

RESUME

PMP certified professional with 17 plus years' experience in life sciences industry in domains such as project and program management, consulting, operations, and quality assurance. Demonstrated success in structuring and leading complex assignments.

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1. Experience

Jul 2022 till date

Global Programs Group lead, Program Management, Intas Pharmaceuticals Ltd.

- Leading multiple early-stage & late-stage drug development programs (Portfolio budget: 200-300 million USD) for global development within defined scope, budget timelines and resources ensuring seamless transition from development to regulatory filing and commercial launch.
- Drive closure of unresolved decisions, issues and risks by bringing to relevant stakeholder's notice and close them before impacting program.
- Accountable for planning of outsourced services (including CDA, contracts, invoices, PO, export, import), procurement for assigned programs.
- Accountable for maintaining program specific risk register, decision register and plans preparation on ongoing basis.
- Alliance/Partner Management: Serve as company-connect for relevant meetings, communications to establish and maintain partner relationship for targeted business outcomes (including managing the contract specified obligations).
- Responsible for preparation and presentation of program updates to CxO and other key meetings.
- Accountable for annual budget process for the assigned programs. To be followed by regular tracking and reporting of program budgets against approved budget.
- Manage day-to-day execution of multiple programs by working directly with cross functional teams for program deliverables (R&D, device, regulatory, drug substance manufacturing, drug product manufacturing, quality, clinical, packaging, supply chain, commercial)

Jun 2019-Jun 2022

Global Programs Group Lead, Program Management, Biocon

Achievements: Established a new team, created governance and program plans for multiple assets under the newly carved out in-house portfolio vertical. Lead company's first in-house program for USFDA filing.

- Leading multiple early-stage/late-stage drug development programs (Portfolio budget: 200-300 million USD) for global development within defined scope, budget timelines and resources ensuring seamless transition from development to commercial.
- Take the oversight lead for outsourced services (SOW, contracts, PO etc.), program specific risk register, decision register and plans preparation, publishing and updating on ongoing basis.
- Drive closure of unresolved decisions, issues and risks by bringing to relevant stakeholder's notice and close them before impacting program.
- Work closely with cross functional teams to track deliverables and enable various stages of program.
- Manage day-to-day execution of multiple programs by working directly with cross functional teams for program deliverables (R&D, device, regulatory, drug substance manufacturing, drug product manufacturing, quality, clinical, packaging, supply chain, commercial)
- Alliance/Partner Management: Served as company-connect for one of the partnered programs for relevant meetings, communications to establish and maintain partner relationship for targeted business outcomes (including managing the contract specified obligations).
- Responsible for overall preparation and presentation for assigned assets for program management updates to senior management and other key meetings.
- Accountable for annual budget process (CAPEX and OPEX) for the respective programs. To be followed by regular tracking and reporting of program budgets against approved budget.
- Responsible for instituting & maintaining governance structure for new/assigned programs.

Nov 2014- Jun 2019:

Project Manager (Associate Director), Project Management, Dr. Reddy's Laboratories Ltd.

Achievements: Because of demonstrated success, given the responsibility to manage company's first biosimilar asset (program) targeted for developed market filing. Received appreciation from senior leadership for alliance management.

- Leading and managing a program within defined scope, timelines and budget for company's first biosimilar asset targeted for developed markets.
 - Develop overall project plan and budget in consultation with key stakeholders and manage/drive projects underneath the program.
 - Tracking and driving project/program milestones and deliverables, drive risk identification and mitigation for timely closure.
- Other responsibilities: Same as defined under previous role in the company.

Project Manager (Manager), Project Management, Dr. Reddy's Laboratories Ltd.

- Managing projects (within defined scope, timeline and budget) related to variation filing for commercialized biosimilar drugs targeted for emerging markets, novel biologic development as well as first time filing to developed markets.
- Prepare and publish project progress report to senior management on regular basis.
- Work collaboratively with project leader and senior management throughout project lifecycle to enable project delivery, risk and issue mitigation, decision making.
- Responsible for vendor scouting, selection and contracting, contribute to enhance project management systems.
- Responsible for alliance management with partner for co-development programs.
- Liaise effectively and drive integration of functional deliverables for the project from R&D, operations, clinical, regulatory, commercial, SCM for timely delivery.

