**Athul Thomas**

**Validation Engineer/ Analyst**

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Objective:

**Validation Engineer** with 8+ years of experience in validation of computer systems, manufacturing equipment and processes, laboratory equipment and medical devices in pharmaceutical, biotechnology and medical device manufacturing industries with strong domain knowledge, who aspires to offer services and deliverables of the highest standards.

Professional Summary:

* Experienced in **computer systems validation** in pharmaceutical and medical device manufacturing industries in the capacity of a Validation engineer and Compliance specialist.
* Knowledgeable in **process validation and cleaning validation** in biotechnology and pharmaceutical industries in the capacity of a Process/Validation Engineer.
* Experienced in **commissioning and validation of manufacturing equipment and laboratory instrument** in biotechnology and pharmaceutical industries in the capacity of a Validation Engineer and Commissioning and Qualification Engineer
* Well versed in **medical devices validation** in the capacity of a Validation/Design engineer
* Extensive knowledge on regulatory guidelines such as **21 CFR part 11, part 211, part 820, USP C 1058,1224, ISO 13485 and ISO 14971** and in-depth knowledge on GxP recommendations such as **GAMP, GCP, GMP, GLP and GDP**.
* Actively participated in **High Level Risk Assessment (HLRA)** to gauge the impacts of the system under consideration and determine the regulatory scope, and organized **Joint Application Development sessions, interviews, and requirement workshops** with the purpose of gathering and consolidating requirements.
* Employed skills as a technical writer to author **User Requirement Specification (URS), Functional Requirement Specification (FRS) and Design Specification (DS)** and extensive hands-on knowledge on validation protocols like **Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)** for computer systems, manufacturing equipment and laboratory instruments.
* Actively participated in the creation and maintenance of V**alidation Master Plans, Functional Risk Assessment (FRA), RACI matrix, Requirement Traceability Matrix (RTM), IQ/OQ/PQ test scenarios and cases, Test Summary Reports and Standard Operating Procedures (SOPs)**.
* Worked extensively on validating post-implementation activities such as **Change Configuration Management, Incident and Problem Management, Security Management, Audit Trails and Backup/Recovery**.
* 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 and hands-on experience on **Corrective Action Preventive Action (CAPA) and maintaining consistent levels of Data Integrity.**
* **Created, Managed, executed, and reviewed Qualification and Re-Qualification protocols** for manufacturing equipment, laboratory instruments and the software systems associated with them.
* Extensive hands-on knowledge on **implementation, qualification, and validation of process workflows in commonly used equipment** such as Blenders, Granulators, Tablet presses, Tablet coaters, Tangential Flow Filtration Systems, Bioreactors, Clean-In-Place and Sterilization-In-Place (CIP/SIP) systems.
* Hands-on knowledge on conducting qualification/validation activities including **Factory Acceptance Testing (FAT), Site Acceptance Testing (SAT), Process Analytical Technology (PAT), IQ, OQ, PQ** of manufacturing equipment and laboratory instrumentation.
* Experienced in developing and reviewing **cleaning validation master plan**, the validation strategy, cleaning cycle development process, analytical and sampling methods, acceptance criteria, handling and storage procedures, Factory Acceptance Tests, Site Acceptance Tests, Installation Qualification, Operational Qualification and Performance Qualification of **CIP/SIP**s and continued process verification.
* Actively participated in all **phases of the Medical Device Design Control process** from design and development planning till design transfer and market release for Class II and Class III medical devices such as surgical sutures, catheters, defibrillators, joint replacement, bone marrow aspiration and delivery system, vertebral replacements
* **Prepared the Design Validation Plan, the manufacturing plan, the protocols for testing under actual or simulated use conditions** and consolidating the information through a **Design Validation Report**.
* Participated in **Design Transfer** activities which include **preparing a Design Transfer Plan**, gauge the existing manufacturing facilities and utilities and identify the required enhancements, validate the manufacturing processes, ensure the adequate training of the involved personnel.
* Manage and validate the **Design Change protocols, performance monitoring, Corrective and Preventive Action (CAPA), Periodic review, backup and restore**.
* **Maintaining and validating all Design Documentation** **with assurance of Data Integrity,** associated with the lifecycle of the product including **the Device History file and the Device Master Record**.
* Preparing the R**isk Management Plan, perform Preliminary Hazard Assessment, Risk Assessment and Risk Control activities** through methods such as **Failure Mode and Effect Analysis (FMEA) and Hazard Analysis Critical Control Point (HACCP**) **and preparing the Risk Management report**.
* Consistent demonstration of leadership, problem-solving and inter-personal skills bolstered by strong communication skills.

