Majesha Mercado

Validation Engineer - Merck Sharp and Dome

North Wales, PA - Email me on Indeed: indeed.com/r/Majesha-Mercado/bda4dc9b684004e6

Twelve (12) years of combined experience in Validations, Commissioning, Project Management and Compliance in the following areas: Facilities, Utilities, Process, Equipment, Cleaning, Clean in Place (CIP), Sterilization in Place (SIP), Systems and Computer System Validation (CSV) at Bio-Technology, Pharmaceuticals, Medical Devices, Animal Health and Government Industries.
Experience covers coordination with other consultants, engineering firms and construction contractors, leadership, and project management. Knowledge of: OSHA, FDA, EPA, ISO and GMP regulations. Leader, committed to customer satisfaction, focused on quality as top standard and disciplined.

WORK EXPERIENCE

Validation Engineer

Merck Sharp and Dome - West Point, PA - 2012 to Present

Develop and execution of Cycle Development Protocols (CD), Developmental Protocol and Initial Validation Protocol (IVAL) "Performance Qualification- PQ" for Fedegari Walk-In GMP Autoclaves.

• Develop and execution of Cycle Development Protocols (CD), Developmental Protocol and Initial Validation Protocol (IVAL) "Performance Qualification- PQ" for Skan Isolator Equipment with Vaporous Hydrogen Peroxide (VHP 49.0 - 49.9%) Technology.

• Execution of Cycle Development Protocols (CD) and Initial Validation Protocol (IVAL) "Performance Qualification- PQ" for Belimed Parts Washer.

• Execution of Cycle Development Protocols (CD) and Initial Validation Protocol (IVAL) "Performance Qualification- PQ" for Filtration Skid Ultrafiltration (UF) and Microfiltration (MF) Equipment Clean-In-Place (CIP) and Sterilization in Place (SIP) Technologies.

• Execution of Continuing Cleaning Validation Protocol for WFI Clean in Place (CIP) on 2000 L Tanks and Transfer Lines used for manufacture of Chemical and Salt/Buffer Culture Media, and Sterilization in place (SIP) on full vessel equipment.

• Excellent skills in XpertVal software as well as Thermocouples (thermal validation equipment), performed Pre Calibration and Post Verification using Lives Ametek International Temperature bath equipment. Excellent skill on building reports, statistics, advance statistics, and trending on XpertVal Software. Good Handling Biological Indicators (BI's), Chemical Indicators (CI's) and swabbing techniques performed on Cleaning Validation.

Validation Engineer

Novartis - Humacao, PR, US - 2011 to 2012

Develop and execution of Installation and Operational Qualification (IQ/OQ) and Cleaning Protocol for Down Flow Booth equipment.

• Develop and execution of Installation and Operational Qualification (IQ/OQ) Protocol for Facility Cleans Rooms.

• Develop Functional and Design Specifications/Risk Assessment for the Compressed Air System Modifications at Animal Health Area.

• Develop and Execution IQ/OQ Protocol for new compressed air points of use at Animal Health Area.

• Develop and Execution IQ/OQ/PQ Protocol for the addition of five point of use to the USP Purified Water System.

• Develop and Execution IQ/OQ Protocol for the new Air Handling Units (AHU's) with BMS Integration.

• Develop and Execution IQ/OQ Protocol for the new Condensing Units.

• Develop and Execution IQ/OQ Protocol and SOP for Mettler Toledo Vertex Floor Scale Model 2158 with IND 560 Terminals.

Validation Engineer

Mc Neil - Las Piedras, PR, US - 2010 to 2011

Develop IQ/OQ Protocols for New SS Tote Stand Installations for Printer Stations in Manufacturing Line 2 thru 8 (Feed Stand Project).
• Develop IQ/OQ and FSD Specification Addendum Protocol for the IMA Tablet & Capsule Filling Machine due Filler Platform Replacement.
• Develop Backup and Archiving Assessment Form, Regulatory Assessment and Risk Assessment for IMA Tablet & Capsule Filling Machines.

Senior Project Consultant

Aqueduct and Sewer Authority (PRASA) "Water Industry of Puerto Rico" - San Juan, PR - 2009 to 2010

Develop and execution of Qualification Protocols for Facilities and Utilities such as Water Filtration Plants, Wells, Tanks, Pump Stations, Pump Station with Tanks and Lift Stations to Telemetry Department as part of Actions agreed in the PRASA Consent Decree.
• Gather and evaluate supporting documents such as Compliance Start-up, Automation Software Upgrade Reports, Continuous Monitoring Reports, Communication Assessment and others as part of Compliance Monitoring Validation Package.
• Interact with utilities owner for the deviations resolution.

Baxter, Carolina, PR
• Statistic and Quality Studies.

Netcom Computer, San Juan, PR
• Anthropometrics, Ergonomics, Noise and Illumination Studies.

Playtex, Dorado, PR
Time studies in MTM, Stop Watch, Work Sampling, Cost Analysis and Layout.

Mayor's Office, Guaynabo, PR
• Project Management Evaluation in the Construction of New Mayor's Office.

