

Diane M. Ward, Ph.D.

Capabilities and Experience

Work Experience

Director: MyRAQA, Inc.

2009 - present

Leading PMA application project team. Consulting with clients regarding study design and reports. Developing and consulting on product development procedures for diagnostic products.

Associate Director: XDx

2006 - 2008

Established Product Development lifecycle procedures, Design Control and Project Management processes. Worked collaboratively to create and maintain good design control practices. Instituted good manufacturing practices (GMP) for reagent manufacturing process and documentation. Established the company's Process Development core competency.

Associate Director: Predicant Biosciences

2004 - 2005

Established the company's Product Development and Systems Integration baseline. Directed the development and maintenance of company Systems Integration functional expertise. Created core competencies in the Systems group (e.g. design integration, software development & evaluation) and managed associates. Worked collaboratively with Research functions to create and maintain good design control practices.

Quality Scientist: Affymetrix

2003 - 2004

Had responsibility for establishment and guidance of design control processes on multifunctional program teams. Mentored teams in product development processes from feasibility to transfer to Operations, ensuring that the design history file was complete and that all documentation met current FDA/ISO requirements.

Project Scientist / Manager: Becton Dickinson

1990 - 2002

Held progressive responsibilities in the management of program teams. Participated in audit of development records and helped revise several company procedures, including product development life cycle and risk analysis. Lead multifunctional verification teams for new clinical systems. Established design input documentation, schedules, and contingency plans. Prepared sections of FDA 510(k) filings and timely responses to FDA inquiries.

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

- » Extensive clinical diagnostic industry experience with expertise in new product development in immunology, hematology, therapeutic drug monitoring, and laboratory automation
- » Established Product Development / Design Control / Project Management lifecycle infrastructure. Mentored associates in IVD assay development processes.
- » Led multifunctional group during a focused development phase. Spearheaded effort to develop shared vision of a new product and customer work environment.
- » Led a re-engineering effort of acquired technology
- » Introduced and implemented Systems Engineering approach to requirements generation for new products

Education

- » Ph.D. in Microbiology and Immunology: University of Arizona
- » Bachelor of Arts in Microbiology and Immunology: University of California Berkeley

