Luis Rivera Arroyo

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787-616-3485

Objective

To obtain a challenging and rewarding position that will provide career growth and opportunity, as well as to contribute to the development of the company.

Background

Over twenty years of professional management experience in positions of increasing responsibility in pharmaceutical, biotechnology, and consumer products industry.

Strong background using HPLC, GC, Dissolution Bath, pH Meters, KF, Potentiometric Titration, Thermo gravimetrical Analyzer, Differential Scanning Calorimeter, FT-IR Validations Dissolution Bath and Compliance. Knowledge in FDA, GMP's, GAMP4, GxP, CQE, Kaye Validator 2000, OSHA. Method transfer, Method validation Method development and PAT Technology.

I have work with several manufacturing and laboratory investigations projects, which have save to the company 4.5 billion in product, some of the investigations I have work improving product yield from a 78% to a 98%.

I have work these investigations form the beginning through the impact analysis, identification/implementation of countermeasures, closing investigation and auditing.

Performed cGMP audits, writing audits reports, performed CAPA and GAP Assessment for equipment, computer systems and process validations (solid dosage, parenteral, lotion, cream, ointment and packaging).

Experience developing full-life-cycle project plans and delivering full-life-cycle validation projects and Qualification IQ, OQ and PQ.

##### Experience writing validation documents, performing executions and summary reports for equipment, computer systems, utilities, laboratory, information technology application and process validations (solid dosage, parenteral, lotion, cream, ointment packaging and Project engineering).

I have experience working with biological equipment such as Vitek System, also performing DNA Testing.

Experience

**Validation Specialist Manufacturing Sterile Area**

**Jansen Manati PR**

**, P.R.**

**Oct 2016 – Jan 2017**

Essential Functions

* Perform CSV validation to the plant manufacturing software.
* Supervise calibration activities for equipment such as: Weighing Scale, Laboratory Balances, FT-IR, UV-Vis etc.
* Verifying compliance with government requirements and regulations (USP, EP, ICH, etc.).
* Performing Data Integrity assessment to all related equipment.
* Preparing a plan to remediate Data Integrity gap’s.
* Writing SOP, preparing and conducting training and coaching.
* Using Power Point presentations to write working instructions, etc.

**Remediation plan for Microbiology/Chemistry Laboratory Calibration Program**

**Baxter Inc.**

**Jayuya, P.R.**

**Jun 2016 – Aug 2016**

Essential Functions

* Supervise the Microbiology and Chemistry Laboratory Calibration activities.
* Verify compliance government requirements and regulations (USP, EP, ICH, etc.).
* Writing SOP to comply government requirements and regulations.
* Training on Calibration SOP,s.

**Microbiology/Chemistry Laboratory Supervisor**

**PharmaBioServ**

**| Dorado, P.R.**

**Dec 2015 – Jun 2016**

Essential Functions

* Supervise the Microbiology and Chemistry Laboratory.
* Supervise personnel Instrument Qualification Team as well as Utilities technician that provided service to the QC Laboratories.
* Monitor performance of validation team quality to ensure effectiveness and efficiency.
* Verify Oversee workers including, inspectors, or laboratory workers engaged in calibration activities.
* Verify Microbiology Data, Incubation Times, Growth Promotion, Culture Media Preparation, Aseptic Areas and Identification by DNA (MicroSeq 3130 and MicroSeq 3500).
* Verify Chemistry Data, High Performance Liquid or HPLC, gas chromatographs or GC, Total Organic Carbon or TOC, Fourier Transform Infrared Spectroscopy or FT-IR and ultraviolet-visible (uv-vis) spectroscopy.
* Direct the tracking of equipment defects; test results, or other regularly reported quality control data.
* Responsible for the coordination of activities required from QC in the transfer of new products and or existing products.
  + Development of Protocols, reports and specifications
  + Review/approval of regulatory documentation
* Responsible for the coordination of activities required on the Laboratories
  + Equipment Calibration, PM and non – routine services
  + Equipment Validation
  + Method Validation and / or methods improvements.
* Acts as a liaison between technical development and QC during the transfer of new products.
* Coordinates and supervises the quality of the vendor service and equipment.
* Serves as liaison in the coordination of new equipment quotations, existing equipment upgrade, new equipment demonstration and equipment repairs.
* Maintains accurate equipment inventory and supply.
* Responsible for the equipment service contracts.
* Responsible for the validation of new/existing testing equipment and systems.