**Skill Set:**

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| GxP compliances | FDA guidelines, GAMP categories, 21 CFR part 11, 211, part 820, Data integrity, USP C 1058, 1224, ISO 13485, ISO 14971 |
| Validation Tools | HP ALM, Tricentis Tosca |
| MS Office | MS Office, MS Project, MS Visio |
| Data Bases | Oracle, SQL |
| Programming Languages | SQL, C/C++, Visual Basic, VB.NET, |
| Validation Analyst Tools | Jira, Tableau |
| GxP Applications | LabVantage, Open Lab, LabX, Empower 3, TrackWise, IBM Maximo, Documentum, Chromeleon, Essential FTIR |
| Laboratory Equipment | Liquid chromatography (LC) system, gas chromatography (GC) system, Mass Spectrometry (MS) system, LC/MS, GC/MS, Particle/Cell counters, UV-Vis Spectrophotometer, Fourier Transform Infrared (FTIR) Spectroscopy, Stability chambers, Incubators, Microplate readers |
| Manufacturing processes | Incubation, wet/dry granulation, tablet pressing, tablet coating, encapsulation, sterilization, lyophilization, fermentation, bioprocessing, harvesting, primary capture, up-concentration, buffer exchange, purification, formulation |
| Manufacturing Equipment | Granulators, Tablet pressing machine, Tablet coating machine, encapsulation machines, packaging and sterilization machines, Incubators, bioreactors, homogenizers, centrifuges, ultrafiltration systems, diafiltration systems, Tangential flow filtration systems, checkweighers, CIP/SIPs |

**Work Experience**:

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| Name of the company: Sanofi, Bridgewater, New Jersey | Role: Validation Engineer, Compliance Specialist | Time Period:  Feb 2020 – Present |

Project Title: Implementation/Enhancement of Laboratory Information Management systems, Laboratory Standalone applications, and Electronic Document Management Systems

Responsibilities:

* Gather and consolidate requirements by organizing **Joint Application Development sessions, interviews, and requirement workshops**.
* Utilizing MS-Visio to **create updated workflows** and process charts.
* Coordinate between the development team and the vendor to determine the feasibility of the requirements.
* Authored the **URS** and the **FRS** based on the information from requirement gathering efforts.
* Manage and execute the **FRA** and identify the risk class and mitigating actions related to all functional requirements.
* Drafted the **Validation Master Plan outlining the scope, RACI matrix, validation approach and strategy, SOPs to be followed, acceptance criteria, data migration protocols** and the information about different environments.
* Construct **IQ, OQ and PQ test scenarios** and cases, verify their accuracy using **dry runs and manage the pre/post execution sign-off** in different environments.
* Manage and facilitate **execution of IQ, OQ, PQ test cases** on various environments according to the respective protocols.
* Manage **data migration,** including:
  + Develop **Data Migration Plan** and Reports for data that need to be represented and maintained in the application Database.
  + Create and manage **Pre/post-migration test scenarios and cases.**
  + Validate the protocols regarding the **transformation of data and the mapping of fields** between the legacy and target system.
  + Conducting the User Acceptance Test on the migrated data.
* Use Microsoft Project to schedule and organize qualification activities to ensure their completion in a timely and effective manner.
* Create test methods to verify the implementation of **data integrity** in the validated system and developing controls to ensure that data integrity principles are maintained over the lifecycle of the system.
* Verify compliance of the configured system with **21 CFR part 11 guidelines, and respective GAMP 5 categories.**
* **Deviation management** using the HP ALM platform and ensure that the deviations recorded are properly addressed.
* Maintain consistent **CAPA** procedures and manage the change control procedures.

