SHIVA

Quality Control Manager

Email: shivasravan0910@gmail.com

Mobile: 469 598 1471

Linked In : https://www.linkedin.com/in/shivasravan-naidu-b6206b165/

Quality Control Manager with experience of over 10 years in the Pharmaceutical and Biotechnology

industry. Skilled in Analytical and wet chemistry, Validation (IQ/OQ/PQ), Good Laboratory Practice (GLP) and GMP. Validation, CAPA, deviations, Quality events, Training, Audits, Scheduling and GXP. Self-

motivated, flexible, quick learner and able to effectively manage large teams.

# Professional Summary

* Served as QPTL (Quality Product Team Lead) or QA Operational Lead (OL) for assigned programs
* Experienced in Investigation of Out of Trend (OOT) and Out of Specification (OOS) results, handling laboratory events (LE), Quality Events (QE) and deviations. Handling and review of Change controls, CAPA (Corrective and Preventive actions), Effectiveness Checks (EC), Impact and Risk assessments.
* Managed a team of Lab Analysts and responsible for hiring, leading and develop team members to ensure that the department has the appropriate talent and level of performance to meet business objectives. Assure training and development of subordinates. Assist subordinates in problem solving. Identify and resolve people issues without direct supervision.
* Experience in solid understanding of relevant FDA, EU, and ICH regulatory guidelines and pharmacopeia as applicable to bioassay execution and method qualification/validation.
* Experiences in Various molecular biology assays (immuno-assays, ELISA, SDS-PAGE, CE-SDS, etc.),

classical cell-based virology assays (TCID50, plaque assays, titer reduction assays, neutralization assays etc.) as well as analytical chemistry methodologies and principles.

* Assured conformance to all government and corporate regulations. Responsible for developing, providing, defending, persuade Corporate/Plant practices with outside organizations. Routinely meet with regulators (FDA & EU) and customers to ensure no interruption in business due to compliance issues.
* Directs area of responsibility to meet production objectives within planned budgets. Provides input to SLT (Site Leadership Team) for resources needed to construct budget, updates, and changes in financial plan. Manages area supplies and equipment within budgeted amounts.
* Established and executed plans and commitments consistent to Development, Manufacturing, Customers and Business needs.
* Conceives, designs, conducts, and advanced independent scientific research activities per strategic business needs. Ensure research activities/projects are on track per business needs and established timeline.
* Develop, negotiate, finalize timeline and cost estimates for projects and/or service contracts to support business operations and/or external customer’s needs.
* Provided timely testing or execution of in-process, raw materials, intermediates, API, finished goods, continuous improvement initiatives, QA training, laboratory equipment validation and stability depending on area of responsibility.
* Conducts business and interacts/ negotiates with external contacts and customers to develop positive business relationships.
* Familiarize with electronic databases. (LIMS, ELN, ERM, Labvantage, Veeva Vault eQMS, SAP, LMS)
* Preparing, revision and review of various Standard Operating procedures (SOP), CoA generations,
* Work instructions (WI), Validation documents. Review of Quality Control (QC) Analytical data and Kneat Validation protocols.
* Ran training programs which encompass coordinating and training Analysts on different

methods/techniques of Quality Testing. Worked on creation and revision of various training documents like On-the-Job Training (OJT), Training Memo, Impact Assessments & Standard Operating procedures (SOP).

* Handling Audits, managing projects/assignments in response to health agency audit responses. Handling various projects which include Stability reports review for regulatory submission, validation of Chromeleon report templates, clearing backlog of CTU Alarms and analyzed samples, scheduling

testing for Analysts.

* Aiding in requirements gathering for integration of new software and update of analytical software’s to newer versions. Worked with digital team aiding in Labvantage 8.7 issues and SmartQC integration for QC scheduling. Hands on experience working with Labvantage (LIMS), Veeva, Chromeleon and

LabChem.

