

COVERING LETTER

To
The Head (HR),

Dear sir/Madam,

I (Manjeera Polamreddy) completed Master of Technology in Industrial Biotechnology from Bharath University, Chennai. In my recent position as a Senior executive in PAR Active Technologies, Chennai and had work experience in the area of Audits & Compliance, Regulatory supporting, Documents Management & Archival system Maintenance and Quality Management System like Change control, Deviations, CAPA, Market/Customer Complaints, Recall Procedure.

I possess excellent technical skills, Interpersonal and organizational skills with vast experience in API exploration and also worked in Formulations Unit (OSD).

My attention to detail and excellent problem-solving skills ensure that every project. I work on is done accurately and to the highest possible standard. My verbal communication skills, hard work and positive attitude make me an effective communicator with all my loyal customers.

I look forward to the opportunity of discussing my application with you further and how I can significantly contribute to the ongoing success of your reputable company.

Thanking you sir.

Yours obediently,

Manjeera Polamreddy



CURRICULAM VITAE

PERSONAL PROFILE:

Name: Manjeera Polamreddy

Gender : Female

Date of Birth: 14.10.1986

Marital Status: Married

CONTACT INFORMATION:

Mobile : 9985134934

E-Mail:

manjeerareddy@gmail.com

EXPERIENCE:

Total of 10 years experience

PRESENT ADDRESS:

F-BLOCK 8A, ALTA VIDA
Aparments, 46 Rajiv Gandhi
Salai, Old Mamallapuram Road,
Kelambakkam, Chennai -
603103, TN

PERMANENT ADDRESS:

26-II,3309-2, Near LLF School
Opp.Vinayakaswami Temple
Vedayapalem, Nellore-524004

TECHNICAL SKILLS:

Software systems:
Trackwise, LIMS, SAP, SAP SF
vLMS, DMS, Veeva Vault & DOC-
PRO

CAREER OBJECTIVE:

To build a career as a valuable team member, contributing quality ideas and work using my educational & work experience, at your service to achieve organization goal.

PERSONNAL SKILLS :

- Good oral communication and report writing skills
- Strong presentation skills
- Active and take own responsibilities.
- Meeting committed timelines.

JOB PROFILE:

Working with PAR Active Technologies Pvt. Ltd., API Division, Alathur in Quality Assurance Department as Sr.Executive.

CURRENT ROLES/RESPONSIBILITIES:

- Oversee change control, deviations, CAPA , customer compliants in Trackwise software
- Perform impact assessment for change controls and complete the activity as per action items
- Preparation and review of Investigation reports and other supporting documents for QMS and to track the implementation of CAPA actions
- Preparation of CAPA effectiveness monitoring once in three months
- Preparation and review of QMS Trending and its summary reports.Prepare and review of Annual Product Quality review reports withing the defined time frame.
- Preparation, review and approval of Standard Operating procedures
- To prepare the audit plan and organize internal Audits as per schedule and to ensure the timely closure of the audit observations.As a Learning Management System Admin and Department Training Coordinator in assigning and handling of applicable department trainings and ensuring GxP activity performed before the training prerequisite.
- Coordinate the Issuance of Controlled documents, retrieval, archival of documents through Doc-pro software and maintain a organized document storage system.
- To conduct and coordinate cGMP trainings, quality system oriented trainings through scheduled Periodic trainings and to ensure the



PACKAGES : MS-Office

Languages Known to speak and write:

Speak: English, Hindi, Telugu, Tamil

Write & Read: English, Hindi & Telugu

tracking of attendance and completion of individual Training assignments with out overdues in Compliance wire learning module.

- To facilitate and ensure the walkthrough inspection is conducted as per schedule and routinely monitoring the area for GMP compliance
- To prepare the presentations for the monthly Quality review board meetings and ensure the completion of the action points
- Collection and compilation of report for QMS related data and presenting the data in weekly pentatonic.
- Preparation of presentation on signification investigations as a part of Employee awareness training.
- Evaluate the new supplier for the inclusion of new vendor othrough evaluation form and ensuring the vendor documents received for the Vendor approval status of each material. Monitoring of vendor performance on yearly basis.
- Participated in USFDA regulatory inspection and arrange necessary documents as needed on timely manner.
- Supporting to provide the required documents to Regulatory Affairs for DMF filings.

