

Mark M. Sweeny

Capabilities and Experience

Work Experience

Director: MyRAQA, Inc.

2008 to present

Taking the lead on multiple 510(k) and EU IVD projects. Providing clinical support on diabetes project. Collaborating with MyRAQA personnel on providing comprehensive IVD quality system and safety training.

**Director, Regulatory and Product Compliance
Applied Biosystems (now Life Technology)**

1990 to 2008

While working with AB, played a key role in the 510(k) for the 7500 Fast Dx. This included preparation of an extensive software risk analysis.

Was responsible for \$3 million budget and an organization of approximately 30 employees. Provided strategic planning and process development for worldwide operations consisting of more than 50 product lines. Managed global quality systems and product compliance in both Research and Development and in Manufacturing. Served as a member of Global Quality, Regulatory Compliance and Business Systems management team. Was involved in all phases of project management. Performed supervisory duties including recruitment and selection, performance management and appraisal, discipline and termination.

With respect to Organizational Development, created Department and integrated mission into corporate strategy. Developed and implemented training classes in quality systems and product compliance. Was special project coordinator for human resources projects focusing on organizational planning and management development. Responsibilities include diagnosing problems, developing strategic interventions, and creating exercises. Was involved in all phases of organizational development process from issue identification, program conception and program evaluation. Served as lead facilitator for employee enrichment programs focusing on organization development processes.

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

- » Manager Regulatory/Quality Compliance, Document Control, Environmental Health and Safety, Compliance Engineering and Chemical Compliance and Risk Management Departments.
- » Provide regulatory direction on multiple requirements including 21 CFR Part 820 and Part 11, In Vitro Diagnostics Directive 98/79/EEC, EN 13485:2003, ISO 9001:2000, UL 61010A-1, CSA 1010-1, ICES-001, Low Voltage Directive 73/23/EEC, EMC Directive 89/336/EEC, and U.S. Environmental Laws and Regulations.
- » 7500 Fast Dx 510(k) submission and worldwide regulation.
- » Developed and presented classes on leadership, communication and organization processes.

Education

- » MA in Human Resources: University of San Francisco
- » Teaching Credential: San Jose State University
- » BA in Journalism, EE, Political Science: San Jose State University

