**TIM DAVID**

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**Overall Summary:**

* Experienced Validation Engineer with a main emphasis on Sterilization & Cleaning Validation in the Pharmaceutical and Biotech industries.
* Skilled in Good Laboratory Practice (GLP), Microsoft Word, Failure Mode and Effects Analysis (FMEA), Good Distribution Practice (GDP), and FDA GMP.
* Experience in the FDA-regulated environment with a good understanding of cGXP (cGMP) standards.
* Proficient with Corrective Action Preventive Action (CAPA) workflow including Investigation, Investigation Task, Action, Request, Request Extension, and Closure phases.
* Experience in creating the following Validation deliverables - Risk Assessments, Requirement Specifications, Qualification Protocols, Gap Analysis documents, IQ/OQ/PQ test protocols, Trace Matrices, and Validation/Qualification Summary Reports.
* Experience in performing SIPs of various Bioreactors and Process skids such as Media, Harvest, Buffer, and UFDF.
* Experience with qualification of freezers, incubators, coolers, and refrigerators.
* Experience in using LIMS, DocCompliance, and Blue Mountain Regulatory Asset Manager, Trackwise.
* Expertise in Swab Collection techniques and Sampling techniques.
* Validate/qualify equipment systems, computer systems, and processes in accordance with regulatory requirements and company manufacturing standards.
* Well experienced with various aspects in cleaning validation CIP, COP, CH.
* Experience in thermal mapping using Data Loggers and Kaye Validator.
* Aseptic and Non-Aseptic area cleaning validation approaches.

**EDUCATION**: Bachelor/Master of Science, Mechanical Engineering, UNIVERSITY OF SOUTH FLORIDA.

**PROFESSIONAL EXPERIENCE:**

**Cambrex, Longmont, CO**

**Feb 2021 – Present**

**Validation Engineer**

**Responsibilities:**

* Responsible for authoring of Validation deliverables such as Installation Qualification, Operation Qualification, Performance Qualification, Requirement Traceability Matrix and Summary Reports for various GxP systems.
* Helped streamline the process of setting up lab and validated lab equipment as per GCP and GLP guidelines.
* Managed system upgrades and maintenance in a cGMP environment.
* Developed and authored of Standard Operations Procedures (SOP) with the help of Business owners.
* Authored SOPs and WIs around the GXP processes and various equipment used within the lab.
* Perform facility qualification operation (New/Modifications/Expansions) in a cGMP compliant facility.
* Performed GAP analysis to ensure 21 CFR Part 11 compliance and devised Remediation plans
* Authored Qualification Protocols, Test Scripts and User Manuals
* Authored Test scripts to ensure they follow FDA regulations and checked to ensure compliance with 21 CFR Part 11 requirements.
* Conducted periodic reviews and monitored change controls and CAPAs for validated systems.
* Executed validation protocol (SIP PQ’s/RQ’s) for Bioreactors and Pool tanks.
* Authored and reviewed: SOP’s, protocols, equipment reports, operations, and validation assessments.
* Prepared Traceability matrix in accordance with Requirements and IQ, OQ, PQ Test scripts.
* Responsible for Testing all Crystal Reports (Including 3 Non-Reg and 6 Reg Reports)
* Managed the Change Control creation, execution and coordinated the review process with Quality team.
* Develop test scripts for GxP systems implementation for distinct phases of testing for e.g., system testing, regression testing, user acceptance testing and performance testing.
* Provide support to develop strategy for periodic review and risk assessment.
* Responsible for initiating Trackwise Deviations and to perform Investigations.
* Performed IOQ on Walk-in cold room and authored summary report.
* Resolved deviations and non-conformances reported during validation.
* Responsible for managing TOC Assay and Swab Method confirmations.
* Responsible for managing Cleanability study for NPI.
* Coordinates & executes validation change control and preparation of draft protocols, and reports.
* Responsible for developing and executing on validation plans according to approved procedures, collation of test results, and organizes data packages and maintains all documentation pertaining to validation.
* Compiles and analyzes validation data, prepares reports and makes recommendations for changes and/or improvements.

