CURRICULUM VITAE

GAURAV KUMAR

Mobile : +91-9725868605

Email : gkdipsar@gmail.com

RA EXPERIENCE:

- **Concord Biotech (6 Year+)** *Ahmedabad*
- **Cadila Pharma (6 Year+)** *Ahmedabad*
- **CDSCO HO (1.8 Year)** *New Delhi*

QUALIFICATION:

- **Master of Pharmacy (*DU*)** (Quality Assurance)
- **Bachelor of Pharmacy (*DU*)**
- **PGDPRA (*Jamia Hamdard*)** (Post Graduate Diploma in Pharma Regulatory Affairs)

CURRENT ADDRESS:

A-302, Gulmohar Nirvana, Bopal - Ghuma Rd, Near Pleasure Club, Ghuma, Ahmedabad, Gujarat

PERMANENT ADDRESS:

D – 8/8, Jagatpuri Extension, Near G.T.B. Hospital, Delhi

PERSONAL DETAILS:

Date of Birth	:	18.09.1982
Sex	:	Male
Nationality	:	Indian
Marital Status	:	Married

14 Years+ Experience in Pharma Regulatory Affairs (Formulations)

OBJECTIVE

To work with full enthusiasm and creativity to get the maximum output of the efforts applied thereby achieving desired goal of the organization and to excel in the field of Drug Regulatory affairs

PROFESSIONAL EXPERIENCE:

1. Concord Biotech Ltd, Valthera, Tal. Dholka, Ahmedabad, Gujarat.

- **Manager Regulatory Affairs (April 2021 – Present)**
- **Sr. Assistant Manager Regulatory Affairs (Dec 2017 – Mar 2021)**

- Preparation & Review of various kind of Technical Applications pertaining to Drugs as per the requirements of Drugs & Cosmetics (D&C) Act and Rules there under for submission to Drugs Controller General (India) (DCGI) and Food and Drugs Control Administration (FDCA) Gujarat.
- Follow up with CDSCO and State FDA (FDCA Gujarat) for Timely approval of the applications.
- Review of BMRs, BPRs, APQRs, Change controls, Specifications, Stability Protocols etc.
- Review of Drug Product Artworks for In-House and Third-Party Formulations.
- Providing Regulatory inputs in Product Development projects.
- Monitor Regulatory changes and assess their impact and advice strategies for implementation.
- Supervising and Guiding International Regulatory Affair Teams (ASEAN, GCC, CIS, MENA, LATAM Regions).
- Pharmacovigilance system setup in the organization. Review of SAE, PSUR, RMP and PvMF.

2. Cadila Pharmaceuticals Ltd., Dholka, Ahmedabad, Gujarat.

- **Manager Regulatory Affairs (Jan 2017 – Nov 2017)**
- **Deputy Manager Regulatory Affairs (Jan 2014 – Dec 2016)**
- **Assistant Manager Regulatory Affairs (Sep 2011 – Dec 2013)**

- Preparation & Review of various kind of Technical Dossiers pertaining to IND, New Drugs, Vaccines, Clinical Trials, BA/BE Studies as per the requirements of D&C Act and Rules there under for submission to DCGI.
- To provide Regulatory inputs for New Product development projects.

PROFESSIONAL EXPERIENCE

- Monitor regulatory changes and assess their impact and advice strategies for implementation.
- Preparation & review of applications pertaining to Import (Commercial and R&D), Test License NOC and Export NOC as per the requirements of D&C Act and Rules there under for submission to CDSCO.
- Preparation & review of documents & applications for Department of Biotechnology and CBN Gwalior.
- Review of Chemistry, Manufacturing & Control (CMC) documents as per the regulatory guideline and providing regulatory input.
- Review of Non-clinical and Clinical data for safety and efficacy of New Drugs
- Review of Serious Adverse Event reports and its submission to CDSCO as per Indian drug regulation.
- Review and Approval of Drug Labels and Package Inserts as per Indian drug regulation.
- Providing regulatory guidance to Cadila CRO and CPL Biologicals for timely regulatory approvals.
- Timely follow-up of NPD Calendar for approvals.

3. Central Drugs Standard Control Organization (HQ), FDA Bhawan, ITO, New Delhi

- **Technical Data Associate – New Drugs Division (Jan 2010 – Aug 2011)**

- Review of New Drug applications pertaining to Global Clinical Trial division and Investigational New Drug division for verification of their compliance with Drugs & Cosmetics Act and Rules, Good Clinical Practices and other applicable Regulatory requirements.
- Verification of SAE and PSUR Reports submitted by Pharmaceutical firms.

