**Ankit J
Validation Analyst/ Engineer**

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Experienced Validation Engineer with extensive experience in Medical and Pharmaceutical industry with proficiency in Laboratory and Manufacturing Equipment Validation, Computer System Validation, Medical Device Validation, Process Validation, and Cleaning Validation with strong comprehension ability and interpersonal skills along with proficiency in handling communication among the team about project details.

**PROFESSIONAL SUMMARY:**

* Strong working knowledge of Laboratory and Manufacturing Equipment, Medical Device Validation, Instruments Validation, Process Validation, and Cleaning Validation.
* Prepared and executed Validation Plan, Vendor Assessments, Commissioning, and Qualification protocols for the Manufacturing and Laboratory Equipment.
* Actively participated in High-Level Risk Assessment (HLRA), to gauge the impact of the system under consideration and determine the regulatory scope and organized Joint Application Development (JAD) sessions, Brainstorming, meetings, and requirement workshops to gather and consolidate requirements.
* Worked closely in developing and reviewing the User Requirement Specifications (URS), Functional Requirement Specifications (FRS), Design Specification (DS) as well as Configurational specifications of various.
* Experience in Validation activities including Factory Acceptance Testing (FAT), Site Acceptance Testing (SAT), Facilities, Utilities, Manufacturing equipment laboratory equipment qualification, and temperature mapping.
* Experienced in developing and reviewing a Validation Master Plan (VMP), objective, Validation approach, Test methods, process outputs, Control limits of critical parameters, validation protocols, Validation planning, Validation trial, and validation findings of manufacturing processes.
* Knowledge of Oral Solid Dosage, Tablet Manufacturing, Bioprocess/Vaccine Manufacturing, and Lyophilization processes which includes several pieces of equipment like a Bioreactor, HPLC, Incubators, CIP, SIP, RODI water system, tablet pressing and coating machine, Granulator, Encapsulation, Packaging, and labelling machine.
* Experienced in the development of validation protocols like Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) for Computer systems, Equipment as well as Manufacturing Processes.
* Authored reports such as Risk Assessment, Validation Master Plan, Functional Risk Assessment (FRA), RACI matrix, Requirement Traceability Matrix (RTM), Validation Protocol, IQ/OQ/PQ, Test Plans and Validation Summary Report.
* Excellent working knowledge of ePAS, MES Web tool, IBM Maximo, QMS-TrackWise, AQC VERA, HP ALM.
* Consolidated and verified the Design Input and design Outputs by organizing and participating in the design review process, manage tests, inspections, and analyses, and preparing the Design Verification/Validation Plan and Reports. And then Validating the Design Transfer Process.
* Experienced in consolidating and Reviewing the Design Verification plan and executing the included protocols in design Validation, and Test Method Validation (TMV).
* Maintaining the Design History File (DHF), Device Master Record (DMR), and Device History Record (DHR) for the medical device.
* Experienced in conducting Risk Assessments (FMEA, PFMEA, DFMEA) and Gap analysis in determining the criticality of the requirements.
* Good understanding and practice of GxP (GMP, GLP, GDP, GCP) standards, FDA regulation 21 CFR part 11, part 820, part 210, part 211, ISO 13485 (QSR), ISO 14971 and GAMP 5 regulations.
* Maintained ALCOA principles to secure Data Integrity of the computer system and/or medical Device.
* Proficient in Clean-In-Place (CIP) and Sterilization-In-Place (SIP), and all stages of the cleaning validation life cycle such as Process Design, Process Qualification, and Continued Process Verification.
* Performed adjustments for the critical cleaning parameters to meet acceptance criteria using the shortest and most energy-efficient cleaning cycle which consists of Prewash, Wash, Rinse, Final Rinse, Drying and Sanitizing/Sterilizing.
* Experienced in authoring the general Standard Operating Procedures (SOPs) and system-related SOPs with guidance from business owners.

