DEEPTHI M P

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Project Management Leadership position

CAREER SYNOPSIS & SKILLSET

- Qualified, experienced, and result-driven Pharmaceutical Professional with rich cross-functional exposure of 13+Yrs in Project Management role, Business development, Analytical services, QA, RA, R&D, AR&D.
- Presently working as **Project Manager-Analytical Service Unit** with Recipharm Pharmaservices Pvt., Ltd., Bangalore.
- Acquired domain expertise in PM/BD in Analytical services for Drug product & Drug Substance throughout the Life cycle management**,** hands-on experience in Microsoft projects**, Gantt charts, expertise in Project Management tool-PPM- such as planning & forecasting, risk management, budgeting, tracking & monitoring, PM methodologies, Meeting facilitation, SME, Quality management, writing & reporting, research, scope management, leadership, communication, collaboration, time management, problem solving, adaptability, critical thinking, team building, & interpersonal skills, conflict resolution, delegation, decision making. Also skillful in other areas such as Regulatory filing support, Indian government liasoning for drug substances (DCGI), proficient in SAP, QMS, cGMP trainer on ICH guidelines and other regulatory guidelines, LIMS, Track wise.**
- **Trained & certified PMP from Simplilearn, Executive certificate program in Project Management from IIM Raipur, lean Six sigma certification course, ISO 9001:2015 (QMS) certification, certified GMP trainer, certified vendor auditor, certified train-the-trainer. Preparing for PMP exam with PMI during Aug 2023.**
- **Goal is to be an impactful Leader in Project Management and make a difference on triple bottom line of People, Planet & Profitability.**

CAREER OBJECTIVE

Seeking a leadership position in PMO in pharmaceutical company CRO/CDMO/CRDMO/Product development where I can utilize my strong leadership, Managerial and technical skills to make a significant contribution to company success and growth.

PROFESSIONAL EDUCATION

Siddaganga Institute of Technology, Karnataka: B.E Chemical Engineering
Grade: Distinction

IIM, Raipur: Executive certificate program in Project Management
Grade: Distinction

PMP exam with PMI: Registered & enrolled for Project Management Professional exam during Aug 2023.

REWARDS/RECOGNITIONS

- **Biocon Limited:** Received an award of **"Go-Getter PM**" during "International Project Management Day" during Dec 21.
- **Apotex Pharmachem India Pvt. Ltd.:** Awarded "**An individual contributor**" in successfully completing Stability chamber installation and qualification on time in Analytical lab along with CSV support to IT.
- **Jubilant Pharmova Limited:** Received an award **"Mission Directed team award"** in the year 2011 & 2013 and **8 individual spot-on awards.**

PROFESSIONAL EXPERIENCE

PRESENT PROFILE:
M/s Recipharm Pharmaservices Pvt., Ltd, Bangalore, Karnataka
Project Manager-Analytical Services Unit (Aug2022 to till present)

- Leading a Project management team of 5 personnel.

- A fully Integrated Project Manager for all projects of Analytical service unit.
- Sole responsibility in communicating with the existing customers on on-going projects & availing new projects.
- Responsible for MIS with business development and project management expertise in getting new business, initiating project, follow up with internal stakeholders on the milestone activities, intimating customers on the status of projects, kick off meetings, budgeting, financials, closure of projects for Analytical services, Stability programs, Nitrosamines testing, E&L, Elemental Impurities testing.
- Responsible in streamlining SAP process, financial process, import/test license trackers.
- Responsible for preparation of business proposals, check on market trends & competitors, preparing project costing structure, resource management, capabilities need, FTE model, drawing lead time for each project.

M/s Biocon Limited Ltd, Bangalore, Karnataka
Deputy Manager-PMO (Sep2018 – Aug2022)

- A fully Integrated Program Manager for Semisynthetic projects and Analytical lab for testing.
- Responsible for driving the projects from making the strategic plan based on the approved business case in coordination with the cross functional team.
- Responsible for projects which are vertically integrated beginning from drug substance development, drug substance manufacturing followed by DMF submission and product launch, end-to-end project management role.
- I coordinate and communicate with all the functional stakeholders and facilitate the decision making process to resolve the exigencies.
- Responsible for driving all API projects for Non-Carry Over (NCO) Studies & Nitrosamines evaluations at third party laboratories. The program which begins during the feasibility stage based on the approved business case in coordination with the cross functional team.
- Responsible for addressing regulatory & customer queries for all APIs from process & analytical teams perspective.
- Responsible for close monitoring on qualifications and validation activities for AR&D instruments such as HPLC, GC, GCMS, pH meter, Humidity chambers and all other instruments used for analysis of the raw materials, in process & finished drug substances.
- Responsible for Identifying third party lab, proposal review & negotiations, budget allocation, preparation of micro planner, status coordinating tracking and monitoring & controlling the progress and closure which includes report submission to the stakeholders followed by payments to the third party service providers.
- I co-ordinate & communicate in conducting technical discussion on weekly, fortnightly and monthly basis to drive the program and provide program status to the ELT members on weekly and monthly basis.
- Implemented set of comprehensive tracking process to monitor performance on daily basis.
- I am the one-point contact for all third-party manufacturing, testing and obtaining relevant reports.
- **As a program manager, my job role covers, all internal and external communications maintaining the risk register, categorization, mitigation plan and timely escalation.**
- I extensively involve in CapEx management for Small Molecules Vertical.
- I am proficient in SAP, Legal & Financial management such as MSA, CDA, SOW, Negotiations, PO, Invoice, payment closure with all third-party labs.

