# PROFESSIONAL EXPERIENCE

13 years of experience as a Quality Assurance professional within Pharmaceutical and Medical Device industries including Combination Products. I have a proven track record of implementing Good Manufacturing Practices (GMP) within an FDA, and MHRA regulated facility. I have a broad experience base in Quality Assurance Systems for Supplier Management, GMP Training, Change Control Management, Non-Conforming Materials, CAPA, Product Complaint Handling, Process Validation, Manufacturing, and Root Cause Investigation.

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|  | **Key Skills** |  |
| * GMP Training | * CAPA System Implementation | * Validation Protocols (IQ/OQ/PQ) |
| * Risk Management | * Change Controls | * Material Qualification |
| * Master Batch Records | * Auditing Quality Systems | * SOP and Specifications |
| * Investigating Processes | * Documentation | * Inspecting Incoming Materials and Finished Products |

# INDUSTRY / PROJECT EXPERIENCE

**Nonconformance Investigator Consultant, AMGEN, October 2014 - September 2015**

* Leaded Investigations: Investigation Planning, Root Cause Analysis, Product Impact Assessment, and Conclusion.
* Acted as technical specialist in Corrective and Preventative Actions (CAPA).
* Provided coaching, guidance and direction to Manufacturing, Facilities and Engineering staff in regards to compliance and quality systems, and participated on inspection readiness walk throughs.

**QA Consultant, ALLERGAN, September 2013- August 2014**

* Performed internal and external audits for conformance with FDA, Canadian, Korean and EU guidelines (MDD) with regards to purchasing/supplier controls, equipment calibration /qualification/validation, training, document control, Production and Process controls, design controls, and nonconforming product.
* Suggested and implemented CAPA and coordinated effectiveness checks.
* Managed the Supplier Qualification Program, and established agreements as applicable.
* Leaded the Change Control team and supported the Master Validation Plan.
* Evaluated risk assessments for potential extractable released materials into manufacturing process.
* Participated in a team for the strategic transfer of a medical device class III product.

**Compliance, Quality, Technology Consultant, MAETRICS LLC. IN – September 2011- August 2013**

* Worked on large scale remediation projects for leading pharmaceutical/consumer health products manufacturers.
* Conducted Quality System Assessments.
* Developed and Delivered Quality System/cGMP Training presentations.
* Developed Good Documentation Practices (GDP) Training presentation.
* Provided remediation strategy and remediation plans in the area of CAPA, Training, and Customer Complaints systems.
* Developed Correlation Studies for qualification of equipment.
* Investigated and provided responses to quality related customer complaints and product recalls.

**QA Supervisor of Documentation Control and Quality Systems, AVEMA PHARMA SOLUTIONS FL – September 2010- July 2011**

* Supervised the implementation and revision of documented procedures (SOP), and specifications (SPC) for packaging, raw materials, labels and components.
* Served as change control manager for equipments, facilities and documentation such as Master Batch Record (MBR) Development and Protocols for R&D and Validation purposes.
* Leaded the Material Review Board, and reviewed and approved Deviations and Investigations.
* In charge of CAPA system; brainstorming, implementation, and effectiveness monitoring.
* Monitored, Investigated and Responded Customer Complaints.
* Ensured compliance with internal Policies and Regulations.
* Audited suppliers, distributors and supplier selection process.
* Oversaw Product Registration in Latin American countries.

