

IT Lead IT Lead Laboratory Systems Professional Humacao, PR Authorized to work in the US for any employer Work Experience IT Lead J&J Consumers - Fort Washington, PA and Las Piedras, PR February 2014 to Present Responsibilities Responsible to make sure all activities for the Beckman retirement were completed on time. Provides written and verbal communication including status reports, progress reports, and documentation to IT management and business partners Manage Project through PMX Project solution Partners with business partners to understand and define business drivers and requirements of the initiated programs and/or projects.

Ensures adherence to Computer System Validation, Software Development Life Cycle and internal and external compliance requirements. Accountable to ensure operational support models are in place and manage the overall system availability and service levels as it relates to incident, service requests and overall system compliance. Act as liaison between the related IT organization business partners to ensure successful delivery of initiatives. Participate in cross-functional team through the Johnson & Johnson sectors (Pharma, Medical Devices and Consumers) to align the strategies for Laboratory Systems implementations. Accomplishments Lead Consent Decree commitment to retire Beckman LIMS and support the retirement of SmartLab LEN and implementation of Empower 3 and Labware LIMS at McNeil sites in US and PR. Support the implementation of LabWare LIMS in Guelph, Canada and Pomezia, Italy sites. Support the implementation of Empower 3 in Cali, Colombia. Support the efforts to connect J&J Consumer sites with the Pharma Enterprise SDMS System Lead the efforts to select the vendor that will provide the Global solution for a Laboratory Execution System (LES) in the J&J Consumers sites. Lead the efforts for the retirement of legacy Beckman LIMS systems in 5 J&J Consumers sites and the data migration into Informatica ILM. Skills Used Lead, Execute, Collaboration, Attention to Details, Analyze, Partnership, Project Management, Continuous Improvement, Technology Lifecycle Management, Communication QA Lab Systems Administrator Merck Pharmaceuticals 2007 to 2013 Responsible for the operation, configuration and troubleshooting of LIMS, Chromatographic Data Acquisition System (Empower), Bruker NIR, Infinity QS and standalone computer systems. Management of Quality Operations projects such as improvement, construction and expansion of

the Quality facilities, new equipment purchases, new computerized systems implementations, etc., from the preparation of the capital request to the development, negotiation, implementation, cost tracking and completion of the project. Responsible for all Master Data creation and updates in Empower and Labware LIMS systems to support new product introductions, test methods and specification changes. Assure that computerized systems are operating properly, are in full compliance with cGMP, and are maintained in good working condition. Implementation of new Global initiatives such as Global LIMS, Global Change Management System, new NIR System for Raw Material ID, among others. Contributed to the laboratory Lean projects and 5S initiatives. Participate in Kaizen events in the laboratory and Quality Assurance areas. Support other business computer systems within the site that are GMP related such as Documentum, MIDAS and Trackwise. Responsible for the coordination of all system updates and changes to minimize their effect on the operations. QA Lab Systems Administrator Cordis LLC 2003 to 2007 Administration of laboratory software systems Labware LIMS, Empower CDS, Chemstation and OMNIC. Maintain the validated status of all systems. Prepared, revised, approved and executed computer systems validation (CSV) deliverables and change requests. Appointed as Subject Matter Expert to the Global Labware LIMS implementation. Train system users and potential system administrators in the use and management of the systems and in all related standard operating procedures (SOPs) and forms within all organization levels from operators to upper management. Support Laboratory Equipment qualifications and upgrades Assist and Creates laboratory investigations and CAPAs related to systems. Develop and approve Laboratory Incident Reports, SOPs and forms. Support internal and external audits and collaborate in the observations' answers. Coordinate validation and qualification projects related to laboratory computerized systems, data acquisition softwares and laboratory equipments. Responsible for the development and execution of validation protocols and others validation deliverables such as User Requirement Specifications, System Requirement Specification, Validation Strategy Documents, Technical System Design, Part 11 Assessments, Risk Analysis, User Design Review Reports, Validation Reports, etc. Responsible to create and update Computer Systems SOPs for Operational Use, System

Administration, Disaster and Recovery, Archiving and Restoring, etc. Laboratory Analyst OMJ Pharmaceuticals - San German, Puerto Rico, US 1997 to 2003 Finished Product Laboratory Cell Coordinator Back-up System Administrator of Millennium Data Acquisition System and Instrumentation Specialist responsible for the maintenance and troubleshooting of the HPLC's Waters Alliance 2695 and GC's Agilent 6890. Romelia Rodriguez Member of the PSGA Computer Software Validation Team, responsible for the implementation and validation of the Millennium 4.0 and Part 11 Compliance in all PSGA sites (OMJ San German, Ortho Manati and Janssen Gurabo). Expert in the development of Automatic Custom Calculation using Millennium and Empower Software. Experience as Analytical Chemist responsible for Finished and Stability Products testing of Ophthalmic Solutions, Biological Products, Raw Materials, Controlled Substances, Sterile and Lyophilized Products. Experience in Methods Transfers and Methods Validations. Analytical Chemist responsible for Finished and Stability Products testing of Ophthalmic Solutions, Biological Products, Raw Materials, Controlled Substances, Sterile and Lyophilized Products. Experience in Methods Transfers and Methods Validations. Bulk Pharmaceutical Operator Eli Lilly Pharmaceuticals - Mayaguez, PR 1994 to 1996 Responsible for the execution of multi-step synthesis in bulk drug manufacture. Experience with process equipment such as: reactors, centrifuges, filters, pumps, etc. Education Bachelor in Science in Chemistry Interamerican University of Puerto Rico, San German Campus - San German, Puerto Rico, US May 1997 Skills Microsoft Project, Computer Literacy, Lean Manufacturing, Root Cause Analysis, Spanish Additional Information IT Lead responsible for establish and drive the strategy for the automation of Quality Laboratory functions. Responsible for business relationship management activities to collaborate with business partners to identify opportunities to improve, automate, and simplify business processes. Function as a leader for technology and applications and ensuring business partners are aware of new and emerging technologies. Ability to manage projects and timelines to ensure system deployments comply with the targeted timelines and budget. Experience in validation and administration of laboratory systems (Labware LIMS, LES, Empower CDS, Chemstation, OMNIC, OPUS, Infinity QS). Teamwork oriented with excellent interpersonal and

communication skills.

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