# 

# 

# ***SWATI***

# [***SWATI.372897@2freemail.com***](mailto:SWATI.372897@2freemail.com)

|  |
| --- |
| **Career Objective:** |

To pursue a long term career in Pharmaceutical field where my qualification & skill would be an asset and where I can learn and add more value to my skill to attain greatest possible heights while contributing my best towards the growth of the organization with my positive thinking & hard working skills.

# 

|  |
| --- |
| **Work Experience:** |

* Previously worked as ***Manager in Sun Pharmaceutical Industries Limited (erstwhile Ranbaxy Laboratories Ltd.),*** Gurgaon in Drug Regulatory Affairs with an experience of more than 5 years in regulated markets with USA FDA (generic drugs regulations and food laws as per USDA and FSIS) and Health Canada.
* Worked as Executive Purchase in Religare Wellness Limited, with an experience of dealing with vendor interactions and ensuring the supply of drugs to the retail pharmacies. Handling and maintaining of inventory record for retail stores depending on demand and supply, along with routine Drug Store visits. Also handling special hospital medical equipment project for the company and ensuring to deliver the best of medical devices to the patients visiting Religare wellness pharmacies at Fortis Hospitals.

|  |
| --- |
| **Job Profile:** |

* Taking ownership of projects from commencement to final delivery.
* Understanding business needs and objectives and deliver final output with insights and recommendations.
* Conducting team meetings to review project progress and discuss to mitigate any related risks and challenges.
* Compile Labeling files for submissions US FDA and Health Canada and prepare response to deficiencies to secure approval.
* Life cycle management of products to include renewals/ re-registrations and ensure product continuity through filing and timely approvals of variations/CBE’s/Notifiable Changes for US and Canada Market.
* Support product continuity activities through co-ordination with various stakeholders
* Ensure regulatory compliance from product development to commercialization
* Ensure necessary creation of systems and procedures in the department and compliance to the same with current regulatory requirements
* Coordinating and collaboration with cross functional teams in R&D, Project management, manufacturing location and other relevant stakeholders
* Communication with all functional groups for regulatory requirements.
* Keeping abreast about current regulatory guidance’s/ requirements viz. USA and Canada Market
* Completion and co-ordinating commercial launch activities for new/existing approved Rx/OTC products for Ranbaxy/Acquired products, and Customers.
* Communicate with regional regulatory on requirements/clarifications arising during product development that has impact on product labeling.
* Coordination with various departments for preparation of variation packages (specifically wrt labeling part) and submit the same to regional offices.
* Working with teams for preparation of SOP’s and work instructions for preparation and submission of documents.
* Started working on polymers, however would like to learn and explore the subject area in detail.

**Interface:**

***Internal***

* Product Development and Research, Process Development Lab, Manufacturing, Quality Assurance, Clinical Pharmacokinetics and Pharmacodynamics, Intellectual Property Rights, Medical Affairs and Clinical Research, Packaging, Regional Regulatory colleagues.

***External***

* Vendors (SPL software)

**Competencies**

* Mentorship-conducting trainings to help fresher’s get on board.
* Communication in technical matters.
* Regulatory Requirements\*
* Software knowledge to support e-submissions

\* Regulatory knowledge: Includes, to but is not limited to the following:

* Regulatory guidelines including those on ANDA/NDA/ANDS submission, variations, post approval changes, regulatory inspections, regulatory actions arising out of these.
* Regulatory guidelines for Rx/OTC products labelling.
* Electronic formatting and submission.

|  |
| --- |
| **Qualification** |

* Bachelor’s in Pharmacy from Delhi Institute of Pharmaceutical Sciences and Research (DIPSAR, formely known as College of Pharmacy) in 2011.
* Diploma in Pharmacy from Delhi Institute of Pharmaceutical Sciences and Research (DIPSAR, formely known as College of Pharmacy) in 2008.
* Senior Secondary from The Air Force School in 2006.
* Secondary Schooling from The Air Force School in 2004.

|  |
| --- |
| **Technical competencies** |

* Knowledge of basic pharmaceutical concepts and regulatory requirements.
* Demonstrates strong knowledge of technical writing and reviewing standards within the regulatory framework.
* Ability to coordinate and communicate in a group.
* Good communication skills and Positive attitude towards work.
* Adaptable, Focused approach and Result oriented.
* Always ready to take Initiatives.

|  |
| --- |
| **Professional Qualifications:** |

* Completed Training in Pharmacy of Sir Ganga Ram Hospital for 90 days in 2008.
* Completed Training in CGHS Dispensary (Finance Ministry, New Delhi) for 15 days in 2010.
* Awarded spot award by Ranbaxy for making a difference and driving excellence.

|  |
| --- |
| **Employment History** |

|  |  |
| --- | --- |
| **Company** | **Period** |
| Religare Wellness | July-2011 to June-2012 |
| Ranbaxy Laboratories Limited  (Executive-Labeling) | July-2012-June 2014 |
| Ranbaxy Laboratories Limited  (Senior Executive-Labeling) | July 2014-Jan 2016 |
| Sun Pharmaceutical Industries Limited  (Erstwhile Ranbaxy Laboratories Limited)  Manager-Labeling | Feb 2017 till Aug 2017 |

|  |
| --- |
| **Computer Proficiency:** |

# Microsoft Application viz. MS Word, MS Excel, MS Power Point, Microsoft Office Visio.

Internet

|  |
| --- |
| **Personal Details:** |

# Date of Birth :     07 February 1989

# Marital Status : Married

Linguistic Proficiency : English & Hindi

# Hobbies    :     Listening music, Reading books, Internet surfing, Watching Movies.

|  |
| --- |
| **Declaration:** |

I hereby declare that the above written particulars are true to the best of my knowledge and belief.