Sanjay Sharma

Project Manager, Drug Development

Core Competencies

- Formulation Development
- Project Management
- Process Validation
- Regulatory Authoring
- CMO transfer
- Due Diligence
- CHADD technology

Professional Summary

Mr. Sharma serves as a senior Project Manager for DSI. With a technical background that includes formulation development knowledge of, liquids, topicals, gels, transdermal patches and aerosols.

As a Project Manager, Mr. Sharma supports a variety of client projects including, but not limited to, the management of regulatory submission milestones (Mod 2 and Mod 3), managing multi discipline teams in support of product transfer and production. Also included in this role are CMO searches on behalf of a client and various other CMC related activities. As a central point of contact, his ability to coordinate resources within a defines project scope and budget makes him invaluable to clients.

- Providing expertise on process scale-up and CMC documentation based on QbD approach.
- Develop engineering studies and process validation studies to improve process variability.
- Review FDA's 483 observations and develop an appropriate CMC response.
- Experienced in developing products based on Risk analysis using QbD approach.
- Expertise in due-diligence of products and organizations for in-licensing.

Mr. Sharma earned a master's degree in chemical engineering from the University of Utah and an MBA from Brigham Young University. He is a member of the American Association of Pharmaceutical Scientists. He has over twenty years of formulation experience at Watson Labs and Zar Pharmaceutical.

Education

M.S.	Chemical Engineering	University of Utah
M.B.A.	Business Administration	Brigham Young University
B.S.	Chemical Engineering	Osmania University

Professional Experience

DS InPharmatics, LLC

Consultant

- Leads multi-discipline CMC teams,
- Responsible for the management of a Client's project budget, forecasting, deadlines and milestones,
- Experienced in developing products based on Risk analysis using QbD approach,
- Drug product formulation of small molecule products,
- Facilitates and manages CMC gap assessment projects on behalf of the client
- Manages client authoring activities for Mod 2 (QOS) and Mod 3 Content

Hercon Pharma

Director Research and Development

- Led technology transfer of analytical methods and process for manufacturing of a generic product from an overseas organization,
- Developed process for CTM manufacturing and authored CMC sections for ANDA filing,
- Evaluated resource gaps in the R&D group, developed job requirements and hired resources to staff the organization,
- Determined analytical and process equipment needs. Purchased HPLC and Dissolution equipment and managed IQ/OQ/PQ of equipment prior to use,
- Redesigned manufacturing and scale-up facility added security to building and process areas for handling of schedule II drug and drug products,
- Directed meetings with project teams to accomplish analytical and process transfer including manufacturing of product for clinical studies and registration batches,
- Created project plans, monitored progress, cost and timelines.

ZARS Pharma

Associate Director Technical Operations

- Responsible for technology transfer of manufacturing commercial product to a new contract manufacturing organization. In addition, streamlined the analytical methods for raw material testing and product release for both European and the US regulatory filing.
- Used design of experiments to optimize process for CMC section of NDA filing.
- Suggested and implemented a short-term strategy and a long-term strategy to eliminate defect rate for commercial product.
- Proposed and led a strategy to reduce COGS of commercial product by 42%. Estimated cost was > $8 million with ROI < 2 years.
- Designed and managed experiments to investigate OOS and OOT. Performed root cause analysis and collaborated with the quality group to develop corrective and preventive action plan.
- Wrote and reviewed CMC sections for pre-investigational new drug (pre-IND), IND, and end of phase 2 briefing and registration documents, various amendments to INDs, and annual updates.
- Developed novel transdermal and topical formulations in pain, dermatology, and for other indications.

- Led inter-disciplinary team of QA, Manufacturing, and Research in solving stability issues with late stage product.
- Contributed to 2 pre-IND meetings, one EOP 2 meeting and one pre-phase 2 meeting with the FDA.
- Selected and worked with consultants/thought leaders on trouble-shooting project development activities.
- Led technical efforts on one commercial product, one late stage clinical project and 3 early stage clinical projects.
- Managed an operational budget of over $2 Million and a capital budget of $1.5 Million.
- Worked closely with Regulatory, Internal and External QC, Sales and Marketing, and Senior Management to develop project plans and ensure successful completion of projects.
- Oversaw forecasting, budgeting, hiring, and training for the technical operations group and supervised activities of Engineers and Scientists.
- Participated and contributed in annual strategy meetings with senior management to develop organizational goals, strategy and vision.
- Developed deliverables for projects, determined critical paths, prepared development reports, and recommended strategies for steering projects.

Watson Pharmaceuticals

Manager, Research and Development

- Authored technical reports, product development reports and technology transfer reports for scale-up to operations.
- Developed and transferred two (2) novel gel formulations and one (1) matrix formulation for NDA in 15 months.
- Supervised and mentored different functional groups as formulation design, polymer science, and analytical method development.
- Served as the project lead for a P & G sponsored project with cost estimate of $1 million/year.
- Developed collaborations with partners to explore novel product ideas for drug delivery.
- Developed protocol and conducted irritation and sensitization studies with animals