**Skill Set:**

**FDA and GxP Compliances:** FDA guidelines, GAMP regulation, 21 CFR part 11, 210, 211, Part 820, ISO 13485 (QSR) and ISO 14971, Data Integrity, cGxP (GMP, GCP, GLP, GDP) Regulations,

**Validation Skills:** User Requirement Specification (URS), Functional Requirement Specification (FRS), IQ/OQ/PQ, ITP, FTP, HLRA, Characterization, Change Control Management, Deviation Management, FMEA, FAT, SAT, Validation Report, Validation Summary, Design Input, Design Output, Design Verification/Validation, Design Transfer, Test Method Validation (TMV), Gap Analysis, DOE, Trace Matrix.

**Validation Tools:** ePAS, MES Web tool, IBM Maximo, QMS-TrackWise, AQC VERA, HP ALM.

**MS Office:** MS Excel, MS Word, MS Project, MS Visio, MS PowerPoint, Outlook.

**Laboratories Equipment and**

**Instrument:** High-Performance Liquid Chromatography (HPLC), Bio Safety Cabinets, Autoclave, ARCHITECT/Alinity (Immunoassay Analyzer), Incubators, Data logger, Refrigerator, Cooler, Freezer and Ultra Low Freezer.

**Manufacturing Equipment/**

**Utilities/Facilities:** Mixing Tank, Autoclave, Glasswasher, Bioreactor, Data Logger, Deionised Water (DIW or RODI) System, Distilled Water System (DWS), Filler, Labeller, Leak Detector, Granulator, Encapsulation, CIP/SIP System, RHFU, Printer, PLC/HMI Control System, Clean Room.

**Medical Devices:** Immunoassay, Insulin Pump, Catheter, Suction Instrument, MRI.

**EDUCATION:**

* Bachelor of Technology in Mechanical and Automation Engineering – Northern India Engineering College, GGSIPU, New Delhi, India.
* Master of Science in Mechanical Engineering – University of Bridgeport, Bridgeport, CT.

**Work Experience:**

**Abbott Laboratories, Lake Bluff, Illinois Mar ‘21 - Till Date**

**Validation Engineer**

**Project: Qualification of Various Filling Process Support Equipment.**

**Mixing Tank and Its PLC/HMI Controls**:

* Initiating, Drafting, and reviewing validation/qualification deliverables for Mixing Tank and HMI/PLC Controls such as Validation Change Request (VCR), User Requirement Specification (URS), Design Constraints (DC), Functional Specification and Design Specification (FS/DS), Functional Requirement Specification (FRS), Installation Qualification and Operational Qualification (IQ/OQ) protocol, Installation Test Plan (ITP) and Functional Test Plans (FTP), Trace Matrix, Performance Qualification (PQ) protocol.
* Utilized, IBM Maximo for drafting Service Requests (SRs) and Calibrations for new equipment, components, and instruments.
* Executing the IQ/OQ Protocol along with ITPs and FTPs. Drafting Unplanned Validation Event (UVE), Implementing the change, Version Control.

**CIP Reporting Tool**: Participated in planning phase of the project to identify the objective and scope of the controls, capturing the initial design and development plan, collecting URS, FS/DS from the offshore team through discussion. Initiating, drafting, and reviewing the validation/qualification deliverables for the reporting tool.

**Autoclave**:

* Initiating, Drafting, and reviewing validation/qualification deliverables for Autoclave such as (VCR), (DQ), (URS), (FRS), (IQ/OQ) protocol, (ITP) and (FTP) for different Sterilization Cycle and (PQ) protocol.
* Utilized, IBM Maximo for drafting Service Requests (SRs) and Calibrations for new equipment, components, and instruments.
* Executing the IQ/OQ Protocol along with ITPs and FTPs. Drafting Unplanned Validation Event (UVE), Implementing the change, Version Control.

**Glasswasher**:

* Initiating, Drafting, and reviewing validation/qualification deliverables for Glasswasher such as (VCR), (DQ), URS, FRS, IQ/OQ protocol, (ITP) and (FTP) for different Wash Cycle and PQ protocol.
* Utilized, IBM Maximo for drafting Service Requests (SRs) and Calibrations for new equipment, components, and instruments.
* Executing the IQ/OQ Protocol along with ITPs and FTPs. Drafting Unplanned Validation Event (UVE), Implementing the change, Version Control.
* Manage employee training for all new recruits and offered continuous advice, guidance and mentorship on duties and best practices.