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| Name of the company: Stryker,  Allendale, New Jersey | Role: Validation/Design Engineer | Time Period: Oct 2018-Jan 2020 |

Project Title: Design and Validation of Class II/III medical devices

Responsibilities:

* **Actively participate in the planning phase of the project** to identify the scope and objectives of the device, **capture the initial Design and Development plan, the prospective Quality Plan, and the Risk Management Plan**
* **Drafting the Project Plan** by engaging with the development team, management, sales and marketing team and the quality assurance/quality control team to collect preliminary details about the product.
* **Determining project timelines, documentation requirements and department responsibilities** for the project.
* **Gathering Design inputs** through Joint Application Development (JAD) sessions, interviews, and requirement workshops and documenting them
* **Creating the Risk Management Plan, performing the Risk Analysis** using the product specifications as per the Design Inputs and **determining the risk levels involved along with potential mitigating actions.**
* **Consolidating the Design Outputs, performing risk evaluation, organize design review meetings** at various stages of the design and **updating the DMR index.**
* **Participating in creation and review of the Design Verification plan** and executing the included protocols in Design Validation, including the **validation of the test methods**
* **Managing and documenting clinical trials** required as per FDA regulations and the class of the medical device.
* **Performing Risk Control** activities to evaluate the existing risks in the system along with the determining the residual risk and its acceptance and **creating the Design Validation Report and ensuring compliance to ISO 14971.**
* **Managing the Design Transfer process**, evaluating the manufacturing facilities and utilities, and creating a Manufacturing Plan to handle the process.
* **Validating the Manufacturing Plan** and ensuring **training of the affected personnel**
* **Ensuring data integrity** of all the design documentation including the DHF and DMR.
* **Creation of the Risk Management Report** and handling the **post-market release risk assessment**.
* Employing **Gage Repeatability and Reproducibility (R&R), statistical process control, process capability indices** for statistical data analysis of the validated manufacturing processes and workflows.
* **Actively participating in Corrective and Preventive Action procedures** to capture all identified hazards and complaints and ensuring timely resolution.
* The scope of the project included medical devices such as Surgical sutures, catheters, defibrillators, joint replacement, bone marrow aspiration and delivery system, vertebral replacements.

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| Name of the company:  Bio Diagnostics, Trivandrum, Kerala, India | Role: Validation Engineer | Time Period:  August 2016 – July 2018 |

Project Title: Validation of associated software for medical devices and manufacturing: control software, Manufacturing Execution Systems and Electronic Document Management Systems

Responsibilities:

* Consolidating and documenting the **User requirements, system requirements and the Concept of Operations** for the control software for the medical devices and assessing the regulatory compliance required.
* Drafting the **Software Requirements Specification (SRS)** that describes the **system description, interface requirements, functional requirements, performance requirements, safety requirements, design constraints** and the **traceability matrix**.
* Actively participating in Risk Analysis using techniques such as **Failures Modes and Effects Analysis (FMEA) and Fault Tree Analysis (FTA)** along with documenting and the validating the results obtained from them.
* Preparing and updating the **Software Validation Plan** as the project passes through different phases and organizing review meetings and important project milestones.
* Validating the **Software Design Specification (SDS)**, ensuring the traceability from SDS to SRS, drafting the **Software Quality Assurance Plan** describing the programming guidelines and documentation standards and validating the results of the test protocols.
* Verifying and validating the **software installation and duplication procedures during the Design transfer phase** along with ensuring the accuracy and regulatory compliance of the user documentation
* Identify the related electronic records that are to be captured from end user application of the medical device or from the manufacturing process of the medical device and evaluate the feasibility of their integration and risk assessment into the established Electronic Document Management Systems.
* Verifying the status of the updated manufacturing workflows in the Manufacturing Execution system and ensuring the traceability of all the process involved.
* Gathering information to be updated in the user manual documents and SOPs based on the approved change requests and verifying their status in the Electronic Document Management System.
* Collect information from manufacturing engineers and business process owners to capture the updated User Requirements and Functional Requirements, if any, and employ change control procedures to initiate the required changes.
* Execute change control procedures by performing impact assessment, creating a change implementation plan, and deploying the approved change requests.
* Manage **CAPA process, incident/problem management** and the **change control** procedures.

