ANN STEPHY

REGULATORY AFFAIRS PHARMACIST

CONTACT

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CORE QUALIFICATIONS

- Extensive experience in quality assurance and regulatory affairs work environments
- Superior expertise in medical device regulations and reporting
- Proficiency in making SOPs,Psmf,Psur,Icsr,RMP, etc.
- Thorough knowledge on FDA and Eu regulations.
- Excellent proficiency with software tools and metrics
- High skills in maintaining professional relationships with all levels of staff
- Outstanding analytical and problem-solving abilities
- ISO 13485

EDUCATION

- Masters in Pharmacy (Pharmaceutical Analysis
- Bachelor of Pharmacy Calicut University
- Fundamentals of Pharmacovigilance - PVigilantHealth-June 2023

RESEARCH PAPER

An overview of Antioxidant Activity on International Journal of Phytopharmacy research (Vol 7/Issue 2/2016/71-77)

HONOURS & AWARDS

- First Rank-Gold medal M Pharm KUHS
- Third Rank B Pharm Calicut University

LANGUAGES

English, Hindi, Tamil, Malayalam

PROFILE

Astute Regulatory affairs pharmacist with 5 years of experience navigating complexities of Ministry legislation and procedures. Thorough and methodical individual maximizes regulatory compliance through document management, open communication and legal advising. Strongly reliable and focused with great depth and breadth of experience in medical device review and evaluation. Superb multitasker able to handle multiple projects efficiently and accurately. Effective independent worker as well as excellent coordinator with other members of a regulatory affairs team

WORK EXPERIENCE

Regulatory Affairs and Warehouse Pharmacist

Gulf and World Traders 2018-2023

- Develop regulatory requirements and licenses for the medical devices with strong software troubleshooting skills
- Prepare and submit internal regulatory file applications for Classification and registration of medical devices as per MOHAP
- Establish and maintain a trusted relationship with local health authorities through regular meetings, discussions, training etc.
- Acquiring the quality certificates such as FDA, CE and ISO from respective manufacturer
- Provide guidance and feedback to regulatory affairs management
- Measure, track, report, and plan future capacity requirements of the warehouse Experience in a product development role
- Successfully registered and maintained product registration over 30 medical devices
- Assisted in ESMA registration of Medical devices
- Better understanding of Registration of Pharmaceutical drugs
- Reviewed and learned the usage of Dubai Municipality Software Portal for Medical devices

Analyst R and D (Trainee)

Sami Labs Limited, Sabinsa Group 2016-2017

- Conducted and submit the report for Calibration of analytical instruments
- Performed Stability analysis of Formulation batches, raw materials
- Worked with technical aspects of HPLC, UV Spectrophotometer, FT-IR, Gas Chromatography and Mass spectrometry, dissolution apparatus
- Maintained quality life cycle and worked to satisfy cGMP, GLP norms
- Prepared and standardized number of volumetric solutions
- Assisted in new product development, validation and launch
- Reviewed and revised department Standard Operating Procedures (SOPs) Trained in compiling filings for FDA submissions

Pharmacist

Life Pharmacy group August 2017 -November 2017

PROJECT WORK

- M pharm : Development and validation of UV Spectroscopic method and HPLC method for simultaneous estimation of Curcumin and Quercetin in Tablet formulation
- B pharm :A comparative In-vitro Protein binding study of Nisoldipine using Equilibrium Dialysis method