SARASWATI KULKARNI

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SUMMARY:

- Validation Engineer with over 4+ years of experience in Commissioning, Qualification and Validation (CQV) programs (Equipment, facilities, systems, and utilities) for manufacturing sites and supported the QA activities.
- Pursuing Post Graduation course on Project Management.
- Expertise in developing and executing the qualification of equipment and validation programs ensuring adherence to SOPs.
- Experienced in qualification/requalification, validation, and change management support and oversight for complex equipment and facilities projects.
- Expertise in providing commissioning and qualification (C&Q) of Equipment and Utilities.
- Developed and reviewed pre and post execution qualification and validation protocols (IQ, OQ, and PQ), calibration forms, and change management documents of equipment, facilities, and laboratory instrumentation.
- Experienced in validating new lab instruments/ equipment and decommissioning existing equipment/instruments as per ISO standards and FDA Regulations including 21 CFR Part 11/Annex 11, USP 1058.
- In-depth knowledge in reviewing and approving Validation Documents (Risk Assessment, Validation Plan, Design Configuration/ Specification, User Requirements, Functional Requirements, IQ/OQ/PQ, Trace Matrix, Validation Summary Report), SOPs, Maintenance Procedures, Calibration Procedures, and other instrument support documents.
- Outstanding organizational skills, evidenced by successful management of projects throughout the System Development Life Cycle (SDLC).
- Strong project management capabilities, ensuring seamless execution of tasks related to system audit and validation in the medical device or pharma industry

KEY SKILLS:

- Validation/Qualification
- Facilities/Utilities/Equipment
- Validation Master Plans (VMP)
- URS/FRS
- Design Specifications
- FMEA
- IQ, OQ, PQ
- Requirement Traceability Matrix (RTM)
- Validation Summary Report (VSR)
- Change Control Management
- Temperature Mapping
- Computer System Validation(CSV)
- SCADA
- Wonderware
- Minitab
- Trackwise
- LIMS
- SQL
- SDLC
- Aseptic Manufacturing
- CAPA Management System Reports
- Equipment and Automated systems(E&AS)
- Change Management
- Change Controls
- FAT/SAT
- Root Cause Analysis
- QA Audits
- cGXP principles
- Microbiology concepts and techniques

WORK EXPERIENCE:

Senior Consultant – BKSAY Pvt.Ltd, India (April 2021-April 2022)

- Responsible for the preparation of site validation documentation such as qualification protocols, validation master plans, risk assessments and periodic reviews.
- Supported cGMP program including: Risk Analysis, Change Control, and Standard Operating Procedure using Trackwise. Support Site Expansion and Renovation activities including Commissioning and Qualification for Facility, Utility and Equipment related systems.
- Provided recommendations for equipment, instrument, and control system upgrades.
- Working on Qualifying Automation Systems such as Wonderware and FactoryTalk SCADA.

- Maintained Documents as an Electronic Document Management System to store and the project and validation related deliverables.
- Responsible for documentation of User Requirement Specifications and Functional Requirement Specifications.
- Authored and Reviewed test scripts for IQ/OQ/PQ and coordinated with testers to make sure the system gets qualified through complete IQ/OQ/PQ execution.
- Authored QA Summary Report and Requirement Traceability Matrix (RTM).
- Developed and maintained Requirement Traceability Matrix for mapping User Requirements to Functional Requirements and their testing coverage.
- Developed and reviewed interim and final reports to document the outcomes of the various activities during the validation cycle and ensured that the approach outlined in the validation plan had been followed and documented the conclusion of acceptance criteria.
- Documented, reviewed, and updated training materials, user manuals, SOPs and Work Instructions for system use and maintenance.
- Demonstrated proficiency in conducting thorough system audits and validations.

