**Priyanka**

**Newark, NJ**

**Sr. Validation Engineer**

**469-277-0254**

**Professional Summary**

* Around 7 years of experience in Clinical Data Management with 3 years of experience as a Clinical research Associate and 4 years of Computer System Validation Engineer.
* The Process Validation Engineer I, CAR T is responsible for supporting the production of personalized cell therapy products for both global clinical trials and commercial supply.
* Experience with FDA regulation, 45 CFR, 21CFR Part 11, 50, 56 and 58, 210, 211, 820.
* The Process Validation Engineer I develop qualification/ validation documents (e.g. protocols and reports) satisfying internal and external regulatory expectations.
* Experienced in performing, commissioning and validation for a new manufacturing facility and create qualification protocols.
* Compilation of summary reports for activities like qualification risk assessments and deviation responses.
* Knowledge in equipment validation for facilities, cold rooms, HVAC, CIP, COP, critical utilities and laboratory equipment.
* Executed temperature mapping studies and engineering test plans prior to validation activities.
* Great experience in EDC with knowledge of GCP, ICH AND ISO guidelines.
* Ability to translate business requirements, ability to develop use case scenarios and representing them as use case diagram using MS Visio.
* Implemented and executed qualification procedures for chromatography systems, clean steam, dispensing stations, WFI, HVAC, CIP, SIP, COP, UF/DF Skids, cold storage rooms, fume hoods, floor scales, and critical utilities.
* Experience on equipment qualification and validation activities including Controlled Temperature Units (CTU) temperature mapping. Equipment calibration, maintenance, and repair activities in both laboratory and manufacturing areas
* Perform independent execution of validation activities required for the production operations to ensure rapid, flawless, compliant, and cost-effective delivery of quality products.
* Experience in handling different type of systems Veeva, BluePira T, SAS, SAP, Oracle, LIMS.

**Technical Skills**

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| **Medical Coding Dictionaries** | MedDra, WHO Drug Dictionary |
| **Tools** | CDMS, JReview |
| **EDC** | Medidata Rave, Inform, OC RDC |
| **Operating Systems** | MS Windows |
| **Others** | DMP/DTA, Vendor Management, eCRF Design, UAT, Data Analysis, Data Reconciliation and Discrepancy Management. |

**Professional Experience**

**Boehringer Ingelheim, CA Nov 2016-Present**

**Sr. Validation Engineer/CSV ENGINEER**

* Responsible for quality performance monitoring and evaluate internal process to ensure continued delivery of quality products and services.
* Involved in performing Packaging Validation to identify the defects.
* Execution and report generation of IQ/OQ/PQ/PV protocols for Liquids and Solid Dosage manufacturing, filling and packaging equipment.
* Developed Functional Requirements and Test Scripts for large scale SAP ERP implementation, maintaining traceability across design, user and functional requirements, and test protocols.
* Proficiency in maintaining Risk Management, DFMEA, PFMEA, and CAPA
* Extensive hands-on experience in performing Process Validation Test protocols (IQ/OQ/PQ) for equipment process in the packaging line, Process Validation Plan (PVP), and preparing PVP Report
* Good expertise in performing GAP analysis in identifying gaps and correcting them
* Participated in the preparation and revision of risk assessments using tools such as DFMEA/PFMEA
* Equipment Validation and technical documentation as per FDA/ISO 13485 and GAMP regulations
* Experience in Data Migration, Periodic Review, Change Controls, Change Reporting, Root Cause Analysis, GAP Analysis, CAPA, FMEA and Remediation Process
* Authored and executed Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and Test Method Validation (TMV) for mechanical
* Experienced with Criticality Analysis (CA), Maintainability Information (MI), Fault Tree Analysis (FTA), Event Tree Analysis (ETA), Statistical Process Control (SPC) and Risk Management
* Preparation of Multiple cGMP Documents such as Commissioning, Validation, Qualification Protocols, SOP, Forms, Vendor Checklists, etc and also document quality issues and quality performance.
* Prepare, Review and execute Facility Qualification protocols including equipment's that have been built and installed in compliance with their design specifications and as per OSHA Regulation.
* Prepared and execute cleaning validation protocol to clean a system or a piece of equipment using method such as Swab Sampling and Rinse Sampling.
* Worked with medical and clinical data on annotated CRF, SDTM and ADAM data set level and created tables listing and figures in a format that can be reported to FDA (Medical Data Acquisition and Storage.
* Created and Modified Change control, Change Plan, Impact Analysis, RA Tracking records In the Track Wise Application.
* Involved in all stages of product development and testing Inc.: FMEA, DOE, RCA, DVP&R, maintenance and preparation for DV, & PV tests.
* Performed design verification pertaining to device QMS ISO 13485, 14971 for risk management.
* Worked on GAMP, GxP's (GCP, GLP, GDP and GMP), and 21-CFR Part 11 regulation of Electronic Records, Electronic Signatures and Audit Trails.
* Responsible for providing Software Quality Assurance (SQA) engineering support for all lifecycle phases of computerized systems that include MES, TRS and PDM.
* Performed ERES Assessment, developed Validation Master Plan (VMP) for the SAP implementations.
* Verification and Validation of new product design and evaluation of design changes in accordance with 21 CFR part 820.
* Performed Detailed Risk Assessment by Failure Mode Effects Analysis (FMEA) for managing the risk levels used before validating the system.
* Drafted standard operating procedures (SOPs), and supported QA audits of existing operating procedures to ensure the compliance with company current regulatory requirements and Involved in all activities in SDLC life cycle.
* Created and coordinated the execution, review and closure of multiple Change Controls for SAP along with that performed Verification and Validation testing in an FDA/UL regulated environment.
* Managed traceability between requirements, design elements, and test cases in HP ALM also repaired Validation Master Plan (VMP) for validating analytical laboratory equipment's and LIMS the Workflows implemented included complaints, CAPA and Change Control.
* Involved in defect development life cycle (HPQC) and assigned the created defects to developers. Once the defect is fixed, Retested the defect and it moved to the closed status.
* Updated the following validation deliverables for projects -Issues Log, Incident Reports, IQ Protocol/Report, OQ Protocol/Report and Trace Matrix.
* Performed a variety of general validation activities, including the IQ/OQ/PQ activities for equipment such as agitators/mixers, bench scales, centrifuges, and storage vessel.
* Performed a variety of general validation activities, including the IQ/OQ/PQ activities for equipment such as agitators/mixers, bench scales, centrifuges, and storage vessel.
* preparation of test equipment and execution of validation studies (cleaning, process, steam sterilization, temperature mapping, and equipment requalification’s, etc.) in a manufacturing environment
* Perform temperature mapping and humidity monitoring using Kaye validator & Ellab Portable dataloggers for Manufacturing & laboratory support equipment which require temperature and humidity control

