for planning and implementing the quality and regulatory compliance budget

DIRECTOR OF QUALITY COMPLIANCE & SUPPLY CHAIN Feb 09 – Apr 12

* Product development core team member with R&D, Clinical and Regulatory for the development and commercialization of the LipiFlow and LipiView systems
* Accomplished the design transfer of our LipiView Interferometer (electro-mechanical device) to a contract manufacturer in 8 weeks.
* Transferred manufacturing of the LipiFlow Activator (disposable device) from a prototype manufacturer to a full turn-key contract manufacturer.
* Expanded ISO 13485 certificate to include CMDCAS to achieve Canadian clearance.
* Created, implemented, and validated an electronic nonconforming material process
* Implemented an electronic inventory management system.
* Responsible for company QMS including: management review, document & record control, training, design controls, risk management, supplier & internal audits, CAPA, NCMR, and Complaints.
* Completed audits of our contract manufacturing partners and critical/key suppliers.
* Responsible for the manufacturing and distribution of medical devices.
* Oversaw process validation (IQ/OQ/PQ) of QC and manufacturing equipment
* Responsible for product quality assurance including: incoming, in-process, and final QC of product.
* Ensure products are developed, manufactured, tested and delivered according to established procedures that will assure that they meet all quality requirements.
* Responsibility for planning and implementing the quality and supply chain (manufacturing) budget.

QUALITY ASSURANCE AND COMPLIANCE MANAGER Nov 07 – Feb 09

* Product development core team member with R&D, Clinical and Regulatory for the development of the LipiFlow and LipiView systems including development and review of the:
  + Design control plan; design inputs; design outputs including product specifications, drawings, material specifications, assembly instructions, QC requirements & instructions; design verification plan, design verification protocols/reports, design validation protocols/reports, Clinical Study protocols & reports,
  + Risk management plan, risk assessments, risk management report,
  + Design transfer plan, Process validation protocols/reports, Commercialization plan/checklist
  + Design Changes: Production change order review including review of all material specification & drawing changes, required design verification including protocols/reports
* Created and implemented a Quality management system with achieving ISO 13485 certificate within 3 months of hire.
* Implemented the company product shelf-life validation and stability testing program.
* Created and/or reviewed and approved product packaging, product labeling, and Instructions for Use
* Implemented and validated an electronic document management and training system in 15 weeks.
* Created, implemented and validated an electronic complaint management system in 12 weeks.
* Received FDA DeNovo clearance for regulation 21CFR866.5200 within 90 days of submission.
* Created Technical file and received CE certificate in 2 weeks for the LipiFlow System.
* Responsible for company QMS including: management review, document & record control, training, design controls, risk management, supplier & internal audits, CAPA, NCMR, and Complaints.
* Completed audits of our contract manufacturing partners and critical/key suppliers.
* Oversaw and promoted company efforts to develop, implement and continually improve systems to ensure customer requirements are implemented into company products.
* Responsibility for planning and implementing the quality budget.

**July 06 – Nov 07 W.L. GORE & ASSOCIATES Flagstaff, AZ / Elkton, MD**

W.L. Gore & Associates is multi-national manufacturing company, active in consumer products, textiles, electronics, medical and healthcare, sealants and filtration. The W.L. Gore medical device division implant biomaterials and membranes includes but is not limited to: vascular grafts, sutures, hernia patches, endoprosthesis for the endovascular, vascular, general surgery, interventional cardiology and radiology, and cardiovascular fields.

PROJECT MANAGER / QUALITY ASSURANCE

* Project manager for transfer of a medical device product line including a pharmaceutical coated medical device from southwest facility to east coast facility
* Oversaw creation of quality assurance testing capability (X-Ray Fluorescence, Titration, and GC)
* Oversight of design firm responsible for the design and building of the manufacturing equipment.
* Managed installation, operational, and performance qualifications (IQ/OQ/PQ) of manufacturing equipment and analytical testing center equipment
* Implemented manufacturing assembly and quality control testing procedures.
* Responsible for implementation of the east coast facility product stability testing program.

**Sept 04 – July 06 ETHOX INTERNATIONAL Buffalo, NY**

Ethox International is a privately held medical device manufacturer of blood pressure cuffs, pressure infusion products, gastric lavage and tubing. Ethox International is also a contract manufacturer, contract EtO sterilizer, and contract testing organization for medical device, biotechnology, and pharmaceutical industries.