Jan 2011-Sep 2014

Consultant (Senior Analyst-I), Prescient Healthcare Group

Achievements: Assigned responsibility to lead and manage consulting assignments in a client facing role. Received client accolade for high quality delivery and insights.

- Leading and managing multiple consulting projects (direct client facing) for top-20 pharmaceutical companies.
- Design and manage multi-functional analytic approaches to answering key business questions to support brand(s)/disease area(s) commercial strategy.
- Client & project management: Manage consulting assignment budget and resources, ensure continuous liaison with clients throughout the assignment and accountable for on-time delivery.
- Other responsibilities: Same as defined under earlier role in organization.

Consultant (Senior Analyst-II), Prescient Healthcare Group

Achievements: Awarded internal appreciation award for high quality contributions to consulting assignments.

- Generate high value analysis of therapeutic area and market through primary and secondary research, provide clients with insights for about-to-launch brands, in market and pipeline (including product profiling).
- Analyzing commercial and clinical strategy in various therapeutic areas to generate high value insights.
- Competitive intelligence: Pipeline analysis, competitors landscaping, analyzing brand, clinical, manufacturing and marketing strategy of client's competitors.
- Conference coverage: Attending key international conferences with the objectives of speaking to a wide range of delegates on predetermined topics and attending key symposia, presentations, posters and booths to generate high value insights for therapeutic area.

Oct 2009 – Jan 2011:

Quality Assurance Lead, Quality Assurance, CIPLA Biotec

Achievements: Establishment of QA department and team. Successful management of DCGI audit.

- Conduct internal audits, IPQA and trainings to raise competence & scientific knowledge on biosimilars related topics for QA/QC/production.
- Reviewing documents such as TT protocol & report, IQ/OQ/PQ protocol and reports, AMV protocols and reports, product and raw material specification.
- Prepare a list of non-compliance and develop timeline for CAPA to be completed by the appropriate function.
- Preparing and reviewing documents such as: VMP, site master file, BMR, SOP, validation protocols & reports, change controls, deviations, technical agreements, FMEA.

Sep 2005- Oct 2009:

Downstream Manufacturing Operations Lead, Serum Institute of India Ltd.

*Achievements: Part of team that did scale up and produced **low-cost Meningitis vaccine, MenAfrivac™**, with support from PATH.*

- Accountable for downstream operations of polysaccharide conjugate vaccines.
- Accountable for production planning and inventory management.
- Responsible for preparation and review of BMRs, SOPs, validation and qualification documents, product development report.
- Responsible for change control and deviation management, manage audit preparation for downstream operations.

2. Academic Qualifications and trainings

Degree/ Certification	Specialization	Educational Institute	Board/University	Class	Year
B.Pharm	Pharmacy	L.M College of Pharmacy	Gujarat University	First class	2003
M.Tech	Bioprocessing	Institute of Chemical Technology (Formerly UDCT)	University of Mumbai	First class	2005
PMP	Project management	PMI	PMI	N.A.	2013
NHMP	Leadership development	Dr. Reddy's Laboratories Ltd	N.A	N.A	2018

3. Publication

- Paper published on "A Modified Method of Estimation of Total Alkaloids from Rauvolfia serpentina by colorimetric method" in *Indian Drugs*, March 2006.

4. Extracurricular Activities -Achievements

- Stood third in state level essay writing competition organized by Space Application Center (division of ISRO).
- Volunteered as teacher for under-privileged children through Teach India program of Times of India group.

5. Skillsets

- Microsoft projects, procurement planning (including RMP, raw materials), contracts/agreement preparation, client/alliance management, cGMP, stakeholder management, communication management, budget preparation and management, risk management, understanding of licenses/permits required for product development, understanding of manufacturing operations and quality assurance, competitive intelligence, secondary and primary research (including drawing strategic insights from information)