

CURRICULUM VITAE

Rohini Gorak Babar.

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CAREER OBJECTIVE:

To Excel in the field of Science by virtue of hard work and proper application of knowledge also aiming to associate with a progressive organization that gives me scope to update my knowledge and skills in accordance with the latest research and be a part of the team that dynamically works towards the growth of the organization.

EXPERIENCE DETAILS:

1. Quality Assurance Officer, Raptakos, Brett & Co. Ltd, Thane.

- Period: July 2019 to till Present.

➤ QMS Activities:

- To carry out issuance, retrieval and review of Change control, Deviations and Incidences.
- Ensure Change control, Deviations, Incidences related actions are implemented, verified and closed within set timeframes.
- To carryout impact assessment and review of Change control, Deviations, Incidences after receipt from initiator.
- To ensure Change control, Deviations and Incidences impacting the validated status of Equipment, Utility, System, Process is raised, reviewed and tracked for completion.

➤ Vendor Activities:

- To review the reports of pre-approval Samples received from R&D.
- To review the vendor questionnaire and other documents received from vendor and communicate with vendor through Purchase department for any further clarification and requirements.
- To inspect the first three consignments received from new vendor for conformance to the labeling and other general requirements.
- To evaluate the performance of first three consignments from new vendors and report the findings to seniors for decision on final approval of vendors.
- To update the approved vendor list, provision vendor list and keep all RBCL sites updated of the approved vendor list and material received.
- Coordination with Production, Warehouse, Purchase, Quality Control for quality issues observed in consignment of RM and PM.

➤ APQR Activities:

- Handling of SAP system.
- Compilation and Review of APR/PQR report (Review of Batch disposition/Release status, Change Controls, Investigations and Stability Reports etc.)

➤ Validation Activities:

- To carry out Autoclave, HVAC and LAF Validations as part of Validation team.
- Monitoring and executing Process Validation.

➤ **IPQA Activities:**

- Issuing of line clearance at every step of Batch Manufacturing & Batch Packing.
- Hands on performing In-process quality assurance (IPQA) checks for Tablet & Powders, Injections (LVP), Ointment, Oral Liquids, Foods & Intermediates.
- Handling of Stability Samples and Retention Samples.
- Carry out In-house Calibration of Balance, Measuring Cylinder.
- Preparing annual product quality report (APQR) and Trends.
- To prepare trend data for active Raw material for APQR
- Release of BMR and BPR through SAP system.
- QA Issuance & Retrieval of various documents i.e. Batch manufacturing Record (BMR) and log Books for all departments.
- Planning and Scheduling of monthly report delivery.

2. Jr. QA Chemist in Maneesh Pharmaceuticals LTD, Mumbai.

○ **Period: 2018 to July 2019.**

- Documentation:- Preparing of standard operating procedure, master formula record, BMR & BPR.
- Give the line clearance at the start of new product.
- Maintaining the control sample record.
- Carry out In-house Calibration of balance, friability test apparatus, Disintegration Test Apparatus, Hardness and Thickness Tester.
- Review of BMR & BPR for final release.
- Monitoring the all IPQA activities-Tablets, Capsules, Liquid, Sachets.
- Validation- coordination of validation activities, preparation of validation protocol and reports, removal of validation samples.
- External calibration- monitor and maintain the records of external calibration like temperature and pressure gauges, Vernier calipers, thermometer, hardness tester
- Training-maintain the records of training and it's evaluation for the staff as well as workers.
- Inspection of bulk finished tablets, capsules before issuance to packing department for further processing.
- Responsible for verification of printed proofs of packing materials such as blisters, cartons, labels, etc. in packing department.
- Release- giving final release of product.

AUDIT FACED:

- WHO –GMP (World Health Organization – Good Manufacturing Practices)
- FDA (Food and Drug Administration)

CERTIFICATION:

- Registered Pharmacist of Maharashtra State Pharmacy Council,2017.

EDUCATION DETAILS:

Qualification	Institute/ University	Academic Year
B.Pharmacy	Siddhant College of Pharmacy, Pune. (Pune University)	2017
HSC	S.K.Somaiya Vinay Mandir, Vidyavihar (Maharashtra State Board)	2013
SSC	NutanVidyaMandir, Mankhurd. (Maharashtra State Board)	2011

PERSONAL DETAILS:

Date of Birth : 17th October 1995.
Marital Status : Single
Languages known : English, Marathi, Hindi.
Gender : Female
Hobbies : Playing games, Drawing
Strengths : Self Motivated, Honest, Hardworking and Sincere.
Address : 20/589, PMGP Colony, Mankhurd. Mumbai-400043.

DECLARATION:

I hereby declare that the information given above is true to the best of my knowledge and belief.

Date: / /

Place: Mumbai.

ROHINI GORAK BABAR