

Jason Bender

Head of Supply Chain Services

Core Competencies

- 15+ years PM Professional
- CMO External Transfer
- Supplier Agreements
- Complex Gantt Charts
- Intl. CMO Management
- Generic & Branded Products
- Third Party Packaging
- Clinical Supply Management
- Consumer Products

Products

- Torisel ®
- Methylnaltrexone ®
- Nocita ®
- Lidoderm ®
- Fortesta ®

Professional Summary

Mr. Bender has extensive experience in project management, clinical supplies and commercial supply chain development. He serves as the primary liaison between client and consultant teams. CMC Project Manager for portions of Module 2 and all of Module 3 including creation and maintenance of submission trackers, section review, quality checks, comment resolution and formatting.

He provides clinical supply protocol review, forecasting, supply/demand scenarios, domestic & international labeling text & translations, packaging/labeling/relationship management at CMOs & depots, batch record review, API & bulk shipment management (including cold-chain), FDA & Customs release, comparator sourcing and VAT maintenance.

Mr. Bender manages client activities across all aspects of CMC including drug substance, drug product, analytical, regulatory, quality and supply chain. Products included oral solid tablets & semi-solid capsules, oral solutions, sterile products (liquids/frozen liquids, lyophilized powder injectables, liposome injectables) and antibiotics.

Education

B.S.	Chemical Engineering	Rensselaer Polytechnic Institute
	Minor: Economics	

Professional Experience

DSI

2016-Present

Head of Supply Chain Services

- Responsible for managing 3 NDAs, 1 NADA, 5 initial INDs and 8 later phase IND amendments, 4 annual reports, 4 CBEs (zeros and 30s) and 4 Prior Approval Supplements,
- Sole clinical supply support for 1 client's set of oncology projects (3 products, ~14 studies) for >3 years,
- Assisted with vendor selection, tech & method transfers, engineering, clinical trial materials, registration batches, briefing books, etc.

Endo Pharmaceuticals

2009-2016

Senior Project Manager, External Supply (2014)

- Lead largest analytical & technology transfer in the history of Endo that included 6 APIs across 17 bulk products and 12 ANDAs from a Canadian CMO to a Spain CMO and through USA secondary packaging,
- Lead internal core team including Analytical Services, Quality Assurance, Regulatory Affairs, Supply Chain & Technical Operations, along with the Plant Manager and management team of the CMO in Spain,
- Initiated discussions and became primary negotiator for the supply agreement with the Spain CMO,
- Performed specification and batch record reviews to ensure timely and accurate approvals of documents,
- Assisted Regulatory Affairs with writing/compiling documents to submit site transfer CBE-30s,
- Lead effort with the tax department to analyze potential cost & tax savings to move management of products being transferred to Spain from the Endo USA office to the Endo Ireland office,
- Project lead for 5 new product launches across 4 different CMOs in the USA and China with 3 packagers,
- Assumed supply chain responsibilities (in addition to normal project management responsibilities) for 50 products across 8 CMOs,
- Worked with finance team and third-party consultant on VAT valuation and registration in Europe.

Senior Manager, Clinical Supplies (2011)

- Quickly built solid working relationships and managed 4 vendors that performed packaging, labeling, distribution, return management and destruction activities for all clinical studies,
- Responsible for forecasting drug needs and obtaining comparators and ancillary supplies for 6 active studies,
- Review protocols, maintain IWR, monitor drug dating, perform reconciliation and manage budgets for all studies,
- Provide training for monitors and sites on pharmacy binder and distribution agreements.

Senior Supply Chain Specialist (2009)

- Quickly built solid working relationships and managed 4 vendors that performed packaging, labeling, distribution, return management and destruction activities for all clinical studies,
- Responsible for forecasting drug needs and obtaining comparators and ancillary supplies for 6 active studies,
- Review protocols, maintain IWR, monitor drug dating, perform reconciliation and manage budgets for all clinical studies,
- Provide training for monitors and sites on pharmacy binder and distribution agreements.

Merck Research Labs (Contract Position)

2008-2009

Clinical Supply Program Manager

- Responsible for managing clinical supplies for 14 Phase I & II studies for two oncology compounds and 12 experimental medicine studies for the Oncology and Experimental Medicine therapeutic areas,
- Primary responsibilities included writing protocols & packaging agreements, forecasting API/bulk/packaged drug supply, maintaining packaging/shipping schedules, clinical label management and expiry date management,
- Responsible for leading Clinical Supplies Sub-team to better manage drug supply project timelines,
- Involved in numerous cross-functional teams that included areas such as basic research, formulation, chemical engineering, clinical research, regulatory, procurement, operations, and vendor management.

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Wyeth Pharmaceuticals (Contract Position) Supply Chain Leader

2007-2008

- Supply Chain Leader in the Global Supply Chain group for Methylnaltrexone, launched in Q1 2008,
- Analyzed and ensured completeness of global demand from the USA and all international affiliates,
- Planned initial high-level production schedules at one domestic third party filling location and three international filling locations (one internal and two CMOs) along with four packaging CMOs,
- Responsible for running capacity analyses for the entire Methylnaltrexone supply chain network,
- Additional responsibilities of Global Network Planner to plan finished goods for Torisel (June 2007),
- Implemented new S&OP process for Methylnaltrexone and Torisel as part of a Global Supply Chain initiative.

Sensitech, Inc. (Division Of Carrier Corp.) Planning & Purchasing Manager

2005-2008

- Responsible for all company planning and purchasing activities with three direct reports,
- Maintained forecasts and managed production at five global and three domestic CMOs along with more than 40 additional suppliers at an annual spend of approximately \$20MM with year on year growth of 27%,
- Negotiated 20% price reduction on TagAlert product and 22% reduction on TempTale4 Dry Ice product for a total estimated 2007 savings of \$1.4MM. Helped reduce TempTale4 product cost by 16% (~\$240M in 2006),
- Successfully implemented and managed VMI (vendor managed inventory) models at two overseas CMOs,
- Appointed by the President to represent Sensitech as the Business Practice Officer (Carrier ethics initiative).

Unilever Home & Personal Care Supply Management Manager (Purchasing)

2001-2005

- Buyer for \$100MM worth of packaging components across two categories. Brands include Dove, Suave, Lever 2000, Caress, Vaseline Intensive Care (VIC) lotions, Vaseline Petroleum Jelly & Lip Therapy and VIC Bath Beads.
- Responsible for maintaining relationships and negotiating contracts with over 20 suppliers.
- Lead initiative to bring multiple international Unilever cap/bottle molds to USA for an annual savings of \$500M,
- Lead the supply management portion of the Unilever HPC Skin Transition Team yielding net savings of \$15MM per year.