Wendy's Rest,. Isla Verde, PR
• Queue Studies and Simulation in Witness Program.

Hermanos Melendez Hospital, Bayamon, PR
• Medical Faculty's Parking Layout.

Validation Engineer

Wyeth Consumer Healthcare - Guayama, PR, US - 2007 to 2009

Develop and execution of Installation and Operational Qualification (IQ/OQ) Protocols, Test cases, Validation Plan, Validation Matrix and Summary report for the National Drying Ovens in Analgesic Area.
• Develop of mapping test utilizing Temptales and Kaye Validator to challenge the temperature distribution of drying ovens.
• Develop Commissioning and Reports for Air Dryers; develop environmental monitoring verification protocol of compress air system to demonstrate that after the installation and operation of the Air dryers, the compress air system complies with all the requirements.

• Execution of Mechanical and Computer System Validation (CSV) Installation and Operational Qualification Protocols for Pellegrini Sugar Coater in Analgesic area.
• Execution of IQ/OQ Protocol for different type of scales in Analgesics and Dietary Supplements Areas.
• Develop commissioning and reports for the Korsch XL800 Tablet Press located in Compression Area.
• Develop and execution of commissioning for the New Compressed Air Point of Use to be used in the Compression Area.
• Develop and execution of commissioning for the Air Handling Unit (AHU) and Dust Collector (DC) for the Low Cost Project Phase 1.
• Develop and execution of commissioning for the non-critical utilities located in compression rooms.

Validation Engineer

Pall Corporation Life Science - Fajardo, PR - 2006 to 2007

Develop and execution of Installation and Operational (IQ/OQ) protocols for the Clean Rooms including utilities (Electrical, USP Water, Chilled Water Supply, Chilled Water Return, Compressed Air, Clean Air, Hose Vacuum, and Process Vacuum) within building 1 "Biopharm Life Sciences" and building 3 "Profile/Industrial" for the new PPR-1 Improvements 8,000sq.ft Clean Rooms.
• Develop Engineering Study and Summary Report for manufacturing and packaging facilities.
• Execute Installation and Operational Qualification Protocols.

Validation Specialist

Bristol Myers Squibb - Humacao, PR, US - 2006 to 2006

Update, compare and match retrospective protocols data from 10 years ago to present with the MAXIMO program, drawings and field verification of the following equipment such as; Vessels, HEPA, Transmissions, Valves, HVAC, Motor, Instruments, General (Autoclave, Blender, Reactor, Air Handling Unit, Turbine Agitator), etc.

Validation Specialist

Amgen Manufacturing Limited - Juncos, PR, US - 2006 to 2006

Develop and execution of Installation and Operational Qualification (IOQ) Protocols for HC Checkweigher Machine located at Packaging Area.
• Develop of Requirement and Design Specification for Dividella Neo Top 904.
• To provide support executing the following packaging equipment: PAGO Labeling Machine, Dividella Neo Top 904 and HC Checkweigher Machine at Packaging Area within the Fill and Finish Plant (AML-1).

Validation Specialist

Schering Plough Corporation - 2004 to 2006

Develop critical utilities certification statement for DI Water, HVAC, Nitrogen, Negative Exhaust, Central Vacuum, and Solvent System as part of the actions agreed in the Consent Decree of permanent injunction dated May 20, 2002.
• Gather and evaluate utilities performance data.
• Assess cGMP's compliance of supporting documents.
• Assess systems control status.
• Issue relevant utilities control statements as required.
• Interact with utilities owner for the resolution of noted deviations.
• Develop commissioning and IOQ protocol for the solvents system supporting the API Manufacturing Operations.
• Provide support to technical services department for the product transfer and validation of the Afrin presentations.

• Execute Process Validation Protocols, Development Studies, Primary and Secondary Packaging Validations and Special Packaging Testing.
• Participate on Special Study conducted to identify and isolate problems on the primary packaging area.
• Preparation of Summary Reports for the related protocols.

Validation Engineer

IPR Pharmaceuticals - 2002 to 2003

Prepare project close-out documentation: Equipment Data Books for Pharmaceutical process.
• Collect and revise technical and vendor specifications, vendor and project drawings, submittals and among others.

EDUCATION

BS in Industrial Engineering

Polytechnic University of Puerto Rico

ADDITIONAL INFORMATION

SPECIALTIES:

• IQ/OQ/PQ
• Validations
• Initial Validation
• Process Validation
• Continuing Validation
• Commissioning
• Cycle Development
• Developmental
• Engineering Study
• Utilities
• Facilities
• Equipment/ System
• Computer System Validation CSV
• Manufacturing
• Packaging
• Cleaning
• Cleaning in Place (CIP)
• Sanitization in Place (SIP)
• Decontamination Equipment
• Sterilization Equipment

IT/AUTOMATION:

• AutoCAD 13
• Statgraphics
• Microsoft Project
• MAXIMO

SPECIALIZED TRAINING:

- Six Sigma Black Belt Training Completed (Certification ongoing)
- Clean Room Regulations and Monitoring
- Industry Trends in Pharmaceutical Water Purification
- HVAC Recovery System