SENIOR VALIDATION SCIENTIST

Professional Overview

A highly driven professional with over seven years of experience in Equipment Validation lifecycle and technologies, Quality and compliance, drug manufacturing processes and Project Management in the Pharmaceutical and Biotech industries.

*Experience of working within cGMP, FDA 21 CFR, EMA regulations, GDP, FDA Consent Decree and ISO regulations.

Core Qualifications

- Cleaning (CIP and COP), Sterilization (SIP), and Process Validation
- Load Pattern development (Girton/ Belimed Washers)
- CAPA and NC investigations
- Visible Residual Level (VRL) Determination
- Cleaning Assessment
- Validation Master Plan
- Packaging and labelling
- Software: Symphony (Change Control), Connect, Global Trackwise, MIDAS, WonderWare (CIP/SIP Trends), Kay Validator (GE Certified), Compliance wire, Microsoft office, LIMS, Share Point, Wonderware Historian Trending, SAP, Microsoft Project & Visio

Accomplishments

- Temperature Mapping (Kay Validator for SIP).
- Autoclave Sterilization.
- Risk Assessment and GAP Analysis.
- Swab and Rinse Sampling.
- Change Control Management.
- Piping and Instrument Diagram interpretation.
- Isometrics drawing determination.
- Laboratory Information Management Systems (LIMS).
- Project Management skills : Experience in root cause analysis tools (Six Sigma methodologies (DMAIC), fishbone analysis, failure-mode analysis), Risk management, Stakeholder analysis.

Education

December 2013

Project Management certificate Lehigh University Post Graduate Institute of Medical Education & Research, India.

July 2006

Bachelor of Sciences University of Delhi India

Experience

07/2014 to Current

Senior Validation Scientist

- Involved in leading validation of cleaning processes for the equipment used in manufacturing of OTC drugs.
- Authored and reviewed cleaning validation technical reports, protocols, validation master plans, assessments, batch records for production equipment and processes.
- Led the change control management process through the entire change control life-cycle (change control initiation to review to approval of proposed changes) and timely closure of deliverables.
- Extensively involved in the cleaning validation projects in a consent decree environment for liquid Over the Counter Drugs (OTC) for the facility certification.
- Created Audit readiness checklist and Participated in internal, Quantic, VRC (Validation Review Committee) and FDA audits.
- Resolved technical issues on a regular basis related to process defects, generated and reviewed Deviations, Investigations, CAPAs, technical summary reports for validation of pharmaceutical production equipment and processes in accordance with Standard Operation Procedures (SOPs) and industry guidelines.
- Reported status updates on project progress to all stakeholders.
- Excellent knowledge of LIMS, TrackWise, electronic routing systems such as MIDAS, Connect.
- Dealt with customers (Quality, Operations, Technical Operations, on an ongoing basis for coordinating cleaning development/validation related activities and developing CAPAs to process deviations with a buy-in from operations and quality.
- Provided instructions to manufacturing operators on floor for tech-transfer associated activities.
- Excellent knowledge on P n ID route markup, Isometrics analysis and Equipment surface area calculations and determination of cleaning acceptance criteria.
- Act as execution lead and liaison between the analytical laboratories and process validation.
- Involved in establishing the Visible Residue Limits (VRLs) for APIs manufactured at FW Plant.
- Clean-in-Place and Clean-Out-of Place cycle development activities for processing tanks, cabinet washers including parameter selection, recipe design, determining order of operations, troubleshooting, sampling, and trend data analysis.
- Prepared Quality Risk Management (QRM) for cleaning validations.
- Served as lead executor and facilitated training of two (2) new hires for manufacturing equipment testing, data interpretation, trending and analysis, and troubleshooting issues.
- Supervised an independent project on introduction of sucrose convey system and management of activities associated with design of cleaning development and validation activities.

- Led the root cause analysis and process improvement initiatives during the execution of the project.
- Involved in successful completion of Benadryl Certification Project for Consent Decree, and validation activities for Children's Tylenol and Children's Motrin suspensions.

01/2013 to 05/2014
Engineering Specialist Quantum-Si Incorporated ï¼ Palo Alto , CA

- Independent project lead for listed projects.
- Ran project data metrics and periodically send updates on the progress of the projects to stakeholders and tracking them to completion.
- Projects :.
- SOP updates to support regulatory inspection response (MHRA): Revision of SOPs for fulfilling the MHRA commitment.
- CTU Qualification of new lab equipment (Varicella Flow Cytometry Antigen Expression Assay Laboratory).
- Support cleaning and sterilization validation of new equipment in Rota Bulk Capacity Expansion Project.
- Support validation of new equipment in Vaqta manufacturing.
- Supported periodic re-validation of existing equipment to remain compliant.
- Cleaning Validation.
- Performed Cycle development and Initial Validation; COP Validation (Parts-washers) and CIP Validation (Process Tanks, Filtration Skids, Unicorn Chromatography columns).
- Ensured all validation and qualification activities were consistent with company validation policies and procedures and federal regulations.
- Created, populated or maintained databases for tracking validation activities, test results, or validated systems.
- Authored validation protocols for new manufacturing systems, technical memos, protocol addendums, and, Change Request assessments.
- Prepared validation summary and test method summary reports based on validation data analysis.
- Designed validation study features such as sampling, testing or analytical methodologies.
- Performed swab sampling for CIP/SIP.
- Identified deviations from established product or process standards and provide recommendations for resolving deviations.
- Participated and presented in company meetings related to changes in processes, process improvement and proper decision making.

09/2009 to 12/2012
Documentation Specialist Eaton Corporation ï¼ Lewiston , ME

- Integrated raw data to assemble, write and issue summary reports according to SOPs for equipment cleaning validation studies.
- Reviewed documents for data accuracy and control all aspects of documents (Compilation to Approval and Archival) ensuring overall quality of GMP documentation for the organization.
- Developed and implemented comprehensive templates, checklists according to SOPs for the validation studies.
- Coordinated review and approval process of SOPs, analytical methods, specifications, equipment and analytical validation documentation by checking these documents against current GMPs, Quality Policies, company SOPs, and departmental conventions.
- Led Piloting efforts for transitioning the new sterilization final report compilation to the entire Documentation group.
- Ensured all aspects of documentation are effectively controlled.
- Assisted in implementation of MIDAS, a SAP based software for documents archival.
- Additionally, contributed to a huge regulatory initiative "Tracking Open Documentation Project".
- Involved in Assessment of recent past (2005- present) documentation systems and also developing suitable systems to ensure proper close-out and archival for future Validation records.
- System Administration- Served as an admin and Steward of the organization for MIDAS (an electronic repository) helping resolve issues related to the software, granting accesses to people.

Skills
Biotechnology, Cleaning Validation, data analysis, databases, decision making, Documentation, equipment cleaning, features, GMP, inspection, interpretation, LIMS, meetings, Microsoft office, Microsoft Project, Share Point, MIDAS, Packaging, Policies, processes, process improvement, progress, project lead, Project Management, protocols, Quality, Research, Risk Management, routing, SAP, SOP, Symphony, System Administration, trend, troubleshooting, Validation, Visio, WonderWare