HIMABINDU KOPPUSETTY

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EDUCATION

Northeastern University, *Boston, MA* **Sep 2019 - Jul 2021**

Master of Science in Regulatory Affairs for Drugs, Biologics and Medical Devices

Relevant Coursework: Medical Device Development, Therapeutic Product Development, Global impact of eCTD, Regulatory Strategy for Product Development, Pharma and Medical device law, Regulatory Compliance

Gitam University, Visakhapatnam, India **Jul 2015 - Apr 2019**

Bachelor's in pharmacy

PROFESSIONAL EXPERIENCE

Breegi Scientific, Inc., *Boston, MA*. **April 2021- July 2021**

Regulatory Affairs Intern

- Prepared technical documentation for FDA 510(k) submission
- Developed a regulatory strategy for MDR to gain EU marketing strategy
- Utilizing a strong knowledge about FDA Emergency Use Authorization in the submission

LEADING PHARMA LLC., *Middlesex, New Jersey* **Jan 2021- Apr 2021**

Regulatory Affairs Intern

- Assisted in preparing regulatory submissions such as ANDA's, Annual reports, labelling, Post marketing Periodic Adverse Event Drug Experience Reports, Pharmaco-vigilance activities and ADE responses
- Operated the regulatory reviews of Customer complaints, ADE's and define regulatory reportability with developing and maintaining regulatory department's process and systems
- Maintained current knowledge of FDA regulation, guidance, industry practice and SOPs to define requirements for regulatory submissions. Actively participated in evaluation of regulatory compliance of document/product/process
- Worked collaboratively with regulatory, R&D, Production, Quality Assurance and Quality Control to meet project deliverables to ensure timely submission
- Utilized a strong knowledge of FDA regulation, cGMP and GMP standards, regulatory guidance documents, state and federal regulation to ensure documentation production efficiently

MSN LABORATORIES, *Telangana, India* **May 2019 – Jun 2019**

Quality and Regulatory Intern

- Reviewed and validated product information in packaging, instructions for use and labels
- Analysed and conducted a review on SOP development
- Conceptualized in quality control, assurance and production departments
- Provided input on developmental activities of the product evolving regulatory and its registrations
- Prepared documentation for FDA 510(k) submission and experienced with Class II medical devices
- Executed batch manufacturing records, batch packaging records, stability, finished product specifications

VERAS PHARMACEUTICALS PVT. LTD., *India* **May 2018 – Jun 2018**

Intern (QARA)

- Provided technical, process related and administrative support to drug safety management (Clinical trials and Post Marketing)
- Identified and devised a new manufacturing process of pharmaceuticals, drug manufacture and its Quality control
- Assessed and collaborated measures on Management Safety and allied applications and trained on manufacturing
- Coordinated and evaluated with regulatory and quality management

SKILLS

- **Technical Skills:** Regulatory submissions like IND, NDA, ANDA, BLA, 510(k), PMA, De Novo. Knowledge in submission of Annual Reports, PADER, PAS. Fundamental knowledge of Regulatory Marketing in Asia, Latin America, Canada, European countries. Basic skills in ISO 13485, ISO 14971, ICH Guidelines, EU-MDD & IVDD. Fundamental knowledge of eCTD
- **Software Skills:** MS Office, MS Project, MacOS, Adobe Acrobat

ACADEMIC PROJECTS

Review and Phytochemical analysis and invitro antioxidant activity of Uncaria Tomentosa **Aug 2018 – Apr 2019**

- Congregated information relating to taxonomical classification, history, morphology, taxonomy, Phytoconstituents, medicinal uses, Ethnomedical uses, Pharmacological activities, adverse effects and conclusion
- Gathered materials and conducted Preliminary phytochemical screening, Nitric oxide radical inhibition N assay, Assay of in vitro antioxidant activity, Xanthine oxidase inhibitory activity, Cupric ions reducing assay and final report concluded that Uncaria Tomentosa to be an effective antioxidant