Les Mintzmyer, M.S.

Senior Biologics Manufacturing Consultant

Core Competencies

- Executive Leadership
- Biologic Manufacturing
- CMO Management
- Liposome Development
- Tech Transfer
- Supply Chain
- FDA PAI
- Process Improvement
- Upstream Manufacturing

Products

- Nulojix®
- Orencia®
- Taxol®
- Vyxeos®

Professional Summary

Mr. Mintzmyer is our hands-on expert for managing and directing biologics contract manufacturing organizations (CMO). He has led the commercial and clinical manufacturing operations for two multi-product facilities, led manufacturing operations at two CMOs, and managed Directors of materials management, inoculum, cell culture, purification, facilities, filling, engineering and strategic support.

Over the course of his more than 20 year career, he has successfully prepared a full service 6x5kL biologics facility for an FDA PAI and received manufacturing approval; was key CMC interface with FDA at meetings and during FDA PAI gaining approval for a liposomal product; and represented Manufacturing in multiple FDA, EMA, and Client audits. He has prepared organizations for growth and transition to commercial operations.

Education

Ph.D.	Chemical / Biochemical Engineering	Colorado State University
M.S.	Chemical Engineering	Colorado State University
B.S.	Biology/Chemistry	University of Nebraska

Professional Experience

Design Space Inpharmatics, LLC **2018 - Present**

Senior Biologics Manufacturing Consultant

- Technical interface with Contract Manufacturing Organizations, assisting in their preparation of proposals for consideration as a second manufacturing site for a client product,
- Provided process knowledge input and experimental design guidance for obtaining data leading to process improvements and manufacturing robustness securing drug product supply to market,
- Collaborated with client's internal team to bring a new product and technology to the manufacturing site.

Jazz Pharmaceuticals/(Celator Pharmaceuticals Inc.) **2013 - 2017**

Vice President of Manufacturing and Technical Operations

- Assembled and led the CMC team for a successful FDA & EMA submission, approval and launch of a liposomal Oncology product, Vyxeos,
- Key interface with FDA on CMC topics pre- and post-NDA submission,
- Oversaw process validation program, documentation and performance at CMO in Germany,
- Optimized the production process and supply chain logistics aligned with cGMP compliance,
- Directed contract testing, supply and manufacturing organizations supporting production.

Laureate Biopharmaceutical Services **2012 - 2013**

Vice President of Manufacturing Operations

- Delivered a broad spectrum of service offerings for contract clients, ranging from early development through manufacturing and filling of commercial and clinical products,
- Directed eight (8) departments including upstream process development, upstream manufacturing, downstream process development, downstream manufacturing, supply chain/materials control, sterile filling, facilities & engineering, and information technology,
- Key member of leadership team, quality review board, and change control committee,
- Interfaced with project managers, business development personnel, clients and potential clients throughout the business relationships and supported due diligence activities,
- Introduced and implemented Lean practices across operations,
- Reorganized line management in preparation for meeting company strategic targets,
- Strengthened cGMP culture across the manufacturing teams,
- Co-led a quality task force with the VP of Quality and reported directly to CEO,
- Collaborated to improve operations support groups and increase reliability of production systems.

Avid Bioservices (Peregrine Pharmaceuticals) **2010 - 2012**

Vice President of Manufacturing Operations

- Manufactured commercial and clinical biologic bulk & fill/finished products for Peregrine Pharmaceuticals, contract manufacturing clients, and the U.S. government,
- Directed five (5) departments that comprise manufacturing operations including manufacturing, facilities & engineering, manufacturing science & technology, validation, and supply chain,
- Interfaced with clients and potential clients, vendors, project managers, board of directors,
- Established Six Sigma/Lean Program and led methodology implementation throughout the company,
- Improved systems that included capabilities, reliability, optimized capacity and prepared for facility expansion,
- Prepared personnel, processes and facilities for successful FDA biannual inspection; additionally, for second and third PAI for client products,
- Developed personnel and assured top talent selection for key hires,
- Established key training programs to drive a performance step change in management, manufacturing, support, and quality organizations,
- Presented to BOD and reported directly to CEO.