M/s Apotex Pharmachem India Pvt., Ltd, Bangalore, Karnataka
Assistant Manager (April 2016 – Jul 2018)

- I was responsible for Total Quality Management Systems at Analytical lab.
- I was responsible for all time readiness during any Regulatory/Customer audits in ensuring strict adherence of personnel to compliant to GMP activities throughout.
- I was responsible for Training and development at Analytical lab for all new joiners to be aware of the departmental SOPs, guidelines, work instructions and all relevant on-the-job activities. On-time updation of Training Master Application (TMA) for all the training sessions for the department personnel.
- I was responsible for close monitoring on qualifications and validation activities for Analytical lab instruments such as HPLC, GC, GCMS, pH meter, Humidity chambers and all other instruments used for analysis of the raw materials, in process & finished drug substances.
- Responsible for preparation of test protocols-CSVC validations for all the instruments connected to 21CFR compliant.
- Responsible to raise IS requests for all the Analytical lab personnel in different levels of authorizations.
- Responsible to identify suitable vendor for procurement of the desired instruments at AR&D followed by discussions and finalization of the vendor.
- Responsible to prepare and review CapEx for procurement of Analytical lab instruments.

- Issuance & monitoring of instruments breakdown forms and Lab investigation reports.
- Providing support to the team leaders in investigation findings for the instrument breakdowns and LIRs.
- Identifying and preparation of departmental SOPs as & when required and also during system improvement.
- Review & approval of CAPA relevant to investigations for QMS activities and periodic monitoring of effectiveness at Analytical lab.
- I was responsible for preparation and monitoring of PM schedules for all instruments at Analytical lab.

M/s Jubilant Pharmova Limited, Mysore, Karnataka
Assistant Manager (April 2010 –April 2016)

- **LMS:** I was majorly responsible for GMP trainings across the site. Role involved such as develop, Train, qualify and motivate all employees on cGMP, SOPs, corporate policies and regulatory guidelines to ensure all personnel are properly trained and qualified to execute their duties.
- Preparation of Annual cGMP training schedule for the entire site, periodic refresher trainings and ensure compliance and an expertise in QA LMS. Coordinating the internal / external training programs.

  - ***Identified, trained & certified a pool of 25 experts from different departments as Qualified Trainers for conducting in-house trainings, Qualified Auditors for internal audits and certified investigators, reviewers and approvers for carrying out investigations against failures.***

- **QMS:** Sound exposure in handling change control, deviation, out of trend and out of specification, root cause identification, CAPA implementation & monitoring its long-term effectiveness.
- **Regulatory exposure:** Single point of contact for Indian FDA (State Govt. & CDSCO) in obtaining product licenses for all site products. Role included preparation of the license document, filing, following up for obtaining manufacturing licenses. Supported RA with provision of required documents for DMF submissions.
- I was responsible to obtain No Objection Certificate (NOC), Manufacturing Licenses, product permission letters, Certificate of Pharmaceutical Product (COPP), Written Confirmation (WC), Free Sale Certificates (FSC), Certified Technical Staff approval (CTS) & other certifications for all existing products as well as new products from local & central Government Drugs Control Authorities.
- **Validation and Engineering Assurance:** Sound knowledge & exposure in close monitoring on qualifications and validation activities and subsequent continued verifications. Ensure quality and compliance review process is in place and adhered for qualification activities.
- Review & approval of as-built drawings of facilities, utilities, HVAC system; SOPs , change control and other GxP relevant documents related to engineering and projects. Update water manual / site master files of all the blocks. Facilitate training on engineering procedures.

  - ***Sound Knowledge of validation concepts - URS/DQ/IQ/OQ/PQ of equipment, HVAC, utilities and other ancillary systems***
  - ***Basic knowledge of equipment construction, building management system, working principles and maintenance requirements***
  - ***Understanding of drawings and layouts of manufacturing area, air flow, material flow and personal flow***

CONTRIBUTION IN KEY AUDITS

- ***Played cardinal role during various regulatory inspections like USFDA, MHRA, WHO, Novartis Global audit and other regulatory and customer inspections.***

US – FDA (USA), TGA (Australia), PMDA (Japan), COFEPRIS (Mexico), ANVISA (Brazil), ANSM (France), DCG(I), (India) (Both State Govt. & Central Govt.), ISO 9001:2008, Various customer audits viz. Pfizer, Teva, Apotex, AstraZeneca, Sanofi, Strides, Ranbaxy, Mylan, Micro labs, Intas Pharma, Pharma science to name a few.

PERSONAL INFORMATION

D.O.B.	- October 06, 1981
Gender	- Female
Marital Status	- Married
Children	- Daughters (2)
Hobbies	- Playing Carnatic instrument Veena (secured 91% in Karnataka Junior exam), cooking, reading books, teaching and mentoring children,
	Social service: Entail taking care of bereaved children and elderly people.

Co-Curricular Activity

- Anchor/MC for family day event and 'International Jubilant Meet' at Jubilant Generics Limited during 2013 & 14.
- Anchor/MC for New Year event at Apotex Pharmachem Pvt Ltd 2017.
- Won Second Place in Technical Paper Presentation at "Technoscope"-College fest, at SDM College of Engineering, Dharwad.
- Students' Convenor of the technical Committee for "ChESS"-Chemical Engineering Students Seminar-Departmental Technical Sympisium at Siddaganga Institute of Technology, Tumkur from 2001 to 2003.
- Anchor/MC for the cultural fest at Siddaganga Institute of Technology, Tumkur during 2003-04.
- Secured State Level 3rd Rank in "Science Talent Examination" during SSLC.