

Mrs. Gopi Jeenal Kumar Shah
D.Pharm
Email address: shahgopi8@gmail.com

Career Objective

To perform the task assigned to me with the best of my ability and to work dedicatedly towards the success of the organization. Trying to become the woman of values & the woman of success.

Academic Qualification

Examination	Year	Board /University	Percentage
DIPLOMA PHARMAC	2006	M.N.College of Pharmacy, Khambhat, Gujarat/ Gujarat	65.13%
HSC	March-2004	GHSEB	57.00 %
SSC	March-2002	GSEB	87.71%

Area of Interest

International Regulatory Affairs

Work Experience

Sr. No.	Company Name	Designation	Year	Department
1	Zydus Lifesciences Ltd, Ahmedabad	Senior Scientific Officer	Since 2007 to April-2013	Regulatory Affairs
2	Amneal Pharmaceuticals Ltd., Ahmedabad	Senior Officer	Since June-2013 to January-2014	Regulatory Affairs
3	Zydus Lifesciences Ltd, Ahmedabad	Officer	Since December 10, 2014 to 17 April 2017	Corporate Quality Assurance
4	Zydus Lifesciences Ltd, Ahmedabad	Sr. Executive	Since April 18, 2017 to till date	Regulatory Affairs

Technical Skill

Good skill in Handling and supporting the Various labeling related activities for US market

Job Responsibilities

Handling the labeling activities (for all Tablets, Capsules, Injections and Nasal Spray):

Post approval activities for Oral Solid, Topical and Injectables	Closely monitoring safety RLD changes and Labelling Supplement compilation and track timely implementation.
	Regulatory support for third party products (New art work preparation and product cycle management)
	Revision of insert labeling for patent or exclusivity addition or expiration
	Annual reportable changes for labeling and preparation of labeling part in Annual report submission
	Any new proposed changes implementation which effects to all commercial labeling (i.e., paperless medication guide, company logo changes etc.)
Commercial activities Oral Solid, Topical and Injectables	Drug listing of all approved products for distributors and manufacturers
	Review of LIF and Artwork approval and proof approval in Art work management system
	Labeling for all commercial products to meet the business requirements In US (CBP Activities)
	Post Approval REMS submissions
	Coordination with all relevant departments for RLD revisions for effectively implementing it on time
Other Activities	Labeling activities for Third parties
	Maintaining databases for commercial labeling activities, Change Controls, Regulatory Support to QA team for APQR Preparation and PV team for Reconciliation report preparation
	Maintaining and providing NDC number for all Zydus products of US market
	Learning and sharing: To provide training/Guidance to team to align with the FDA's current guidance/requirements/Deficiencies
Support for ANDA compilation	To extend support to Injectable team for preparation of Controlled Correspondence and labeling of preapproval submission (For ANDA and DRLS, CRLS)
	To extend the support for labelling activity related to ANDA compilation, Amendments

Certificate Course

I have completed certificate course for Diploma in Clinical research from ACEAS Clinical research.

Personal Details

Husband's Name	Jeenalkumar Shah
Date of Birth	October 21, 1986
Sex	Female
Marital Status	Married
Address	B/39, Omkar Residency, Nr. Parasnagar Busstop, behind Samrat Nagar, Isanpur, Ahmedabad-382443
Contact No.	+91-9601284592

Declaration:

I hereby declare that the information furnished above is true to the best of my knowledge

Yours faithfully,

Gopi Shah