**QA Production Manager AZOPHARMA, FL – September 2008- August 2010**

* Responsible to oversee the daily activities for QA Engineer, QA Inspectors, QA Specialist, and BMR Reviewer. Motivated my team and delivered coaching conversations.
* Managed recruitment: pre-screening resumes, interviewing and processing new hires.
* Executed business strategies that supported company objectives and streamlined the workflow of operations. In charge of overseeing GMP; and engineering activities such as equipment PM and calibration maintenance; manufacturing, warehouse and overall facility audits; incoming and intermediates sampling, testing, review of engineering blueprints, and final disposition for Raw Materials, Components and Finished Product; pest control and safety throughout the facility. Participated in meetings with clients and other departments for planning and scheduling purposes.
* Successfully launched a manufacturing process for a commercial product with my team, and it was approved by the MHRA. Participated in the initial documentation preparation for European and US Regulatory Inspection.
* Responsible for document control; design, revision and implementation of SOPs; SPC for Raw Materials and Components as required; Approved MBR, and Protocols regarding with IQ/OQ/PQ equipment evaluation for Manufacturing, Packaging and Labeling.
* Evaluated key performance indicators (KPI); Trend and Investigated Non-Conformances, Complaints, and Deviations and lead CAPAs as required.
* As Documentation Manager, supervised 1 BMR Reviewer, and 2 MBR Documentation Specialists; and 15 Manufacturing Operators as acting Manufacturing Manager.
* As Training Management: Created training modules for Project Managers, Packaging and Labeling operations, and QA Department. Administrated the Intelex System for training and safety compliances. Prepared the welcome package for new employees and assigned their respective trainings. Scheduled all training activities for overall administrative personnel, including warehouse, engineering, laboratory, manufacturing and R&D.

**QA Engineer Associate, WATSON, FL – October 2006- August 2008**

* Performed Annual Product Reviews.
* Responsible for monitoring Quality System.
* Audited internal facilities and suppliers.
* Interfaced with external auditors (FDA and ISO).
* Worked to resolve quality issues from conception to production.
* Integrated CAPAs into the system and monitored effectiveness.
* Ensured Supplier Corrective Actions were completed as agreed.
* Reviewed Non-Conforming Material System to ensure product safety, and disposition followed internal SOP and regulations.
* Performed and executed all validation process.

**QA Specialist, NOVEN, FL – May 2006 - October 2006**

* Assured the quality of components, raw materials and all manufacturing stages, including Intermediates, and Finished Transdermal drug products against GMP Requirements.

**QA Specialist I, WYETH, PR – January 2002- May 2006**

* Improved SOP for Non-Conformance Investigations to ensure compliance with ISO 9000 and Supplier program.
* Involved in systems launch: SAP and Trackwise.
* Served as liaison between Purchasing and Quality Assurance Department.
* Prepared summary reports for deviations and non-conformances and communicate findings and resolutions to Management Team.
* Introduced CAPA tracking for supplier quality events.
* Prepared yearly reviews for components used during the manufacturing of company products as part of the Annual Product Review as per 21CFR211.180.
* Audited parenteral drug manufacturing processes.
* Reviewed QC Records for Finished Product, and Components to determine disposition.
* Audited suppliers.
* Enforced GDP.
* Followed SOPs and ANSI/ASQC standards as part of the sampling plan method for Incoming materials and Finished Parenteral drug products.
* Performed warehouse cycle count as part of Inventory control.
* Audited validation protocol and activities regarding with IQ/OQ/PQ throughout the manufacturing of a parenteral drug product.
* Designed, implemented, and monitored the incoming materials sampling, disposition and improved method to reduce cycle time for Six Sigma Project.
* Reviewed documentation and monitored warehouse and aseptic environment: Microbiology Sampling Results, Temperature, Relative Humidity, Pressure, Water for Injection, Reverse Osmosis, and City Water.
* Trained in manufacturing equipment operations such as: Autoclave, Lyophilizers, Conveyors, Blenders, ICOS sterilization, and Rockwell ovens.
* Cleaning, Sanitization and Monitoring of Aseptic Areas.

**Computer Assistant, UNIVERSITY OF PUERTO RICO, PR, May 1997 - December 2001**

* Programmed windows NT/98 and consistently maintained computer lab for PC and Mac, software and hardware systems.
* Aided students on their researches using Internet Network, UPR Intranet, and Journals among others.

**EDUCATION**

* Bachelor of Science, Environmental Science, University of Puerto Rico, Puerto Rico
* 1 year of studies towards Master of Science in Management, Ana G Mendez University System, Puerto Rico.