

MUKESH SHARMA

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Synopsis:

I have 19 years of experience in Quality Control department of reputed pharmaceutical companies. Exposure to regulatory audits like **USFDA, EU-GMP, WHO, MHRA** & have successfully cleared such audits. Well versed with documentation, validation, calibration, stability studies etc.

Educational Qualification

Master of Science with **Chemistry** from Himalyan Garhwal University, Pauri Garhwal, Uttarakhand.

Bachelor of Science with Physics, Chemistry and Mathematics from Garhwal University, Garhwal Shrinagar, Uttarakhand.

Professional Skill:

- Handling and Calibration of analytical instruments like HPLC, UPLC, GC, GC-MS, UV-Spectrophotometer FTIR, Polarimeter and Dissolution Apparatus.
- Stability Study of Intermediate and Finish Goods
- Installation & Qualification of new lab instrument.
- Working in SAP, LIMS and Trakwise application.
- Handling of USFDA, TGA, EDQM, cGMP, ISO and MHRA audit.
- Handling of QMS (Quality Management System) like Deviations, OOS/OOT, Lab Event and Change controls,
- Analytical Method validation and verification, Process Validation and Cleaning validation

Current Role and Responsibilities

Company Name/Location: M/s Kumar Organic Product Ltd., Dahej, (Gujrat)
Designation: Manager – Quality Control
Period Oct - 2023 to Till Date.

- **Quality Control Strategy:** Develop and implement a comprehensive quality control strategy, including quality assurance, sampling plans, and testing protocols.
- **Testing and Analysis:** Oversee the testing of raw materials, intermediate and finished goods to ensure they meet established quality standards.
- **Stability Study:** Management of stability study sample charging, testing and withdrawal. Maintain stability chamber qualification and daily verification.
- **Quality Management System:** Develop and implement quality management system to maintain consistent product quality. like deviations, incidents in quality control, change controls, out of specification and out of trend results.
- **Laboratory Management:** Supervise and manage the quality control laboratory, including equipment, Standard, Column, Reagent, personnel, and testing procedures.
- **Validation and Calibration:** Validate analytical methods validation, method verification, hold time study, process validations, cleaning validations for analysis to ensure accurate and reliable results. performed instrument qualification and analyst validation.
- **Quality Documentation:** Maintain accurate records of all quality control activities, including test results, quality reports, and documentation of non-conforming products.

- **Quality Audits:** Conduct regular internal quality audits to identify areas for improvement and ensure adherence to quality control procedures.
- **Customer Complaint Resolution:** Investigate and resolve customer complaints related to product quality and implement corrective and preventive actions as necessary.
- **Regulatory Compliance:** Ensure that all quality control activities align with regulatory requirements, industry standards, and customer specifications and maintain data integrity.
- **Supplier Quality Management:** Collaborate with procurement and suppliers to ensure the quality of incoming raw materials and chemicals.
- **Training and Development:** Provide training and guidance to quality control staff to enhance their skills and knowledge.

Professional Details:

Company Name/Location **M/s Ranbaxy Laboratories Ltd., Mohali (PB)**
 Designation **Supervisor -Quality Control**
 Period November 2003 to April 2006.

Company Name/Location **M/s Ind-Swift Laboratories Ltd., Derabassi (PB)**
 Designation **Officer -Quality Control**
 Period April 2006 to April 2007

Company Name/Location: **M/s Parabolic Drugs Ltd, Dera Bassi, (PB)**
 Designation: **Manager - Quality Control**
 Period April 2007 to June 2014.

Company Name/Location: **M/s G.S. Pharmbutor Pvt. Ltd., (UP)**
 Designation: **Manager – Quality Control**
 Period July - 2014 to April - 2017.

Company Name/Location: **M/s Sun Pharmaceutical Ltd., Ropar (PB)**
 Designation: **Sr. Executive – Quality Control**
 Period Oct - 2017 to Sep - 2023.

Personal Details:

- Date of Birth : 6 Feb 1978
- Gender : Male
- Nationality : India
- Father's Name : Sh. P.L. SHARMA
- Marital Status : Married
- Permanente Address : Village - Majendi, Post - Diuli
 Via - Luxman Jhulla,
 Distt. - Pouri Garhwal, Uttarakhand.