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| Name of the company:  Megasys Biotek Pvt Ltd, Koratty, Kerala, India | Role: Process Engineer, Compliance Specialist, Commissioning and Qualification Engineer | Time Period:  Oct 2012 – July 2016 |

Project Title: Scaling up of bioprocessing and pharmaceutical processes with qualification of equipment involved.

Responsibilities:

* **Consolidating and evaluating historical data with updated information for scaling up activities** regarding equipment purchases/upgrades, formulation changes, process variations and changes in test methods and analyses from the R&D department, sales and marketing team, business process owners and the management.
* **Verifying that the Factory Acceptance Test has been completed** at the manufacturer’s facility and that the equipment is ready for shipment and installation.
* Managing and verifying the **execution and completion of the Site Acceptance Test** along with consolidating the associated documentation
* Conduct **Pre-process validation studies and GxP evaluation**, examining batch records, change controls, investigation reports, **Risk Assessment, and failure mode assessment** of critical system functions to assess the scope and impact of the scaling up operation.
* **Assessing the OEM parameter ranges and tolerances** for impacts to Qualification, identifying the critical modules and variables defined by process capability and testing program in place, and **determining the control limits of the critical variables.**
* **Preparing and reviewing the validation master plan** which outlines the scope of the project, validation protocols for facilities equipment, process, number of validation trials, sampling frequency, size, type, tests to perform, methods used and acceptance criteria, protocols for Installation Qualification, Operational Qualification and Performance Qualification, the Requirement Traceability Matrix (RTM) and capturing the results in the validation summary report.
* **Organize the validation activities by** **determining the responsibilities that are to be borne by different departments** such as Material Science and Technology (MS&T), Quality Assurance (QA), User/Manufacturing Operation and Engineering, and **planning the validation timelines** using Gantt Charts, PERT charts, and factors such as material availability and disposal.
* **Managing the calibration activities** to be conducted using validated SOPs, ensuring the calibration of the test instrument.
* **Managing the verification of Delta V DCS controls** for recording and monitoring process parameters
* Actively participated in **preparing updated user manuals and SOPs** for the scaled-up process and verifying their status in the Electronic Document Management System.
* **Consolidating** **requirements for the cleaning equipment** to be used and preparing the **User Requirement Specification** for the equipment to be procured.
* **Preparation of cleaning validation master plan** outlining the validation strategy for cleaning equipment, the critical cleaning parameters, the protocols for handling and storage procedures, the Standard Operating Procedures (SOP), the acceptance criteria involved.
* Managing and reviewing the execution of the **Factory Acceptance Test, Site Acceptance Test, IQ, OQ, PQ, and coverage testing using Riboflavin** for cleaning systems.
* **Employing a continued process verification on the cleaning procedures** including regular reviews of performance of the procedures, training programs used, Deviation Management, change control protocols in place, Corrective and Preventive Actions and preventive maintenance activities.
* **Ensuring that CAPA procedures are adhered to** in the scaled-up process and validated change control and incident/problem management are followed so that compliance is assured.

**Educational Background**

* Bachelor of Technology in Mechanical Engineering, Sree Chitra Thirunal College of Engineering, Trivandrum, Kerala, India.