

Yuliana León

Merck Manufacturing Division - Specialist Engineer - Merck & Co

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WORK EXPERIENCE

Merck Manufacturing Division - Specialist Engineer

Merck & Co - West Point, PA - February 2014 to Present

PedvaxHIB Derivatization & Conjugation B60, BBM)

- Manufacturing Engineer/ Subject Matter Expert - Bulk PedvaxHIB Derivatization & Conjugation (Mening.Vaccine)

Provided technical support to operations/production during bulk manufacturing campaigns

- o Assessed product/process impact during deviations and proposed path-forward plans and ideas for CAPAs
- o Collaborated with technicians to identify continuous improvement projects
- o Trended Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs) on a per batch basis
- o Authored, revised, reviewed, and approved SOPs, batch records, and technical documents
- o Ensured cGMP documentation compliance with most up to date regulatory and departmental requirements
- Project lead for change to buffer formulation source manufacturer
- o Authored Category 3 Change Request (CR) and tracked progress of CR using TrackWise
- o Developed execution plan, timeline, and resource allocation model & tracked status using the Project Web App (PWA)
- o Authored mixing and comparability study protocol, executed studies and analyzed data in corresponding final reports
- o Initiated batch record, BOM, and master data updates
- Building Compliance Action Team (BCAT) Lead for the Pedvax/Pneumovax IPT
- o Performed weekly shop floor walkthroughs and worked with Ops to remediate gaps
- o Performed log book audits for accuracy and completeness
- o Presented compliance trainings to shop floor (sterility assurance, cGMP documentation and material control)
- Project Engineer/Project Manager - Implementation of PedvaxHIB Gamma-Irradiated Sterile Filtration Assemblies

Initiated project to comply with Regulatory Sterility Assurance Guidelines

- o Authored Charter and developed project execution plan, timeline, and resource allocation model
- o Managed cross functional team consisting of Procurement, Tech-Ops, Operations, Quality, EM, USW, and external vendors
- o Authored Category 3 CR for the bulk process and Category 2 CR for the process simulation
- o Initiated MBR, BOM, SOP/CJA, Master data, and LIMS updates
- o Initiated validation assessments (CCI, Filters, L/E, Gamma, Sterilization)

Merck Manufacturing Division - Engineer (OMPC Purification, B65, BTM)

Project Engineer - OMPC Manufacturing Facility Start-up & Sterile Boundary Improvements

Merck & Co - West Point, PA - August 2010 to December 2012

Led OMPC process simulation runs

- o Authored change request and initiated validation assessments
 - o Coordinated and managed instrument qualifications (OQ and PQ of welders and filter integrity testers)
 - o Led batch record redesign and SOP Updates (including RFT SOP consisting of written and pictorial instructions)
- Led safety/ergonomic centrifuge cart project
- o Designed and implemented a customized cart for transporting OMPC product (cost saving of ~ \$45MM per broken bottle)
- Provided Technical support and supervision during Process Performance Qualification (PPQ) and Engineering batches
- o Collaborated with shop floor to identify gaps & implement process improvements leading to reduced human error deviations

EDUCATION

B.E in Chemical Engineering

City College of the City University of New York - Grove School of Engineering Honors Program - New York, NY

March 2010

ADDITIONAL INFORMATION

Chemical Engineer with 4.5 years of experience in pharmaceutical bulk manufacturing technical operations. Extensive experience in cGMP documentation, RFT improvements, project management, change control, technical writing, product impact assessments, team leadership, and downstream purification operations (sterile boundary). Exceptional organization, prioritization, time management, and, communication skills. Ability to work efficiently and effectively both independently and within cross functional teams.

SKILLS

Computer Applications: Microsoft Office (Outlook, Excel, Word, PowerPoint), TrackWise, SAP, LIMS, Visio, MII, and JMP

Languages: Native Fluency in Spanish