DHRUMESH SIDAPARA

Ahmadabad, Gujarat | **+91-9714604859** | ✉ *dhrumeshpatel2000@gmail.com*
M.Pharm (Regulatory Affairs)-2023 | Gujarat Technological University (GTU)

PROFESSIONAL SUMMARY

Regulatory Affairs professional with 2+ years of expertise in ANDA/DMF submissions, USFDA/EU compliance, and cross-functional coordination. Proven ability to align regulatory strategies with business objectives, ensuring timely market approvals. Strong experience in vendor qualification, Sourcing Intermediates ,Plant Operations.

KEY SKILLS

Regulatory Submissions: ANDA/DMF/CTD, APQR, Market Compliance (EU/Africa)
Business Development: Market Research, Client Liaison, Proposal Drafting
Soft Skills: Leadership , Team Collaboration, Training
ERP Software Proficiency

PROFESSIONAL EXPERIENCE

Apistar Lifescience Pvt Ltd — dec-2024 - Present

(Formerly Known as a Shree Harikrishna Pharmaceuticals)

QA/RA Officer

- **Collaborated with BD teams to align regulatory timelines for product launches.**
- **Supported regulatory strategies for market expansion (export campaigns)**
- **To Issue, archive and control of all Documents like SOP,BMR,Formats and logbooks of all departments.**
- **To prepare/update the list equipments, instruments and quality systems related documents.**
- **To take a plant round of mfg area for ensuring cGMP Practice.**
- **To Collect the data for Preparation of APQR & Continues Process Validation.**
- **Physical verification of pre-dispatch finish material.**
- **to Assist in investigation,OOS,CAPA & various validation activities in EQMS Software.**
- **review and Approved vendor Qualification.**
- **Make a schedule for product campaign for export .**
- **review and Compile data for DMF.**
- **Coordination with cross Functional teams for the documents availability as per regulatory submission plan.**
- **Maintain regulatory information as per allocated task, and ensure the no delay in drafting and compiling the regulatory submission.**
- **Market Complies as per country specific guidelines.**

➢ **Shree Harikrishna Pharmaceuticals** **Sep-2023 - dec-2024**
(Kerala GIDC,BAVLA,Ahmedabad)

Trainee Officer QA

- **To Issue, archive and control of all Documents like SOP,BMR,Formats and logbooks of all departments.**
- **To prepare/update the list equipments, instruments and quality systems related documents**
- **To review quality system related documents ex. Analytical records, log books, monthly updated doc. etc.**
- **to review the executed batch production record, Batch packing record and equipment cleaning record etc.**
- **to take a plant round of the manufacturing are for ensuring cGMP & cGLP practice.**
- **To Prepare The Approved Vendor list and handling of vendor questionnaires.**
- **To Comply, review the training record and update.**
- **training History of all employees.**

➢ Internship:

✓ **STEPUP PHARMTECH (Aug-2022 to Jan-2023)**
Scientific & Regulatory Affairs division Consultancy
Add:703-704,VIVAATELIER,OPPB.D.PATELHOUSE,NARANPURA, AHMEDABAD

During 6 months training I observed and learned how to prepare and submit dossier for various region (US, Europe, Africa etc.)

✓ **Vital Pharmaceuticals Ltd (July– August2021) Anand,Gujarat,India**

During 1 months training I observed and learned basic details of pharmaceutical industry GMP,GLP or WHO Standards' or process pathway of intermediates (Api) to Finish formulation of Drugs

Projects

✓ **Quality risk management (QRM) in pharmaceutical industry :**
Applied ICH Q9 guidelines to mitigate manufacturing risks.(Tools and methodology) (B.Pharm)

✓ **Dossier registration requirements for ANDA (USFDA) filing of Amlodipine besylate, hydrochlorothiazide, Valsartan and comparative study between USA and EU regulations (M. Pharm)**

Educational Qualification

2023 Master of pharmacy (Pharmaceutical Regulatory Affairs) (M.PHARM) Gujarat Technological University (GTU) – Ahmadabad

CPI– 7.6

2021 Bachelor of pharmacy (B.PHARM)

Gujarat Technological University (GTU)-Ahmadabad

CGPA – 7.0

2017 H.S.C. Science (B group)

Alpha Vidhya Sankul - vadal (junagadh) Percentage:

63%

2015 S.S.C. General

Shree Sarasvati Vidhya Mandir – Mendarda

Percentage: 70 %

Computer Proficiency

- **Ability to use WINDOWS OPERATING SYSTEM Like MS OFFICE.**
- **ERP Software**
- **E-ctd Software for Dossier Compliance. (Beginner leval)**

Seminars and Work shops Attended

- **The Center For Entrepreneurship Development (Govt. Of Gujarat) (Module 1-2)- 2021**
- **National Conference on Startup: Igniting innovations & Leadership**
- **GTU TEC-HFEST-2018,2019**
- **NirmaQuest'192019atNIRMAUNI.Ahmedabad-2019**
- **Scintilla'19atM.SUNI.Vadodara-2019,2020**
- **WORK SHOPS on "Resume preparation and Interview skills"**
- **Webinar on "Regulatory Science"**
- **National Conference on Start-up: Igniting innovations & Leadership**
- **Training programme on Ectd software and Regulatory submission**
- **Certificate Course on Pharmaceutical Regulatory Affairs**
- **Attended and presented poster presentation in 2nd NIRMA e-Conference for International Connect (NCIC)–2023**

Co-Curricular and Extra-Curricular Activities:

- ✓ **Member of Core Committee of Sports at Anand Pharmacy College.**
- ✓ **NSS Volunteer for college.**
- ✓ **Student cell member at Anand Pharmacy College.**
- ✓ **Student council president Anand Pharmacy College.**

Personal :

Name	**:-**	**Dhrumeshkumar Animeshbhai Sidapara**
Date of Birth	**:-**	**February28'2000**
Nationality	**:-**	**Indian**
Gender	**:-**	**Male**
Language Known	**:-**	**English,Hindi,Gujarati(Full Professional proficiency)**
Permanent Address	**:-**	**"VRAJMOTI" ,D.D.nagar Society, Opp police headquarters, Mendarda(GIR) Dist:Junagadh,Gujarat.PIN:362260**

DECLARATION

I hereby inform that all the above furnished information is true to the best of my knowledge and belief. If given an opportunity I would prove myself worthy for the said post ensure to serve the organization with almost integrity.

Mr. Dhrumesh Sidapara
M. Pharm (Regulatory Affairs) 2023
Mob: 9714604859