john r. lugo-toro

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**Objective**

* To become an experienced and effective Regulatory Affairs professional to assist in the approval process of Pharmaceutical, Biopharmaceutical and/or Medical Device products.

**Summary Of Qualifications**

* Extensive GMP/GLP/Non-GLP experience
* Master’s in Regulatory Affairs – Drugs/Biologics/Medical Devices
* Bachelor of Science - Microbiology
* Effective troubleshooter/ communicator
* Auditor for system/study audits
* LIMS software
* Military veteran

**Work Experience**

TOXIKON INC., Bedford, MA

**Senior Quality Assurance Associate** October 2016 – Present

* Quality Assurance reviewer of preclinical studies covering Biotechnology, Pharmaceutical, and Medical Device industries
* Primary reviewer of studies assigned to Vitro and Microbiology departments
* Responsible for GMP, GLP and non-GLP study compliance with reference to SOPs, State and Federal Regulations (U.S. and International)
* Conduct in-phase, data, and final report audits for accuracy, compliance, and reliability in a high paced environment to deliver consistent, exceptional products to Sponsors
* Participate in quality system audits and the implementation and closeout of preventive/corrective actions (CAPA) directed at enhancing company performance
* Assist in preparation and review of documents for accuracy and compliance supporting ISO 17025 re-accreditation

**Laboratory Supervisor/Senior Research Associate,**

**Microbiology Services** April 2014 - October 2016

* Assisted Department Head in Microbiology Department management
* Improved efficiency of departmental order system, resulting in 16% decrease in cost while maintaining reagent and consumable stocks necessary for completion of studies
* Improved rate of completion of departmental equipment cleaning/up-keep monthly work orders resulting in an overall increase of departmental key performance index (KPI)
* Assisted Study Directors and Department Head in the preparation of new standard operating procedures (SOPs) for medical device studies and in the revision of previously prepared SOPs to ensure conformance to ISO 17025 and other applicable guidelines (USP, ASTM, AOAC, ISO, AAMI)

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* Conducted GMP, GLP, and Non-GLP studies in accordance with applicable guidelines
* Developed and implemented test procedures and associated validations per study director instructions for assigned studies
* Ensured media stocks were prepared per SOP guidelines, manufacturing procedures, or otherwise established references
* Promoted and performed Quality Control checks on all media prepared adopting USP sterility and growth promotion criteria to ensure integrity of studies
* Improved inventory management procedures to decrease instances of SOP deviations

UNITED STATES Navy Reserve, Worcester, ma August 1999 – August 2009

**Fire Controlman First Class**

* Assisted Reserve Center’s Medical Officer in the upkeep of medical records, including personnel immunizations logging; Health Assessment Questionnaire preparation, delivery and collection; and proper documentation of semi-annual physical assessment scores
* Assisted Reserve Center's Training Officer in the update of training records, documentation and filing of training sessions, and the acquisition and administration of materials required for personnel participating in their advancement examinations
* Assisted Reserve Center’s Personnel Officer in the documentation of attendance requirements in accordance with applicable directives, and assisted in the acquisition of transportation and lodging for personnel in annual training exercises

**Additional Work Experience**

UNITED STATES Navy (Honorably retired)

**Fire Controlman, First Class**

 Managed and supervised personnel in the upkeep of shipboard electrical equipment

**Security Guard – Portsmouth Naval Shipyard, Portsmouth, New Hampshire**

 Served as part of security force (Operation Noble Eagle - 2001)

**Education and Training**

**Master of Science, Regulatory Affairs for Drugs, Biologics, and Medical Devices**

NORTHEASTERN UNIVERSITY**,** Boston, MA

**Certificate in Applied Biotechnology, BioScience Academy**

Boston University Schl of Medicine/Metropolitan college, Boston MA