



Curriculum Vitae

DIRECTOR OF QUALITY OPERATIONS ANNE SCHULER

Phone: 419-693-5307

Summary of Qualifications

Anne has over 25 years of technical/quality/regulatory experience within the medical device industry. She has a strong background in quality control, domestic and international regulatory compliance, customer service, project management, internal and external consultation and document preparation. Furthermore, she possesses additional strengths in organizational skills, problem solving and quality system management.

Professional Experience

DIRECTOR OF QUALITY OPERATIONS, *Lexamed, Ltd.*

- Implement, expand and maintain company quality systems, including failure investigations, CAPA programs, document control, and complaint handling.
- Perform QA review and approval of protocols, lab reports, procedures, specifications.
- Develop material and conduct GMP, quality system and technical training.
- Responsible for compliance to USP, AAMI, ISO, QSR and GLP guidelines.
- Author company quality manual, standard operating procedures, and study protocols.
- Conduct internal and vendor audits.
- Serve as management representative, organize and conduct management review meetings.
- Manage customer and FDA inspections.
- Provide auditing services in the areas of:
 - Quality systems,
 - QC microbiology,



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- Laboratory operations,
- SOP Content & USP Testing Methods,
- Training Programs
- Regulatory Submissions

SENIOR REGULATORY AFFAIRS SPECIALIST, *Depu Orthopaedics (a Johnson & Johnson Co.)*

- Prepared 510k and PMA documents in order to receive FDA clearance/approval for Class II and Class III products in a timely manner.
- Maintained Tech Files on Class II and II devices as well as prepare Design Dossiers for Class III products for European submissions.
- Interacted with regulatory bodies on issues that may arise with devices in for review.
- Reviewed and approved NCR's and CAPA's to assess affect of non-conformance on regulatory requirements.
- Kept current with FDA regulatory standards and guidelines to ensure updated standards were being followed.

BIOCOMPATIBILITY / STERILIZATION SPECIALIST, *Boston Scientific*

- Responsible for ensuring that biocompatibility testing conducted in support of FDA, Japanese and European submissions was compliant with current regulatory standards.
- Assisted Regulatory Affairs Specialists with submissions to FDA, Notified Bodies and Japanese Ministry of Health.
- Designed testing programs for new and approved medical devices undergoing change to ensure acceptance by FDA and European notified bodies.
- Reviewed biocompatibility programs set up at various BSC sites across the country to determine if they are ISO/FDA compliant and acceptable for IDE, PMA or 510k submissions.
- Prepared responses to questions from FDA and Notified Body reviewers regarding biocompatibility issues.
- Provided assistance to BSC microbiology departments for testing issues.
- Designed and present a corporate training program for biocompatibility.
- Kept current with various AAMI and ISO standards dealing with sterilization and biocompatibility and quality systems to ensure updated standards were being followed.

TECHNICAL SPECIALIST, *BEC Laboratories, Inc.*

- Responsible for overseeing the day-to-day operations of the Microbiology, Chemistry, and Quality Assurance Departments.
- Ensured resources and supplies were in place to meet testing and production deadlines.



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- Maintained the Quality System so that BEC met FDA and ISO criteria for continued certification/registration.
- Ensured systems are in place so that company meets all requirements of FDA 21 CFR 820 Quality Systems regulations and ISO 9001:2000 and 13485 Quality Systems.
- Professionally represented company in interactions with the FDA and Notified Bodies.
- Kept current with appropriate AAMI and ISO documents to ensure all testing methods are in compliance with the most up-to-date methods.
- Developed and implemented training programs for various laboratory procedures as well as quality systems training.
- Monitored and maintained CAPA and NCR systems.
- Acting Study Director for testing conducted under formal "GLP" regulations.

BIOCOMPATIBILITY/REGULATORY TECHNICAL SPECIALIST, *North American Science Associates (NAMSA)*

- Designed medical device test programs for clients seeking approval from the FDA and other regulatory bodies.
- Provided management suggestions for business development.
- Followed various ISO, AAMI and FDA regulatory documents to prepare appropriate test programs.
- Interpreted testing data, generated technical reports, and provided client solutions for unacceptable test results.
- Served as sales representative for clients seeking company services.
- Visited clients to troubleshoot problems and discuss testing needs.
- Represented company at medical device trade shows.
- Updated testing data collection sheets which reduced errors and improved quality.
- Prepared and presented both internal and external seminars.
- Trained and advised sales staff on testing and regulatory requirements to promote sales.
- Served as liaison between client and laboratory.
- Acting Project Manger for designated clients for various programs.

SECTION MANAGER, CUSTOMER SERVICE UNIT, *North American Science Associates (NAMSA)*

- Responsible for supervising staff of five employees who received, processed and distributed client testing orders.
- Assisted clients with questions/complaints about orders.
- Reorganized staff which reduced data entry errors and decreased time required to get product to the laboratory by 100%.
- Trained staff on technical issues in order to improve service to clients.



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- Worked with lab personnel to address client concerns about in-house testing and to assure client needs were being met.
- Discussed client issues with sales staff in order to retain their business.
- Authored and maintained department SOPs

LABORATORY SECTION MANAGER, *North American Science Associates (NAMSA)*

- Responsible for managing a designated portion of the Toxicology department.
- Reviewed data and wrote reports for specialized testing.
- Acted as scientific advisor to the department.
- Developed an audit schedule for the Quality Assurance department to use in monitoring the department activities.
- Designed training programs that decreased test errors and reduced repeat testing.
- Discussed test results with clients and developed action plans for failures.
- Assisted department manager with budget.
- Professionally represented company at technical seminars.

LABORATORY SUPERVISOR, *North American Science Associates (NAMSA)*

- Supervised the day-to-day operations of a designated portion of the Toxicology department.
- Organized department to ensure high quality testing in the shortest amount of time.
- Trained associates on test methods.
- Prepared department SOP's.
- Acting Study Director for large test programs.

Education

- ◆ Bachelor of Education, Comprehensive Sciences, University of Toledo, Toledo, Ohio

Technical Certifications and Achievements

- ◆ Continuing education through seminars, and business management.
- ◆ Certified ISO 17025 lead auditor.
- ◆ Completed training courses in Project Management, Effective Training Skills, and Microsoft Project.
- ◆ Development, Supervision Skills and numerous ISO and FDA regulations.

Professional Associations

- ◆ Anne is member of American Society of Microbiology (ASM) and AAMI.



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