



DIANA L. MANDLI, RAC

AccuReg, Inc.

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QUALIFICATIONS:

- Regulatory Affairs Certified professional with 18 years of progressive regulatory, technical and administrative experience in medical device, software and pharmaceutical manufacturing environments.
- Highly familiar with QS Regulation, cGMP and cGCP requirements for medical devices and pharmaceutical products.
- Experienced auditor of software quality systems and FDA- and ISO-compliant Quality Systems for medical devices.
- Industry-recognized expertise in the design and execution of medical device software/computer system validations.
- Working experience across the range of medical devices, from Class I (exempt) products, such as clinical chemistry analyzers, to Class II software products, such as blood bank software, to Class III implantable products.
- Hands-on experience in the:
 - ⇒ Preparation of regulatory submissions for medical devices containing software
 - ⇒ Development of Standard Operating Procedures (SOPs) for Quality System processes
 - ⇒ Evaluation, development and implementation of design control processes for medical device and software products
 - ⇒ Evaluation of software and computer systems for 21 CFR Part 11 compliance, and development/implementation of corrective action/process improvement plans
 - ⇒ Preparation and delivery of custom training programs in the Quality System Regulation, design control requirements, software verification and validation, and traceability methods.

PROFESSIONAL EXPERIENCE:

AccuReg Inc., Plantation, Florida

(1993-present)

Executive Vice President, 2001 to Present

Director of Corporate Services/Sr. Regulatory Associate, 1993-2001

Responsible for technical, regulatory and compliance services to client firms:

- Develop regulatory strategy for new medical devices and software medical products.
- Prepare Premarket Approval (PMA) submissions and Premarket Notifications [510(k)s] for medical devices, including software-controlled and standalone devices.
- Conduct compliance (21 CFR Part 820) audits, software quality audits, design control audits and 21 CFR Part 11 compliance audits for client firms with recommendations for establishing and/or maintaining compliance.
- Conduct clinical research audits for compliance to protocol and cGCPs.
- Develop and execute Computer System Validation programs for manufacturing, laboratory and business GxP systems.
- Manage project teams in the execution of Computer System/Software Validation projects including the following activities:
 - ⇒ Develop project proposals including cost and time estimates
 - ⇒ Train, supervise and review deliverables of project team members
 - ⇒ Track project actual timelines and costs against project plans

- ⇒ Perform strategic project planning with client to reduce cost and time to execute projects
- ⇒ Develop and implement validation programs, project plans and documentation.
- Conduct critical review of risk management documentation, practices and procedures
- Develop risk management programs and procedures
- Perform critical review of Design Dossiers; prepare risk analyses and clinical risk/benefit summaries
- Evaluate and implement design control programs and processes for computer- and software-based medical devices.
- Develop and conduct QS Regulation, design control, Part 11, software validation and related training programs.

Also responsible for:

- Project management and central client liaison for medical device regulatory and compliance projects
- Preparation of project proposals and RFP responses
- Preparing and delivering oral/visual presentations on software validation, design controls, traceability and other topics at industry conferences and seminars.
- Writing and editing technical publications on various regulatory, compliance and software topics.
- Programming and administration of The Regulatory Forum Web site (www.regulatory.com).

DME Engineering, Ft. Lauderdale, FL
Technical Writer, Publications Division

(1992-1993)

- Responsible for writing, editing, and typesetting all technical documents generated by the Publications Division of this avionics engineering firm, including:
 - ⇒ User's Manuals
 - ⇒ Service Manuals
 - ⇒ Responses to RFPs and other Proposals
 - ⇒ Compliance to MIL-STD or SBA specifications.

EDUCATION:

- Bachelor of Arts, English, Florida Atlantic University (Summa cum laude)
- Regulatory Affairs Certified (RAC), Regulatory Affairs Professional Society
- Member, IEEE (Computer Society)
- Member, ISPE
- Additional Training: ISO 9001/13485 Quality Systems; ISO 14971 Risk Management, ISO Lead Auditor; Medical Devices; Software Quality Assurance (ASQ CSQE); Software Testing (IEEE); Industrial Marketing