Curriculum Vitae

DIRECTOR OF TECHNICAL SERVICES AND STRATEGIC INITIATIVES
DAVID J. BRODERSEN

Phone: 419-693-5307

Summary of Qualifications

David is a results-oriented Global Quality leader who combines strategic thinking and business knowledge to achieve organizational improvements. He leverages vision-driven leadership, extensive Quality Assurance, Risk Management, Microbiology, Sterilization and Biocompatibility knowledge, and has experience managing across matrix organizations to drive design/execution of innovative solutions, quality improvement initiatives and robust compliance practices and strategies. He has proven success in leading high-performance organizations and cross-functional cooperative initiatives to develop quality solutions and strategies to achieve stated objectives and goals. He is a leader in Strategic Planning, Analysis and Execution with a proven ability to act as a change agent and lead organizations through change management.

Professional Experience

DIRECTOR OF TECHNICAL SERVICES AND STRATEGIC INITIATIVES, *LexaMed, Ltd.*

Performance and management of organization's services in all areas of sterilization, validation, and microbiological compliance including, but not limited to SOP content and USP testing methods, client and internal audit preparation, training programs, environmental monitoring, bioburden and microbial quantitation, product stability programs, sterilization processes and validations, development and protocol documentation, equipment and process validations, and regulatory submissions.

DIRECTOR OF STERILIZATION, MICROBIOLOGY AND BIOCOMPATIBILITY, *Medtronic/Covidien*

Directed the implementation of Sterilization Validations, Microbiology, Biocompatibility and Environmental Control for the global business. Involved with strategic planning, defining and developing standard processes, sharing and implementing best practices and promoting cross-functional collaboration and cooperation. Responsible for

continuously reviewing FDA regulations, ISO standards, quality control philosophy and practices to recommend compliant procedures and cost effective solutions.

- Covidien representative on multiple ISO /AAMI TC198 Sterilization working groups and Organization Lead for
- ISO TC194 Biocompatibility managing working groups Covidien representation.
- Maintained total and complete understanding and compliance with the requirements of FDA, ISO, EN, MHLW, and Covidien regulations and standards regarding sterilization, biocompatibility, microbiological quality control, and medical products manufacturing environments.
- Conducted or participated in internal audits, vendor audits and contract manufacturer audits.
- Supported technical oversight for New Product Development and Sustaining Change Control for responsible subjects.
- Assured state-of-the-art methodology and results using documented procedures, equipment and accept/reject criteria.

DIRECTOR OF QUALITY ASSURANCE AND COMPLIANCE, *Covidien – Sustainable Technologies*

Developed and implemented quality management system for new startup franchise with global organization. This included but not limited to Quality Operations, Systems, Compliance and Design Control. Directed the implementation and maintenance of quality management principles and tools to promote continuous improvement of systems, product and service quality. Maintained quality systems to ensure conformance with international and local requirements by review and surveillance that QA practices incorporate current and appropriate worldwide (including FDA, QSR, ISO 13485, CMDR, and European Medical Device Directive) regulatory compliance expectations. Site Management Representative, managed regulatory inspections and interfaced with Regulatory agencies.

- QA oversight and cleanroom technical lead for design, construction and successful opening of brand new FDA registered manufacturing facility.
- Successfully launched 2 product lines, the first Covidien Reprocessed products in the market.
- Covidien representative on multiple ISO/AAMI TC198 Sterilization working groups with focus on Reprocessing and Organization Lead for ISO TC194 Biocompatibility managing working groups Covidien representation.

DIRECTOR OF STERILIZATION, MICROBIOLOGY AND BIOCOMPATIBILITY, *Covidien – Respiratory and Monitoring Solutions*

Directed the implementation of Sterilization Validations, Microbiology, Biocompatibility and Environmental Control for the global Respiratory business. Strategic planning, defining and developing standard processes, sharing and implementing best practices and promoting cross-functional collaboration and cooperation. Responsible for

continuously reviewing FDA regulations, ISO standards, quality control philosophy, practice and procedure to recommend compliant procedures and cost effective solutions.

- Managed change control of products, processes and facilities with regard to impact on sterilization, biocompatibility and microbial control, by means of document change requests, audits and project participation for 8 international facilities.
- Covidien representative on multiple ISO/AAMI TC198 Sterilization working groups and Organization Lead for ISO TC194 Biocompatibility managing working groups Covidien representation.
- Coached and mentored large and diverse, multinational laboratory quality control personnel.
- No major NCs from internal or external audits. Successfully closed out closed out legacy warning letter elements associated with environmental monitoring and product cleanliness.
- Converted 7 cycles to parametric release for an average $315K cost savings.
- Successfully managed DEHP plasticizer replacement projects for 5 product lines.

