

# Cindy Van Duker, MS

## Capabilities and Experience

### Work Experience

#### **Manager: MyRAQA, Inc.** 2010 – present

Providing expertise and advise to IVD clients regarding regulatory compliance and strategic planning.

#### **Manager, Regulatory Affairs: Volcano Corporation** 2006 – 2010

Developed strategies for Class II and Class III cardiovascular medical device submissions. Participated in Pre-IDE meetings. Responsible for 510(k) submissions, CE marking, coordinated Shonin submissions. Assessed engineering, manufacturing and quality changes for regulatory requirements.

#### **Program/Project Manager: Intel Digital Health Group** 2006

Developed and implemented a Quality System for regulatory planning and clinical trials for a new medical device division. Developed strategy for CE marking medical devices in Europe. Responsible for Quality System and 510(k) submission requirements in co-development projects.

#### **Manager, Regulatory Affairs: Dade Behring** 1998– 2006

Managed 510(k) submissions to FDA for IVD product line. Participated in preparation of PMA submissions to FDA and CE marking of European product line. Lead team to re-register all product lines in Japan to maintain regulatory compliance. Participated as escort in FDA and ISO quality system audits. Represented RA, QA, and Operations on R&D Project Teams.

#### **RA Specialist/Project Manager: Biomune Systems** 1995 – 1997

Updated CMC section of IND. Prepared clinical/statistical reports and study protocols for Phase I and II studies. Developed procedures for validation of in vitro assays. Coordinated clinical studies. Authored company business plan and overview of scientific information used to develop strategic alliances.

#### **RA Supervisor: HGM Medical Laser Systems** 1993 – 1994

Filed MDRs, initial/model change reports, annual reports and recall effectiveness reports. Created documentation including DMRs, DHRs, complaints, operator's manuals and service manuals. Conducted GMP audits.

### 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 RA experience, 10+ years specifically in IVDs.
- » Experience with all major submissions: Pre-IDEs, IDEs, PMAs, 510(k)s, CE Design Dossiers, Technical Files, Canadian Licenses, ROW registrations and Japanese Submissions.
- » Proven ability to lead teams of engineers and technicians.
- » History of building productive relationships with manufacturers, employees and management from diverse backgrounds.

### Education

- » Master of Science in Electrical and Electronic Engineering: California State University
- » Bachelor of Science in Electrical and Electronic Engineering: California State University
- » Bachelor of Science in Biochemistry: UC Davis

