

PROJECT MANAGEMENT SERVICES



DSI's approach is to assign every project a Project Manager (PM) as a single point of client contact. DSI PMs are not junior Subject Matter Experts (SMEs) that only handle the MS Project portion of the work. Each PM is an experienced pharmaceutical professional that has led teams of experienced SMEs to address clients' project goals.

PM EXPERIENCE AND TECHNICAL DEPTH

Every DSI PM has a strong combination of technical background and industry experience in drug substance, drug product, manufacturing, Regulatory, Supply Chain, and/or Quality, generally including prior consulting experience. Your PM will be assigned to your project by matching the goals of the project with a specific PM's expertise. The project team will consist of SMEs that match the needs of the project whether it be the manufacturing of DS or DP, Quality, supply chain and/or regulatory submission. DSI PMs have led teams composed of DSI and client Subject Matter Experts through the drug development process to successfully navigate the pathway to market. Since DSI PMs are some of the most experienced DSI employees they are aware when new needs arise on a project and will add or remove SMEs from the team, as needed. As the project evolves, the team evolves under the PM leadership for project execution to meet new needs.

PM SERVICE APPROACH – FLEXIBILITY IS KEY

- DSI PMs provide structure around the client's project and handle a myriad of tasks that allow the client to focus on other aspects of the project
- DSI's PM approach allows the client to have the expertise needed to advance projects through their pipeline without hiring additional staff and bringing them up to speed. DSI provides instant help.
- PMs lead project teams composed of pharmaceutical-veteran SMEs in DS, DP, Manufacturing, QA, QC, Regulatory and Supply Chain
- PMs lead meetings of clients, CDMOs and DSI SMEs
- PMs can assist in the identification of new DS, DP and novel excipient CDMOs using an RFP approach and provide options and recommendations to the client.
- Audit new CDMOs and present viable CDMO options to clients.
- Provide an interface to CDMOs, monitor with accountability by following the progress of their performance
- Provide regular updates to the client contact on the progress of the project
- Provide assistance in due diligence projects for in-license, mergers and acquisitions, facility purchases or outlicensing of products
- Maintain project timelines and keep scope aligned with project goals

SIZE AND COMPLEXITY OF PROJECTS

- Every client's project is different and every project evolves
- Client interaction can begin with a PM assigned to organize a client's resources
- As a project evolves and gaps in expertise are identified, DSI PMs are capable of quickly marshaling additional resources from DSI's SMEs
- Flexibility in DSI's approach means that additional resources with the right skills can be a short-term consultation or the SME can be added as a team member if required
- As the project evolves and the client's needs evolve, the DSI team will respond nimbly to expand or contract as needed to fit the client's project
- DSI PMs have led projects to produce small and large molecule APIs, biomolecule APIs, combination products from full CMC and clinical development through process validation and commercialization to specific Regulatory filings
- A major portion of DSI's projects involve obtaining first-time approval of NDAs, BLAs and ANDAs and receiving prompt authorization via INDs and IMPDs to commence clinical studies as well as addressing regulatory issues

DSI PROJECT MANAGEMENT LEADS THE WAY!

DSI supplied PM and API and Analytical SMEs to a client that was struggling with their API CDMO but had no small molecule chemists on their staff to interface with the CDMO. The small DSI team began working with the CDMO to solve problems in the API manufacturing process. DSI SMEs made several key discoveries regarding the process by working closely with the API CDMO. The manufacturing process was modified and the API was more easily and efficiently prepared. Within two years the company passed a PAI and was acquired by a major pharma company for over \$5 billion.

Contact Us

DSI, a PLG Company
P: 855-805-8402
solutions@dsinpharmatics.com