

Pratiksha Shinde

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Objective

Challenging and growth oriented assignments in Regulatory Affairs/QA/Documentation.

Experience

- Johnson and Johnson Pvt Ltd** Nov 2018 - Oct 2022
Stability administrator
 - Oversaw sample receipt, temperature monitoring, and cleanliness of laboratory chambers, ensuring adherence to regulatory requirements and industry standards. Managed sample testing activities, tracked turnaround times, and prepared monthly and annual reports to meet defined deadlines.
 - Connect with business partner/ project partner to resolve queries related to development plan and product release specifications as per ICH guidelines, SOP's, 21 CFR
 - Facilitated stability sample management, including initiation, staging, labeling, testing, and disposal, while maintaining accurate documentation in LIMS.
 - Preparation of specifications and protocols in LIMS and maintain stability sample inventory in LIMS
 - Responsible for sample reconciliation and disposal process.
 - Storage, archival and retrieval of laboratory documentation with GMP and procedural compliance
 - Issued laboratory documents and records, including notebooks, logbooks, and technical documents, while maintaining strict adherence to GMP standards.
 - Coordinated import/export documentation and shipment clearance for consumer products, dangerous goods, and impurities, ensuring on-time delivery and proactive communication with stakeholders and logistic partners. Maintaining records of adequate license copies, end user letter, invoice, BOE
- RXN Chemicals Pvt Ltd** June 2018 - Sep 2018
Sales and purchase coordinator
 - procurement and vendor management, including sales and purchase of raw materials, conducting market research, and fostering business development.
 - Skilled in telecommunication with clients and vendors, adept at creating purchase orders, pro forma invoices, tax invoices, and certificates of analysis (COA).
 - Experienced in maintaining records of vendor qualifications and shipments to ensure smooth operations and compliance.
- Sharon Biomedicine Ltd** Feb 2018 - May 2018
Trainee Chemist
 - Making of COA, GRN (Good Receipt Number), Making indent (PERP 2017)
 - Water Analysis, Preparation of volumetric solutions, calibration of pH meter Balance.
 - Entries of sampling and testing record in LIMS (GRN - PERP2017)
 - Maintaining records of data logger temperature of chambers and cleanliness of chambers or cabinet
 - Reconciliation of solvents and chemicals
 - Sampling of API's
- PAPL (Padmaja Aerobiological Lab)** May 2017 - Jul 2017
Intern
 - Food, Drug and Cosmetic analysis
 - Microbiology analysis
 - Air Quality monitoring
 - Water analysis

Education

- K. J. Somaiya College of Science and Commerce** 2017
Masters of science
6.10 CGPA
- SIES college of Commerce and science and arts** 2015
Bachelor's of science
6.17 CGPA

Skills

- Knowledge of working in Regulatory compliance as per ICH guidelines, SOP's, 21CFR. Import and export documentation. LIMS coordination and Communication Stability samples management, disposal process of cosmetic samples, data integrity, archiving and retrieval, document issuance. Safety and Handling Procedures.

Projects

- **M.Sc. Part II**
 - a. Semester 3
Internship of 4 days in National Test House, Mumbai on GCMS, FTIR, AAS
 - b. Semester 4
Analysis of constituents present in milk.

Activities

- Contribution in organizing the activities of science association of the college as joint-secretary. (SY B.Sc.)

Languages

- English, Hindi, Marathi

Personal Details

- Marital Status : Married

Additional Information

1. Completion of Course of Maharashtra State Certificate In Information Technology (MS-CIT)

Certificate Course

- **Completed Advanced PG Diploma**
Regulatory Affairs (6 months Course) from Institute of Pharmaceutical Management in 2022

LinkedIn Profile

- <http://www.linkedin.com/in/pratiksha03>