Curriculum Vitae

SENIOR CONSULTANT, REGULATORY AFFAIRS
ROBERT O. DEAN

Phone: 716.876.7746

Summary of Qualifications

Robert has over 35 years of experience providing expertise in all facets of sterile medical device, pharmaceutical, bio-technology, infection control operations, including regulatory affairs, quality assurance, engineering, lean manufacturing / planning, materials / MRP, MIS, and, sales, providing for a strong ability and energy to contribute and channel an organization to accomplish extraordinary objectives. Robert has strong focus and capabilities in accomplishing corporate visions, focus and leadership providing measured management and accountability.

Professional Experience

SENIOR CONSULTANT, REGULATORY AFFAIRS, *LexaMed, Ltd.*

Robert provides consulting services for clients from pharmaceutical and medical device companies. Responsibilities to date include technical guidance with respect to regulatory affairs and quality assurance.

VICE PRESIDENT, GLOBAL RA/QA AND OPERATIONS INITIATIVES
VICE PRESIDENT, ENGINEERING & STRATEGIC BUSINESS DEVELOPMENT
VICE PRESIDENT, OPERATIONS, *Buffalo Filter*

- Responsible for direct corporate management of RA/QA, manufacturing, materials, MRP, purchasing, PIC, shipping & receiving. Organized and implemented team focused operations management with LEAN Operations implementation
- World wide product licensing (Europe-CE, Pac Rim, Canada)
- Comprehensive risk based assessment, preparation and execution of protocols specific to FDA/regulatory situations

- Engineered, validated and manufactured 60+ new products capturing several million dollars in new initial sales
- Prepared successful FDA 510(k)s for advance design feature sterile medical devices
- Project team building and participation
- Improved On-Time delivery to 95+%
- Upgraded shipping response time to 97% of orders shipped within 24 hours
- Product sales orders shipped to 99% accuracy
- Budgetary control implementation
- Reinforced procedures to significantly improve company regulatory compliance
- Turn around from essentially bankrupt corporate position

GENERAL MANAGER, *Air Lock Plastics, Inc.*

- Responsible for day to day activities, planning and P&L reporting for departments; manufacturing, materials, sales, engineering, quality control, and regulatory affairs
- Reorganized operations to include Engineering Services and Material Control (MRP/IC) for more effective response to customer requirements and future strategic marketing plans
- Redesigned manufacturing scheduling and planning system for enhanced operations performance
- Directly participated in successful renegotiations of three-year union contract

DIRECTOR OF OPERATIONS, *Buffalo Filter*

- Responsible for direct departmental management of manufacturing, materials, MRP, purchasing, PIC, quality control, shipping & receiving, internal regulatory affairs (FDA, ISO, OSHA, EPA)
- Organized and implemented team focused operations management
- Improved On-Time delivery to 95+%
- Upgraded shipping response time to 80% of orders shipped within 24 hours
- Streamlined inventory to result in 98% accuracy
- Reduced COGS from 40% to 28%
- Instituted procedures to significantly improve company compliance
- Product CE marking and ISO planning

DIRECTOR OF MARKETING AND GOVERNMENTAL AFFAIRS, *Safetec of America*

- Responsible for marketing of infection control products, providing direct input and coordination to a sales team with a customer base consisting of over 3,000 accounts
- All governmental affairs, inclusive of FDA and EPA compliance
- Team oriented approach to product development and enhancements
- Coordinated three new infection control products through the FDA regulatory approval process and market introduction

- Installation of a Novell / Windows based LAN system including sales and operations support software

VICE PRESIDENT, CONTRACT CUSTOMERS
NATIONAL SALES MANAGER, CONTRACT CUSTOMERS, *Ethox Corporation*

- Responsible for contract negotiations and customer servicing of multi-million dollar worldwide major medical device companies, quotation and pricing preparation. Direct customer interface on resolving engineering/quality specifications
- Strategic and Market planning and analysis; Forecasting, near and long term
- Formal cost analysis and pricing reduction programs, direct participation on product development teams for major "State of the Art" medical technologies, and contract manufacturing marketing and advertising
- Increased new sales and closed several high volume accounts
- Designed, installed and implemented a dedicated flexible manufacturing workcell, reducing delivery lead-times from 12 weeks to 5 days, through custom software and operational procedures

MANAGER, SYSTEMS & INFORMATION, *Ethox Corporation*

- Responsible for managing a 70 station Novell LAN, Day to day operation of closed loop MRPII manufacturing Control System, Management of computer based FDA/GMP and quality documentation/traceability systems, Computer Aided Design (CAD) systems, and ongoing management of all regulatory affairs, inclusive of FDA, OSHA, EPA, NYDEC responsibilities
- Installed one of the first operating Local Area Networks in the east coast, starting from a 3 station LAN to a +70 LAN
- Selected and installed a comprehensive MRPII computer system
- Computerized all product specifications and manufacturing/quality traceability

SENIOR SUPERVISOR OF TECHNICAL SERVICES/QUALITY CONTROL/ASSURANCE, *Ethox Corporation*

- Responsible for Regulatory Affairs, inclusive of FDA, EPA, OSHA and NYDEC
- FDA/GMP compliance inclusive of all GMP audits, FDA product approvals via 510(k), IDE, PMA, All product documentation and specifications, Technical Services and Drafting
- Centralized all regulatory/product specifications and manufacturing history traceability
- Prepared GMP manual and compliance procedures for FDA compliance

Education

- MBA, University at Buffalo, Buffalo, NY

- B.A., Liberal Arts, State University College at Buffalo, Buffalo, NY

Seminars and Coursework

- ISO 9000 Implementation
- Forecast Modeling Courses
- Blood Processing Technology
- Key Manager Entrepreneurial
- Computer Network Training
- International Market Development
- FDA Compliance Seminars