SPECIALIZED AREA:

- Handling of Training Management as a Site Training Coordinator
- Internal & External audits and its proper implementation and closure.
- Handling of change controls & providing support during the change control initiation and verification of changes for its proper action points implementation and timely closure.
- Filling of vendor questionnaires, customer satisfaction survey reports and submitting the customer required documents along with the filled VQ forms in timely manner
- Supporting for RA filling and Marketing mail communications to support required docs & info.
- Investigation report preparation using the investigation statistical tools to identify the route cause and proper implementation of CAPA action points.

ACHIEVEMENTS:

- Received Certificate of Appreciation on behalf of management (Alivira Animal Health Limited) for the efforts in the successful completion of New Product Diclazuril filing for US regulatory.



- Received Value Card for the immense support in collaborating and providing Diclazuril documents for DMF filing
- In the category of Rewards and Recognition received Best Employee of the Month in Processing Quality assurance Dept at Biocon Limited.
- Engaged in organizational culture development by providing a three numbers of good catches in a year at PAR Active Technologies.

OVER ALL WORK EXPERIENCE:

- Handling of Deviations & its proper implementation and closure.
- CAPA action points implementation and ensuring effectiveness monitoring.
- Preparation, review and handled Stability study related documents and reports.
- Coordinating internal and external audits and ensuring the relevant documents.
- Review and handling of Technical packages like Technology transfer Documents.
- Filling of vendor questionnaires, customer satisfaction survey reports and submitting the customer required documents along with the filled VQ forms in timely manner.
- Handling of Complaints & its proper implementation and closure.
- Handling of change controls & verification of changes for its proper action points implementation and timely closure.
- Controlling and Issuing of all documents to the user departments.
- Implementation and Maintenance of cGMP at all levels of Industry.
- Collection of addl. Documents and communicating with marketing department and upgradation to the customer.
- Handling of Trainings, Internal Audits & its proper implementation and its closure.
- Handling and Review of LDRs & LIRs
- Supporting for Filling USDMFs, PMDA Japan Accreditations, ASMF, CMCs and Vet. USDMfs

AUDITS FACED:

- Faced customer audits like Sanofi, Bayer, Merck Inc., Zydus Cadila, Bhoeringer, Cipla, Lupin, Teva etc.

REGULATORIES:

USFDA - USA; COFEPRIS - MEXICO; MFDS (KFDA)- KOREA; PMDA - JAPAN

ACADEMIC DETAILS:

- Master of Technology in Industrial Biotechnology from Bharath University, Chennai, TN
- Post Graduation in Biotechnology fromeriyar University, Salem,
- B.I.P.C in Ratnam Jr.College, Nellore, AP
- S.S.C in Sri Balaji Vidyalayam Eng. School, Nellore , AP



WORK HISTORY:

Total 10+ years of experience in Quality Assurance Functions.

- Sep 2023 to Present: Sr.Executive - QA at PAR active Technologies, Chennai, TN
- Mar 2023 to June 2023: Sr. Executive -Delta Biopharma Pvt.Ltd (A zifam Pinnacle Healthcare), Naidupeta, AP
- May 2021 to Feb 2023: Sr.Executive- Biocon Limited, Visakhapatnam, AP
- Dec 2020 to Mar 2021: Executive - Valary labs (Hetero Group), Visakhapatnam, AP
- Oct 2017 to Dec 2020: Executive - Alivira Animal Health Limited
- Oct 2012 to Dec 2015: Sr.Officer - Metrochem API Pvt. Ltd, Hyderabad, TS

DECLARATION

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

Yours obediently,

(Manjeera Polamreddy)

Place:

Date :