Consultant – Molecular Connections, Bengaluru, India **(Jan 2020 – April 2021)**

- Created and executed commissioning and qualification protocols/test plans for facilities, utilities and equipment using a risk-based approach.
- Implemented and coordinated commissioning and qualification of manufacturing equipment and computer systems for use in regulated and non-regulated operations.
- Developed and executed IQ, OQ, PQ documents, UAT, FAT, SOPs, and Engineering Change Requests
- Prepared IQ, OQ, and PQ protocols for new or modified manufacturing equipment, processes, systems, facilities, and Utilities.
- Responsible for validation of Computer System Validation, Equipment and Instrumentation Qualification, Test Method Validation, and Facility and Utility Qualification
- Planned and performed validation activities including Installation Qualification/Operations Qualification/Performance Qualification (IQ/OQ/PQ).
- Performed re-qualification of equipment, facility, and utilities.
- Identified deviations encountered during IQ/OQ/PQ execution and work with supervisor to implement mitigation solution.
- Performed environmental qualification as a part of IOQ for HVAC system.
- Facilitated and supported validation training, change management, and periodic review of validated systems.
- Collaboratively conducted Risk Assessments and Impact assessments, and established system boundaries.
- Generation, Review and editing of Standard Operating Procedures. Review and verification of ETOP's.
- Generation and execution of protocols for DQ, FAT, SAT, IV OV, IQ, OQ, and PQ.
- Supported equipment troubleshooting and close out of discrepancies and deviations.
- Responsible for the site requalification plan execution and implementation. Streamlined testing requirements while maintaining regulatory and corporate compliance.
- Responsible for the preparation of site validation documentation such as qualification protocols, validation master plans, risk assessments and periodic reviews.

Scientific Analyst - Molecular Connections, Bengaluru, India **(May 2017 – June 2018)**

- Responsible for preparing, reviewing and executing Commissioning documents, IQ/OQ's for equipment validation protocols.
- Responsible for Authorizing Change Controls using Trackwise, Drafting and Executing IOQ Protocols for Filling and Finishing Equipment, and Drafting IOQ Summary Reports.
- Responsible for development of verification/qualification deliverables including requirements documents, functional and design specifications, test protocols (IQ/OQ/PQ), and summary reports for process systems, autoclaves, and other process equipment.
- Prepared and executed commissioning and qualification protocols/test plans for new and existing equipment, utilities, facilities, and support systems.
- Performed different types of testing on Incubators to Qualify the Equipment such as Equipment Range, Temperature mapping, Operational Qualification (OQ) and Performance Qualification (PQ).

- Performed temperature mapping/qualification of Warehouse and Cold-Rooms.
- Conducted change management assessments and create/review CQV plans, study/test protocols, and summary reports.
- Created and executed IQ, OQ, PQ documents, UAT, FAT, SOP, and engineering change requests for HVAC systems, water systems, autoclaves.
- Executed critical test protocol and non-critical test protocol including empty and loaded chamber by temperature mapping using thermocouples and Kaye Validator for Liquid Nitrogen Freezer.
- Performed 72hour temperature mapping study and open-door challenge on Liquid Nitrogen freezer using Kaye validator as a part of IOQ protocol.
- Developed, and executed validation protocols (IQ/OQ/PQ), validation reports, and commissioning documents on both equipment and the facility.
- Led and Validated an aseptic filling procedure through media fills executed under a performance qualification protocol.
- Performed Gap Assessments and Defining Resolutions in accordance with cGMP Requirements.
- Supported Qualification, Valuation, and Change Management and Overseen Complex Equipment and Facilities Projects, developing and implementing Test Plans and Test Scripts.
- Reviewed User Requirement Specifications (URS), Design Qualifications (DQ), site acceptance testing (SAT), Functional acceptance testing (FAT), and design documents.
- Reviewed and Approved change control documents, work orders, and document change requests to assess their impact on validated systems.
- Performed Final Reviews and approvals for New Equipment Certification (NEC), HEPA and BSC Certification, Logbooks review & final Approval and Daily Alarm Reports for Cell Therapy (CT) Manufacturing, Quality Control (QC), Facilities and Equipment (FE) and Material Management (MM).
- Reviewed and Approved of CAPA including tracking, follow-up, reporting/trending and evaluating CAPA and action plan for effectiveness.
- Reviewed and Approved QA Summary Reports & RTM, Using Kaye Validator for Temperature mapping on Autoclaves, Freezers, Incubators, Fridges, and Warehouses
- Performed change control assessments and wrote/reviewed Equipment Qualification plans, study/test protocols, and summary reports.
- Developed Validation and QA documents including templates for validation related documentation such as Qualification Protocols, Technical Specification Document, Validation Plans, testing documents, RTM and Interim/Final Summary Report using PLM (Product Lifecycle Management) for Team review.
- Demonstrated proficiency in conducting thorough system audits and validations.

