

SHAIK ABDUL GAFUR

PHARMACEUTICAL - QUALITY DEPARTMENT PROFESSIONAL

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PROFESSIONAL SUMMARY

Experienced in quality management systems, analytical techniques, and laboratory investigations, bringing expertise in instrument qualification, audit compliance, and method verifications. Skilled at addressing deviations, initiating CAPAs, and optimizing workflows to ensure regulatory compliance. Offering abilities in compendial management and training to support continuous improvement in pharmaceutical quality operations.

SKILLS

- Quality management systems
- Instrument qualifications IQ/OQ/PQ and CSV
- Analytical techniques: HPLC, UV, KF.. GC
- CAPA initiation and effectiveness check
- Change Control Initiation
- Laboratory OOS, Incident. Deviation Investigations
- Biosimilars (mAbs) Analytical
- Analytical Method Verifications
- Analytical Method Transfers
- Audit Compliance and GDP &GLP
- Preparation of protocols and SOPs
- Compendial/ Pharmacopeia Updates

EXPERIENCE

ASSISTANT MANAGER MATRIX PHARMACORP Pvt Ltd. Hyderabad

September 2022 - Present

- Executed new Instrument qualifications in QC with document preparation for IQ/OQ/PQ & CSV.
- Addressing internal and customer audit responses in collaboration with management.
- Responsible for compendial management for USP, Ph.Eur, PMDA, BP, WHO, and IP -Method verification.
- Training Coordinator for department MyUniversity trainings and presentations & Analyst Qualifications.
- Prepared protocols and SOPs, facilitating uploads via D2 Application and periodic STP revisions.
- Laboratory incidents, deviations investigations, effectiveness of CAPA measures

DEPUTY MANAGER BIOCON BIOLOGICS INDIA Ltd. Bangalore

December 2019 - April 2022

- QC-Analytical / Biosimilars/monoclonal antibodies: Qualified and established Biologics reference standards (Trastuzumab, Bevacizumab) with testing protocols post-vial filling.
- Executed new Instrument qualifications in QC with document preparation for IQ/OQ/PQ & CSV.
- Regulatory department approvals for qualified reference standards, and maintained precise vial reconciliation.
- Investigated deviations/ Incidents if arise during standards qualifications, swiftly resolved any issues.

EXECUTIVE E-1 NATCO PHARMA Ltd. Hyderabad*May 2018 - December 2019*

- Laboratory compliance and documentation Review & achieving zero non-conformances.
- Reviewed QC Analytical Documentation, electronic data review & laboratory incidents investigations.
- Implemented new procedural inclusions in SOPs and preparation of effective protocols.
- Initiated Caliber LIMS implementation, optimizing documentation workflow.

JUNIOR MANAGER APOTEX PHARMACHEM INDIA LTD, Bangalore*May 2015 - April 2018*

- Executed quality control testing for batch release, ensuring product integrity through effective use of HPLC, GC, and wet chemistry techniques.
- Achieved zero non-conformances during FDA and Health Canada audits by ensuring compliance with GLP and GDP practices.
- Strong analytical knowledge and experience to carryout assigned investigation activities.
- Coordinated retrospective review of Empower-3 audit trails during Labware LIMS implementation to enhance operational reliability

OFFICER MYLAN LABORATORIES Ltd. Hyderabad*May 2013 - May 2015*

- Executed quality control testing and batch release to ensure product integrity utilizing HPLC and wet techniques. Self-review of analytical data for accuracy and completeness
- Employed LIMS, SAP, and Empower 3 software applications for efficient data management and improved accuracy.
- Testing of raw materials, intermediates, finished products, environmental samples, etc. Worked as per simple priorities inline with SOPs and Report all testing results and deviations if any.
- Adhered to good documentation practices (GDP), enhancing data accuracy through use of Caliber LIMS 3.2.0.

TEAM MEMBER Dr. REDDYS LABORATORIES Ltd.*August 2007 - May 2013*

- Conducted Sampling and instrumental & Wet analysis of pharmaceutical intermediates finished products, ensuring compliance.
- Report problems related to instrument, methods, to the Supervisor immediately and ensure to keep the workplace clean, tidy and safe.
- Supporting to release of finished products, intermediates, raw materials and recovered materials upon approval after review by QCD.
- Performed calibration on analytical instruments including HPLC, UV, Malvern PSD, and FT-IR.

EDUCATIONAL QUALIFICATIONS**MASTER OF SCIENCE IN ANALYTICAL CHEMISTRY**
Sri Venkateshwara University*April 2011***B.SC IN MATHS, PHYSICS, CHEMISTRY**
ANDHRA UNIVERSITY*April 2003***ASSOCIATE OF APPLIED SCIENCE IN INTERMEDIATE (IPE) 10+2**
Sri Siddardha College*April 1998***HIGH SCHOOL DIPLOMA**
C B M High School*April 1996*