**Xellia Pharmaceuticals, Ohio Dec 2015- Nov 2016**

**Sr. Validation Engineer/CSV ENGINEER**

* Over 3+ years of experience as Sr. Validation Consultant/Analyst in Pharmaceutical and Medical Device Industry.
* Demonstrated experience in Computer System Validation and Business Analysis. Specific expertise in Reviewing and updating Validation documents in accordance with SDLC and company SOPs.
* Reviewed and updated Validation documents for SAP ECC 6.0 (Manufacturing, Quality Management, Warehouse Management etc.), Oracle AERS, CTMS, SharePoint 2013 and Laboratory Information Management System (LIMS) in accordance with 21 CFR Part 11 & GxP regulations.
* Specialist in reviewing, updating and creating all the Validation deliverables - Regulatory Assessments, Risk Assessments, Validation Plans, 21 CFR Part 11 Assessments, Qualification Plans/Test Plans, Trace Matrices, IQ/OQ/PQ Test protocols and scripts, Qualification Reports, Deviation/Incident Reports, Problem Reports, Change Controls, Addendums and Validation Summary Reports.
* Practical knowledge of applying GAMP5 fundamentals in validation of computer systems.
* Excellent experience as an SQA in reviewing all the pre-requisites and/or status of activities at Phase gates, suggesting/creating mitigation plans for non-complying tasks and signing off on Phase gates as the SQA/SR. VALIDATION AND COMPLIANCE CONSULTANT.
* Experience in being the gate keeper for Requirement Change Controls and downstream project and documentation updates.
* Excellent knowledge of testing methodologies, strategies and Software Development Life Cycle (SDLC) methodologies - waterfall and agile.
* Experience in Reviewing and updating Data Migration plans, requirement specifications, test cases and summary reports.
* Documented various validation deliverable of system life cycle as required by FDA regulations under 21CFR Part 11.
* Reviewing the User Requirement Specification (URS) and the Functional Requirement Specification (FRS) document and analyzing the causes leading to discrepancies and failure of the pre-executed OQ scripts.
* Created design verification protocols/reports and test method to ensure each claim has supporting evidence in the DHF.
* Involved in creating test bed to check the Installation and Operational Qualification (IQ/OQ) for the application.
* Performed the ERES assessment of the overall functionalities of Argus Safety and evaluated the functionalities with a risk assessment based on the impact to the three core criteria: patient safety, product quality and data integrity and defined the testing strategy.
* Experience in Data Migration, Periodic Review, GAP Analysis, and Risk analysis, FMEA and Remediation Process.
* Implemented GxP (GMP, GCP, and GLP) and GAMP guidelines in the systems and the TMV's for Visual Inspection dimensional measurements.
* Developed Operation Qualification (OQ) test scripts for Track Wise Change Management modules and CAPA system.
* Drafting the Requirement Traceability Matrix document to track the URS and FRS are fulfilled by executing the OQ and PQ scripts.

**COGNIZANT Sept 2012- Sept 2015**

**CLINICAL RESEARCH ASSOCIATE**

* Liaise with CRO's, external customers (affiliates, clinical research units) and directly with internal customers (Clinical, Biostatistics, Quality Assurance, and Regulatory Affairs) to cover all aspects of data management for assigned studies.
* Ensured departmental companion groups (i.e., Coding, CRF design, SSD, PM, DMS) were consulted appropriately on study decisions.
* Ensure that CRO's are meeting timelines for data deliverables by requesting/reviewing metric reports, keeping internal clinical teams informed regarding project status and issues as they arise and working closely with CRO's to develop effective solutions to operational data management problems to bring them to resolution.
* Evaluate ongoing quality of CRO provided data management services by sampling EDC discrepancies and reviewing DCF generation, tracking and processing.
* Contribute actively to the review of working practices and the development of SOP's.
* Communicated with internal customers from Clinical, Biostatistics, Quality Assurance, and Regulatory Affairs industries
* Developed target specific project strategies for external customers including affiliates, CROs, clinical and research units
* Created and documented CRF process design; Integrated Report Form (CRF) pages onto the server for data entry into the clinical database for clinical trials
* Reviewed clinical data using Clinical Trials and posted reconciliations of outstanding queries as needed
* Performed in-house monitoring and data quality control processes in compliance with CRF Completion Guidelines
* Implemented SAS edit checks within the EDC system. Analyzed and edited comparison reports between Sponsors and Database Design vendors SAS datasets
* Demonstrated use of Websys, approval, and request change controls

**Education**

* Master’s in Information technology – University of Potomac VA, USA
* Bachelor’s Doctor of Medicine (MD) –Atlantic University of school of Medicine, St. Lucia