QUALITY ASSURANCE / REGULATORY AFFAIRS

* Addressed twenty-eight FDA 483s Ethox received prior to myself joining and then achieved successful FDA audit with only 1 nonconformance.
* Regulatory & Quality Specialist for product development team charged to bring four new products to market in five months.
* Upgraded the corporate quality management system to achieve ISO 13485:2003 compliance including revision of Quality Manual, all corporate SOPs and creating Risk Management program.
* Proposed and completed revision of design control process which speeds product to contract manufacturing customers by 30%.
* Initiated lab improvement team: incorporated procedures into document control system and developed out of specification procedures
* Quality & regulatory review of raw material sourcing for medical devices manufactured in China.
* Oversight of analytical method development for QC testing of combination products, coated medical devices, and pharmaceuticals including HPLC, GC, and UV/VIS.
* Responsible for lab and manufacturing process validation (IQ/OQ/PQ)
* Reviewed and updated technical files for historical products
* Completed FDA 510k submissions and technical files for CE certificate.
* Oversaw Laboratory Quality including: Lot Release, document review, CAPA, NCMR, method validations, quality trending, environmental monitoring, and out of specifications
* Corporate quality responsibility: CAPA team, material review board, management review, lead internal auditor, customer complaints, and host for customer, FDA, and ISO audits.
* Responsible for hosting customer FDA, ISO, and CE certificate audits.
* Appointed corporate Safety committee co-chairperson

**Feb 98 – Sept 04 STERIS CORPORATION Mentor, OH**

STERIS Corp. is a publicly traded medical device company with approximately 2 Billion in revenue. STERIS is the world's pre-eminent infection prevention, decontamination, and surgical and critical care company. My focus was in STERIS’s research, development, design transfer, and commercialization of liquid chemical sterilants & sterilizers, liquid chemical high level disinfectants & processing systems, and low temperature VHP sterilizers for the hospital setting.

GROUP MANAGER, SENIOR SCIENTIST Jan 02 - Sept 04

* Group Manager of R&D, Advanced Sterilization (including Chemistry & Microbiology)
* Responsibilities: budget, NPD process, FDA & ISO audits, regulatory submissions, associate review
* Manager of the development, design controls, and validation of the VHP 136 Low Temperature Sterilizer
* Identified and solved project technical challenges through a design of experiments utilizing fluid dynamics software.
* Developed & proposed concept for redesign of consumable product to increase profits ~8 million/year
* R&D representative on cross-functional team for platform development of Class II medical devices
* Presented project status to executive steering committee at gate reviews & quarterly business meetings
* Responsibility for planning and implementing the R&D, Advanced Sterilization group budget.

PROJECT MANAGER, SENIOR SCIENTIST Sept 00 - Jan 02

* Project Manager of R& D, New Product Development Chemistry Group
* Completed Reliance Endoscope Processing System 510k in 2 weeks achieve target submission date.
* Coordinated the development, verification, and validation of a generational high-level disinfectant and washer- high level disinfector per AAMI, GMP and GLP.
* R&D member of cross-functional team charged to create and implement a company wide New Product Development process.
* Oversaw the development & validation of HPLC, UV/VIS, and FTIR methods for R&D design verification testing and manufacturing quality control testing.
* Oversaw development of Product Specifications and testing requirements for germicide chemistries.
* Responsible for the development of a novel line of chemical and process indicators for generational liquid chemical high-level disinfectant.
* Completed design transfer to pilot manufacturing process for generation liquid chemical sterilant.
* Implemented revision of corporate Design Control procedure decreasing revision and review time.
* Determined root cause of a particulate issue identified during design verification testing through a DOEs.
* Completed Design History Files, Technical Files, and 510(k) submission

SCIENTIST Mar 99 – Sept 00

ASSOCIATE SCIENTIST Mar 98 – Mar 99

**1995 – Mar 1998 SUPERIOR FLUX Mayfield Heights, OH**

Superior Flux is a formulator and manufacturer of soldering, welding, and brazing fluxes.

CHEMIST & SAFETY COORDINATOR

**EDUCATION**

**1995 Washington State University Pullman, WA**

• Bachelor of Science (Chemistry and Biology)

• Recipient of Division 1 scholarship and letter on WSU Women's Varsity Soccer Team

REFERENCES FURNISHED UPON REQUEST