* Collaboratively worked with manager and colleagues to explore alternative approaches to solve problems and find solutions.
* Performs in-house testing on stability and release samples using in-house methods and USP monograph as per USFDA regulations.
* Working Knowledge of Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP) as 21 CFR Guidelines.
* Performs Quality Control Assays on marketed products to meet GMP guidelines.
* Maintain electronic lab notebook documentation. Ensure that all experimental methods and results are recorded timely, accurately, consistently, and according to established formats.
* Maintained performance of and troubleshoot issues encountered while working on various instruments.
* Knowledge of CGMP, ICH, USP and global compendial regulations and guidance.
* Perform work according to established internal safety guidelines and procedures, and as specified by appropriate external regulatory agencies (e.g., OSHA). Make recommendations and act as appropriate to keep the lab a safe environment for all team members, including regular housekeeping tasks.
* Responsible for writing/executing protocols, writing reports, qualifying, and distributing reference standards, writing SOPs and methods as required.
* Performs method development and validation tasks and implementing continuous development initiatives under the supervision of the QC Laboratory management.
* Generating intellectual properties and providing technical solutions. Practiced in instrument monitoring and analytical performance.

# Skills

|  |  |  |
| --- | --- | --- |
| **Extensive Hands-on Experience in depth Knowledge on:**   * Veeva Vault eQMS * Adhere to GMP/GLP Practice * Deviations/Lab Investigation * LIMS(Labvantage) * HPLC(EMPOWER/CHROMELEN)   **Professional Experience** | * ICPMS * ELISA, SDS-PAGE * Six Sigma * Trackwise * Wet Chemistry |  |

### Manager- QUALITY CONTROL (QC) CHEMISTRY

***Moderna Inc., Boston-MA 2023 May-Present***

***Roles and Responsibilities:***

* Served as QPTL (Quality Product Team Lead) or QA Operational Lead (OL) for assigned programs
* Review and approve change control requests, lab investigations, deviations, and proposed corrective actions and preventative actions (CAPAs) to ensure compliance with Gilead procedures, cGMP, and all other applicable regulations. Collaborate and escalate as necessary.
* Manage a team of Lab Analysts and is responsible to hire, lead and develop team members to ensure that the department has the appropriate talent and level of performance to meet business objectives.

Assure training and development of subordinates. Assist subordinates in problem solving. Identify and resolve people issues without direct supervision.

* Assure conformance to all government and corporate regulations. Responsible for developing, provide, defend, persuade Corporate/Plant practices with outside organizations. Routinely meet with regulators (FDA & EU) and customers to ensure no interruption in business due to compliance issues.
* Directs area of responsibility to meet production objectives within planned budgets. Provides input to manager for resources needed to construct budget, updates, and changes in financial plan. Manages area supplies and equipment within budgeted amounts.
* Provide technical leadership and subject matter expertise to the cell culture and bioassay team to ensure the successful execution of all GMP release and stability bioassays executed in support of requirements.
* Conceives, designs, conducts, and advanced independent scientific research activities per strategic business needs. Ensure research activities/projects are on track per business needs and establish

timeline.

* Develop, negotiate, finalize timeline and cost estimates for projects and/or service contracts to support business operations and/or external customer’s needs.
* Provide timely testing or execution of in-process, raw materials, intermediates, API, finished goods, continuous improvement initiatives, QA training, laboratory equipment validation and stability depending on area of responsibility.
* Applies advanced technical writing skills to prepare project protocol, and final reports to support product registration and/or business needs.
* Conducts business and interacts/ negotiates with external contacts and customers to develop positive business relationships.
* Review and approve GMP facilities, utilities, and equipment changes for IQ/OQ/PQ
* Review and approve protocols and reports (e.g., method qualification/validation, method transfer, stability, etc.) for product manufacturing and packaging.
* Review existing quality workflows, perform gap assessments, and assist in identifying areas for improvement.
* Author, revise, and review standard operating procedures.
* Manages QA personnel, including organizing and prioritizing daily tasks, provides training and writing performance reviews
* Responsible for final batch review, approval and release of manufactured products.
* Review manufacturing, packaging, and labelling Drug Product batch records and in-process quality control data and assess the completeness of change controls, deviations, and test results to ensure timely disposition of drug products intended for commercial or clinical use.
* Interact with key stakeholders to ensure that clinical and commercial products are manufactured according to established procedures, cGMPs, and appropriate regulations.
* Lead a sub-team of Quality professionals supporting the product/program, and ensures visibility and communication of key project timelines and CMC milestones
* Acts in a project manager capacity to ensure, change controls, deviations or other issues, lab

investigations, lot release status, test methods, method transfer and transfer status, stability studies, risks, metrics, regulatory inspections, audits, and other associated activities related to the

product/program are accounted for and managed to timely completion.

