ISHWAR CHANDRA PANDA PMP®
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BIOPHARMACEUTICAL AND PHARMACEUTICAL PROFESSIONAL(PROJECT / PROGRAM MANAGEMENT, GLOBAL PHARMACOVIGILANCE & R&D)

Summary

12 Years of experience in the field of Healthcare Industry (Biopharmaceutical and Pharmaceutical)

- **Ensures that budget have been developed to provide for quality management program through the life of project.**
- **Dossier submission, Response to regulatory queries and DMF Filing.**
- **Pharmacopeia and QSAR Evaluation**.
- **Analyze CEP Filing status in agency database for mapping competitors landscape based on patent expiry.**
- **Evaluate agency warning letter to optimize strict adherence to regulatory compliance at our site.**
  Day to day communication, co-ordination and management of client's project team.
- **Co-ordination and assistance in development of schematic design development and construction documentation for all disciplines (including document review) and overall leadership quality control program (for project under their management).**
- **Financial budgeting, Capex and opex-expenditure, Stage gate meetings.**
- **Regulatory queries, Cost improvement programs.**
- **Monthly report, Weekly report preparation to track the smooth execution of ongoing projects completion with in timeframe.**
- **NPD, CIP, KSM & AVD program Initiation.**
- **Timesheet management, project costing and business support Estimation.**
- **Method Validation & Development**
- **Analysis of Injectable Drugs, API Molecules, recombinant proteins and monoclonal antibody**
- **Process characterization of Biosimilar, Biomolecules, peptides, API & Monoclonal antibody with advanced analytical instruments**.
- **Stability Indicating study of different projects.**
- **Process Development, Scale Up and media optimization.**
- **SAS Programming**
- **Clinical data Management certification by IOCB**
- **PMP Certification course and agile practitioner on-going under PMI sponsored by Simplilearn. (Successfully completed course of Project Management Professional by Simplilearn on 21st October 2021.)**

Objective

Intend to build a career with committed & dedicated people, which will help me to explore myself fully and realize my potential. Willing to work as a key player in challenging & creative environment

Professional Experience

April 2023 to till date
Organization: Sun Pharma. (Gurgaon - NCR)
Designation: Project Manager (Project Management and Regulatory Affairs)
Reporting To: PMO Head (SGM)
Key responsibilities: PMO, Regulatory Affairs & Global pharmacovigilance – Individual contributor

- Part of global program management team of Sun Pharma.
- Project management of formulation and API development at India R&D Centre for global markets (US, Europe, Japan, Brazil, Myanmar, Philippines, South Africa, Canada etc.
- Co-ordination with manufacturing site in India and other countries.
- Single point of contact for co-ordination with global portfolio team, marketing team, IP team & RA.
- Cross functional co-ordination at global level.
- Managing formulation development and manufacturing projects.

- Evaluation of the project to access the criticality and commercial feasibility.
- Replying to customers RFQ, RFP and preparing proposals.
- Co-coordinating with R&D, purchase, regulatory, plant and other internal and external stakeholders to make sure that projects move as per the committed timelines.
- Support customer with quick responses and timely updation of project status.

June 2021 to March 2023
Organization: Jubilant Pharmova Limited. (Noida- NCR)
Designation: Deputy Manager (Project Management and Scientific Affairs)
Reporting To: Vice President (R&D Centre API-Noida)
Key responsibilities: Business, Financial Budgeting, Customer queries – Individual contributor

