COLLEEN KISTLER, PSM, RAC

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PROJECT & QUALITY SYSTEMS MANAGER

Multi-skilled professional with track record of planning, managing and implementing complex functional projects in various environments and platforms (e.g. medical / diagnostic devices, education, government, state, non-profit and healthcare agencies). Ability to work independently and on teams. Successful in both detail oriented and high-level communication styles, adapting to the situation and audience. Adaptable and flexible with key skills for different work environments and technologies.

Project Management	Organization / Planning
Quality System Development/ Testing	Technical Writing
Regulatory Compliance	Technical Support
Requirements/Business Analysis	FDA Premarket Submissions
Product Development	International Regulatory Submissions

PROFESSIONAL OVERVIEW

CANTON GROUP, Baltimore, MD 2014 - Present

Director, Quality Assurance and Program Manager: Manage all phases of diverse technology projects for education, government, state, non-profit, and healthcare agencies. Oversee entire project lifecycle from user requirements, design, and technology concepts through development, testing, launch and support.

- Manage project milestones, schedule and budget. Prepare client reports as needed.
- Define and document business requirements; prepare concept documents for review with clients; align requirements with quality testing.
- Perform software quality assurance using full system development lifecycle, including designing, developing and implementing test plans/test cases as part of test-driven design.

STONEFLY SYSTEMS / BLUE WATER MEDIA, Parkton/Greenbelt, MD 2012 - 2014

VP, Quality & Regulatory and Program Manager: Managed range of non-profit, educational and large government-based web projects. Provided regulatory and quality guidance for medical sterilization company.

- Improved relationships with several key accounts through enhanced communication within the organization and with clients regarding project plans, requirements, progress, schedule/risk and budget updates.
- Standardized software quality strategies and test plans, including 508 compliance.
- Managed usability sessions for user interface updates on an educational project.
- Provided regulatory and quality guidance for medical device software verification and validation test plan; organized and prepared final verification and validation summary report; reviewed and approved individual test case reports.
- Established software processes for requirements management and traceability reports.
- Refined and updated software content for user and service manuals.

CSA MEDICAL, Baltimore, MD 2008-2012

VP, Quality Systems, Regulatory and Supplier Management: Served as management representative for company; coordinated, organized and led management reviews. Provided regulatory and quality strategies for new product development. Directed supplier management activities for transferring new

product into production. Created/updated procedures to meet ISO14971 standards. Led coordination of web-based quality tracking system and complaint/CAPA backlog resolution within first six months of hire.

- Established ISO/FDA processes for organization.
- Coordinated, managed and led FDA inspections/ISO audits.
- Improved and refined design control, supplier management, order fulfillment, risk management, complaint and CAPA processes within the quality system.
- Created procedures and processes for software configuration management.
- Conducted internal audits and coordinated supplier audits with outside consultant.
- Organized and updated legacy design history files and technical files.
- Managed adverse event investigations and submitted medical device reports to FDA.
- Provided regulatory and quality guidance for new product verification and validation test plan; organized and prepared final verification and validation summary report.
- Developed regulatory strategy, prepared and filed submission; obtained FDA clearance for next generation cryospray ablation system platform.

EARLIER ENGAGEMENTS

BECTON, DICKINSON and COMPANY, Sparks, MD

Director, Regulatory Affairs (Molecular Diagnostics): Managed staff of regulatory professionals in submission/registration activities. Created functional strategies in alignment with molecular diagnostic business goals. Implemented process for functional project reviews. Led department in development of standard operating procedures for new product development and regulatory activities. Planned, managed, and executed regulatory strategies for several in vitro diagnostic product development teams, in accordance with applicable US and international regulations (Europe, Canada, Japan). Developed and maintained relationships with regulatory agencies regarding pre-submission strategies, potential regulatory pathways and submissions under review. Obtained FDA clearance within two months of submission for a semi-automated instrument that secured $100M contract with a national reference laboratory (Quest). Provided regulatory leadership for BD's first molecular diagnostic assays; simultaneously obtained FDA clearance for both new assays 25% below average industry clearance time. Received "Howe Award" for Contribution to Product Success and BD ProbeTec™ ET Core Team and Individual Superstar Awards.

Sr. Regulatory Specialist, Regulatory Affairs: Organized, prepared and supported regulatory submissions for various infectious diseases for US and international regulatory agencies.

Technical Service Manager: Provided service support to BD medical diagnostic product lines. Assured customer satisfaction and regulatory compliance for medical products and procedures.

EDUCATION & CERTIFICATIONS

BS, Medical Technology, University of Maryland, Baltimore, MD
Professional Scrum Master (PSM)
US Regulatory Affairs Certification (RAC)