Ms. Namitha Mohan C

Global Regulatory Intelligence Associate

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Summary

Well-qualified regulatory intelligence professional, proficient in regulatory and quality processes, and monitoring of regulatory updates from various markets. Skilled in coordinating applications, reports and supporting paperwork. Outstanding research and reporting experience. Capable of mastering new technologies and thrive confidently in this competitive world.

Core Competencies

- Written and oral communication skill
- Attentive Learner
- Strong decision maker
- Independent
- Team Management
- Active listener
- Adaptability

Languages

- English
- Malayalam
- Telugu
- Tamil
- Hindi

Education

- **MS. Pharm** in Pharmaceutics, 11-2020 to 06-2022, 9.27 GPA, National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad, Telangana
- **B. Pharmacy**, 09-2016 to 09-2020, 9.06 CGPA, SVU College of Pharmaceutical Sciences - Sri Venkateswara University , Tirupati, Andhra Pradesh.
- **Intermediate**, 06-2012 to 03-2014, 95.7 %, Narayana Junior College, Tirupati, Andhra Pradesh
- **SSC**, 06-2011 to 03-2012, 91.1 %, Govt. Higher Secondary School, Kodungallur, Kerala

Areas of Interest

- Regulatory Submissions
- Regulatory Intelligence
- Content and report writing
- Quality Assurance
- Regulatory subject matter expert
- Regulatory publishing

Technical Skills

- Basic knowledge in MS office
- Beginner in Minitab
- Regulatory content writing
- Documentation and record-keeping
- Data analysis and interpretation
- Computer systems and software

Projects/Training

- Academic project (MS. Pharma): Dissolution improvement of an antiepileptic matrix ER formulation
- Academic project (BPharmacy): Preformulation, formulation and evaluation of chlorpromazine loaded nanoparticles.
- Industrial training : Ratna Bioteck, 10-05-2019 to 25-06-2019, Banglore, Karnataka

Co-curricular Activities

- Poster Presentation on Hashimoto's Thyroiditis in National Level Seminar
- Attended ''Awareness course on Recent changes in indian and Global Regulatory Landscape"

Achievements/Awards

- Qualified NIPER JEE 2020 AIR 86
- Qualified GPAT 2020 AIR 1553
- University Topper in BPharmacy

Work Experience & Responsibilities

Regulatory Intelligence Associate | Freyr Solutions

Hyderabad, India |Dec 2022-Current

Regulatory Intelligence Surveillance

- Keeps a track of regulatory changes in the assigned geographical region and pharmaceutical products
- Reads through RI data, write good summaries and compiles data in predetermined templates
- Innovates to build the tracking and monitoring system that ensures availability of any new or revised regulations in any part of the world

Quality Checks

- Review the RI data collected from various sources
- Works in close coordination with all the stakeholders to make necessary correction and to improve the quality of data
- Maintains quality metrics about the regulatory intelligence data in the form of dashboard that can be presented to the management

Techno-functional Role

- Understand the product features and end-to-end user journey to forecast the challenges that product users may face
- Evaluated regulatory intelligence data coming from multiple sources for their technical suitability to upload in the product

Project related responsibilities

- Uploads the regulatory intelligence data into product after validation
- Collection and compilation of regulatory data necessary to train BOTS
- Provides regulatory documents for stakeholders
- Act as a subject matter expert
- Create BOTs for global markets
- Regulatory intelligence expert for USA, Australia, Saudi Arabia, France, Slovakia, Austria, Guyana, Paraguay,Liberia, Mozambique including various trade associations and international standards
- Provides support to regulatory submission team for regulatory information

Regulatory Intelligence Technical Associate | Genpact

Mumbai, India |July 2022- Dec 2022

- Preparation of Regulatory database for post approval changes for various markets
- Maintenance and Collation of RI data
- CMC PA Changes
- Trained in General publishing

Project Intern | Dr.Reddy's Laboratories

Hyderabad, India |Oct 2021- May 2022

- IPQA in coordination with RA team for preparation of justification report for In-process skip testing
- Preparation of SOPs
- MSAT (Pilot R&D) Dissolution improvement of an antiepileptic matrix ER formulation