SHRUTI MEHTA

QUALITY CONTROL ANALYST - Analytical Instrumentation, Data Analysis & GMP Compliance

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SKILLS

- **Analytical Instrumentation**: HPLC, GC, UV-Vis, FT-IR, Dissolution, Wet Chemistry, Sample Preparation.
- **Quality Control Testing**: Assay& Stability Testing, Impurity Analysis,Titration, Karl Fischer, System Suitability.
- **Data Analysis**: CDS Software, ChemStation, Excel Data Analysis, Data Review & Calculations, Trend Analysis.
- **Method Validation**: Method Validation, Root Cause Analysis, Deviations, CAPA, OOS/OOT Investigations.
- **GMP Compliance**: cGMP/GLP, SOP Adherence, ALCOA+ Principles, FDA/ICH/USP Guidelines, LIMS.

WORK EXPERIENCE

Research Assistant **January 2023 – June 2023**
Borivali Healthcare *India*

- Compiled and executed 10+ pediatric patient case records for a laparoscopic hernia repair study, enabling structured clinical data analysis and evaluation of surgical outcomes.
- Verified and directed 50+ clinical data entries using spreadsheet-based tools to ensure dataset accuracy and reliability prior to analysis.
- Conducted literature reviews across 20+ peer-reviewed medical articles to support study design and strengthen the research protocol framework.
- Facilitated in preparation of 5+ technical research summaries supporting interpretation of surgical outcomes and documentation of study findings.
- Collaborated with the supervising researcher to resolve inconsistencies across 15+ research data points, improving dataset reliability for final evaluation.

Quality Control Analyst **January 2022 – December 2022**
Raj Metachem *India*

- Assessed quality control testing on 20–30 fertilizer samples weekly using wet chemistry techniques to verify compliance with established product specifications.
- Conducted HPLC and GC-MS analysis across 40+ laboratory test runs supporting impurity detection and trace compound identification for batch validation.
- Investigated out-of-specification results affecting 5–8% of tested samples, performing root cause analysis and supporting corrective action implementation.
- Maintained GMP-compliant laboratory records for 100+ batch test documents, ensuring traceability and readiness for internal quality audits.
- Performed calibration and system suitability testing for 3 analytical instruments to maintain testing accuracy and reduce laboratory downtime.

PROJECT EXPERIENCE

Academic Project – SOP Development for OOS/OOT Investigations
SOP Development Contributor – QC Investigations (Team of 2)

- Developed a structured SOP framework for managing OOS, OOT, and suspect analytical results in a QC laboratory, defining investigation workflows and documentation requirements across 5+ investigation stages.
- Established procedures for retesting, resampling, and triplicate analysis while incorporating GDP and CAPA documentation practices, strengthening traceability across 10+ laboratory investigation steps.

EDUCATION

Post Graduate Certificate - Pharmaceutical Sciences September 2024 - April 2025
Durham College, Oshawa, Canada
Post Secondary Diploma - Biotechnology Advanced September 2023 - April 2024
Durham College, Oshawa, Canada
Bachelors of Science - Biochemistry July 2019 - July 2022
University of Mumbai, Mumbai, India

CERTIFICATIONS

Workplace Hazardous Materials Information System (WHMIS) January 2024
Introduction to Biosafety September 2023
Workplace Violence and Harassment Prevention January 2024