CAPABILITIES AND EXPERIENCE

SHAWNTEL DEL ROSARIO

WORK EXPERIENCE

Landrich Group (2020 – Present)

- Writing and reviewing protocols, maintaining auditable clinical trial files, monitoring clinical trial sites (both at a clinical site and in house), writing and reviewing clinical reports, and monitoring trial master filing.
- Implementation of the clinical trials/research activities for medical device studies and for assisting with any necessary CRO activity support clinical trials through to completion, Study Plan, the Clinical Protocol, and Case Report Forms.
- Coordinate and distribute study materials.
- Maintain study management forms, clinical trial files, training plan, and monitoring plan. Document activities and progress on each of these.
- Act as the main line of communication among Landrich Group, the Investigator, the Investigational Site, and Regulatory/Clinical consultants.
- Lead meetings and direct team members in completing project task
- Ensure applicable clinical trials are appropriately entered into the US National Institutes of Health (NIH) clinicaltrials.gov registry. Document the reasoning if the trial is not determined to be "applicable".
- Review data, create the database, lock database, and review database to ensure accurate reporting of data.
- Ensure the trial data are accurate, complete, and verifiable from source documents.
- Assist in the creation of the Product Insert or Instructions for Use.
- Participate in writing the Final Study Reports.
- Assist in preparation of regulatory submissions.

Biomedical Manufacturing Associate I: Nanomix (2018 – 2019)

- Responsible for the development and manufacture of nanoelectric biosensors, electromechanical instruments, and consumable multiplex medical devices.
- Performed verification, validation, and qualification of product specifications.
- Maintained inventory and safety stock of electronic, biological, and chemical materials.
- Executed timely preventative maintenance equipment.
- Processed clinical data including receipt, entry, and verification of information.

Nursing Intern: Valley Care Medical Center (2013 – 2014)

- Provided Clinical data management support.
- Partnered with other interns to collect and chart vital signs of patients.
- Completed tasks given by nurses: sanitized medical equipment, delivered lab work to labs, helped discharge patients and restocked medical equipment.
- Observed medical procedures such as open-heart surgery, angioplasty, and appendectomy.
- Completed 180+ volunteer hours.

EXPERIENCE HIGHLIGHTS

- Strong communication skills obtained through diversity of work experience
- Great organization and maintaining abilities accomplished from diversity of work experience
- Understanding of the process of production in a Biomedical field to the process of Clinical Trials

EDUCATION & ACCREDIATION

- Master of Science, Chemistry – California State University of East Bay
- Bachelor of Science, Biochemistry with a Minor in Biological Sciences – California State University of East Bay
- Good Clinical Practice (December 2020 – present)