**Akshay Netke
Validation Analyst/ Engineer**

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**Objective:** To add value to the industry with professional expertise and knowledge gained during the 7 years of validation experience in computer systems, pharmaceutical manufacturing and medical devices industry by helping to achieve compliance with applicable regulations and creating high quality and robust systems.

**Professional Summary:**

* Experienced in **computer systems validation** in pharmaceutical and medical device manufacturing industries in the capacity of a validation engineer and validation analyst.
* Extensive knowledge of regulatory guidelines such as **21 CFR part 11**, **part 820**, **ISO 14971**, **ISO 13485** and **GxP** guidelines such as **GMP**, **GLP**, **GDP** and **GCP**, **USP 1058** and **USP 1224**.
* Strong understanding of computer systems validation life cycle and Software Development Life Cycle (**SDLC**).
* Experience in validating Class 2 medical devices with good understanding of design control procedures pertaining to medical devices starting from design and development planning to design transfer and market release.
* Strong working knowledge of Oral solid dosage manufacturing and vaccine manufacturing, including various equipment such as **Incubators**, **Bioreactors**, **HPLC**, **CIP**, **SIP**, tablet pressing machine, tablet coating machine, granulator, encapsulation machine, packaging and labelling equipment.
* Experienced in developing and reviewing **cleaning validation master plan**, validation strategy, cleaning cycle development process, analytical and sampling methods, acceptance criteria, handling and storage procedures, Factory Acceptance Tests, Site Acceptance Tests, IQ, OQ and PQ of **CIP/SIP**s and continued process verification.
* Experience with authoring User Requirements Specifications (**URS**) and Functional Requirements Specification (**FRS**) for computer systems, equipment and medical devices.
* Hands-on application-based knowledge of validation protocols and their tests – Installation Qualification **(IQ)**, Operational Qualification (**OQ**) and Performance Qualification (**PQ**).
* Experience with commissioning procedure of equipment involving **FAT** and **SAT**.
* Documented various Standard Operating Procedures (**SOPs**), Qualification Summary Reports (**QSR**), Validation Master plans (**VMP**), **RACI** matrices, Deviation reports.
* Performed Functional Risk Assessments (**FRA**), **Vendor selection/assessment**, **Root Cause Analysis** and Impact Analysis and **FMEA**.
* Organized and facilitated **Data Migration** activities including pre/post-migration testing protocols, transformation of data to be migrated and mapping of fields between legacy and target systems.
* In depth understanding of **Gage R&R** studies.
* Good working knowledge of **change control**, **deviation management** and Corrective and Preventive Action (**CAPA**) systems.
* Well acquainted with **Data Integrity** practices and experience with **Audit trails** and **Data migration**.
* Good working experience with Laboratory Information Management Systems (**LIMS**) and Electronic Document Management System (**EDMS**).
* Excellent communication and writing skills with ability to work alone and in a team.

**Skill Set:**

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| CSV Skills / Regulations / Guidelines | GAMP regulations, 21 CFR part 11, part 820, ISO 14971, TR 24971, ISO 13485, ISO 15223, Data Integrity, cGxP (GLP, GCP, GDP, GMP) regulations |
| Validation Tools | HP ALM, Jira, Tableau |
| MS Office | Word, PowerPoint, Excel, Project, Visio |
| Laboratory Standalone Applications | temp-chart, Chromeleon, UV Win, Malvern Mastersizer |
| Medical Devices | Powered Wheelchair, Catheter, Nebulizer machine, Insulin Pump |
| Laboratory Equipment | pH Meters, HPLC, Gas Chromatography, Incubator, Autoclave, Particle Analyzer, Data logger, Refrigerator and Freezers, UV Vis Spectrophotometer |
| Manufacturing Equipment | Bioreactors, Granulators, Encapsulation machines, Tablet coating and pressing machine, Packaging and Sterilization machine, check weighers, CIP skid system, SIP system |
| GxP Applications | LabVantage, Documentum, Vineti |