### Supervisor- QUALITY CONTROL (QC) CHEMISTRY

***Moderna Inc., Boston-MA 2022 Apr-2023 Apr***

***Roles and Responsibilities:***

* Investigation of Out of Trend (OOT) and Out of Specification (OOS) results, Laboratory events (LE), Quality Events (QE) and deviations.
* Handling and reviewing of Change controls, CAPA (Corrective and Preventive actions), Change actions, Effectiveness Checks, Impact and Risk assessments.
* Review of Quality Control (QC) Analytical data and its approval. Coordinate with other departments (i.e., Manufacturing, Supply chain) to ensure that sample release is completed swiftly to support operations.
* Working with Analytical development and Validation departments to troubleshoot issues with various Quality Control methods. Assist analysts in troubleshooting during their analysis and conduct 1 on 1 meetings with them to advance their training and career.
* Handling Audits, managing projects/assignments in response to health agency audit responses. Handling various projects which include Stability reports review for regulatory submission, validation.
* Review of Quality Control (QC) Analytical data and its approval. Coordinate with other departments (i.e., Manufacturing, Supply chain) to ensure that sample release is completed swiftly to support operations.
* Working with Analytical development and Validation departments to troubleshoot issues with various Quality Control methods. Assist analysts in troubleshooting during their analysis and conduct 1 on 1 meetings with them to advance their training and career.
* Worked with digital team aiding in launch of Labvantage 8.7, clearing issues and SmartQC integration for QC scheduling. Review of Kneat Validation protocols for digital updates & method/template

modifications.

* Creation and revision of various training documents like On-the-Job Training (OJT), Training Memo (TMEMO) and Training Impact Assessments (TIA). Working on updating Training Curriculum and LMS for Quality Control Chemistry Group.
* Assist analysts in troubleshooting during their analysis and conducted 1 on 1 meetings to advance their development. Coordinated QC meetings for providing awareness about new updates and gathering feedback/problems from Analysts and reviewers.

### QC SCIENTIST-III

***THERMOFISHER SCINTIFIC- Greenville, NC June 2021-Apr 2022***

***Roles and Responsibilities:***

* Directs area of responsibility to meet production objectives within planned budgets. Provides input to SLT (Site Leadership Team) for resources needed to construct budget, updates, and changes in financial plan. Manages area supplies and equipment within budgeted amounts.
* Handling Audits, managing projects/assignments in response to health agency audit responses. Handling various projects which include Stability reports review for regulatory submission, validation of Chromeleon report templates, clearing backlog of CTU Alarms and analyzed samples, scheduling

testing for Analysts

* Performs HPLC Analytical testing Analysis in Purity and ID testing for mRNA samples.
* Prepares/reviews/approves sampling plans, protocols, reports, data tables, test methods and writes SOPs.
* Regularly performs 1:1's with direct reports, coaching, mentoring, and developing.
* Actively participate in scheduling meetings with management and the QC Scheduler.
* Perform complex assays and assay reviews as needed.
* Manage and coordinate all Assay Qualification/Validation work. Mentored Scientists and Lab Associates. Coordinate tech transfer methods and review all associated documents, including Tech Transfer Protocols, SOPs. Drive functional, technical, and operational excellence.
* Responsible for continually improving the department via operational excellence initiatives, advances in technology, changes to regulatory landscape or other organizational changes.
* Review data generated by reports and solved issues.
* Function as a subject matter expert (SME) for Analytical Assays.