**Utility and Facility Qualification: Distilled Water System (DWS), Deionised Water System (DIW), ISO 8 and ISO 7 Clean rooms.**

* Initiating, Drafting, and reviewing validation/qualification deliverables for Utilities and Facilities such as (VCR), (DQ), URS, FRS, IQ/OQ protocol, (ITP) and (FTP) for different Wash Cycle and PQ protocol.
* Executing the IQ/OQ Protocol along with ITPs and FTPs. Drafting Unplanned Validation Event (UVE), Implementing the change, Version Control.

**Project Title:** Periodic Review Validation of Facility, Utility, Equipment, Process Validation and Test method Validation.

* Conducting PVR for FUE systems which consist of reviewing FMEA, Design Qualification, Work Orders, Service Requests, IQ/OQ/PQ protocols, and reports.
* Authoring and executing Instalment Qualification, Operational Qualification and Performance Qualification for R&D and Manufacturing Facility, Utility and Equipment (FUE).
* Reviewing all Demand Maintenance Work Order in Maximo and Cognos, Calibration work order, maintain ePAS documentation and relationships.
* Conducting PVR for Test Method Validation (TMV) and Process Validation (PV) which consist of reviewing the FMEA, SOPs, CQAs, Standard Control Procedure (SCP), Standard Test Procedure (STP), Manufacturing Formula (MF).
* Identifying Worst case conditions for the temperature Controlled Equipment like Cooler, Freezer, Ultra Low Freezer, Incubator. As well as Bio Safety Cabinet (BSC), Abbott instruments (ARCHITECT and Alinity), Bioreactor, Label Printer etc.
* Identifying Gaps by using Gap analysis and initiating remediation plan for identified gaps.

**Project Title:** Compressed Air (Oil Free) Distribution System Utilization List and Drops Addition/Removal.

* Drafting the Utilization list for all CAOF drops by inspecting and reviewing the Redlined Documents of the flow chart and layout diagrams of controlled building.
* Initiating the Validation Change Request (VCR) for addition and Removal of the drops and initiating the IOQ and PQ protocol and reviewing the same.
* Identifying discrepancies and initiating remediation plan for identified discrepancies.

**Beckman Coulter, Indianapolis, Indiana May ‘20 – Feb ‘21**

**Lead Validation Engineer**

**Design control and Validation of Medical Device.**

**Responsibilities:**

* Participated in the planning phase of the project to identify the objective and scope of the medical device, capturing the initial design and development plan, Quality Assurance (QA) plan, and Risk Management plan.
* Collecting Design Inputs through the Joint Application Development (JAD) session, Meetings, requirement workshops, talking to the end users and documentation.
* Helping team in creating Risk Management Plan, preformed Risk Analysis as per the design inputs, determining the risk level involved along with the possible mitigation plan and mitigation action.
* Utilized the knowledge of regulations like Part 820, and ISO Standards: ISO 13485 (QSR), and ISO 14971 to check process and documentation compliance as well as Quality Assurance and Quality Control for the medical device.
* Converting the Design Inputs in Design Outputs, performing the risk evaluation, conducting design review meetings at various phases of the design, and updating the Device Master Record (DMR) index
* Consolidating and Reviewing the Design Verification plan and executing the included protocols in design Validation, and Test Method Validation (TMV).
* Drafting and Reviewing Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) for the Medical and Diagnostic devices.
* Managing the Design Transfer Process, evaluating the Manufacturing Facilities, Utilities and Manufacturing Equipment like CIP/SIP, Reverse Osmosis Deionised (RODI) water system, creating Manufacturing Plan to handle the process.
* Reviewed the Design History File (DHF) and Design Master Record (DMR) that summarizes the design and development processes as well as assuring the Data Integrity.
* Responsible for development and execution of the validation plan, standard operating procedures, and templates for the manufacturing process.
* Developed test cases, test strategy, test plan and test summary report.
* Used extensive knowledge of quality tools like Design of Experimentation (DOE), statistical process control (SPC)- to ensure the quality standards.

