CHAITANYA KATTA

REGULATORY AFFAIRS

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Hyderabad

SUMMARY

Corporte Quality Assurance Officer having experience in Vendor Qualification and External Audit. Deep Knowledge on Pharmaceutical Regulatory Requirements. To be Associated with a progressive organization that gives scope to apply my knowledge and skills, and to be part of a team that works with dynamism towards the growth of the organization.

EDUCATION

MAM College of Pharmacy

Regulatory Affairs in Master of Pharmacy
2021 – 2023

Andhra University College of Pharmaceutical Sciences

Bachelor of Pharmacy- CGPA- 6.98
2017 – 2021

SKILLS

- Good Knowledge on Regulatory Guidelines.
- Knowledge on Regulatory Approval Process of Drugs in all Markets.
- Knowledge of Dossier Preparation in CTD and eCTD.
- Vendor Audit Preparation and Review.
- Compliance Report (CAPA) Review.
- Vendor Qualification Documents Review and Quality Compliance.
- Expertise in Microsoft Office.

CERTIFICATIONS

- I have participated in the Two day joint workshop by USFDA and Andhra University on “Current Good Manufacturing Practices (cGMP)” Conducted on 23rd and 24th February, 2023 at Andhra University College of Pharmaceutical Sciences, Visakhapatnam.

- I have participated in the “A Deep Dive: FDA Draft Guidance on Statistical Approaches to Establishing Bioequivalence” Webinar held on March 14, 2023

PROFESSIONAL EXPERIENCE

Corporate Quality Assurance- 2 Years

Hetero Company | Jun 2022- May 2024

Training on Pharmaceutical Quality Hetero:
I’m Certified for a 60 day comprehensive course in Manthan-Q on Quality Assurance and Quality Control Practices in Hetero Labs Limited .

ROLES AND RESPONSIBILITIES

- Coordination with Purchase and Site Quality team and ensure vendor audits are conducted as per plant schedules.
- Preparation and Review of all vendor audit reports.
- Review of compliance reports received from the vendors.
- Review Quality Agreement and Vendor documents.
- Support to vendor Sites for implementation of the Quality Management System.
- Extending support to Marketing and Regulatory Affairs team in providing the vendor qualification documents.
- To implement and follow the GMP, GLP, Safety norms and adhere to company’s policy.

PROJECTS

Regulatory Affairs : Dec 2022 - Dec 2023

Comparison of Regulations of Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy In India, United States.

LANGUGES

- English
- Telugu
- Hindi

HOBBIES

- Playing and watching cricket
- Listening Music
- Watching Movies