

Contact

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Top Skills

Sterilization
Project Management
ETO

Languages

English
Spanish

Certifications

Master Electronic Technician License
Photovoltaic System Installer Certification (PV)
Industrial Validation Specialist
Master Electrician License
Certified Professional Parliamentarian (CPP)

Honors-Awards

Valedictorian Award

Frances T. Berríos, BSIE, MEME, CPP, ECIII

President at Colegio de Peritos Electricistas de Puerto Rico
Puerto Rico

Summary

Industrial engineering professional with over (20) years in the pharmaceutical and medical device industry; excellent problem solving, communications and leadership skills across all levels. Experience in Project Management, Lean Six Sigma, Calibrations, Maintenance , Sterilization, Third Party Audits, Consent Decree, Manufacturing, Change Control, Training, CAPA, Investigations and Validations, SAP, Maximo, Minitab, Microsoft Project Bilingual: English – Spanish.

Experience

Parliamentary Consulting Group
Associate Parliamentary Partner
May 2022 - Present (4 years 1 month)
San Juan, Puerto Rico

Instituto Derecho Parlamentario
Certified Instructor ECIII
May 2022 - Present (4 years 1 month)
San Juan, Puerto Rico

Colegio de Peritos Electricistas de Puerto Rico
President
August 2020 - Present (5 years 10 months)
San Juan, Puerto Rico

VIS Technologies
Engineering Consultant
October 2017 - Present (8 years 8 months)
Puerto Rico

Emergent BioSolutions

Facility & SAP Engineer consultant

April 2018 - July 2018 (4 months)

Canton, Massachusetts

Haemonetics

Sr. Process & Compliance Quality Engineer

April 2017 - October 2017 (7 months)

Fajardo, Puerto Rico

Medtronic

Sterilization Project Manager

March 2015 - March 2017 (2 years 1 month)

Villalba, Puerto Rico

- Technical Lead for Sterilization, guide and direct cross-functional teams.
- Guide and address all technical discussions and related to ETO Sterilization.
- Apply project management tools and methodology for planning and tracking.
- Guide the team through Deliverables Concurrence with ANSM.
- Guide and direct planning, design and implementation for Sterilization Validation project, and execution of assigned Validation protocols.
- Communication with relevant site management; ensuring informed decision making relative to Sterilization warning letter efforts and base business impacts.
- Ensure that industry best practices are applied in meeting the requirements of any governing standards Manage / track performance measures of project where appropriate.
- Designed and implement Sterilization process Interim controls during the ANSM remediation.
- Responsible for developing and implementing compliant and sustainable solutions including the closure of all Sterilization gaps identified.
- Identify and report risks and progress.
- Apply Six Sigma tools and methodology for validation and technical reports.
- Accountable for Sterilization Validation project.
- Ensured that industry best practices are applied in meeting the requirements of any governing standards Manage / track performance measures of project where appropriate.
- Identified and report risks and progress.

Mcneil Pharmaceutical

C&M Project Lead

October 2013 - February 2015 (1 year 5 months)

Las Piedras, Puerto Rico

- Technical Lead for Calibration, guide and direct cross-functional teams of LP McNeil Consumer Healthcare colleagues and outside consultants through the completion of the Numbered Steps in the Consent Decree work plan related to Calibration.
- Designed and Lead Protocol for Instrument Data and characteristics for the SAP designated fields (Puerto Rico site).
- Created 51 SOP's for transaction for the CMMS SAP System with the corresponding test scripts and execution (Fort Washington site).
- Reviewed CSV protocols and test scripts for the Use for fit SAP project.
- Guided and address all technical discussions and resolution related to Calibration and Maintenance during the CD.
- Responsible for developing and implementing compliant and sustainable solutions including the closure of all gaps identified in the QSE Roadmaps (derived from 483's, Quantic Baseline Inspection, deviations, Interim Controls, etc).
- Accountable for achieving all CD work plan deliverables associated with their assigned components throughout the plan/design, implement, operate and verification phases of the work.
- Remediated Calibration and Maintenance Systems for LP McNeil in accordance with Quality standards.
- Guided the team through Deliverables Concurrence with internal, ERC and Quantic verifiers.
- Guided and direct planning, design and implementation in use, and verify activities for the assigned components and numbered steps.
- Ensured appropriate evidence to document process and completion of the work.
- Assured that the attributes of a robust system are addressed in the Quality System Element design.
- Assured utilization of Process Excellence tools and methodologies in completing the Numbered Step work.
- Applied project management tools and methodology for planning and tracking.
- Communication with relevant site management; ensuring informed decision making relative to consent decree efforts and base business impacts.
- Ensured that industry best practices applied.

Warner Chilcott

Instrumentation Specialist

January 2009 - October 2013 (4 years 10 months)

fajardo facilities

- Performed process, utilities and laboratories instrument calibration.
- Evaluated and audit external calibration laboratories.
- Maintained and improve working standards.
- Developed and improve calibration procedures and data sheets.
- Evaluated and determine the most efficient and reliable instrumentation to purchase.
- Reviewed and perform calibration assessment for new instrumentation.
- Prepared capital appropriation requests for new instruments acquisition.
- Evaluated, recommend, or implement corrective actions to maintain and improve instrument efficiency, utilization, productivity, and quality at the assigned manufacturing work units.
- Coordinated, prioritized, organized and direct the workloads and task assignments to insure timely and accurate calibration of test equipment.
- Provided technical, engineering support and assists manufacturing personnel. On a daily basis and for validation initiatives evaluate process and machinery problems affecting production, quality, and service.
- Performed calibration “Failure and Out of Tolerance” investigations.
- Provided assistance in the manufacturing and packaging new equipment qualification and validation (PK Solid Processor, IMA Killian Tablet Press, Kikusui Tablet Press, CP600 Thermo Former, Semi Solids) Design, develop and provide trainings for calibration, cGMP, Quality, engineering as the “Train the Trainer” area leader. Apply Lean Six Sigma techniques in the calibration laboratory.

Honeywell

Field Service Representative

April 2004 - November 2008 (4 years 8 months)

Guaynabo

- Performed pharmaceutical process, utilities and laboratories instrument calibration.
- Evaluated and audited working standards.
- Developed calibration procedures.

Education

Universidad Politécnica de Puerto Rico

Masters Engineering Degree, Manufacturing Engineering · (2010 - 2012)

Universidad del Turabo

Bachelor of Science (B.S.), Industrial and Management
Engineering · (2006 - 2010)

Instituto Tecnológico de Puerto Rico-Recinto de San Juan
Associate's degree, Second Specialization in Instrumentation Engineering
Technology · (2002 - 2004)

Instituto Tecnológico de Puerto Rico-Recinto de San Juan
Associate's degree, Electrical Engineering Technology · (1996 - 1998)