- To coordinate with internal & external teams to complete the response for regulatory requirements of different agencies/markets (US, FDA, EU countries, Japan, China, Brazil, South Africa and ROW within the committed timeframe.
- Pharmacopeia Evaluation and QSAR study of API.
- Response to regulatory queries received by agencies.
- Regular monitoring of CEP application filing status of our competitors to map our landscape projection based on their products patent expiry and withdrawal in different agency database.
- Active participation in the meetings like AVD, NPD and other CFTs to be in line with the ongoing activities and requirements of the manufacturing site.
- Co-coordinating with CFT members for timely execution of NPD/CIP/KSM projects.
- Monthly report circulation and collecting information for meetings and reviews.
- Maintain timesheet & capital expenditure for API R &D Noida and Nanjangud plant site to extend support for financial budgeting.
- DMF / CEP filling for 4-6 projects to initiate the studies, their timely completion and active coordination with regulatory & other cross functional teams to complete the task within timelines.
- Timely review and release of technical packages of NPD, KSM and CIP.
- To update the project quality profile along with the trend data.
- To monitor the activities release to regulatory audits (FDA/health Canada TGA/DGCI etc.) with CFTs and support/closure of CAPA and to ensure the quality/regulatory compliance in R&D-1.
- Develop alternate vendor development programs by coordinating with all the CFTs and organize weekly review meetings.
- Conducting meeting related to operability review and stage gate.
- Maintain and circulate PMO Dashboard for API & formulation on monthly basis.

July 2020 to July 2021
Organization: Immacule Life Science Private Limited. (Himachal Pradesh)
Designation: Project Manager
Reporting To: Managing Director
Key responsibilities: Lead multiple project teams as Project manager.

- Manages customer project delivery.
- Planning, development and updating of overall project schedule.
- Project program development and documentation.
- Oversee financial aspects of the project contract by reviewing monthly invoices to ensure accuracy and compliance with contract provisions. Responsible for monitoring monthly cost using contract budget monitor, tracking contract expenditures against budget and total obligated funds.
- Preparing project presentation and lead in client presentations.
- Fosters and maintain a collaborative professional working relationship with the project leadership team.
- Manages project financials including purchase and procurement.
- Recommends changes to policies and establishes procedures that effect immediate organization.
- Understand quantity updating and work with superintendents to maintain accurate labor forecasts.

January 2018 to October 2020
Organization: Alembic Pharmaceutical Limited. (Gujarat)

Designation: Senior Research Scientist
Reporting To: Group Leader
Key responsibilities: Mainly dealing with Injectable Formulated Drugs.

- Method development of Assay content, Impurity Profiling and separation by reverse phase chromatography (HPLC Software: Chemstation-Agilent, Empower-Waters, chromeleon-Dionex& LC Solution-Shimadzu [HPLC Detectors-PDA, DAD, and VWD, ELSD] GC Software: Agilent- Detector-FID).
- Method development for Cation and Anion content in formulated drugs by Ion chromatography.
- Method optimization for Solvent content by Gas Chromatography.
- Carry out Admixture & Infusion Study as per project Requirement.
- Carry out Hold time study to analyze the Impurity Content and Stability of formulated drugs.
- Pre method Validation of different Drugs as per requirement.
- Carry out Cleaning Validation according to the necessity of the Project.
- Forced Degradation Study of Different Drugs as per requirement.

January 2016 to January 2018
Organization: Aurobindo Biologics. (Hyderabad)
Designation: Research Associate – III
Reporting To: Team Leader
Key responsibilities: Mainly dealing with monoclonal antibody (Therapeutic proteins).

- Method development for monoclonal antibody by reverse phase chromatography. (HPLC Software: Chemstation-Agilent, Empower-Waters, chromeleon-Dionex& LC Solution-Shimadzu [HPLC Detectors-PDA, DAD, and VWD, ELSD] GC Software: Agilent- Detector-FID).
- Method development for charge variants present in monoclonal antibody by IEX chromatography.
- Method optimization for different projects by SEC chromatography.
- Method development for methionine oxidation, stability test of different parameters and enzymatic degradation by protein A and peptide mapping.
- Carryout real time and accelerated time stability stress study of different projects.
- Optimization of protein analysis by SDS GEL electrophoresis and Iso electric gel focusing.
- To search and browse scientific journals, articles and literature for method development.
- Operation of all advance analytical instrument like surface plasma resonance, PCR, Capillary electrophoresis, Maurice SDS &Iso electrofocussing, MALS, FTIR.
- To develop analytical methods/assays as per the need of upcoming projects.
- To train juniors on instrument operation/calibration and execution of method assays, akta pilot, akta prime, TFF.
- To execute ERP related activities based on the requirements by coordinating with team members.
- To take up any other activity assigned based on the need and team's requirement.

