CURRICULAM VITAE

From:

HYMAVATHI KOMMI,
KAKATHIYA HILLS, PRAGATHI NAGAR,
HYDERABAD-500090.
Mobile No.: **+91 9550420865**
Email address: **hyma.chemist6@gmail.com**

Dear Sir,

Sub: Application for the post of Suitable position in QUALITY ASSURANCE & REGULATORY AFFAIRS.

I have been working in Quality Assurance for Ten years and Two years in Quality Assurance & Regulatory Affairs, definitely I would handle QUALITY ASSURANCE & Regulatory Affairs activities. I understood the functions and role of Quality Assurance & Regulatory Affairs which is end to end responsibility, Co-ordination among various functions have done on routine basis.

CAREER OBJECTIVE :

To achieve a Top position in Pharmaceutical industry, where I can initiate my skills and abilities to improve the Quality systems and strength of Pharmaceutical Organization.

ORGANIZATIONAL EXPERIENCE :

Total experience : 12 YEARS

- **From Sep 2021 to Till date :**
  - I am working as " Deputy Manager" in Quality Assurance & Regulatory Affairs Department in **ZAINT HEALTH CARE PHARMA PRIVATE LIMITED** (Formulation Unit).
- **From May 2018 to Aug 2021 :**
  - I Worked as "Deputy Manager" in Quality Assurance Department in **Del Excel PHARMA PRIVATE LIMITED.** (Formulation Unit).
- **From Jun 2016 to Apr 2018 :**
  - I Worked as "Executive" in Quality Assurance Department in **HONOUR LAB LIMITED.,** (Hetero Group, API Unit).
- **From Dec-2015 to May-2016 :**
  - I worked as "Team Leader" in Quality Assurance Department in **SIFLON DRUGS & PHARMACEUTICALS PVT. LTD.,** (Formulation Unit).
- **From July-2010 to Oct-2015 :**
  - I worked as an **Executive – L2** in **Quality Assurance** department in **GLOCHEM INDUSTRIES LIMITED** (API Unit: It has **USFDA, KFDA, TGA**, **EDQM, WHO GMP, NMA, GHA** certified Organization) for **five years three months.**

INDUSTRIAL TRAINING EXPERIENCE :

Duration : 2 months (Apr 2010 to May 2010)

- **Industial training at NATCO REASEARCH CENTER (Sanathnagar, Hyderabad). And METROCHEM (Jeedimetla, Hyderabad)**
- **Pharmaceutical Industrial oriented course in HYTECH INSTITUTE OF ADVANCED PHARMACEUTICAL SCIENCES at Natco House, road no-2, Banjarahils, Hyderabad-500033.**

CERTIFICATIONS :

- Certified **TRAINER**
- Certification Course in **REGULATORY AFFAIRS**
- Certified **NLP BASIC PRACTITIONER**

AUDITS FACED :

- **USFDA, KFDA, TGA, EDQM, WHO GMP, NMA & GHA.**
- Good exposure in customer audits like **Aceto Pharma, Adcock, Apotex, Aurobindo, Biopharma, Cadila, Cipla, Dr.Reddys, Intas, Ipca, Lupin, Micro Labs, Mohes, MSN Laboratories, Nippon Boehringer, Novarties, Pol pharma, Teva Torrent,** etc along with the department head.

AREAS OF EXPERTISE:

- Vendor Qualification
- Expert in documents Review
- Quality Management System like..
- Change Management
- Deviations
- Complaints
- OOS, OOT
- Investigations for Evaluate Root cause

- Risk Assessment
- Validations
- Equipment/System Qualifications

KNOWLEDGE IN REGULATORY AFFAIRS :

- Monitor and set timelines for licence variations and renewal approvals
- Undertake and manage regulatory inspections
- Maintain up-to-date knowledge on international and domestic regulatory requirements
- Ensures compliance with local regulatory requirements
- Knowledge on CTD, e-CTD Format & modules.
- Dossier submission of ROW, EU & US Markets.
- Compilation and review the Product dossiers for submission in CTD, ACTD.
- Knowledge on Regulatory guideline for finished product registrations.

ROLE IN THE ORGANIZATION :

- Ensuring that 'Quality system' is implemented and maintained throughout the organization.
- Implement a document system to develop, maintain, distribution and controlling for proper archiving and retrieval of all documents.
- Making sure that internal audits (self-inspections) are performed and necessary correction, corrective and preventive actions are taken.
- Train the employees by providing training for them in quality systems and procedures.
- Handling of Quality Management System such as Change controls, deviations, complaints, OOS, CAPA
- Approving the all changes in facility, procedures and potentially impact on drug product quality.
- Making sure that Critical deviations & Out Of Specifications (OOS) are investigated.
- Co-ordinate with all the departments while investigating the process related deviations Market Complaints and OOS and Investigate the reasons for the non-conformances and provide the effective corrective and preventive actions in order to prevent reoccurrence.
- Monitoring, Reviewing and approving the qualification (IQ,OQ/PQ) documents related to Equipment/ Instrument & System.