Intern- Anugraha Chemicals, Bengaluru, **(June 2015–June 2016)**

- Responsible for the site requalification plan execution and implementation. Streamlined testing requirements while maintaining regulatory and corporate compliance.
- Created and executed commissioning and qualification protocols/test plans for facilities, utilities and equipment using a risk-based approach.
- Implemented and coordinated commissioning and qualification of manufacturing equipment and computer systems for use in regulated and non-regulated operations.
- Developed and executed IQ, OQ, PQ documents, UAT, FAT, SOPs, and Engineering Change Requests
- Prepared IQ, OQ, and PQ protocols for new or modified manufacturing equipment, processes, systems, facilities, and Utilities.
- Performed re-qualification of equipment, facility, and utilities.
- Generation and execution of protocols for DQ, FAT, SAT, IV OV, IQ, OQ, and PQ.
- Supported equipment troubleshooting and closed out of discrepancies and deviations.

EDUCATION:

- Post Graduation course in Project Management (online) |Symbiosis University, INDIA 2024-Pursuing
- M.Tech, Masters in Chemical Engineering | Visvesvaraya Technological University, INDIA 2014 - 2016
- B.E, Bachelors in Biotechnology | Visvesvaraya Technological University, INDIA 2010 - 2014

PUBLICATIONS:

1. A comparative study on the synthesis and properties of suspension and solution precursor plasma sprayed hydroxyapatite coatings - published in "Elsevier, Ceramics International journal; Volume 43, Issue 13, April 2017, Pages 9715-9722"
2. Green synthesis of zinc oxide nanoparticles using fruit peel extracts and its application in antimicrobial activity and adsorption studies - published in "International Journal of Management, Technology and Engineering: Volume IX, Issue VI, JUNE 2019, Pages 4034-4043".
3. Isolation of LPL Gene from Human Blood sample - published in "International Journal of Medicine and Pharmaceutical Sciences (IJMPS);Vol-5,Issue-5;Edition: Oct2015" (PaperId:IJMPSOCT20154)
4. Isolation and characterization of antibiotic resistant Bacteria from Dental plaques - published in "TJPRC: International Journal of Medical Microbiology &Research (TJPRC:IJMMR);Vol-1, Issue-1;Edition:Jun2017"(Paper Id:TJPRC:IJMMRJUN20152)
5. Presented the research work "Synthesis and characterization of silver nano-particles impregnated into bacterial cellulose and study on its anti-microbial properties" in "International Conference on Functional Materials, IIT Kharagpur, West Bengal" in 2014.

ACADEMIC PROJECTS:

- **Comparative study between suspension plasma sprayed and solution precursor plasma sprayed hydroxyapatite coatings:**
  Description: This project aims to compare the mechanical properties like corrosion, wear study and surface roughness of suspension plasma sprayed and solution precursor plasma sprayed hydroxyapatite coatings on Ti-6Al-4V bio-implant and in-vitro studies using fibroblast cells. Coating characterization by XRD, EDS and FESEM. In addition, attempts made to synthesize the HAp by solid synthesis method and development of synthesized HAp coating on the bio-implant Ti-6Al-4V substrate.
- **Synthesis and characterization of silver nano-particles impregnated into bacterial cellulose and study on its anti-microbial properties**: project of Research Experience for Undergraduates (REU).
  Description: The project aims to synthesize the silver nano-particles and study on its antimicrobial property, synthesis of BC & study on its properties and impregnation of silver nano- particles into the BC using silver nitrate (AgNO3) by using both in-situ and ex-situ methods, study on its antimicrobial and environmental application, Characterized by SEM, TEM, FTIR and XRD.
- **Phyto-chemical analysis and Purification of Flavonoids extracted from medicinal plant- Simarouba glauca (LakshmiTaru) leaves.**
  Description: the project aims to the extraction of the finely powdered dry leaves of S.glauca using various organic solvents. The qualitative test for checking the presence of many phytochemicals like phenols, flavonoids, resins etc. Antimicrobial activity of the extracts were analyzed against pathogenic bacteria and fungi. Purification of Flavonoids using column chromatography using silica gel column. Analysis of Flavonoids and Phenols using thin layer chromatography. Analysis of hydrogen peroxide scavenging activity.
- **Isolation of LPL gene from Human Blood sample and study on its mutation.**
  Description: The project aims to isolate the Lipoprotein Lipase gene from Human Blood sample using TritonX-100 method, amplifying LPL gene using PCR by using the primers designed by Primer3 tool and test the sample for mutations by subjecting them to gel documentation.
- **Characterization of Antibiotic Resistant Organisms from Dental Plaques and isolation of their Plasmids.**
  Description: The project aims at identification and isolation of pure cultures from dental plaques, i.e, S.mutans, S.salivarius, S.mitis and Enterococcus species, and screening them for antibiotic resistance and study on their resistance, further isolating the plasmid responsible for antibiotic resistance from the organism and study on it.