CAPABILITIES AND EXPERIENCE
DANA LAGMAN

WORK EXPERIENCE

Landrich Group (2021 – Present)

Clinical

- Implement clinical trials/research activities for IVD assays and assist with any necessary CRO activity. Support clinical trials through completion.
- Write and review protocols, maintain auditable clinical trial files, monitor clinical trial sites (both at a clinical site and in house), write and review clinical reports.
- Maintain study management forms, clinical trial files, training plan, and monitoring plan.
- Act as the main line of communication among Landrich Group, the Investigator, the Investigational Site, and Regulatory/Clinical consultants.
- Ensure applicable clinical trials are appropriately entered into the US National Institutes of Health (NIH) clinicaltrials.gov registry.
- Review data, create the database, and review database to ensure accurate reporting of data. Lock database.
- Ensure the trial data are accurate, complete, and verifiable from source documents.
- Coordinate and distribute study materials.
- Participate in writing the Final Study Reports.
- Maintain and manage documentation necessary in assistance to the support of clinical trials.

Quality and Regulatory

- Perform in depth inspections Quality System audits to assess potential gaps, identify opportunities for improvement and develop strategies to achieve compliance with FDA regulations, ISO 13485, FDA 21 CFR 820 Quality System Regulations, and medical device directives.
- Stay updated with relevant laws, regulations, and guidelines governing the clinical and healthcare industry.
- Interpret and apply regulatory requirements to ensure compliance in clinical operations, product development, and quality management systems.
- Provide guidance to ensure that all clinical activities adhere to regulatory standards throughout the product lifecycle.
- Provide training and educational programs on regulatory requirements, quality standards, and best practices.
- Create and review device labeling against regulatory requirements.
- Assist in the preparation of regulatory submissions.

Quality Assurance Auditor/ University of Texas Health (2023 – 2024)

- Conducted comprehensive desktop and onsite audits for 116 providers, to evaluate compliance to processes and procedures, adherence to contract, quality standards, state agency rules, and regulatory requirements.
- Developed, maintained, and manage comprehensive audit plans, schedules, worksheets, and procedures for a fiduciary responsibility within a $28M project.
- Completed comprehensive contract reviews upon contract renewal through 22 network purchase service agreements and statements of work for contractors and subcontractors, to assess compliance with internal policies, industry regulations, and quality standards.
- Collaborated with cross-functional teams to address, investigate, and identify any quality issues or possible harm to patients, ensuring proper service delivery and patient safety.
- Analyzed data and quality metrics to identify trends, patterns, and regulated continuous quality monitoring to recommend potential areas for improvement.

Quality Assurance Associate Manager/Nanomix inc. (2018 – 2021)

- Quality - Successfully led BSI External Audits with 100% pass rate under ISO 13485, while managing quality processes and closing 80 CAPAs. Mentored and trained 20 staff, ensuring compliance with standards, and fostering collaboration with Engineering and R&D. Developed, implemented, and monitored quality systems processes including CAPA, change control, design control, supplier oversight, internal audit, nonconforming materials, and deviations. Managed, scheduled, and reported the performance of the quality management system and metrics to executive management annually. Communicated and built consensus for quality objectives.
- Regulatory - Evaluated documents for FDA and EU submissions, ensuring compliance and designed product labeling to meet regulatory requirements. Compiled regulatory submissions for multiple regions and maintained communication with regulatory authorities throughout the process. Created, designed, and reviewed proposed product claims/labeling against labeling and regulatory requirements for compliance.

EXPERIENCE HIGHLIGHTS

- Strong communication skills obtained through diversity of work experience
- Proficient in documenting and complying to Standard Operating Procedures with accordance to FDA's GMP/GLP guidelines and ISO/EU standards
- Understanding of the process of production in a Biomedical field to the process of Clinical Trials

EDUCATION & ACCREDIATION

- Bachelor of Science, Biochemistry – California State University of East Bay
- Good Clinical Practice (GCP)
- Certified ISO 13485:2016 Auditor