- Prepare & Update the site master file current details as per SOP.
- Preparation of Validation master plan and Reviewing and approving validation procedures.
- Ensuring preparation, Review and approval of Standard Operating Procedures, Trial batch reports, Process Validation Protocols, Process Validation Reports and Co-ordinate in carrying out the validation studies.
- Ensuring the destruction of obsolete documents as per the respective procedure.
- Prepare / review of Annual Product Review. Make sure trends of different stages of product yield and quality, water system, key raw material quality and address OOTs.
- Review and Approve the Master documents such as Master formula Records, Batch Manufacturing Records before execution.
- Make sure Review of Executed Batch Production documents and laboratory control records of critical in-process steps, Certificate Of Analysis, and Product deviations for compliance before releasing the finished product for distribution.
- Monitoring vendor approval process for Raw and Packing materials.
- Qualifying the alternative vendors/New vendors and requalifying the existing vendors
- Co-ordinate with all the departments.

PREVIOUS JOB RESPONSIBILITIES :

- Qualifying the alternative vendors/New vendors and requalifying the existing vendors.
- Preparation and review of Process Validation protocols and reports.
- Preparation and planning of training matrix and **training programs** related to **GMP,** ongoing, job oriented. Completing the training evaluations by questionnaires, re-training the required etc.
- Review and Preparation of **Annual Product Reports** like updating the trends, change controls and deviations
- Filling the **Vendor Questionnaires** for Vendor audit purpose.
- Logging of change requests as soon as received from the user departments and reviewing the **CCF's** preliminarily and deciding further course of actions as per the **CCF** format, tracking the **CCF's** and ensuring proper closure of change requests post change implementation.
- Preparation of labels in line with the transfer note with production label requisition and ensuring BPR review, QC protocols before dispatching the product labels on containers.
- Review of Batch Production Records.

- Logging the **deviations** and coordinating with the cross functional teams for investigation. Tracking and ensuring proper closure of deviations after taking necessary **CAPA**.
- Conducting of internal audits at stores, production, QC, issuing the observation forms to the concerned department in-charges and follow up the same till closing.
- Handling of customer complaints.
- Handling of Out Of Specification.
- Preparation, Distribution and Retrieval of Standard operating Procedures **(SOP)**

ACHIEVMENTS:

- Actively contributed following regulatory agency audits viz.,
    - **USFDA** (13.04.2015 to 17.04.2015)
    - **KFDA** (28.03.2011 & 29.03.2011)
    - **TGA** (28.05.2012 to 31.05.2012)
    - **EDQM** (05.02.2010 to 08.02.2010)
    - **WHO GMP** (25.09.2014 to 26.09.2014)
    - **NMA** (11.10.2011 to 12.10.2011)
    - **GHA** (07.04.2014 to 11.04.2014)
- Achieved success on decreasing the documentation errors by giving the continuous training programme.

COMPUTER SKILLS:

- M.S. Office, Canva.

KEY SKILLS:

- Problem Solving Skills
- Team Work
- Creativity
- Flexibility

ACADEMIC QUALIFICATION:

- **Certification Course in Regulatory Affairs , Feb to Apr 2023 from SG Pharma.**
- **Post Graduation :**
  - Master of Science in Organic Chemistry, 2009 from Sri Gowri P.G College, Visakhapatnam, (Affliated to Andhra University, Visakhapatnam).
- **Graduation :**
  - Bachelor of Science (B.Sc), 2006 from Jawahar Bharathi Degree & P.G.college, Kavali (Affliated to Sri Venkateswara University, Tirupathi).
  - Subjects: Biotechnology, Zoology, Chemistry.
- **Intermediate :**
  - Intermediate (Bi.P.C), 2003 from Govt. Junior college, Kondapuram (NELLORE District), under the Board of Intermediate Education.
- **SSC (10th Standard) :**
  - **S.S.C** from Z.P High School, 2001,Saipeta, NELLORE (District),Under Board of secondary Education.

PERSONAL INFORMATION :

Name of the applicant	:	Hymavathi.Kommi
Date of birth	:	16th Apr 1985
Gender	:	Female
Marital status	:	Married
Husband Name	:	Mahesh.A
Nationality	:	Indian.
Languages known	:	English, Telugu.
E-Mail Address	:	hyma.chemist6@gmail.com
Present Address	:	Plot.No. 2&3, Incois Road, Kakathiya Hills, Pragathi Nagar, Hyderabad.

Declaration:

With reference to the above, I would like to offer myself as a candidate to serve in your esteemed organization.

I request you to kindly consider my application favorable and provide an opportunity in your esteemed concern.

I hope you will be kind enough to do the needful and I am expecting your favorable reply.

I hereby declare that the information given above is true to the best of my knowledge and faith.

Yours obediently,

(HYMAVATHI KOMMI)