**SADAF QURESHI**

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# Professional Summary

Results-oriented Quality Control (QC) Manager with extensive expertise in pharmaceutical and radiopharmaceutical quality control, regulatory compliance, and laboratory operations. Skilled in leading and developing high-performing teams, optimizing processes, and ensuring compliance with FDA, cGMP, and ICH regulations. Strong track record of driving continuous improvement and operational efficiency while upholding product integrity and regulatory standards. Passionate about creating a culture of excellence that supports innovation, enhances quality, and strengthens cross-functional collaboration.

**Quality Control Manager**

June 2023 - Present

**Orano Med –** Brownsburg – IN

* Oversee IQ/OQ/PQ of equipment, technology transfer, and hiring/training of the QC team during startup phase.
* Manage method validation, including drafting, reviewing, executing, and approving SOPs, tech transfer protocols, and analytical method validation protocols.
* Supervise testing for identification, quantification, and purity of APIs, in-process materials, finished radiopharmaceuticals, and stability samples.
* Lead change controls, CAPAs, and SOP revisions, ensuring compliance with cGMP, FDA, ICH, and other regulatory standards.
* Direct QC lab operations, ensuring regulatory compliance and audit readiness.
* Train and supervise QC analysts, driving high performance and technical proficiency.
* Investigate deviations, OOS, OOT, and contamination events, implementing root cause analysis and CAPAs.
* Collaborate with Production, QA, and Logistics to support product release and continuous improvement initiatives.
* Lead QC team recruitment, training, and development, enhancing expertise and efficiency.
* Review QC test records and batch documentation for final release.
* Maintain audit readiness, defending QC practices in regulatory inspections.
* Monitor QC KPIs, communicate with leadership, and implement process improvements.
* Support the transition from clinical to commercial operations.

**QC Specialist II**

January 2022- June 2023

## SpectronRx – Indianapolis, IN

* Performed analytical testing on raw materials, in-process samples, stability, validation, and finished radiopharmaceutical products in a GMP manufacturing environment.
* Experienced in HPLC, TLC, Endotoxin, pH, Osmolality, Filter Integrity, Immunoreactivity Fraction (IRF), and Reflectometer testing.
* Conducted investigations on complaint samples, OOS, and deviations, performing root cause analysis and CAPA implementation.
* Supported R&D projects, optimizing physical testing for manufacturing improvements.
* Standardized solution preparations, test solutions, indicators, and buffers per USP compendia and in-house test methods.
* Troubleshot and maintained laboratory equipment, ensuring operational efficiency.
* Provided training and mentorship to newly hired analysts on lab systems and instrumentation.
* Reviewed peer data and laboratory notebooks, ensuring compliance with FDA, cGMP, and internal QC policies.
* Ensured all laboratory functions adhered to safety standards, regulatory compliance, and prescribed protocols in a GMP facility.

**Quality Control Scientist**

June 2020 – October 2021

## Catalent Pharma Solution Bloomington-IN

* Performed qualitative and quantitative analysis of in-process materials, finished products, and stability samples using HPLC, UV/VIS Spectroscopy, Auto Titrator, pH, Osmolality, Density, Conductivity Analysis, Particle Size Analysis, Karl Fischer, and Wet Chemistry techniques.
* Conducted technical reviews of analytical testing data to ensure compliance with cGMP, regulatory guidelines, SOPs, and method validation requirements.
* Led out-of-specification (OOS) investigations, assisted in Laboratory Investigation Reports (LIRs), and implemented Corrective and Preventive Actions (CAPA) to address deviations and ensure continuous improvement.
* Evaluated and reviewed chromatographic data for in-process, finished product, and stability testing, ensuring data integrity and accuracy.
* Verified raw data, calculations, and test documentation, ensuring adherence to regulatory requirements and approved methodologies.
* Proficient in LIMS, Chromeleon, and Waters Empower for laboratory data management and compliance tracking.
* Supported the execution of method transfers and validation protocols, ensuring successful implementation and regulatory adherence.
* Identified and contributed to continuous improvement initiatives, optimizing Quality Control operations and laboratory efficiency.
* Provided training and mentorship to junior analysts, enhancing technical expertise and ensuring adherence to industry best practices.

**Lab Assistant**

April 2019 – April 2020

## Alverno Clinical Laboratories (St. Franciscan Health) – Indianapolis, IN

* Efficiently received, processed, and distributed routine and STAT specimens across multiple disciplines, including hematology, urinalysis, coagulation, chemistry, blood bank, and microbiology.
* Provided exceptional communication by responding to phone inquiries from hospital staff, physician offices, and patients, conveying verified test results, handling add-on test requests, and managing critical data entry tasks.
* Accurately performed registration and order entry procedures in LIS and Epic systems, ensuring timely and precise updates to patient and specimen records.
* Expertly handled centrifugation, pipetting, and aliquoting of specimens, ensuring correct processing based on test orders and preparing specimens for referral laboratory testing in compliance with specified requirements.
* Maintained accurate and comprehensive records, identifying and addressing discrepancies in documentation to ensure adherence to laboratory protocols and quality standards.

**Senior Biobank Technician**

December 2015 – November 2018

## Brooks Life Sciences (Biostorage Technologies) – Indianapolis, IN

## Efficiently handled, processed, and registered biological samples (radioactive, drug, and manufactured) while maintaining sample integrity within the Biorepository.

## Ensured strict compliance with regulatory standards, including FDA, GMP, GLP, GDP, ISO, and other industry guidelines, as per established SOPs.

## Utilized the company’s inventory management system to ensure accurate tracking of biological samples, maintaining chain of custody and comprehensive audit trails for all sample handling activities.

## Performed meticulous inventory management, maintaining detailed records and documentation through both the internal system and Microsoft Excel.

## Conducted quality control checks on registered material and managed data entry for the creation of manifests, ensuring all information met accuracy and compliance requirements.

## Collaborated effectively on various projects, both independently and as part of a team, with direct reporting to the Project Manager.

## Generated location management and custom reports to support operational tracking and data-driven decision-making.

## Served as a Designated Trainer, successfully training numerous team members and ensuring adherence to all procedures and best practices.

## Played an integral role in initiating change control requests and addressing event resolutions, contributing to continuous process improvement and compliance.

## Education

**MBA- Marketing**

Isra University- Pakistan

**Bachelor of Science** – **Biology**

University of Sindh – Pakistan