CAPABILITIES AND EXPERIENCE

TINA M. LANDESS

WORK EXPERIENCE

Managing Director, CEO: Landrich Group (2017 – Present)

- Lead Pre-Clinical, Phase I-IV studies and team within the US and ROW
- Audit clinical programs for clients intent to implement changes to infrastructure related to US and ROW GCPs
- Advisory Board member for multiple international biotechnology companies for the CLSI FAST accelerator program

Vice President of Clinical Operations: DermBiont (2018 – 2019)

- Initiate clinical department of early stage dermatology company in accelerator program
- Lead Pre-Clinical & first in human Phase 2 dermatology studies within the US and ROW
- Develop, mentor, and train internal staff while creating program timelines and budgets
- Lead vendor contracts and budget negotiations and report to Executive staff

Director of Clinical Operations: Cerus (2013 – 2016)

- Provide overall direction of multiple studies within the US, Asia, and EU in varying product development stages (Phase I-IV).
- Coordinate and collaborate with multi-disciplinary groups to facilitate successful study execution.
- Support US FDA, Asia, and EU clinical portion of regulatory submissions and ensure clarity of auditable regulatory documentation.
- Manage clinical operations team of 7-10 full time permanent and contract employees.
- Manage multiple CROs and vendors supporting all clinical management tasks.
- Write and review Standard Operating Procedures while maintaining compliance to GCPs, ICH, and U.S. Federal Regulations.
- Support audits of study records by US FDA Biological Monitoring Division (BIMO) and ex-US regulatory bodies.

Director of Clinical Operations: **MyRAQA (2009 – 2013)**

- Provide overall direction of studies throughout the 510(k)/PMA process for multiple clients.
- Plan & execute clinical trials activities and ensure clarity of auditable regulatory documentation in compliance with ICH, GCP, and US Federal Regulations.
- Write and review Standard Operating Procedures while maintaining compliance to GCPs, ICH, and U.S. Federal Regulations.

EXPERIENCE HIGHLIGHTS

An experienced, self-motivated, quality-focused clinical project leader with over 20 years of clinical research management and monitoring experience. Effectively managed clinical activities for Pharmaceutical, Medical Device & In vitro Diagnostic Manufacturers. Practical experience in therapeutic areas such as Ophthalmology, Dermatology, Hematology, Transfusion Medicine, Cardiology, Oncology, Infectious Disease, & Digital Health. Proven track record of well-managed clinical studies resulting in successful inspections and regulatory approvals.

EDUCATION & ACCREDITATIONS

- Arizona State University, Bachelor of Arts in Chemistry, Arizona State University (Recipient of Regents Scholarship)
- Certified Clinical Research Associate, (CCRA), Association of Clinical Research Professionals, November 2001
- Regulatory Affairs Professionals Society, Member since 2011
- GCP for Clinical Trials with Investigational Drugs and Biologics(ICH Focus) Certification