SOWMYA B.M

Quality Chemist | Pharmacist

Pharmaceutical professional with dual expertise as a Quality Chemist and Pharmacist, combining 3+ years of experience in quality assurance within pharmaceutical manufacturing with hands-on pharmacy operations management. M.Pharm graduate with specialized knowledge in process validation and analytical method development. Proven capability in managing quality management systems, coordinating regulatory compliance activities, and ensuring adherence to GMP standards across manufacturing operations. Currently serving as Pharmacy In-Charge, overseeing daily pharmacy functions while maintaining robust quality oversight. Demonstrated strength in investigations, change control management, and cross-functional coordination to drive continuous improvement. Bilingual professional with experience in both industrial and clinical pharmacy settings.

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CORE COMPETENCIES

Customer Complaint & OOS Investigation | Change Control Management | Audit Coordination & Self-Inspection | HPLC Audit Trail Review | Inventory Management & Regulatory Documentation | GMP & ISO Compliance (9001:2015, 22000:2018) | Change Control Management | Process Validation & Protocol Development | Process Validation & Protocol Development | SOP Development & Documentation Control | Pharmacy Operations & Patient Counseling | Customer Complaint & OOS Investigation | Annual Product Quality Review (APQR)

WORK EXPERIENCE

Pharmacy In-Charge

Current Position

October 2024 – Present

- Manage daily pharmacy operations including prescription processing, dispensing, and patient counselling on medication dosage, potential interactions, and safety considerations.
- Maintain inventory control systems, billing records, and comprehensive stock monitoring to ensure medication availability and accurate documentation.
- Supervise pharmacy staff members, providing guidance and oversight to ensure efficient workflow and service quality.
- Coordinate procurement activities with suppliers to maintain optimal stock levels while ensuring cost effectiveness.
- Maintain legal documentation and ensure compliance with regulatory standards governing pharmacy operations.
- Monitor prescription accuracy and verify medication safety protocols are followed consistently.

Quality Chemist

Suprem Pharmaceuticals

September 2021 – October 2024

- Conducted Annual Product Quality Review trend analysis and prepared comprehensive reports to identify quality improvement opportunities and ensure product consistency.
- Developed validation protocols and reports, coordinating validation activities across departments to ensure successful execution and compliance with regulatory standards.
- Managed change control processes as quality coordinator, performing thorough assessments, tracking implementation progress, and ensuring timely closure of all changes.
- Handled customer complaints and Out of Specification investigations, performing root cause analysis and implementing corrective actions to prevent recurrence.
- Prepared and reviewed Batch Manufacturing Records, Batch Packaging Records, and Reconciliation Process Records to maintain accurate manufacturing documentation.
- Verified master SOPs and critical documents, ensuring alignment with GMP requirements and current regulatory guidelines.
- Supported implementation and maintenance of QMS, GMP, ISO 9001:2015, and ISO 22000:2018 (HACCP) standards across site operations.
- Verified log books and finished goods labels to maintain traceability and ensure product identity compliance.
- Collected data for Factory Operations and Key Performance Indicators to support management decision-making and operational efficiency.
- Prepared, stored, and archived quality documentation ensuring accessibility and compliance with record retention policies.
- Participated actively in investigations and incidents, ensuring proper compliance and implementing preventive measures.
- Conducted self-inspections of facilities, operations, and procedures to assure conformance with GMP and regulatory requirements.
- Submitted customer questionnaires along with required declarations and performed audit trail review of HPLC systems.

INDUSTRIAL EXPERIENCE & TRAINING

Pharmacy Intern

St. Joseph Hospital Pharmacy

September 2018 – November 2018

- Completed 150 hours of practical training in hospital pharmacy operations, gaining exposure to clinical pharmacy services, medication dispensing, and patient care coordination.

Quality Assurance Intern

Suprem Pharmaceuticals, Nanjangud

October 2020 – March 2021

- Completed six-month internship in quality assurance, acquiring hands-on experience in pharmaceutical manufacturing quality systems, documentation practices, and regulatory compliance procedures.

EDUCATION

Master of Pharmacy (M.Pharm) | 2019 – 2021
JSS Academy of Higher Education and Research, Mysuru
Bachelor of Pharmacy (B.Pharm) | 2015 – 2019
JSS Academy of Higher Education and Research, Mysuru
Pre-University Course (PUC) | 2013 – 2015
Aishwarya PU College, Kushalnagar, Kodagu
Secondary School Leaving Certificate (SSLC) | 2013
Bharath Matha High School, Koppa

ACADEMIC PROJECTS

M.Pharm Project: Process Validation of Cyanocobalamin (Vitamin B12) in Mannitol – Conducted comprehensive process validation studies to establish manufacturing process consistency and reliability.

B.Pharm Project: Nanoparticulate Drug Delivery in Management of Glioblastoma Multiforme (Brain Cancer) – Investigated advanced nanoparticulate systems for targeted brain cancer therapy.

SEMINARS & CONFERENCES

- International Conference on Advances in Pharmaceutical and Health Sciences, NITTE Mangalore (February 20-22, 2020)
- Bio-Printing in Life Sciences, JSS College of Pharmacy (September 14, 2019)
- QbD in Analytical Method Development and Validation, JSS College of Pharmacy (October 1, 2019)
- Pharmaceutical Product Stability: Quality and Regulatory Perspective, JSS College of Pharmacy, Mysuru

PRESENTATIONS

- Presented E-Poster titled "Impact of Workforce Transformation in Pharmaceutical Industry" at International Conference held at NITTE Mangalore (February 20, 2020)

PROFESSIONAL SKILLS

- **Quality Assurance:** APQR trend analysis, validation protocol preparation, change control coordination, customer complaint handling, OOS investigations, BMR/BPR/RPR preparation and review, log book verification, FG label verification, document archival management.
- **Regulatory Compliance:** Implementation of QMS, GMP, ISO 9001:2015, ISO 22000:2018 (HACCP), Current GMP and GDP practices, self-inspection of facilities and operations, external audit coordination.
- **Pharmacy Operations:** Prescription dispensing, patient counselling on dosage and drug interactions, safety monitoring, inventory and stock management, billing records, legal documentation and regulatory standards.
- **Analytical & Technical:** Problem solving, critical thinking, data analysis, HPLC audit trail review, investigation and incident management, customer questionnaire submission with declarations.
- **IT Proficiency:** Pharma READY eCTD software version 6.0, MS Office Suite (Word, Access, PowerPoint, Excel), Windows XP and Windows 7 operating systems.

LANGUAGES

- Kannada
- English
- Tamil
- Hindi