**Project Engineering** Manager

**PharmaBioServ**

**| Dorado, P.R.**

**Jul 2015 – Dec 2015**

Essential Functions

* Leading ALPROEM Project Engineering Department during the construction of a new Laboratory Expansion Project.
* Direct, coordinate, or advise personnel working on the new laboratory development.
* Acts as a liaison between ALPROEM Project Engineering Department.
* Ensures a safe work environment and equal opportunities for sub-contractors at all times.
* Identifies and implements cost and safe improvements.
* Identifies and implements process improvement opportunities.
* Responsible for the coordination of activities required on the Laboratories
* Participates in root cause problem solving (CAPA).

**Project Engineering Department/ Active Pharmaceutical Ingredient**

**Pfizer Pharmaceutical LLC**

**| Barceloneta, P.R.**

**Feb 2015 – Jul 2015**

Essential Functions

* Work with the Project Engineering Department and Active Pharmaceutical Ingredient Laboratory as a project assistant in the construction of a new laboratory.
* Direct, coordinate, or advise personnel working on the new laboratory development.
* Troubleshoot malfunctions when needed.
* Develop, improve, or customize equipment, processes, or analytical methods when needed.
* Compile and analyze test information to determine process or equipment operating efficiency or to diagnose malfunctions.
* Identifies and implements new technology, systems and equipment for QC Laboratories.
* Provides technical support and training on new testing, systems and techniques.
* Ensures a safe work environment and equal opportunities for sub-contractors at all times.

**QC Technical Specialist**

**Pfizer Pharmaceutical LLC**

**| Vega Baja, P.R.**

**Oct 2007 – Feb 2015**

Essential Functions

* Identifies and implements new technology, systems and equipment for QC Laboratories.
* Provides technical support and training on new testing, systems and techniques.
* Participates in the preparation, analysis and control of assigned portion(s) of annual budget of his or her area.
* Ensures a safe work environment and equal opportunities for subordinates (when necessary).
* Identifies and implements cost improvements.
* Identifies and implements process improvement opportunities.
* Responsible for the coordination of activities required from QC in the transfer of new products and or existing products.
  + Development of Protocols, reports and specifications
  + Review/approval of regulatory documentation
* Equipment Calibration, PM and non – routine services
* Equipment Validation
* Method Validation and / or methods improvements.
* Acts as a liaison between technical development and QC during the transfer of new products.
* Coordinates and supervises the quality of the vendor service and equipment.
* Serves as liaison in the coordination of new equipment quotations, existing equipment upgrade, new equipment demonstration and equipment repairs.

**QC Instrumentation Leader**

**Lilly Del Caribe | Mayaguez and Carolina, P.R.**

**Oct 2002 - Sept 2007**

Essential Functions

* Supervise the Instrument Qualification Team as well as Utilities technician that provided service to the QC Laboratories
* Monitor performance of quality control systems to ensure effectiveness and efficiency.
* Oversee workers including, inspectors, or laboratory workers engaged in calibration activities.
* Direct the tracking of equipment defects, test results, or other regularly reported quality control data.
* Document testing procedures, methodologies, or criteria.
* Instruct vendors or contractors on quality guidelines, testing procedures, or ways to eliminate deficiencies.
* Review and update standard operating procedures or quality assurance manuals.
* Audit and inspect subcontractor facilities including external laboratories.

**QC Instrumentation Leader**

**Bristol Myers Squibb** **| Barceloneta, P.R.**

**Sep 1988 - Oct 2002**

Essential Functions

* Supervise the Instrument Qualification Team, Validation team and Technical Service.
* Support Manufacturing and Production department with Process Transfer.
* Support Manufacturing and Production department with Methods Transfer.
* Support Manufacturing and Production department with Oral Dosage products, Parenteral, Sterile filling and Microbiology areas during methods or product transfer.
* Perform Process Validation and Method Validation.
* Method Development and Process Development.
* Manage Electronic Record and Electronic signature Project.
* Oversee workers including, inspectors, or laboratory workers engaged in calibration activities.

**Electronic Technician**

**Digital Corporation | San German, P.R.**

**1977 - 1979**

Essential Functions

* Repair of computers PDP – 8, PDP - 11.
* Repair of computers board.
* Test Boards.
* Machine language, FORTRAN, BMS and Basic programing.

Education

* BS Chemistry | IAU San German, PR | Jan 1975 – August 1982
* MS Chemistry | Arkansas State, Jonesboro, AR (Not Finished) | 1986 – 1987
* Computer Science | IAU Cupey, PR (In Progress) | 1998 – 2001

Licenses / Certifications

* + - Chemist License (# 3100)
    - Electronic Technician License (# 3556)

Skills

##### English, Spanish 100%

* German, French, Italian and Creole Dialect (Haiti) 50%