CURRICULUM VITAE

Hardik Bhalodiya

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Present Address:
"B-901, Viswa Kunj 1, Opp – Iscon Green Bungalows, Iscon Flower Lane, Ghuma. Ahmedabad-380058

Personal Details:
DOB: 30th Jan 1991
Gender: Male
Marital status: Married
Nationality: Indian
Languages Known: English, Hindi, Guajarati

Career Objective

Seeking assignments in Regulatory Operations Department in Pharmaceutical Sector

Motivation

A versatile, adaptive and fast learning person with broad and acute interest in the Regulatory Operations Department

Academic Qualifications

- **M. Pharm (Quality Assurance)**, Distinction (8.43 CGPA)
  Department of Pharmaceutical Sciences, Rajkot, Gujarat.(Saurashtra University)-2014
- **B.Pharm**, Distinction (7.83 CGPA)
  R.K. College of Pharmacy, Rajkot, Gujarat.
  (Gujarat Technological University)-2012
- H.S.C.- GSHSEB, Dist.(72.40%)-2008
- S.S.C.- GSHSEB, Dist.(84.57%)-2006

Area of interest

Regulatory Operations, RIMS

Work Experience

- July-2014 to April-2015, in Regulatory Affairs department at **Avance Pharma Pvt. Ltd.,**
- May-2015 to October-2016, in Regulatory Affairs department SME at **Sarjen Systems Pvt. Ltd.,** Ahmedabad, Gujarat, India.
- November-2016 to February-2017, in Regulatory Affairs department Executive at **Cadila Pharmaceuticals Ltd.,** Ahmedabad, Gujarat, India.
- February-2017 to Till Date, Sr. Executive in Global Regulatory Operation department at **Amneal Pharmaceuticals Pvt. Ltd.,** Ahmedabad, Gujarat, India.

Professional Competence

- **JOB PROFILE:**
  - Expertise in eCTD Submission managements, planning, publishing strategy and repository.
  - Currently handling motivated team of **8 People** and submitted approximately ***2500*** submission to USFDA/EU including ANDAs, Amendments, Annual Reports, Labeling supplements, PADERs in e-CTD format.
  - 100+ BA/BE studies tagged in STF Format with CSRs, CRFs & Datasets in eCTD/ICH E3 Format
  - Actively involved in developing of Regulatory Operation Manual of policies and Procedure & Established Regulatory Operation Department within short period.
  - Hands on experience in Compilation, Publishing, Submission & Life Cycle management of **e-CTD submission** (NDA, ANDA, DMF) for **US** (US-FDA) and **EU, Canada, Australia, GCC, ROW**.
  - Hands on experience of **e-CTD preparation tools** like **"eCTDXpress", "PharmaReady", "Educe"** and **"KnowledgeNET"**and **Validators** like **Lorenz e-Validator** and **Educe e-CTD Validator.**
  - Aware about the current expectation of different regulatory authorities like USFDA, EU, GCC, Canada, Australia for e-CTD requirements.
  - Experience on submission dossier through **ESG Gateway for US** and **Common European submission portal (CESP)** for **EU** countries.
  - Having good knowledge of **ICH eCTD** guidelines.
  - **SPL (Structure Product Labeling)** Preparation in which includes Preparation, Review and Submission of New Drug Code Request **(NDC)**, Establishment Registration **(ER)**, Drug Listing and GDUFA Facility Registration accordance with FDA requirements.
- **Technical Skills:**
  - Hands on experience in Document level and Submission level publishing.
  - Expert in handling tools such as "eCTDXpress", "PharmaReady", "Educe" and "KnowledgeNET", "Lorenz e-Validator", "Educe e-CTD Validator", "Adobe Acrobat Professional 11", "ISI toolbox" and "SPL Validator i.e. pragmatic Validator".
  - Having knowledge of XML Language
  - Provide technical training to team on timely manner.
- **Professionals Skills:**
  - Excellent time management skills with the ability to prioritize tasks to meet challenging deadlines.
  - Enthusiastic team member, a self-starter who is able to engage colleagues to meet goals.
  - Strong analytical, diagnostic and problem solving skills with the ability to provide innovative solutions.
  - Communicator, verbally and electronically with a high level of attention to detail to a diverse audience.
  - Able to work under pressure and meet deadlines and targets.
  - Ability to adapt and change to different environments and work effectively across different cultures and languages.

Work Database & Computer Skills

- MS Word, MS Excel, Power Point, Global Application for submission tracker, DMS System, Adobe Acrobat, ISI Toolbox, eCTDViewer, EDMS System

Academic Achievements

- Have successfully completed the distance learning **Industry Programme In Pharma Regulatory Affairs** from Jun 2013 to May 2014 in **BII, Noida** .
- Secured **2nd Rank** in M.Pharm in Department of Pharmaceutical Sciences, Saurashtra University Rajkot, Gujarat. **(Silver Medalist)**

Declaration

I hereby solemnly declare that all statements made above are true and correct to the best of my knowledge and belief.

Yours sincerely,
Hardik Bhalodiya