ImClone Corporation (Eli Lilly) **2009 - 2010**

Senior Director of Biologics Manufacturing

- Manufactured mammalian cell biologic bulk drug substance for clinical trials,
- Brought second upstream and downstream production suites online,
- Received tech transfers and successfully scaled up clinical pipeline products,
- Infused accountability for communication and for safety across organization,
- Initiated Operational Excellence Program (5S and Lean) throughout manufacturing,
- Participated in improvement projects and design of new business processes,
- Front Room expert and presenter for partner and regulatory inspections (FDA, MEA),
- Supported site energy reduction plan.

Genentech, Inc. **2006 - 2009**

Director of Operational Excellence (2008)

- Promoted lean throughout Genentech and identified cost opportunity in bulk inventory,
- Designed and supported implementation of manufacturing reorganization model,
- Created and leveraged benchmarking opportunities with peer companies,
- Participated in improvement projects and design of new business processes,
- Constructed due diligence package around second plant excess capacity.

Director of Mammalian Cell Manufacturing

- Started up 8x25kL cell culture manufacturing plant; flawless media and engineering runs,
- Met goals and budget, created staffing plan, hired and trained personnel,
- Assured de-bugging activities supported subsequent validation effort,
- Collaborated on commissioning, qualification and validation activities,
- Aligned and merged startup and validation schedules,
- Assured proper operating documentation, collaborated on licensure plans,
- Interface for community and key external manufacturing partners,
- Co-led STRAT program (Singapore interns/trainees).

Bristol-Myers Squibb Corporation **2000 - 2006**

Director/Process Leader (2006)

- Requestor of $800M project (LSCC) to build a full service 6x20kL biologics drug substance manufacturing plant (now operating in Devens, MA),
- Organized and led process engineering collaboration with Fluor design team,

- Accountable for timeline and operations expense budget ($110MM),
- Communicated the project progress to upper management and support groups,
- Recruited design team members and obtained cooperation/collaboration of knowledge owners,
- Interfaced with Fluor, BMS global engineering, quality, regulatory and senior leadership,
- Created staffing plan for new facility; 400+ headcount, stand alone manufacturing capability.

Director, Biologics Manufacturing Operations (2001)

- Led commercial and clinical manufacturing operations for multi-product facility,
- Directed six (6) departments and 225 full-time employees in materials management, inoculum, cell culture, purification, facilities & engineering, training and strategic support,
- Controlled budgets including $50MM operations budget and $40MM capital budget,
- Attained licensure after passing FDA PAI for BMS first biologic product Orencia® (abatacept),
- Prepared facility and personnel for FDA inspection,
- Transformed a development facility into a fully cGMP compliant manufacturing facility,
- Recruited, interviewed and hired key managers to build new manufacturing capability,
- Achieved six-fold increase in capacity within two (2) years,
- Led facility reliability capital investment to debottleneck utilities capacity,
- Implemented my strategy for rapid hiring and training of technicians,
- Built in-house rapid training programs for floor supervisors and non-exempt personnel,
- Grew the operations function from 60 full-time employees to over 225+ in less than two (2) years,
- Co-led a cross divisional product team to develop and manufacture Nulojix® (belatacept) through phase II and early phase III (FDA approval June 2011).

Associate Director, Chemical Development Pilot Plants (2000)

- Controlled operations and led personnel in two (2) fermentation and three (3) recovery pilot plants,
- Accountable for technical transfer of fermentation processes to manufacturing operations and technical consultation for production scale including plant design,
- Coordinated timing of product delivery requirements balanced with each pilot plant's capabilities.

Phyton GmbH **1999 - 2000**
General Manager

- Commanded all GM activities for this start-up company producing paclitaxel; Taxol® via plant cell culture,
- Completed technical transfer and demonstrated process performance at 70,000-L scale,
- Set up business units to normalize activities; safety, quality, production, warehouse and shipping,
- Participated in candidate selection for key management positions including general manager, QA director, engineering director, and materials manager.