Ms. CHANDRESH BODH

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OBJECTIVE

To work in a highly professional and motivated ambience with a permanent Position in order to enhance my professional skills through continuous learning, where I can effectively contribute my skills as Regulatory professional and provide benefits to the organization from my work to the best of my ability.

AREA OF INTEREST

- International market & Drug Regulatory Affairs

PROFESSIONAL EXPERIENCE (over 8.5 *Years*)

- Currently working as **Sr. Officer Drug regulatory affairs** in **Medipol Pharmaceutical India Private Limited, Since June 2021.**

June, 2018 to June, 2020	**:**	**Name of Employer:** G. D. Laboratories India Pvt. Ltd., India **Position hold:** Assistant Manager Drug Regulatory Affairs
March, 2016 to May, 2018	**:**	**Name of Employer:** Biomed Pvt. Ltd., Ghaziabad **Position hold:** Sr. Executive Regulatory Affairs
Dec, 2012 to Mar, 2016	**:**	**Name of Employer:** Brawn Laboratories Ltd., Faridabad **Position hold:** Executive Regulatory Affairs

Work profile in Medipol Pharmaceuticals India Pvt. Ltd.

EXPORTS DRUG REGULATORY

- Preparation, Compilation, Review and Submission of high-quality dossiers (In **ACTD and country specific** guidelines) for regulatory submission in **ROW MARKET** of **Finished Pharmaceuticals Products** (**Vaccines, Tablets, Capsules, Injections, Suspensions, Syrup, Sachet, Ointment, Cream & Gel formulations etc.).**
- Can work with a team /independently on any project like **ASEAN, AFRICAN, CIS & Latin-American countries** etc.
- **CMC (Quality) documentation** for new Applications, **CTD submissions** and amendments and also maintenance of all product registrations via renewals or variations.
- Looking for prospective agent, Settle terms with the prospective agents
- Design agreements and putting them into place.
- Responsible for coordination and preparation of the regulatory submission, Follow-up with clients or distributor and regulatory authorities to obtain timely product approval.
- Keeping track of registration status
- Supplying additional documents required by them time to time.
- Responding to regulatory **queries** from internal and external sources (different countries).

- Review the supporting documents like **PDR, Stability Protocol & Report, DMF, MFR, PVR, MSDS, AMV, specification, STP's & COA (API, Excipients, Finish product & Packing material). Artworks**, **Summary of Product Characteristics** and **Patient Information Leaflets.**
- Prepare & review content for Artwork (printed carton, printed alu. Foil, label and Inserts.)
- Formulation discussion for applying Permission, **COPP, FSC Manufacturing License & Product permission** with QA, QC, Production & Drug department.
- Preparation of document of NOSQ (Not of Standard quality)
- Coordination with plant for technical requirements for the compilation of dossiers.

STRATEGIC MANAGEMENT

- Coordinating with potential business partners
- Exchange terms and conditions of business with them
- Working on agreements
- Ensure processes desired for starting of potential business.

Work profile in G. D. Laboratories India Pvt. Ltd.

- Preparation, Compilation, Review and Submission of Dossiers in CTD, ACTD and country specific formats for regulatory submission in ASEAN, CIS and AFRICAN countries.
- Responsible for coordination and preparation of the regulatory submission, Follow-up with clients or distributor and regulatory authorities to obtain timely product approval.
- Submission **of responses to deficiencies** received from regulatory agencies.
- . Review the supporting technical documents like PDR, MFR, PVR, AMV, Stability Protocol & Report and Various specification & STP's (Raw material, API & Finish product). etc.
- Review the **Artworks**, **Summary of Product Characteristics** and **Patient Information Leaflets** checking all the information in packing material like labels, unit carton & leaflet as per buyer necessity.
- Review the **Drug master file** from different vendors and co-ordinate with vendors for the other documents
- Co-ordination with concerned department to arrange samples for regulatory submissions.

Work profile in Bio Med Pvt. Ltd.

- Independently handling of all dossiers as per country and client requirements.
- Preparation, Compilation, Review and Submission of documents **(CTD** and **Country specific guidelines)** for regulatory submission in **ASEAN & AFRICAN countries** of Human and veterinary **Vaccines.**
- Got registration about **25+** from different markets (Egypt, Nigeria, Benin, Lebanon, Indonesia, Afghanistan, Bangladesh, Iran, Tanzania, ivory coast, sudan, Cameroon, Cote d' Ivoire, Cambodia, Ethiopia, Georgia, Kenya, Myanmar, Nigeria, Srilanka, Tanzania, Uzbekistan, Yemen etc.).
- Responsible for regulatory **deficiencies response**
- Prepare & Review MSDS, Periodic safety Updated Report & risk management Plan & PPD (Product permission document).
- Review and correction of artwork/labels and carton.
- Check finished product specification from Pharmacopoeia I.P./WHO TRS/ Ph. Euro
- Coordination with plant for technical requirements for the compilation of dossiers.

Work profile in Brawn Laboratories Ltd.

- Working as Senior Executive in Drug Regulatory Affairs Department
- Got registration about **80+** from different markets (Philippines, Vietnam, Iraq, Iran, Burundi, Zanzibar, Afghanistan, Cambodia, Zimbabwe, Ethiopia, Georgia, Kenya, Myanmar, Nigeria, Sri Lanka, Tanzania, and Uzbekistan & Yemen etc.).
- Preparation, Compilation, Review and Submission of Dossiers (In CTD, ACTD and country specific formats for regulatory submission in ASEAN, AFRICAN, CIS & Latin-American countries of Finished Pharmaceutical Products (Tablets, Capsules, (Dry & Liquid) Injections, Suspensions, Syrup, Sachet formulations etc.)
- Preparation and submission of query responses.
- Review the Specification, STP's & COA (Raw material, Finish product & Packing Material), BMR, BPR, AMVR, PVR, Stability Protocol & Report.
- Review and correction of artwork/labels and carton.
- Formulation discussion for applying Permission, COPP (certificate of pharmaceutical product) & FSC (free sale certificate), Manufacturing License, Product permission with QA, QC, Production & Drug department team for issue all above documents from the Central & State FDA.

EDUCATION CREDENTIALS

Education	Name of college	Percentage	Passing Year
M. Pharma	R. V. Northland Institute, Greater Noida (Uttar Pradesh)	72.00%	2012
B. Pharma	Vishveshwarya Institute of Medical Science, Greater Noida (Uttar Pradesh)	65.85%	2009

RELEVANT EXPERIENCE

- Vocational training in QA, QC & Production Department (Parenteral section, Capsule section, Ointment section & finished goods store) taken from **"Alberd David Ltd.",** Ghaziabad, U.P.
- Vocational training taken from **GOVERNMENT OF INDIA** (Ministry of Health & Family Welfare) **Central Indian Pharmacopoeia Laboratory**, Raj Nagar**,** Ghaziabad, U.P.

COMPUTER KNOWLEDGE

- Well versed with MS Office applications like MS Word, Excel & Power Point etc.
- Independent knowledge of the Internet related to Work profile.

PERSONALITY TRAITS

- Initiator, Keen Learner and Result Oriented
- Dedication Towards Work, Time and Quality Conscious
- Multitasking, Flexible and friendly Nature with Positive Attitude
- High degree of Confidence, Hard Working Capacity
- Good Inter-Personal and Communication Skills

PERSONAL DETAILS

- Sex : Female
- Marital status : Married
- Language known : English & Hindi

PROFESSIONAL REFERENCE

References can be provided on request.

Information given above is correct to the best of my knowledge.

[CHANDRESH BODH]