May 2013 to January 2016
Organization: BIOCON Ltd. (Bangalore)
Designation: Scientist
Reporting To : Senior Scientist
Key responsibilities: Mainly dealing with Immunosuppressant drugs proteins, peptides and Enzymes.

- Method validation & Method development experiments for Impurity analysis (HPLC), Assay determination (By HPLC).
- Analysis of Development and Scale Up batches for in process, finished product and Stability stages.
- Preparation of COA, Stability schedule.
- Preparation of Standard Testing Procedures & Analytical Data Sheet for Development Projects (API & Formulation).
- Analysis of Innovator samples and formulation trial samples.
- Process Optimization by Fermentation and Technology Transfer.
- Maintenance and calibration of instruments.
- Preparation and maintenance of Working Standard.
- Protocol preparation and execution of analytical method validations. Carrying assay, dissolution, related substances and cleaning method validations of various dosage forms by HPLC and U.V. Spectrophotometer for regulated markets

- Preparation of Method Validation protocol, Method Validation Report, Analytical Method Transfer Protocol, Analytical Method Transfer Report.
- Responsible for Literature Search for projects, data management in the stages of pre formulation study, In-process study, Finish Product Study, Stability Study.
- Preparation of development STP before validation and final STP after Validation.
- Preparation of Standard Operating Procedures & Analytical Guidelines.
- Review of client's Testing Methods and to list out the method queries, analytical requirements, compilation of report to dispatch it to client.
- To follow and ensure the implementation of approved departmental SOP's and GLP.

October 2012 to April 2013
Organization: BIOCON Ltd. (Bangalore)
Designation: Research Trainee (Selected from Govt. Entrance Examination – Biotechnology Consortium India Limited-BCIL)
Key responsibilities

- Analytical Analysis of various in process fermentation Bio Molecules.
- Working on RP & NP in HPLC (High Performance Liquid Chromatography), Size Exclusion Chromatography, Scalar Techniques (continuous flow test analyzer) and GC Analysis (Gas Chromatography)
- Sample Preparation, Method Validation, System Calibration, Method Development in HPLC and GC.
- Troubleshooting of instrument and procedures and the unit operations as reactions, purification, distillation, crystallization, separation, and drying.

Educational Qualification

- Master in Science (Specialization in Biotechnology) from AMC College (Bangalore University) completed in 2012.
- Bachelor in Science (Specialization in Biotechnology) from M S Ramaiah College (Bangalore University) completed in 2009.
- 12th science from Kendriya Vidyalaya Berhampur, Orissa (All India Secondary School Examination, New Delhi) completed in 2005.
- 10th from Kendriya Vidyalaya Berhampur, Orissa (All India Secondary School Examination New Delhi) completed in 2003.

IT Skills

- Statistical packages: C programming, MS-DOS, SAS/BASE.
- Clinical Data Management Certification by IOCB.
- SAP for approval of Purchase requisition, purchase order & Service entry sheet.
- Derek and Sarah software for genotoxicity study.
- Chem. draw to evaluate complete structure analysis of APIs.
- Nexus software to analyze toxicity impact of APIs.
- Bioinformatics tools (NCBI, BLAST, FASTA, ORF)

- ProtParam tool- Expasy & Codon optimization tool.

