AAKANCHHA VINAYAK PARKAR

Assistant Scientist I – Analytical R&D

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Professional summary:

Strongly reliable and focused Quality professional with 10+ years of experience in Pharmaceutical industry. Worked with compliant team to write and handle the OOS investigations, manage the deviation and its associated CAPA's and Change controls effectively. Tracking of CAPA. Experience in managing the analysis and review of registration Stability studies.

Skills:

- Goal oriented and focused
- Excellent team worker as well as effective leader
- Handled different software like **SAP** and **SLIMS**.

Work Experience:

1) **Perrigo Laboratories**
   Designation: Assistant Scientist I **April 2014 to till date**

Job profile:

- Part of the investigation team for different OOS and atypical results obtained, responsible for writing deviations and raising CAPA and getting the deviations closed by QA in a timely manner.
- Tracking of CAPA
- Performing data review within timelines.
- Determine the root cause and assign appropriate CAPAs to avoid recurrence for any deviations
- Involved in Change control management
- Ensure that the relevant procedures / SOPs are continuously assessed, suggest improvement if required and ensure compliance to the procedures.
- Preparation of Test Methods and Specifications for Finished Products, Raw Materials etc.
- Performing calibration of different instruments like dissolution testers, media preparator, balances, pH meter, HPLC, UPLC, UV etc.
- Been a part of audit preparation team and have successfully faced audit such as USFDA.
- Analysis of Drug Products, performing different tests such as dissolution by UV and HPLC, assay & impurity testing using HPLC and UPLC etc.
- Worked on a CI (Continuous Improvement) project for the lab under 5S program for reduction of time required for various activities and for process improvisation.

2) FDC (Mumbai)
Designation: ARDL Officer **June-2013 to April-2014**

Job profile:

- Routine analysis of QBD Samples and Initial Batch Samples, Trend data analysis.
- Calibration of instruments like HPLC, UV, Dissolution Apparatus.
- Instrumental analysis of stability samples of various ANDA project for Solid Oral Dosage Formulations including Tablets (Coated and Uncoated), Ophthalmic solutions and Oral suspensions.
- Preparation & maintenance of working standard.

3) ARCH PHARMALABS LTD.
Designation: QC Officer **June-2010 to June-2013**

Job profile:

- Instrumental analysis of Finished Product & stability samples.
- Calibration of instruments & also coordinating with external calibration agencies for applicable calibrations.
- Preparation & maintenance of working standard.
- Preparation and Standardization of Volumetric and Standard solution.
- Handling of Change Controls, deviations, OOS, incidents & CAPA
- Preparation of stability study protocols /reports, SOP's
- Preparation of Material Specifications & standard test procedures for Finished Products, Raw Materials, etc.
- Preparing various schedules such as Stability schedules, Calibration schedules, working standard analysis schedule.
- Assisting Head QC during various Quality Audit. (Customer audits, ISO audits)
- SAP Activities: Stability schedule, Calibration schedule in SAP.

Achievements:

- Successfully completed Lean Six Sigma Practitioner
- Successfully completed Lean Six Sigma Yellow Belt
- Successfully faced 2 USFDA audits
- Worked and completed Continuous Improvement process for cost reduction and process improvisation.

Academic qualifications:

- M.Sc. (Chemistry) from Madurai and Kamaraj University **2012**
- Post graduate diploma in Chemical Technology (Food, Drugs & Cosmetics) from VJTI (Matunga) **2010**
- B.Sc. (Chemistry) from Mumbai University **2008**