Shri. Yashwantrao Bhonsale Education Society's

Yashwantrao Bhonsale College of Pharmacy, Sawantwadi – 416 510 (M. S.)

Affiliated to Mumbai University

Approved by AICTE, DTE, MSBTE & Recognized by PCI

E-mail ID: ybpharmacy@gmail.com **Website:** www.sybespharmacy.com

Name : Ms. Manasvi Mayur Sawant

Qualification : M. Pharm in Quality Assurance

Designation : Assistant Professor

Department : Pharmaceutics

Email ID : yogeetanirgun@gmail.com

Professional Experience:

- Quality Assurance officer in Rubicon Research Pvt. Ltd. Ambernath Thane. (Aug 2016- Nov 2018)
- Associate Supplier Quality Audit, Quality Compliance, Johnson & Johnson Pvt. Ltd. (Nov 2018- Feb 2020)
- Regulatory Affairs Specialist, Covance Scientific Solutions Pvt. Ltd. (Jun 2020- Apr 2021)

Core Competency:

I. Administrative

Quality Assurance officer in Rubicon Research Pvt. Ltd. Ambernath Thane. (Aug 2016- Nov 2018)

- Reviewed analytical data regarding finished and in process products
- Performed Regulatory Submissions for various dosage forms as per US-FDA.
- Reviewing data of raw materials, Stability protocols and reports, Method Validation protocols and calibration reports of instruments
- Handled during Validation are HPLC, UV-Visible Spectroscopy, Particle Size Analyzer (Malvern 3000).

Associate Supplier Quality Audit, Quality Compliance, Johnson & Johnson Pvt. Ltd. (Nov 2018- Feb 2020)

- Quality compliances related to supplier quality which deals with management of supplier
- Conducting Audit/Visit of Suppliers for their Quality Compliance as per J&J guidelines and regulatory compliance
- Tracking audit status as per agreed Supplier Corrective Action Plan
- Ensure effective closure of observations as per agreed Supplier Corrective Action Plan
- Driving and completing mitigation plans

Regulatory Affairs Specialist, Covance Scientific Solutions Pvt. Ltd. (Jun 2020- Apr 2021)

- Create and/or revise raw material and packaging specifications using client TRU system.
- Create and manage global change controls for these revisions to the raw material and packaging specification
- Coordinate & interact with various internal departments like Procurement, Analytical, Quality Assurance, and external manufacturers/ sites, Suppliers and Distributors to understand the change, impact assessment, implementation strategy and required documentation governing the change
- Implement use of consistent, efficient, quality process to meet timelines and deliverables according to regulatory requirement
- Ensure compliance of operations with governing regulatory requirement.
- Create, maintain and assume accountability for culture of high customer service.

II. Research

S. Y. M. Pharm project from Glenmark Pharmaceuticals Ltd. Jun 2015 - Dec 2015

Development and Validation of Stability Indicating method of Active Pharmaceutical Ingredient

- Ultra violet visible Spectroscopy method used for used for detection of λ_{max} for drug X.
- Validation of Assay done as per ICH guidelines for drug X by using Ultra- Violet Visible Spectroscopy & UPLC.

- Stability indicating method developed & validated for drug X in bulk & dosage form.

III. Teaching

NIL

IV. Professional Affiliations

- Registered Pharmacist Date of registration- 08 Apr 2015.