David Blasingame

Senior Project Management Consultant

Core Competencies

- API Manufacturing
- Biologics Manufacturing
- Commercial Manufacturing
- Global Supply Chain
- CMO Tech Transfer
- Person in the Plant
- Clinical Supply
- Vendor Management
- Starting Materials

Products

- Kuvan®
- Fostamatinib®
- Tesetaxel®
- Cerliponase®

Professional Summary

Mr. Blasingame is an accomplished Consultant responsible for process research and development, as well as API and drug product manufacturing for clinical and commercial projects spanning small molecules to biologics. He has hands on experience in tech transfers, CMC control strategies, and developing external CMO relationships. With more than 16 years of industry experience, he provides expertise in process development, validation, manufacturing, and supply chain activities from raw material through drug substance and commercialization.

Prior to DSI, Mr Blasingame served as a Director of CMC and a Director of Manufacturing. He earned an M.B.A. from Golden Gate University and holds undergraduate degrees in Chemistry and Biotechnology.

Education

M.B.A.	Business Adminstration	Golden Gate University
B.S.	Biotechnology	University of California, Davis
B.A.	Chemistry	University of California, Davis

Professional Experience

Design Space Inpharmatics, LLC **2017 - Present**

Senior Drug Substance Consultant

- Provides project management leadership for CMC drug development,
- Develops well-defined beginning and end points for project teams,
- Adjusts project plans based on experience and/or encountered problems,
- Organizes and manages resources to achieve project completion within the defined scope, quality, timeline and budget.

Rigel Pharmaceuticals **2019 - Present**

Director, CMC

- Led the development, planning, and execution of CMC strategies and tactics relating to drug substance manufacturing, formulation and analytical development, drug product manufacturing and supply chain operations across multiple geographic regions,
- Developed and executed CMC activities for R788 and R552 projects, including development of goals and associated timelines, budgets, and risk assessment/mitigation tactics,
- Managed complex sets of project activities by utilizing simple tools, exhibiting good judgement and reacting deftly to changes in project scope, timelines or priority,
- Proactively identified issues with respect to CMC projects and developed solutions and drive to resolution,
- Coordinated decisions with, and provided CMC expertise to, the Quality and Regulatory Affairs functions,
- Bridged development projects from the Research organization into the CMC arena and through all subsequent stages of development,
- Acted as the lead and the key point of contact for CDMOs, and made astute and well-thought-out decisions based on an assessment of operational and strategic considerations,
- Supported development and implementation processes for efficient supply of Rigel's product(s) to all non-clinical, clinical, and commercial sites.

Odonate Therapeutics **2016 - 2018**

Director, Manufacturing

- Responsible for drug substance and drug product development and manufacturing for Tesetaxel, a Phase III asset,
- Actively managed CMOs and partners for a virtual company with all CMC activities outsourced,
- Directed all CMO activities including budgeting, planning and supply for starting materials, API, and drug product,
- Led technical transfers for six CMOs in parallel from starting material to drug product,
- Led development efforts from identifying a new route of synthesis to synthesizing impurity and metabolite markers,
- Authored drug substance and drug product sections for regulatory documents, including INDs,
- Generated RFPs and negotiated WOs and MSAs,
- Managed one direct report.

Puma Biotechnology **2015 - 2016**

Associate Director, DS Manufacturing & Head of Quality Assurance

- Served as drug substance subject matter expert on a cross-functional CMC team,
- Led cross-functional teams to select and manage contract research and manufacturing organizations to support small molecule starting material, impurity, and API manufacture,
- Managed manufacturing operations including scheduling, logistics, batch record and deviation review, QA investigations, review of validation protocols and reports, developing specifications, and change management to ensure GMP compliant manufacturing within CMC regulatory filings and QA/QC standards.

BioMarin Pharmaceutical, Inc. **2010 - 2015**

Sr. Manager, Contract Manufacturing

- Managed drug product manufacturing tech transfer and commercial launch activities for the Kuvan Oral Powder and the Cerliponase Alfa products,
- Identified, evaluated, selected, and negotiated a contract with a CMO for drug product manufacturing for both a large molecule and a small molecule product,
- Developed metrics tracking and drove down batch record errors by 50% ,
- Developed, designed, and executed strategies to optimize manufacturing, increase yields and robustness, which included a 5x scale-up while meeting drug product GMP delivery targets,
- Managed tech transfer activities for both a Phase I and a Phase III clinical drug product manufacturing projects,
- Coordinated and supported audits and regulatory inspections at the CMO sites,
- Served as site technical lead, responsible for technical review of process data and management of proposed facility, equipment, system, or process changes,
- Managed all aspects of high-value biologic drug product contract manufacturing across 8 projects at 6 different CMO sites to ensure timely delivery of product that meets cGMP and BioMarin standards to supply clinical and commercial needs.

Gilead Sciences, Inc. **2004 - 2010**

Chemical Manufacturing

- Responsible for person in plant and single point of contact activities for CMO API manufacturing across a global supply chain that produced > 250 MT annually, and ensured that API GMP delivery targets were met,
- Designed and executed strategies to optimize manufacturing, increase process yields and robustness, identify and qualify raw material/intermediate suppliers and reduce costs while ensuring continued compliant API production. This included reducing the API cost by 25% over 2 years, implementing a 25% scale up of the API manufacturing process, implementing a 35% scale up of a final intermediate process, and implementing a new process that converted failing.