

Maureen Mende, RAC, MBA

Capabilities and Experience

Work Experience

Senior Director: MyRAQA, Inc. 2008 - Present
Managing multiple clearance projects and multi-project master agreement with key client. Providing clients with regulatory and quality expertise.

Director of Regulatory Affairs: Affymetrix 2007 - 2008
Was responsible for all regulatory submissions and compliance. Worked closely with the partners on diagnostic products. Obtained 510(k) clearance for GeneChip Microarray system to include gene expression.

Director of RA & QA: Diamics, Inc. 2007
Was responsible for obtaining FDA/Global regulatory approvals for cervical sampling device and cervical cancer screening system for molecular-based cancer screening start-up company. Accomplishments included 510(k) clearance for sampling device, China product registration and OEM supplier qualification, establishing Quality System, and managing clinical trials.

Group Manager Regulatory Affairs: Dade Behring Inc., 1992 to 2007
Had responsibility for regulatory planning/submissions for In vitro diagnostic products, providing regulatory guidance, developing regulatory strategies, interfacing with Regulatory Agencies, managing regulatory staff, ensuring timely product approvals and regulatory compliance. Member of team responsible for developing global regulatory strategies.

Validation Consultant/Technical Writer: Davy McKee & Associates 1987 to 1989
Created validation protocols, IQ, OQ, PQ for manufacturing equipment and processes for the pharmaceutical industry.

Quality Assurance Consultant: Sprawka Inc. 1984 to 1986
Provided GMP compliance support, validations, technical documentation, wrote Standard Operating and Basic Laboratory Procedures.

Quality Assurance Technician: Abbott Laboratories 1982 to 1984
Laboratory technician in QA lab performing Chemistry, Microbiology and Environmental testing, component / finished product testing and inspection.

About MyRAQA

MyRAQA is a full-service IVD Regulatory consulting firm. Founded in 1998, MyRAQA has grown to include leading experts in RA, QA, Design Control, Process Development, Study Design, and Statistical Analysis.

MyRAQA has worked on the full range of US and EU IVD applications, including PMAs, IDEs, 510(k)s, *de novo* 510(k)s and EU technical files.

Experience Highlights

- » More than 25 years' experience in regulatory and quality
- » Successful applications include FDA PMA, 510K, Special 510K, Japan MHLW, China SFDA, Canada Product Licenses, EU/CE Marking
- » Design Controls, V & V, Risk Management, PHA, FMEA, Technical Dossiers, DHF, DMR, Safety/EMC compliance
- » IRB, Informed Consent, Training, Monitoring, Audits, Data Verification, Protocol Development
- » QSR, ISO 9001: 2000, ISO 13485, CMDCAS, MDD, IVDD, Lead Auditor
- » PMA Annual Reports, MDR Vigilance Reporting, Field Corrections / Recalls, CAPA Systems, Complaints, Advertising & Promotions

Education

- » MBA: Golden Gate University
- » Regulatory Affairs Certified, Regulatory Affairs Professional Society (RAPS)
- » BS in Environmental Science: Aurora University