**Scientist, Analytical Development Oct 2020-May 2021 EXELA Pharma Sciences – Lenoir, NC**

***Roles and Responsibilities:***

* Hands-on development and optimization of chromatography-, capillary-, and spectroscopy-based analytical methods to be used for product release, stability, and characterization testing.
* Serve as analytical lead for one or more early clinical CMC team including driving method development, transfer to internal/external QC labs, and qualification activities.
* Generate and critically evaluate analytical data to support method development and product characterization.
* Provide rapid and timely analytical support for cell-line, bioprocess, and formulation development activities.
* Author and review technical documents including analytical test procedures, qualification protocols, development reports, stability protocols, and sections of health authority filings.
* Perform in-depth analytical characterization of complex biologics to build a strong understanding of critical quality attributes (CQA).
* Provide technical guidance during testing-related investigations at CMOs/CROs in collaboration with Quality
* Be actively engaged in cross-functional technical decision making.
* Contribute to the development of analytical control strategy and setting specifications for clinical programs in coordination with internal and external partners
* Execute Validated test methods by Analytical Techniques.

## ANALYTICAL CHEMIST Oct 2018- Sep 2020

**EXELA Pharma Sciences – Lenoir, NC**

***Roles and Responsibilities***

* Mainly focuses on the in-process testing for various drugs.
* Conducts various tests for the finished products and releases them for production after passing all the tests as per USFDA guidelines.
* Conducts Assay and Related Compound tests for various drugs by using EMPOWER software in Waters HPLC.
* Conducts Assay and Related Compound tests for various drugs by using CHROMELEON software in DIONEX.
* Conducts Physical Tests like Ph, Osmolality, Density and some WET chemistry tests for Qualitative Analysis.
* Execute, perform, and process the run for all the testing’s as per the method and software used as per the USFDA guidelines.
* Executing and setting up the instrument performance checks in a timely manner.

## Graduate Teaching Assistant Aug 2017 to May 2018 Texas A&M University -Kingsville － Kingsville, TX

* Promoted to Graduate Teaching Assistant by the Dept of Chemistry and allotted to do the Graduate Chemical labs and handling various lab instruments.

## Teaching Assistant Feb 2017 to Jul 2017

**Texas A&M University - Kingsville** － **Kingsville, TX**

* Worked as a teaching assistant under Chemistry professor. Conducted labs and recitation for Undergraduates under the guidance of Dr. Sajid Liu.
* With 5 months of teaching experience, learned how to handle classes and helps to improve demonstration skills.

## Student Worker Sep 2016 to Dec 2016

**Texas A&M University - Kingsville** － **Kingsville, TX**

* Worked as a student worker in the First Semester of my master’s under Dr. Sajid Liu and Dr. Apurba Bhattacharya. My role was to conduct exams and assign grades to Undergraduates.

## Production Executive Aug 2013 to Nov 2015

**Hippo Labs** － **Hyderabad, Telangana**

***Roles and Responsibilities:***

* Lead and manage manufacturing planning for the development and implementation of the production line with related department. To monitor process performance indices on qualified processes and establish good controls to maintain process performance.
* To ensure timely and accurate submission of reports including daily production, monthly and incident

investigations. To contribute to the preparation of annual budget and goals setting. To periodically review performance against plans and budget, and to account for variances.

# Education and Training

|  |  |
| --- | --- |
| **Master of Science, Chemistry** | **2016- 2018** |
| Texas A&M University – Kingsville-Kingsville, TX, United States |  |
| **Bachelor of Science, Pharmacy**  Vagdevi College of Pharmacy -Guntur, Andhra Pradesh, India | **2009-2013** |

**Academic Project**

## Bachelors:

### Design and Evaluation of Zolmitriptan Oral Strips

* Zolmitriptan is a serotonin (5-HTI) agonist used for the treatment of migraine with or without aura.
* The absolute oral bio availability is about 40 to 50%. The half- life of zolmitriptan is 2.5 to 3hrs and it undergoes hepatic metabolism.
* The main aim of the present work is to improve the bio availability and efficacy, to give rapid and fast onset of action and improved patient compliance.

## Masters:

### Oxidation of phenol to quinone in synthesis of 1,4-dihydroxyanthraquinone

* Phenol is like alcohol yet frames more grounded hydrogen bonds. In this way they are more dispersed in aqueous nature than alcohols and have greater cleavage points.
* In the process of converting the phenol's to quinones, the quinones when reacted with the two proton molecules, lose two electrons to form Hydroquinone and the hydroquinone gains two electrons to form the quinone and vice versa.
* One such oxidant is Frémy's salt, materialized on the right. Diminishing promoters other than stannous chloride (e.g., NaBH4) might be utilized for the one-eighty response.