**Work Experience:**

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| Vineti | San Francisco, California | Senior Validation Analyst | Oct 2019 – Present |

**Project:** Integration of LIMS module and Implementation of EDMS application.

**Responsibilities:**

* Reviewed and approved end to end documentation for LIMS module and EDMS to ensure compliance with company policies and procedures.
* Coordinated activities between on-site and off-site teams and ensured continued communication and accessibility between resources and business teams at both locations.
* Responsible for documentation of all aspects of the Computer System Validation (**CSV**) Life Cycle in accordance with **21 CFR Part11** and **GDP**.
* Prepared work flowcharts in MS Visio to illustrate the User Requirements.
* Developed the **Validation Master Plan** outlining thescope, **RACI** matrix,validation approach and strategy, **SOP**s to be followed, acceptance criteria, data migration protocols and the information about different environments.
* Used MS Project to schedule and organize qualification activities to ensure their completion in a timely and effective manner.
* Participated in High Level Risk Assessment (**HLRA**) session to determine if the system is **GxP** or **non-GxP**.
* Involved in drafting the User Requirement Specifications (**URS**) and Functional Requirement Specification (**FRS**) documents by conducting meetings with the end users.
* Performed Functional Risk Assessment (**FRA**) to assess the risk levels of all the functional requirements.
* Authored and documented Validation Protocol documents such as Installation Qualification **(IQ)**, Operational Qualification **(OQ)** and Performance Qualification **(PQ)**.
* Performed **dry runs** to check if the test cases have covered the functionalities, which need to follow 21 CFR Part 11 rules set by FDA.
* Performed **Data Integrity** checks for the documentation systems.
* Performed deviation investigations, root cause analysis, and implemented **CAPA**s to business units which improved efficiency in accordance to compliance.
* Authored End-User Training Manuals and **SOP**s.
* Prepared and documented Validation Summary Report (**VSR**) including Deviation investigation, Resolution and Quality System Development.

**Data Migration Activities:**

* Developed **Data Migration Plan** and **Data Migration Summary** reports for data that needed to be maintained in the application database.
* Created and managed pre-migration and post-migration test scenarios and cases.
* Created sample **Test Data** and executed the **Test Cases** for verification Data Migration process.
* Validated the protocols regarding the transformation of data and the mapping of fields between the legacy and target systems.
* Conducted the User Acceptance Test (**UAT**) on the migrated data.

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| Medline Industries | Northfield, Illinois | Validation Engineer | Oct 2018 – Sep 2019  |

**Project:** Design control and validation of Medical Devices and associated applications.

**Responsibilities:**

* Worked on design and validation of Class 2 medical devices such as Wheelchairs, Nebulizer, Catheters and Insulin pump.
* Contributed to the design planning phase to determine the scope, objective, timeline and budget for the medical devices.
* Determined the documentation requirements and department responsibilities for the project.
* Participated in design development, design transfer, market release and post market surveillance of the product and maintained quality attributes in conformance with **21 CFR part 820** and **ISO 13485**.
* Assisted in gathering the **design inputs** for medical devices including operating environment, potential shelf life, sterilization method and packaging method.
* Performed risk control activities and created risk management plans in conformance with **ISO 14971** and also assisted in risk assessment using **FMEA**.
* Verified if the design outputs are providing appropriate functionality according to the specified design inputs and was engaged in **design review** throughout the designing process.
* Drafted test case scenarios and test cases for qualification protocols (**IQ, OPQ**) for the devices and associated applications.
* Validated the medical devices by performing tests on **pilot test** batch.
* Validated the **manufacturing plan** and assisted in ensuring training of the affected personnel.
* Validated the **manufacturing equipment** and **facilities** for medical device production.
* Employed **Gage Repeatability and Reproducibility (R&R), statistical process control, process capability indices** for statistical data analysis of the validated manufacturing processes and workflows.
* Maintained Design History Files (**DHF**), Device Master Record (**DMR**) and ensured that **Data Integrity** practices are followed.
* Performed validation of the standalone applications for monitoring systems of the medical devices.
* Actively participated in Corrective and Preventive Action (**CAPA**) procedures to capture all identified hazards and complaints and ensuring timely resolution.
* Prepared **validation summary report**s summarizing the validation activities that were performed on the medical devices and applications.