**Merck Pharmaceuticals, Kenilworth, NJ. Nov ‘19 – May ‘20**

**Validation Lead**

**Commissioning and Qualification for Equipment and Process Validation for Oral Solid Dosage Forms.**

**Responsibilities:**

* Conforming that the Factory Acceptance Test (FAT) has been completed for the manufacturing parameters and that equipment is ready for shipment and installation.
* Verifying that the Site Acceptance Test (SAT) has been completed and executed along with consolidating the associated documentation.
* Maintained 21 CFR Part 11 compliance for computer systems by conducting Risk Assessments, identifying compliance gaps, and developing Remediation Plans as well as maintained Data Integrity (DI) ALCOA Principles into the process of implementation.
* Provided technical support to manufacturing for the utility and equipment validation of new and existing GMP equipment such as autoclaves, tablet presses, blenders, and fluid bed granulators.
* Indulged with validation activities for all validation system lifecycle deliverables from Commissioning, Qualification (C&Q), Testing and Maintenance for the laboratory and manufacturing Equipment and Instrument.
* Indulged with the ongoing Bioprocess Project, especially in Upstream and Downstream processes which includes documentation of preculture, inoculation, harvesting, filtration and purification process testing.
* Assisting for qualification of HVAC and associated systems such as cooling towers, compressors, vacuum system, air circulation system, Freezers, Coolers, RODI water system, Laboratory Equipment (Incubator, Ovens, Autoclaves) and Instruments like bioreactor and Clean-In-Place (CIP), Sterilization-In-Place (SIP) .
* Responsible for preparing and reviewing of validation Protocols IQ/OQ/PQ documentation, VP, VSR, SOPs Deviation management, Risk Assessment, Decommission report, Periodic Review Report.
* Managing the evaluation in working with GxP suites: GLP, GMP, GCP and GAMP5. Has excellent understanding of quality concepts, audits & standards, ISO 9001, Six Sigma, SPC, DHF, and DOE.
* Verified the validation activities and adequately recorded, documented, and carried out the qualification in accordance with the approved Master Validation Plan and Validation Protocols.
* Prepare Deviation Report, as necessary. Conduct investigations for the generated Deviation Reports that includes troubleshoot of issues related to the Human Machine Interface (HMIs).

**Jubilant Life Science, Noida, Uttar Pradesh Feb ‘18 – Aug ‘19**

**Process Validation Engineer**

**Implementation of Electronic Document Management System (EDMS).**

**Responsibilities:**

* The scope of this project was to Implement and enhance the capability of the existing Electronic Document Management System compliance with FDA 21CFR part 11 and GxP and GAMP 5 standards.
* Reviewed the Workflow, Business workflow and process chart created using MS Visio for training module under the EDMS application.
* Played the key role in High Level Risk Assessment (HLRA) and compliance issue concerning the Data Migration activities and during the execution of protocol.
* Develop the Validation Master Plan (VMP) and Validation Protocol along with the Responsibility, Accountability, Contributors, Informed (RACI) matrix.
* Reviewed User Requirement Specification (URS) and verified the User Requirement mapping to the Business Workflows.
* Reviewed Functional Requirement Specification (FRS) and Configurational Requirement Specification (CRS) for the EDMS system and ensured that these specifications were properly traceable and linked to corresponding Test Step Descriptions.
* Performed Functional Risk Assessments (FRA) on the functionality of the system.
* Developed the Requirement Traceability Matrix (RTM) document to map the test steps with the User and Functional Requirements.
* Reviewed Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) for the EDMS system.
* Volunteered in executing Dry Runs and Informal Testing and building User Training Material (UTM).
* Developed the Deviation Log and Change Control Management Report (CCMR).
* Drafted Data Integrity Risk Assessment (DIRA) documents.
* Assisted in RCA leading to identification of discrepancies and failure of the test scripts and made resolutions such that they are following GAMP 5 and 21 CFR part 11 guidelines.