Curriculum Vitae

Rohit Patel

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Summary

- Over 7+ years' experience in the Pharmaceutical industry within Analytical development Department.
- Identify gaps and facilitate improvements to ensure compliance against the EU GMP standards USP Standard and data integrity.
- Participate and interact with Regulatory inspectors (MHRA) and customer audits including compliance report preparation.
- Provide execution support in the implementation of CAPA systems, including training and effectiveness monitoring through communicating with stakeholders.
- Participated in special projects, for examples software implementation, Chromatographic Data System-Chromeleon version 7.2.
- Training of new procedures and updates to team to ensure activities meet the current GMP requirements.
- Managing team of analytical testing of pharmaceutical dosage form for routine testing, method transfer and method validation.
- Auditing of API facility, Quality control laboratory, scheduling, reporting, follow-up and closure with respect to EU GMP and ISO9001 standards requirements working under Lead auditor.

Key Achievements:

- Involved in Validation of Lab Instrument applications like ,Water Hplc With empower software and Shimadzu Hplc and Agilent Hplc series with Chromeleon software, FTIR-UV Spectrophotometer, Metrohm Tiamo and prerative Hplc with LC solutions software and Wet analysis. Basic knowledge of GC Analysis as par method of analysis.
- Conducting audits including API facility, Contract testing laboratory with respect to EU GMP, ISO9001 and USP standards.
- Achieving best employee of year in the organization
- Handling of new projects to completion within timeline as par organization requirements.
- Handling of particular sophisticated instrument of their routes caused.
- Managing of technical issues regarding software and instrument.

Professional Experience

Intas pharmaceutical Ahemdabad, India Feburary 2020 to present

- **Position: Sr.Executive (ADL)**
- knowledge of all sophisticated instruments like HPLC, GC, FTIR, UV/VIS. Spectrophotometer, Polarimeter, Karl-Fischer etc. Also knowledge of Computer operation.
- HPLC analytical method validation, cleaning method validation of Active Pharmaceutical Ingredients and Calibration of HPLC.
- Preparation of validation protocols, reports and general laboratory related documents.
- Requirements of submission of regulatory affairs Query for DMF Files.
- Preparation of Method development report.
- I was looking after all routine chemical & instrumental analysis of Raw Materials, In-Process samples, finished products as per pharmacopoeias requirement & In-House Specification with current guide line.

Gujarat fluorochemical Halol, India **November 2019 to January 2020**
Position: Executive (ADL)

- Development of methods for In-process/Finished products on HPLC and GC.
- Operation of all sophisticated instruments like HPLC, GC, FTIR, UV/VIS. Central, Polarimeter, Karl-Fischer etc.
- Analysis of Chemical as party requirements.

Cadila pharmaceutical, Dholka,India
Position: Executive (ADL) **November 2017 to October 2019**

- Work allocated for Validation project on day to day basis.
- Analysis of routine analysis, validation protocol and report, development report.
- Development of methods for finished products on HPLC.
- HPLC analytical method validation, cleaning method validation of Active Pharmaceutical Ingredients and Calibration of HPLC.
- Method transfer activity
- Operation and calibration of all sophisticated instruments like HPLC, balance, FTIR, UV/VIS. Spectrophotometer, Polarimeter, Karl-Fischer and identification of chemical analysis as regulators requirements etc. Also knowledge of Computer operation.

Amneal pharmaceutical (Raks pharma),Ahemdabad
Position:officers (ADL) **January 2015 to October 2017**

- Lead ADL department in carrying out analysis of incoming materials, components and finished products as well as data in support of the onsite manufacturing and QC functions.
- Ensure the ADL department operate in a fully current GMP manner and ensure all members of the lab have regular training in GMP practices where necessary.
- Responsible for the safety of department members, ensuring that all staff are suitably qualified and trained to undertake the tasks assigned to them in a safe and compliant manner.
- Partake in the writing, reviewing and approving of SOPs, Method of analysis and Specifications.
- Handling of wet analysis lab as per regulatory requirements. For examples KARL FISCHER and auto titrator with tiamo software, FTIR and UV with LC Solutions software.
- Training for new procedures and updates to team to ensure activities meet the current GMP requirements.
- Requirements client correspondence for contract testing, service provider qualification activities. Liaising with them with regard to quality related issues and Technical Agreements.
- Handling of Procurement of major instruments in Laboratory and their PM/OQ contracts.

Professional Training

- Data Integrity Training
- Water with empower software training
- Balance training
- Chromeleon software 7.2
- HPLC/GC trouble shooting
- Method development
- First Aid Training
- Fire safety training
- Attending in house training given by other departments like Regulatory affairs, Supply chain and Sales.

References

- Available upon request

Visa status
India