CURRICULUM VITATE

BRIJENDRA PRATAP SINGH

Address-
C/o Mala Singh
Near Chauhan Dental Como lesser Centre Nigam Road Selaqui Dehradun 248011 U.K.

E-mail:
briju.p77@gmail.com,

Mobile No.: 08860018550
09805284990

Personal Data:

Date of Birth : 08-July-1977

Father's Name:
Late Mr. Sheo Chandra Singh

Mother's Name:
Late Mrs Chandrama Devi

Gender : Male
Nationality : Indian
Marital Staus : Married
Language : Hindi, English

CARRAEER OBJECTIVE

Aim to work with dedication in challenging assignment that will present me with the opportunity to utilize my knowledge, skills and attitude towards growth of the organization.

PROFESSIONAL SYNOPSIS

A focused and proactive Pharma professional with 18 years of experience in pharmaceutical industry and earned skills having worked in Quality control, QA & Regulatory Affairs .
Key focus areas: cGMP, IPQC, managing technical queries on product, right documentation, SOPs, Regulatory documents.
Countries Handle: Asia, ASEAN, African, Latin America & CIS.

PROFESSIONAL QUALIFICATION

- **B. Pharm (2000-2004)** from Ram–Eesh Institute of Vocational and Technical Education, Greater Noida (U.P. Technical University, Lucknow)
- **Post graduate Diploma in pharmaceutical Drug Regulatory affairs (2007-2008)**from Jamia Hamdard university New Delhi,

ACADEMIC QUALIFICATION

- **B. Sc (bio) (1993-1997)** from Gorakhpur University Gorakhpur.
- **Intermediate (1993)** from U.P. Board Allahabad.
- **High school (1991)** from U.P. Board Allahabad.

PROJECT/TRAINING

Five week "Industrial Training in Production Manufacturing and Quality control Department of Win Medicare Pharmaceutical Limited, Modipuram, Meerut. in 2003.

WORK EXPERIENCES

1 M/s UNI MEDICOLABS (26 April 2023 to till date)
Designation: Assistant Manager, Regulatory Affair

2. M/s EUROLIFE HEALTHCAREPVT.LTD (20 December 2022 to 25 April 2023)
Designation: Manager, Regulatory Affair

3. M/s UNI MEDICOLABS (07 July 2020 to 19 December 2022)
Designation: Assistant Manager, Regulatory Affair

4.M/s ZEON LIFESCIENCES LTD. (09 September 2019 to 30 June 2020)
Designation: Assistant Manager, Regulatory Affair

5. M/s THEON PHARMACEUTICALS LTD. (22 September 2017 to 7 September 2019)
Designation: Assistant Manager, Regulatory Affair

6. M/s XL LABORATORIES PVT. LTD. (16 Feb 2017 to 9 September 2017) Designation & Responsibility: Executive Regulatory Affair

7. M/s CUREX PHARMA PVT. LTD. NEW DELHI (7July 2015 to 13 Feb 2017)
Designation: Executive Regulatory Affair

Strengths
: Analytical and logical Dedication towards Work and Positive attitude.

Permanent address
H.No: 1619/8,
Avas Vikas Colony
Basti 272001

Current CTC
10.0 lac /annum

Expected CTC
13.0 lac/Annum
(negotiable)

Notice Period: 2 months

8. **M/s NMC Bio pharm Pvt. Ltd**.(30 Dec 2011 to 30 Jun 2015) Designation: Executive Regulatory Affair & QA
9. **M/s NMC Overseas Pvt. Ltd.** (16 Dec. 2006 to 27 Dec 2011) Designation: Executive Quality control
10. **M/s SHAGUN TESTING LAB, GURGAON** (18 July 2005 to 15 December 2006)
Designation: Analytical chemist

JOB PROFILE

Designation & Responsibility: Assistant Manager, Regulatory Affair

- Prepared and submitted internal regulatory file applications and supporting documentation.
- Review the documents before filing in accordance with current regulatory requirements.
- Reviewed Dossier before sending to Party.
- Reviewed labeling of artworks and advertising materials for accuracy and completeness.
- Coordinate with F&D, Production, Quality control & Quality Assurance for New Product Development.
- Review compliance of Domestic customers.
- Reviewed and responded to all product complaints and queries.
- Provided applicable document for international supply submissions.
- Ensured compliance with company state and federal requirements for all performed work.
- Responded to agency deficiency request within strict timelines.
- Provided ongoing support to junior level associates to help develop their knowledge of regulations & procedures

Designation & Responsibility: Executive Regulatory Affair

- Compile the registration dossier and where applicable any other documentation for submission to regulatory body for the countries.
- To be involved with all registration related task- Post approval Authorization variations, Renewals.
- Preparation and compilation of Re-registration documents.
- Involved in Coordination with Manufacturing units, QA-QC &, Packaging, department for preparation and receiving of documents.
- Compilation of Re registration document and handling related query.
- Work precisely according to procedures, rules and regulations.
- Involved in setting up specifications for different dosage forms.
- Review the documents before filing in accordance with current regulatory requirements

Designation & Responsibility: Executive Regulatory Affair & QA

- Compile the registration dossier and where applicable any other documentation for submission to regulatory body for countries (Philippines, Turkmenistan, Uzbekistan, Kazakhstan & Cambodia)
  Review the documents before filing in accordance with current Regulatory requirements.
- Preparation of Normative Document for Pharmaceutical Products.
  Involved in Coordination with Manufacturing units, QA-QC &, Packaging, department for preparation and receiving of documents.

Designation & Responsibility: Executive Quality control

- In process quality control of finished product.
- Part of internal audit team.
- Audit on Contact manufacturing site.
- Preparation of Export shipping Document
- Key member for setting up New Pharmaceutical Unit according to cGMP.

Designation & Responsibility: Analytical chemist

- Calibration of DT Apparatus, Friability apparatus, Dissolution Apparatus IR moisture Balance, UV apparatus, & weighing machine etc
- Preparation of Standard solution
- Testing of Raw material and Finished good
- Prepared daily activity report and report to manger.
- Fumigation of room
- Biological testing of finished good

COMPUTER SKILLS

- Basic Knowledge of Microsoft Office, MS Word, Power Point, Excel.
- Retrieval of Scientific Data from various Internet portals like Google, Science direct, Pub Med, Medscape

EXTRACURRICULAR ACTIVITIES

- Actively participated in school and college level sports

DECLARATIION

- I, hereby declare that all statements given by me are true to the best of my knowledge and belief.

Place: **BRIJENDRA PRATAP SINGH**