**Merck & Co Inc, Elkton, VA**

**Dec 2019 – Jan 2021**

**Validation Engineer**

**Responsibilities:**

* Draft, Review and approve validation protocols and technical report of cleaning validation, implemented equipment risk assessment for worst case equipment selected for cleaning validation study.
* Performed CIP/COP studies on various WFI hold vessels and was a part of initial validation.
* Support and develop validation deliverables in according with the cGMP and GMP Regulations and Protocol Specifications.
* Conducted periodic reviews and monitored change controls and CAPAs for validated systems.
* Managed the entire testing cycle including IQ, OQ, PQ tests (formal testing and dry runs) using HP Quality Center.
* Involved in resolving all issues with the help of technical resource team.
* Raised deviations during testing and involved in implementing corrective and preventive actions successfully
* Responsible for Decommissioning plans (Exit calibrations, Obsoleting Parts in JDE and Unit removal verification).
* Performed Commissioning on a Bag teardown control temperature system.
* Generated URS/FRS/DSP of the Bag teardown system with the help of Engineering Documents.
* Generated DCAR (Disruptive Construction Active Request), De-tour plans and System Isolation Plans as a part of Decommissioning.
* Generation of PR’s using Trackwise to track the scope and change of work.
* Managed various construction documentation including construction control plans and construction implementation plans.
* OSHA certified “Hot work permit” authorizing individual and responsible for issuing a sitewide Hot Work Permits.
* VEEVA DOCUMENT AUTHOR and OWNER and responsible for obsoleting all the equipment on JDE.
* BMRAM experience with retiring all the instruments associated with the equipment after Exit calibration.
* Responsible for Obsoleting all (2440) non-GMP drawings related to the decommissioned facility (Includes Mechanical, Electrical, Facilities, Architectural, EHS and Process equipment related drawings).

**RTI Surgical Inc, Alachua, FL**

**Jan 2018 – Nov 2019**

**Validation Engineer**

**Responsibilities:**

* Generate, execute, and review expert and completed qualification and validation protocols, and associated data for conformance to regulations, SOPs, specifications, and other applicable acceptance criteria.
* Generate Qualification/Validation documents, such as summary reports, trace matrix, risk assessments, validation plans, etc.
* Responsible for investigation and documentation of issues encountered during the executions or maintenance of the system and developing Corrective and Preventive actions (CAPA).
* Reporting and resolving all equipment/facility related planned and unplanned deviation, NOI during qualifications under compliance with cGMP.
* Prepare equipment, computer systems, and systems for qualification/Validation studies and executes qualification and validation studies according to approved protocols and SOPs.
* Analyze the results of testing and determines the acceptability of results against pre-determined criteria.
* Investigate and troubleshoots problems which occur and determines solutions or recommendations for changes and/or improvements.
* Generate and review deviation notifications, deviation investigations, change controls, and corrective actions.
* Developed a Design Review Plan for all GMP Critical and GMP Non-Critical Requirements in scope of the periodic review.
* Edit and generate SOPs.
* Manage projects and prepares status reports.
* Performing swab collection, rinse collection and other associated sampling techniques.
* Performing pre-and post-calibration for Kaye validators which were used for temperature mapping.
* Performed CIP, COP and SIP Validation techniques on Various Bioreactors, purification vessels and UFDF Skids.
* Authored validation deliverables as a Validation Analyst for Trackwise Complaints implementation projects.
* Drafted Regulatory Assessments, Master Test Strategy Plans, IQ, OQ, PQ test protocols and relevant Test Summary Reports for Trackwise.
* Prepared Functional Risk Assessments to define the test strategy for IQ, OQ and PQ.
* Led a team of two onsite testers for creation of IQ/OQ/PQ test scripts and four offshore testers for the execution of IQ/OQ/PQ test scripts.
* Ensured onsite and offshore testers executed IQ, OQ, PQ test scripts following good testing practices.

**B Braun Medical Inc, Daytona Beach, FL**

**Jan 2015 – Dec 2017**

**Validation Engineer**

**Responsibilities:**

* Responsible for conducting end-to-end validation activities for various Lab equipment.
* Performed Data Integrity assessments and identified the gaps.
* Performed Validation Assessment for the management to provide them a brief review of objectives to be covered during validation.
* Prepare and develop Validation approaches/rationales per cGMP & CQV methods per FDA Guidance Industry Process Validation.
* Participating in equipment – FMEA, CAPA with Quality Assurance and Production departments.
* Assisted in overseeing and managing the company's program of 21 CFR Part 11 Systems Assessment and Remediation; including Electronic Signature Management, and coordination/establishment of Divisional Policies and Procedures.
* Developed a Design Review Plan for all GMP Critical and GMP Non-Critical Requirements in the scope of the periodic review.
* Provided feedback in Configuring and validating different lab system software according to User and CFR Part 11 requirements.
* Developed and reviewed VP, URS, FRS, TP, IQ, OQ, PQ, QR, and VSR deliverables for several systems to bring them to Compliance State and to maintain validated state.
* Participated in meetings with IT Project Manager, and Validation Analyst to track project status and to verify the project progress complies with the project schedule.
* Played a key role in performing Part 11 Assessments, especially contributing to the components involved in the maintenance of Electronic Records (ER), Electronic Signatures (ES), and Audit Trails by 21 CFR Part 11 regulations.
* Led validation activities for Lab Instruments such as HPLC, LCMS, UV-Vis Spectrophotometers, GC, Densitometer, Centrifuges, Refractometers, Incubators, DSC, FTIR and associated software applications.
* Worked on change control documentation such as Change Request Form (CRF’s), Change Control Implementation Plan and Change Control Summary Report.
* Reviewed various validation deliverables Risk Assessments, Quality Assessments, Requirements Specs, Design Specs, Configuration Specs, Qualification Protocol, IQ (Installation Qualification) in Development, Test and Production environments, QT (Qualification Testing include PQ and OQ) in Dev and Test as per policies and procedures.