

Mya Thomae, RAC, CQA

Capabilities and Experience

Work Experience

CEO: MyRAQA, Inc.

1997 - Present

Provide expertise and strategic direction on FDA and EU medical device regulatory issues. Work with clients to implement projects including preparation and participation in FDA meetings, clinical trials, regulatory submissions and quality system development. Lead consulting organization in serving IVD clients with wide-ranging needs and requirements.

Director of Regulatory Affairs: AVI BioPharma

2001 - 2002

Wrote submissions for drug and therapeutic vaccine products including drug master files, CMC updates, SAE reports and annual reports. Negotiated changes to clinical trial protocols with FDA and served as primary FDA contact on all submissions. Acted as team member on project to build manufacturing facility for product of clinical trial APIs. Prepared detailed compliance plan for upper management. Audited contract manufacturers. Hired and trained a regulatory affairs associate.

Manager, Regulatory Affairs: Chiron

1996 - 1997

Executed strategies for all nucleic acid diagnostic products (bDNA) worldwide. Reviewed advertising and promotion materials related to NAT products as well as testing performed by the Chiron Reference Testing Laboratory. Met with FDA reviewers on PMA application and interacted with FDA inspectors. Reviewed and approved clinical trial protocols, labeling and advertising materials. Hired and trained two regulatory affairs associates.

Regulatory Affairs Manager: Epitepe

1992 - 1998

Began at Epitepe as a regulatory affairs associate, promoted to manager in 1994. Active member of team that achieved FDA approval for the OraSure HIV-1 Testing System. Wrote 510(k) for OraSure device. Wrote numerous submissions including PMAs, 510(k)s, ELA/PLA amendments, IDEs and INDs. Participated in multiple pre-approval inspections and worked with team members to implement compliance measures post-inspection. Reviewed and approved clinical trial protocols, labeling and advertising. Supervised two regulatory affairs associates.

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

- » 15+ years of experience in IVD regulatory, encompassing the full product lifecycle and virtually all major technologies
- » Developed and executed many successful approval strategies for FDA and EU
- » Executed novel strategies, including the first "parallel" 510(k) clearance
- » Wrote, reviewed and implemented clinical trial protocols
- » Prepared for and managed FDA inspections, ISO audits and vendor audits
- » Wrote regulatory submissions including PMAs, 510(k)s, IDEs, BLAs, master files, technical files
- » Quality system development, deployment, auditing and expansion (QSR, GLP and ISO)

Education

- » Regulatory Affairs Certified, Regulatory Affairs Professional Society (RAPS)
- » Certified Quality Auditor: American Society for Quality (ASQ)
- » Bachelor of Music: University of Wisconsin