WORKSHOPS AND TRAININGS

- **15th Skill Development Programme on Pharmacovigilance for Medicinal Products** (Online) organized by Indian Pharmacopoeia Commission, Ghaziabad. (*09 to 13 November 2020*)
- **National Workshop on Regulatory Compliance for Accelerating Innovations (BIO-PHRAMACEUTICALS),** Organized by Department of Biotechnology and CDSCO, Conducted by Biotechnology Industry Research Assistance Council and Clinical Development Services Agency at MS University of Baroda, Vadodara, Gujarat**.** (*30 July 2019*)
- **National Training Program on Good Clinical Practice, Current Regulatory and Ethical Requirements for Conducting Clinical Trials/Research in India (GOOD CLINICAL PRACTICE),** Organized and Conducted by Clinical Development Services Agency (CDSA), Department of Biotechnology, Faridabad, Haryana. (*23 to 24 July 2019*).
- **National Workshop on Regulatory Compliance for Accelerating Innovations (NEW DRUG & PHYTO-PHARMACEUTICALS),** Organized by Department of Biotechnology and CDSCO, Conducted by Biotechnology Industry Research Assistance Council and Clinical Development Services Agency at Centre for Cellular and Molecular Platforms (C-CAMP), Bangalore, Karnataka. (*09 April 2019*)
- Seminar on **"Understanding Pharmacovigilance obligations in india"** conducted by Veeda Clinical Research Pvt. Ltd., Ahmedabad, Gujarat, India. (*9 February 2018*)
- **6th Drug Information Association (DIA) Regulatory Conference**, "India, the Upcoming Economy: Encouraging Enforcement of Regulations", at Ahmedabad, Gujarat, India.(*24 & 25 May 2013*)
- One Week "**WHO Interregional Pharmacovigilance Training Course"** at World Health House, Indraprastha Estate New Delhi, India as CDSCO representative. (*21 to 25 February 2011*)

- Three day **"ISO 9000:2000 Series foundation and internal Auditor Training Course"** from Indian Institute of Quality Management (IIQM), Jaipur. (*28 to 30 October,2009*)
- Attended one-week training on **"Management Development Programme on QMS (ISO 9001; 2008)"** at MSME, Okhla, New Delhi. (*27 to 31 July, 2009*)
- Attended one-week training on "**Pharmaceutical Packaging Technology**" at Indian Institute of Packaging, Delhi. (*12 to 16 May, 2008*)
- Attended two Week Workshop on "**Advanced Spectroscopic and Chromatographic Analytical Techniques"** From Shahed Rajguru College of Applied Sciences, Vivek Vihar , Delhi University. (*24 Dec 2004 to 6 Jan 2005*)
- Three Months **Office Assistant's Course** from Bhartiya Vidya Bhawan, New Delhi.

RESEARCH AND POSTER PRESENTATION

- **Development and validation of an analytical method for** the estimation of **Celiprolol hydrochloride** on HPLC and UV Spectrophotometer at Delhi Institute of Pharmaceutical Sciences & Research (DIPSAR), New Delhi-110017. (2008 - 2009)
- Poster Presentation at **IPC (Indian Pharmaceutical Congress) 2009**; Ahmedabad on Topic "HPLC Method Development and validation for the estimation of Celiprolol hydrochloride". (11 Dec 2009)

ACADEMIC QUALIFICATION

EXAMINATION	UNIVERSITY/ BOARD	YEAR OF PASSING
Master of Pharmacy (Quality Assurance)	Delhi Institute of Pharmaceutical Sciences and Research (DIPSAR), Delhi University, Delhi	2009
Bachelor of Pharmacy		2005
Post Graduate Diploma in Pharmaceutical Regulatory Affairs	Directorate of Open and Distance Learning, Jamia Hamdard University, New Delhi	2010
Class XII (Science)	Central Board of Secondary Education, Govt. Boys Senior Secondary School, Dilshad Garden, Delhi,	1999
Class X		1997

ACHIEVEMENTS

- Qualified **GATE-2005** & **GATE-2006** organized by IIT Bombay & IIT Kharagpur Respectively

SOFT SKILLS

- Positive Attitude, Creative, Good Planner, Team player and a Perfectionist.

DECLARATION

I hereby solemnly affirm that all the above information furnished by me is true to best of my knowledge and belief.

Place: **Ahmedabad, Gujarat**
Date:

Gaurav Kumar