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| Marksans Pharma Ltd | Mumbai, India | Validation Analyst | Feb 2016 – Jul 2018 |

**Projects:** Validation of oral solid dosage manufacturing process, lab instruments, equipment and applications.

**Responsibilities:**

* Developed a Validation Master Plan (**VMP**) to document the intent of validation effort in accordance with FDA regulations.
* Assessed **21 CFR Part 11** requirements and analyzed organization’s current validation state.
* Reviewed and approved the **SOP**s documented for the validation protocols for oral solid dosage manufacturing.
* Performed **revalidation** and wrote **IQ**, **OQ** and **PQ** qualification protocols to validate various laboratory instruments, equipment and associated computerized systems (pH Meters, HPLC, Gas Chromatography, Incubator, Autoclave, Particle analyzer, Data loggers, Refrigerator and Freezers, UV Vis Spectrophotometer).
* Assisted Process Validation and Equipment Qualification (**SAT**, **IQ**, **OQ**) and in generation and execution of the protocol for **CIP** and **SIP** systems.
* Managed the **calibration activities** to be conducted using validated SOPs, ensuring the calibration of the test instrument.
* Assisted in revalidation of **bioreactor** and its monitoring system.
* Managed the verification of **Delta V DCS controls** for recording and monitoring process parameters
* Reviewed test cases and scripts and documented the results as per the FDA and MHRA regulations.
* Involved in preparing compliance report about existing status of the cGxP (cGMP, cGCP and cGLP).
* Planned, coordinated and executed GMP System Audits for packaging and labelling processes.
* Performed **FMEA** studies and **Fault tree analysis** in the design of any new parts or systems added to the manufacturing process.
* Managed tracking of temperature mapping equipment and troubleshooted repairs and maintenance of test equipment.
* Assured manufacturing equipment reliability in solid dosage product and optimized production equipment to assure product quality.
* Maintained **CAPA** procedure, initiated investigation of non-conformances through root cause analysis, evaluation of the effectiveness of CAPA process, and initiation of action as required improving effectiveness.
* Prepared and reviewed Validation Summary Repot (**VSR**) to summarize the overall validation effort.

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| Megaware | Mumbai, India | Validation Engineer | Aug 2013 – Jan 2016 |

**Project:** Validation of EDMS and LIMS applications.

**Responsibilities:**

* Worked on the validation of applications such as EDMS and LIMS.
* Coordinated with the business teams and clients to ensure that Business Requirements Documents are prepared to demonstrate the scope of work.
* Authored & reviewed validation deliverables in Validation Life Cycle **– Validation Master Plan**,User Requirement Specifications (**URS**), Functional Requirement Specification(**FRS**) and assured compliance with FDA Regulations (**21 CFR part 11**).
* Performed **Risk Assessment** (**FRA**) of each functional requirement to determine the risk level associated with each requirement and documented it.
* Developed Requirement Traceability Matrix **(RTM)** to map the test cases to new requirements.
* Drafted and executed validation protocols (**IQ**, **OQ** and **PQ**).
* Performed dry runs, pre-execution sign-off and formal validation using the above protocols.
* Supervised the validation activities as per Good Documentation Practice(**GDP**)for regulatory agency submission, keeping **Data Integrity** into consideration.
* Configured **CAPA** management module to include deviations from product components, manufacturing equipment and inventory management functions from legacy system.
* Responsible for the **Deviation Reports** & made recommendation for **Corrective Action** prior to the system release into production.
* Authored & routed **Validation Summary Reports, Change control Document, Validation test Reports** for approval to the senior manager & QA team.
* Communicated the daily operations of validations team, project status updates at weekly report meetings to the management team.

**Education:**

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| Bachelor of Engineering in Mechanical Engineering | Yeshwantrao Chavan College of Engineering | Nagpur, Maharashtra, India |