RAJENDRA KUMAR BAPNA

M.Pharm (Pharma Management & Regulatory Affairs)

Correspondence Address

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OBJECTIVE

Seeking an organization where I can work in team and utilize my knowledge and capabilities which can fulfill organization objectives with continuous inputs that enrich professional skills.

AREA OF INTEREST

- **Drug Regulatory Affairs**
- **Intellectual Property Rights (IPRs)**

WORK EXPERIENCE AND CURRENT EMPLOYMENT

- Presently working in **Sarjen Systems Pvt. Ltd,** Ahmedabad in **Pharma Regulatory Department** as **Executive-Pharma Regulatory (eSubmission & labeling specialist)** from 28/12/2013.
- Work as a **Project trainee** in the **Johari digital healthcare Ltd**. Boranada, Jodhpur (Raj.) in Regulatory Department from 01/12/2011 to 30/06/2012.

CURRENT JOB PROFILE

Sarjen Systems Pvt. Ltd:

Sarjen Systems Pvt. Ltd., is a Pharma based IT company, provide the regulatory solution as well as services to pharma and healthcare industries located at the Ahmadabad, India, with client base across the globe viz.

- Hands on experience in Compilation, Publishing, Review, Submission & Life Cycle management for US FDA such as NDA, IND, ANDA, and for EU-EMA such as CP, NP, DCP and MRP.
- eDMF and ASMF compilation, publishing, and submission.
- Life Cycle management (Variations and Renewals filing in eCTD / NeeS format) for various pharma products registered in EU countries.
- Publish Regulatory Submission for US & EU by using KnowledgeNET Software application.
- SPL (Structure Product Labeling) Preparation in XML language which includes Preparation and Submission of New Drug Code Request (NDC), Establishment Registration (ER), Drug Listing and GDUFA Facility Registration accordance with FDA requirements.
- Provide the Regulatory Information and Resolve queries of Clients for Validation issues raised by Regulatory Authorities during Submission of eCTD, eDMF, SPL, NDC, ER and Drug Listing.
- Analysis of regulatory sites for updated guidance to implement into eCTD software.
- Provides regulatory contents for regularly update the sarjen's website.
- Handling of document management system (DMS) which includes publishing, storing, archiving & restoring of documents.
- Preparation of CTD/ACTD/Region Specific dossiers for ROW market.
- Technical & Functional review of the documents.
- Create CTD/ACTD/NeeS/eCTD template structure for regulatory submission according to client's and regulatory authorities' requirement for various regulatory and non-regulatory countries.
- Knowledge of all Regulatory Standard required during dossier & eDRL preparation.
- Provide Bookmarking, Hyperlinking and set PDF properties according to Guidelines for US & EU regulatory submission.

ACADEMIC QUALIFICATION

S.N.	Description	University /Board	Years	% Marks
1	M. Pharm. (P.M.R.A)	R.U.H.S., Jaipur	2013	71.21
2	B. Pharm.	R.U.H.S., Jaipur	2010	69.33
3	D. Pharm.	M.L.S.U., Udaipur	2007	65.47
4	Senior secondary	BSER, Rajasthan	2003	62.41

RESEARCH PROJECT AND INDUSTRIAL TRAINING

- A comparative study of regulatory guidelines for **Cosmetic Legislation** in US, Europe, and India, and to suggest improvement in the Indian guidelines
- To prepare **patent non-infringement opinion** for **Linezolid (ZYVOX) 600mg** oral tablet with respect to the patents existing in us, Europe and India.
- Preparation and **submission 510(k)** for taking marketing approval of **Electrical Muscle Stimulator (EMS)** in US on the behalf of **Johari Digital Healthcare Ltd Jodhpur.**

AWARDS & FELLOWSHIP

- Post graduate scholarship by AICTE (GPAT- qualified).
- Attending pharmaceutical conference, 2013 held at Mehsana, (Gujrat)
- Attending Training session of 21 CFR Compliance of Computers Systems at Sarjen System..
- Organized the WebEx Webinar on Regulatory Updates, 2015 and Standard PDF Properties Specification at Sarjen Systems.
- Compile and validate lot of eCTD dossier for US region within given timeframe, before the new stability guideline came into the force (from 20th, June 2014).

TECHNICAL SKILLS

- Familiar with the **eCTD Tools & Viewer** such as **KnowledgeNET** and **eCTD Validator** such as **Lorenz**, **EURS** and **SPL Validator** such as **Pragmatic Tool** and **Pragmatic Validator**.
- Compatible to prepare eCTD and eDMF dossier manually for US and EU countries.
- Having knowledge of **XML Language** (Required in the preparation of SPLR4).
- Involved in software implementation, testing and training.
- **MS Office:** Word, PowerPoint, Outlook and Excel
- Well versed with **Adobe Professional**, **Adobe reader** and **ISI Tool**.

PERSONAL VITAE

Mother's Name	Mrs. Nirmala Bapna (House Wife)
Father's Name	Mr. Bheru Lal Bapna (Retd. Principle)
Wife's Name	Mrs. Poonam Bapna (House Wife)
DOB	15th July 1986
Marital status	Married
Linguistic Proficiency	Hindi & English

REFERENCES DECLARATION

I vouch the authenticity of above furnished facts. If given an opportunity to serve, I assure that my performance would be whole hearted.

Place: Ahmedabad
Date: **RAJENDRA KUMAR BAPNA**