



## DIANA L. MANDLI, RAC

### AccuReg, Inc.

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### QUALIFICATIONS:

- Regulatory Affairs Certified professional with more than 9 years of progressive regulatory, technical and administrative experience in medical device, software and pharmaceutical manufacturing environments.
- Highly familiar with QS Regulation and cGMP requirements for medical devices and pharmaceutical products, respectively.
- Experienced auditor of software quality systems and FDA-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, such as human tissues.
- 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 (ERES) compliance, and development/implementation of corrective action/process improvement plans
  - ⇒ Evaluation, development and implementation of software traceability processes and methods
  - ⇒ Preparation and evaluation of software and system requirements and design specifications
  - ⇒ Preparation and evaluation of software validation programs and test protocols
  - ⇒ Preparation and evaluation of validation data summaries and reports
  - ⇒ 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 (QS Regulation, 21 CFR Part 820) audits, software quality audits, design control audits and ERES (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.
- Supervise, coordinate and participate in design and execution of software/computer system validations.
- Evaluate and implement design control processes.
- Develop risk management programs and procedures
- Conduct critical review of risk management documentation, practices and procedures
- Perform critical review of Design Dossiers; prepare risk analyses and clinical data summaries
- Develop and conduct QS Regulation, design control, Part 11, software validation and related training programs.

Also responsible for:

- Developing and maintaining project (resource and task allocation) schedules for extended client projects.
- Preparation of detailed project management plans
- 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](http://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, Comparative Literature (4.0 average)  
University of Florida (Gainesville) / Florida Atlantic University (Boca Raton)
- Supplemental Coursework and Training: ISO9001, Software Quality Assurance, Software Testing, Design Controls, Computer Science, Industrial Marketing
- Regulatory Affairs Certified (RAC), Regulatory Affairs Professional Society
- Member, IEEE (Computer Society)
- Member, ISPE

## **SOFTWARE AND COMPUTER APPLICATIONS:**

- Languages: HTML and CGI (Perl), Java and JavaScript, Unix; limited C++, Fortran, Visual Basic
- Commercial Applications: Most, including Harrington C/A 5; EasyTrak; AxiomSys; DOORS Requirements Management Tool; MS Word, Excel, Project, PowerPoint, and Access; Adobe Acrobat, Pagemaker (Windows and Macintosh) and Photoshop (Windows and Macintosh); WordPerfect, Ventura Publisher, and Corel (Draw, Paint, Photo, Xara); GIF Builder (Animator) and GIF Construction Workshop; and others