**CURRICULUM VITAE**

**Kimi Seth**

**Address**

Mr.Kapoor Chand Jain C/o Kapil Kirana Store

Tendukheda, Dist. Narsinghpur 487337

**Mob no. 9589364609**

**Email:** [**-kimijain123@gmail.com**](mailto:-kimijain123@gmail.com)

**OBJECTIVE:-**

“A Dedicated, confident and quick learner aimed at towards enhancing professional skills through training about the new innovative practice application looking for greater and challenging opportunities ahead. I want to secure a challenging position where I can effectively contribute my skills as a Professional and contribute to the growth of organization.”

# EDUCATIONAL QUALIFICATION:-

|  |  |  |  |
| --- | --- | --- | --- |
| **Degree** | **Institute** | **Year** | **Performance** |
| B.Pharm | Adina institute of pharmaceutical sciences sagar m.p. | 2015 | 8.15 |
| H.S.S.C. | Sarvodaya higher Sec. School Tendukheda | 2011 | 77.6% |
| S.S.C. | Sarvodaya higher Sec. School  Tendukheda | 2009 | 68% |

**WORK EXPERIANCE: -**

**CURRENT ORGANIZATION –**

**Name of Firm:** “Apcer Life Sciences Ahmedabad”

# Designation: Sr. Associate in Regulatory Affairs

**Duration:** November 2021 to till.

**Reporting :** Manager

**Job Profile:**

* Preparation of dossier in eCTD format for US, Europe Markets & publishing of submissions.
* Compilation, review and submission of IND, NDA and ANDA submissions for US market.
* Compilation, review and submission of Marketing Authorization Application for Europe market.
* Compilation of Annual Reports, supplements and query response for US market.
* Working on E-CTD Software (Lorenz).
* Preparation of administrative documents for USFDA (viz. cover letter, Form 356h, Form 2252 etc.)
* Regulatory Intelligence for Pharmacovigilance for drugs, devices, cosmetics and for food/ health supplements etc. (ICSR reporting, PSUR, RMP, Signal).
* Preparation and review of SOP related to Regulatory Affairs.
* Book marking / hyper linking of the document in eCTD format for submission readiness

**PREVIOUS ORGANIZATION -**

**Name of Firm:** “LUPIN Ltd, Bhopal”

# Designation: Executive in Regulatory Affairs.

**Duration:** October 2015 to November 2021.

**Reporting :** Dy. General Manager

**Job Profile:**

* Preparing and reviewing of Drug product annual report, supplements and queries as per USFDA requirement for oral solid, liquid and injectable dosage forms.
* Compilation and review of documents for variations, and Annual notifications for drug products for Europe and registrations, re- registrations and query responses for some regulated and ROW markets.
* Preparing and reviewing Drug Substance DMF, annual reports and Annual Notification and amendments as per US and Europe requirement.
* Book marking / hyper linking of the document in eCTD format for submission readiness.
* Preparing and reviewing documents for submission in US, Europe and ROW.
* Handle with Registration, Re-registration, Variations and Queries of ROW and some regulated markets.
* Coordinating effectively with all cross functional teams (QC, QA, R&D, and Production) to procure the documents and to develop the documents required for compilation of Annual reports and Supplements etc.
* Guiding manufacturing plant personnels about latest regulatory requirements and cGMP requirements, fulfilling responsibilities of Regulatory personnels during inspections.
* Coordinating with Quality Assurance, Quality Control, Formulation & Development departments and reviewing technical documents such as Process Validation, Stability data, Stability protocol, Comparative Dissolution Profile, Specifications (as Raw material, In process, API , Finished product, Packing material), Batch formula records, Batch packing records, Certificate of analysis.
* Reviewing and evaluating change controls.

# SKILL: -

Core Competencies:

* Compilation of annual Reports, Annual Notification, DMF, Supplements, Registrations, Re-registration, Variation, Queries.
* Theoretically and practically sound in registration procedure and filing for USFDA.
* Preparation of dossier in eCTD format for US, Europe Markets. & Compilation and publishing of submissions.
* Compilation, review and submission of IND, NDA and ANDA submissions.

Computer Literacy:

* MS Word, Excel, Power point
* Internet

Personal Traits:

* Competent to get results
* Cooperative & team player
* Possess good documentation & problem solving skills and the enthusiasm to learn relevant new regulatory requirements.

# PERSONEL DETAIL: -

Father’s Name: - Shri Kapoor Chand Jain

Mother’s Name:- Smt. Usha Jain

Date of Birth: - 18th Aug 1993

Marital status: - Unmarried

Languages Known: - English, Hindi

# DECLARATION: -

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

PLACE:

DATE: **KIMI SETH**