

PRESENT ADDRESS

Manjunath Naragund
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PERMANENT ADDRESS

S/o Mr. A M Naragund
Plot No:16,Bendegeri Colony,
Vidhyagiri, Dist-Bagalkot,
Karnataka, Pin code: 567102

CARRIER ASPIRATION

- ☆ Dynamic and Result driven professional with 4+ years of rich experience in Quality Assurance and Regulatory Compliances in the Pharmaceutical Sector. Proficient in compiling the CTD for Domestic regulatory requirements for different applications, Sound exposure in process and system inspection/audit to identify non-compliance and improve efficiency. Demonstrated ability to face regulatory audits including ,CDSCO & EIA.
- ☆ Performing best of my skills and knowledge acquired during education & experience for the organization while contributing to organization goals and try to reach a position where my decision contribute towards growth of organization.

WORK EXPERIENCE

- ☆ Present Organization: **M/s. GELTEC PRIVATE LIMITED.** Sr. No. Yadavanahalli, Attibele, Hosur Road, Bangalore-562107 from Feb-2024 to till date as Executive QA & RA
- ☆ Previous experience in **M/s. MEYER ORGANICS PVT LTD.** Sr. No. VIDHYA NAGAR,PEENYA INDUSTRIAL AREA Bangalore-562107 from September-2021 to Feb. 2024 as Jr. Executive QA & RA.
- ☆ Previous experience in **M/s. MADHAR PHARMA & RESEARCH LABORATORIES,** PEENYA INDUSTRIAL AREA, from April-2020 to May-2021 as IPQA Chemist.
- ☆ Current Designation: **Executive QA & RA**
- ☆ Work experience in: **QA & RA**
- ☆ **Total Year of Experience:- 4+ Years.**

CURRENT JOB PROFILE

- ☆ Reviewing & Compilation the CTD for filing the application for Manufacturing license, Product permissions, Renewed Licence for manufacturing of drugs Formulation & Test license from Drugs control Department, Karnataka.
- ☆ Reviewing & Compilation the CTD for filing the application for Import Licence for Examine, Test & Analysis or for Commercial use from CDSCO, DCGI-INDIA.
- ☆ Handling queries, and documents related to Product licensing & WHO- GMP certification and Site inspection and approvals from Drugs Control dept & other regulatory agency of India.
- ☆ Reviewing & Compilation of the CTD for filing the application for Performance certificate, Free sale certificate, Manufacturing & Marketing Certificate, GMP certificate, & No conviction certificate.
- ☆ Compilation of CTD & Filing the Licensing application for Nutraceutical Products with food and drug authorities of India, FSSAI.
- ☆ Compilation of CTD & Filing the Licensing application to **Central Drug Standard Control Organization (CDSCO) & FDA, Karnataka** to get certificates of pharmaceutical product (COPP), Export NOC from CDSCO.
- ☆ Compilation & Filing of the application to **Export Inspection Agency (EIA)** for getting health Certificates of fish oils for export purpose i.e. both for notified products & non notified products for European Countries & Non-European Countries from EIA, Bangalore, India.
- ☆ Handling queries and documents related to Export Inspection Agency, Bangalore & Kochi.
- ☆ Compilation of Q-certificate for the export of the products weekly & monthly MPEDA statement.
- ☆ Reviewing & Compilation of the documents for pre audit check list
- ☆ Physical inspection of the Audit compliance

IPQA EXPOSURE:

- ☆ Review of batch manufacturing record, batch packing record and stage wise yield reconciliation and log in of yield deviations(if any).
- ☆ In process Quality Assurance during manufacturing and packing like Line Clearance, Sampling, proof checking and process Monitoring in Tablets & Capsules .
- ☆ Responsible for carrying out Disintegration test and measuring hardness of tablets, testing loss of drying, thickness, friability and strength of tablets, Testing of Capsules for disintegration time.
- ☆ Rising of deviation, change control & non-compliance with respect to occurrence.
- ☆ Drawing of samples according to process validation protocol.
- ☆ Preparation, Issuance, Revision/Review and Retrieval of the documents.

WORKING KNOWLEDGE OF: ISSUANCE & QUALITY MANAGEMENT SYSTEM (OMS)

- ☆ Issuance of BMR & BPR for tablets, capsules, and liquids orals departments along with ERP authorisations.
- ☆ Checking the overprinting matter of stereo's before ordering
- ☆ Final reconciliation & receipt of BMR's.
- ☆ Handling of complaints, reports and follow ups with vendors
- ☆ Interaction with R&D and QA-HO for queries related to the products.
- ☆ Online entry and Final Preparation of APQR.
- ☆ To raise the customer complaint whenever the complaints are reported from online jobs.

EXPOSURE TO SUCCESSFUL AUDITS OF:

- ☆ Active participation in the successful TGA-audit conducted at GELTEC Private Limited, on dated **08.10.2024 to 10.10.2024** without fail
- ☆ Successful exposure to audit of SOUTH AFRICA, NETHERLAND, KENYA and SFDA (SAUDHERLANI), IDA (NETD), UKRAINE, BOTSOWANA etc.

AREA OF EXPERIENCE

- ☆ Quality Assurance
- ☆ Drug Regulatory Affairs

RESEARCH PROFILE

Title: Synthesis of Tryptamine derived Schiff base Derivatives & Synthesis of Indole-3-Butyric acid-Hydrazine derived 1,3,4-Oxadiazole derivatives.

Under Supervision: Dr. M.B.Sridhara (M.Sc. M Phil, PhD).

Co-Supervision: Prof .Basavaraj Padmashail (M.sc, PhD.).

Session: M.Sc 3rd & 4th Semester 2019-2020.

University: Rani Channamma University Belagavi,591156,Karnataka

ACADEMIC PROFILE:

- ☆ **Master of science in Chemistry(General Chemistry)**, Rani Channamma institute,Belagavi.591156, Karnataka, Passed out in the year 2020
- ☆ **Bachelors of Science (PCM)** , Basaveshwara Science Collage, Bagalkot, under Rani Channamma University Belagavi Karnataka, Passed out in the year 2017

IT SKILLS

- ☆ Conversant with MS Office Application (Word, Excel and PowerPoint),
- ☆ ERP BASE-9.
- ☆ E-Sugam Portal (CDSCO)
- ☆ E-Sugam Portal by State Karnataka.
- ☆ NSW Portal(CDSCO)
- ☆ Online submission of Quarterly returns of Narcotic Substances to NCB, Bangalore.
- ☆ Export Inspection Agency Portal for filing the on application for Health Certificates for both EU & Non-EU countries.

POSITIVE ASPECTS:

- ☆ Equally effective in working independently and collaboratively in team effort.
- ☆ Enthusiastic
- ☆ Team Leadership
- ☆ Ability to establish strong rapport with teams, and management with a down to earth approach, can judge and adjust quickly to dynamic conditions

PERSONAL DOSSIER

- ☆ Date of Birth- 12th MARCH
- ☆ Marital Status- Single
- ☆ Nationality – Indian
- ☆ Languages- Kanada, English, Hindi
- ☆ Hobbies -Reading Books, Playing cricket, Gym

DECLARATION:

I do hereby declare that the information produced above is true to best of my knowledge, I promise to be a professional seeking every opportunity to learn new things from every day experiences.

Place: Bangalore

Date:

(Manjunath.Naragund)