Instruments Handled:

- HPLC (Reverse & Normal Phase, SEC, GPC, Ion-exchange Chromatography)
- Gas chromatography & Dissolution Tester – USP Type-I,II,III & Type-IV
- HPLC with software of Empower (Waters), Chromeleon (Dionex), Chemstation (Agilent), Open Lab (Agilent), Lab Solution (Shimadzu).
- Continuous Flow Analyzer (Scalar).
- Karl Fischer Apparatus& Coulometer.
- UV Spectrophotometer, PCR, Downstream Filtration Apparatus.
- FTIR, SOR, ELISA plate reader, Surface plasmon resonance & gene cloning technique.

- Lyophilization& Crystallization Apparatus, Haemocytometer, Nanodrop.
- Rheometer, Osmometer, Zeta potential, Densitometer & Mastersizer (PSD).

Awards and Achievements

- Participated in All India General Knowledge Test on Nov 30, 2000 (a wing of USO) and secured first position.
- Participated in All India General Knowledge Test on Nov 30, 1999(a wing of USO) and secured first position.
- Participated in General Knowledge and Intelligence test on 7th Sept, 2000 and secured second position.
- Participated in All India UN Information Test conducted by the Council for UN Information (a wing of USO) on 31st Aug, 1999 and secured second position.
- Participated in The GREEN Olympiad sponsored by the Ministry of Environment and Forest Government of India in the year 2001 & 2002.

Extra Curricular Activities

- Participated in Regional Games and Sports Meet at KendriyaVidyalayaSanghathan, Bhubaneswar region and won first position in kho – kho.
- Participated in Regional Games and Sports Meet at KendriyaVidyalayaSanghathan, Bhubaneswar region and won first position in kabbadi.
- Won Certificate of appreciation in All India Camel Color contest in the year 2001.
- Participated in Volleyball and Basketball Game at Regional Level Meet in KendriyaVidyalayaSanghathan.

Seminar and Project

- Attended National Conference on Genomics Proteomics & System Biology in J.N.TATA Auditorium, Indian institute of Science Campus, Bangalore.
- Won first prize in Working Model of Fermentation Technology at M S Ramaiah College.
- Attended Biosientech-2011, National conference on Frontier of Biotechnology in Pharmaceutical Industries.
- Attended National Conference on Chemistry, Biotechnology & Health care – AN INTERFACE on 25th Nov 2011.

List of Drugs Handled

In Biocon: Insulin, Lispro, Aspart, Pravastatin, Lipstatin, Tacrolimus, Sirolimus, Micafungin, Daptomycin, Immunomycin, Erythromycin, Lovastatin, Glatimer acetate Trypsin & Carboxypeptidase.

In AurobindoBiologics: Bevacizumab, Ranibizumab, Cetuximab, Certolizumab, teriparatide and Trastuzumab.

In Alembic pharmaceutical: Ketorolac, Vancomycin, Epinephrine, Busulfan, Carmustine, Medroxy Progesterone, Amphotericin-B, Sumatriptan, Oxaliplatin.

In Immacule Life Science: Multiple pharmaceutical and biopharmaceutical drugs (with respect to ampoule and vial line), lyophilized products.

In Jubilant Generics / Jubilant Pharmova: Losartan k, Valsartan, Safinamide Mesylate, Saxagliptin free base, Vortioxetine HBr, Donepezil Hcl monohydrate, DMSA, Carbamazepine, Aprepitant, Olanzapine, Citalopram, Escitalopram oxalate, Oxcarbazepine, Tramadol free base, Lacosamide, Pinaverium bromide, Azithromycin dehydrate, Esclicarbazepine acetate, Pantoprazole Sodium, Azilsartan Medoximil potassium, Cyclobenzaprine Hcl.

Certification Course

- Successfully Completed Clinical Research and Data Base Management Certification Course at Centre for Distance Learning Institute of Computational Biology, Bangalore.

- Registered for PMP Certification & Agile Practitioner under PMI sponsored by Simplilearn.

Personal details

Name:	Ishwar Chandra Panda
Date of Birth:	6th June 1987
Passport:	Available on Request

PLACE:

DATE: **SIGNATURE**