

# Tina M. Landess, CCRA

## Capabilities and Experience

### Work Experience

#### **Director: MyRAQA** 2009 - present

Leading the effort to build out a clinical supervision capability as a core competency. Consulting with clients on clinical and regulatory needs.

#### **Clinical Trial Manager: Vermillion, Inc .** 2006 - 2009

Planned and executed clinical trial activities, ensured auditable regulatory documentation. Managed CRO, wrote protocols, monitored sites and data, audited databases. Audited internal departments for adherence to QSR.

#### **Consulting Senior CRA: Chiron Blood Testing** 2004 - 2006

Wrote protocols, performed in-house monitoring and data management for a registration study for a blood-screening assay in Mexico. Monitored a three-center study for the domestic registration of an automated pipetting system for blood screening infectious disease assays.

#### **Consulting Clinical Manager: Bayer Diagnostics** 2005 - 2006

Identified Principal Investigators, managed contracts, performed site pre-qualification visits, wrote protocols for sample procurement, testing. Primary vendor liaison. Lead inter-departmental clinical operations meetings.

#### **Clinical Research Associate II: Bayer Diagnostics 2001 - 2003**

Integrated an ongoing multi-center clinical study into compliance with GCPs. Managed 13 clinical study sites from initiation to FDA submission. Lead creation of infrastructure within the Clinical Affairs department.

#### **Clinical Research Associate II: BioMedicines, Inc.** 2000 - 2001

Monitored and provided direction on multiple pharmaceutical studies. Acted as liaison between CROs, internal departments, and external sites. Maintained several databases for tracking progress of the study.

#### **Clinical Research Associate: Roche Molecular Systems** 1992 - 2000

Designed, planned, implemented, and provided overall direction of medical device studies. Drafted and edited final versions of protocols.

### 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

- » Ovarian Cancer Risk Index Blood Test 510(k)
- » Ex-US Registration Study Management (Mexico)
- » Marketing Study Management (Americas, Europe, Asia)
- » Biologics License Application Supporting Trial for automated pipetting system (US)
- » 510(k) Trial for Genetic Disease Assay (US)
- » CE Mark Trial for Hepatitis B Virus Diagnostic Assay (EU)
- » PMA Trial for Hepatitis C Virus Diagnostic Assay (EU and US)
- » Phase 1b trial for Hepatitis C anti-viral therapeutic (US)
- » Phase II trial for Hepatitis C anti-viral therapeutic (EU)
- » PMA Trial for HIV-1 Diagnostic Assay (US)

### Education

- » Certified Clinical Research Associate: Association of Clinical Research Professionals (ACRP)
- » BA in Chemistry: Arizona State University