STERILIZATION QA MANAGER / SR. QA STERILIZATION ENGINEER, *C.R. Bard, Inc.*
Managed Quality Systems, Operations and Compliance for two EO sterilization facilities ensuring compliance to corporate policies, ISO standards and FDA regulations.

- Implemented Quality Systems, completing full equipment IQ/OQ/PQ and EO sterilization validations for new 28 million dollar, 6 process line sterilization facility.
- Installed and validated new state of the art EO environmental monitoring system for worker exposure.
- Develop and validated low temperature EO sterilization cycle for temperature sensitive product.

CORPORATE STERILIZATION MICROBIOLOGIST, *Arrow International, Inc.*
Microbiology and Sterilization oversight for 8 Arrow International facilities. Manager for Microbiology and Chemistry labs managing a team of 7.

- Technical project manager for design, construction, equipping and staffing 2 new $500,000 chemistry labs (1 U.S. and 1 in Czech Republic). The implementation of the internal Chemistry labs saved an annual contract lab cost of 1.2 million dollars.
- Implemented a reduced incubation process for a 2 day sterility release which realized a cost savings of 3 million dollars.

MICROBIOLOGY LABORATORY SUPERVISOR, *NeoRx/International Isotopes*

- Responsible for providing oversight of the daily operations of the QC Microbiology department to support of manufacturing, R&D, and quality.
- Performed validations/verifications of facility equipment, systems, and both aseptic and sterile processes in support of Parenteral, Medical Device, Radiochemical, and Radiopharmaceutical manufacturing.

- Authored and executed validation protocols and Procedures in accordance with regulatory guidelines: Media Fills, Cleanroom Qualifications, Water Systems (PW and SWFI).
- Initiate and conduct investigation, troubleshooting, and root cause analysis for out-of-specification results and procedural deviations.

MICROBIOLOGY LABORATORY SUPERVISOR, *Mrs. Crockett's Kitchen*

MICROBIOLOGY QC LABORATORY TECHNICIAN (CONTRACT), *Mary Kay Cosmetics*

U.S. ARMY/ARMY RESERVES – SSG E-6 (ACTIVE/RESERVE)
Over 20 years of successful management and leadership experience with a reputation for meeting challenging organizational goals and objectives. A pragmatic and focused individual recognized for "making seemingly impossible situations work." A proven and verifiable record for:

- 91A Combat Medic 1988-1994
- 91C Practical Nurse 1994-1997 [Department NCOIC]
- 91V Respiratory Therapist 1997-2002 [Department NCOIC]
- 79V Retention NCO 2002-2008

Education

- **Emergency Medical Technician [Combat Medic]** – Allied Health Academy, *Ft. Sam Houston, Texas,1988*
- **Primary Leadership Development Course**, *Ft. Chaffee, Arkansas, Squad Leadership, Management and Problem Solving Analysis in Tactical Environment, 1991*
- **Licensed Practical Nurse** – Allied Health Academy, *Ft. Lewis, Washington, 1994*
- **Basic Non-Commissioned Office Course**, *Ft. McCoy, Wisconsin, Platoon Management, Leadership and Problem Solving Analysis in Tactical Environment, 1996*
- **BS, Microbiology**, Kansas State University, *Manhattan, KS, 1997*
- **Certified Respiratory Therapist**, Allied Health Academy – *US Army, 1999*

Technical Certifications and Achievements

- ASQ Six Sigma Yellow Belt, 2006
- Project Management, Krepner-Tregoe, 2008
- Six Sigma DMAIC Green Belt 2009
- Biocompatibility Risk Management (NAMSA) 2010, 2011
- ISO 13485 Lead Auditor Certification, Oriel STAT-A-MATRIX, 2012

- Internal Auditor Certification, ASQ, 2012
- Quality Systems for Medical Devices: FDA's QSR and ISO 13485, STAT-A-MATRIX, 2013
- Fundamentals of Finance and Accounting for Non-Financial Managers, AMA, 2013

Professional Associations

- Senior Member of the American Society of Quality
- Member of the American Society for Microbiology
- Member of the Parenteral Drug Association (PDA)
- Member of the Pharmaceutical Microbiology Forum
- Member of the Association for the Advancement of Medical Instrumentation