



Joan Connolly

SUMMARY

Pharmaceutical Industry Executive with 18 years' experience in Organization Strategy, Operations Management, Clinical Supply, Logistics, Sourcing/Procurement, Supply Chain Management, Process Development, Manufacturing, Regulatory Filings (CMC), Product Commercialization, Relationship Management, and New Product Planning. Knowledgeable in regulatory requirements for GXP manufacturing and development for small molecules and biologics

PROFESSIONAL EXPERIENCE

ImClone Systems Inc. (Subsidiary of Eli Lilly since 2009), Branchburg, NJ

Associate Vice President, Clinical Supply and Logistics

2009 -2011

- Managed team to deliver CMO and TPL solutions for drug product manufacture, packaging and global distribution across all clinical assets, and DP manufacture/packaging for commercial product (distributed via alliance partner). Delivered a capacity model that enabled rapid response to pipeline developments while maximizing resource utilization.
- Built alignment with Commercial Partners, API Manufacturing, Clinical Operations and Regulatory Affairs to deliver a demand driven S&OP and linked manufacturing plan that also supported regulatory requirements for global submissions.
- Developed process and quality agreements for cross-company collaboration on manufacturing and distribution of key clinical assets selected for co-development by both ImClone and Lilly's Development Center of Excellence.
- Developed strategy for comparator and co-therapy sourcing to minimize expense while mitigating clinical execution risk.

Associate Vice President, Strategy and Operations

2008 - 2009

- Worked with CEO to ensure management focus on board objectives, and board education on management goals.
- Led cross-functional review of corporate strategy and priorities. Defined metrics to track progress against goals.
- Provided information and analysis to drive decision making and ensure clear communication of decisions and priorities across the organization.
- Reviewed existing business processes and governance structures to identify inefficiencies, redundancies and best practices. Made recommendations on process improvements and monitored implementation to ensure successful adoption.
- Identified gaps in people, process and technology and developed action plans to close gaps and build organizational alignment.
- Responded to unexpected developments to provide clear assessments of current and desired state, and then worked across functions to implement desired solutions.
- Supported due diligence for M&A activity. Co-led Corporate Integration Team upon acquisition by Eli Lilly and Company

Joan Connolly

Director, Contract Manufacturing

2007 - 2008

- Managed external relationships with partners providing CMO services for oncology pipeline and with API license partners API for global commercial and clinical needs. Coordinated cross-company process optimization activities to ensure harmonization across manufacturing locations, and to deliver improved productivity to maximize margins.
- Built a cross functional team to manage pipeline supply/demand planning and execution, to ensure all active and planned clinical studies are adequately supported to enable rapid clinical progression.
- Directed pipeline manufacturing planning activities to assure manufacturing and development resources were aligned to deliver corporate objective of expediting the pipeline.
- Supported Strategic Planning exercise to assess capacity and capability to secure drug supply in support of all clinical requirements and anticipated commercial launches across a 7-10 year planning period.

Bristol-Myers Squibb, NY & NJ locations

Director, Strategic Sourcing

2005–2007

- Led cross-functional team to rebuild commercial Third Party Manufacturing management systems for API and key intermediates after company reorganization and loss of key support functions.
- Built alignment across sourcing systems for clinical supply operations and product commercialization.
- Trained and mentored sourcing professionals new to organization. Developed sourcing strategies and assist team members in executing against the strategy while adapting to constant change in the project prioritization.
- Managed relationships with suppliers of strategic intermediates and API's, from target identification through technical transfer and/or capability assessment to commercial qualification and launch.

Manufacturing Launch Team Leader, ERBITUX

2003-2005

- Achieved product commercialization within 12 calendar days of FDA approval (vs. corporate objective of 20 days).
- Directed manufacturing planning, PAI preparation and navigation; coordinated regulatory strategy for multiple manufacturing locations; oversaw label art development and logistics for artwork approval and production; managed all aspects of final product packaging, release and distribution to market upon BLA approval.
- Supported creation and launch of a direct to customer drop-shipment system for commercial distribution that allowed detailed product tracking in order to control inventory, capture account-level daily sales and manage low-level hypersensitivity risk.
- Directed LCM activities to improve customer service and support expanded access to and use of the brand.

Joan Connolly

Associate Director, Strategic Sourcing

2000–2005

- Delivered cost savings totaling \$32MM over 5 years.
- Managed relationships with suppliers of strategic intermediates and API's, from target identification through technical transfer and/or capability assessment to commercial qualification and launch. Balanced corporate requirements with external capabilities to maximize value from strategic partnerships.
- Designed and implemented strategies and protocols for cross-divisional sourcing initiatives.
- Completed make/buy analyses to select outsource targets that optimize internal capacity utilization and maximize tax benefits to the corporation. Worked in partnership with global development and manufacturing divisions to manage the external supply chain in support of clinical supplies, new product introductions and commercial products.
- Strengthened intellectual property protection practices for development sourcing activities by expanding IP protection with Confidential Disclosure Agreements and leading organization-wide education initiatives.
- Rotational Assignment: Supported a supply chain optimization and re-design initiative through the development and implementation of Sales & Operations Planning practices across geographies and therapeutic areas.
- Rotational Assignment: Led a multi- supply chain team to optimize capacity utilization and share best practices across the global bulk manufacturing network

Manager, Strategic Sourcing (Plainsboro, NJ)

1997-2000

- Identified and qualified commercial suppliers of critical intermediates and active pharmaceutical ingredients for new drug products, in support of both the former Apothecan generic division for portfolio expansion and the Worldwide Medicines Group for new chemical entities. Collaborated with process development, formulation development, QC/QA, Regulatory Affairs and manufacturing organizations to bring new products through the approval process to commercialization. Leveraged knowledge of the fine chemical industry to maximize cost savings while maintaining optimum capacity utilization within the manufacturing network. Audited potential and active suppliers for capacity, capabilities and general cGMP, Environmental and Process Safety practices to assure security of supply and confirm compliance with company standards of conduct. Oversaw transfer of process technology to third party suppliers, and facilitated evaluation and qualification of new process technology developed outside BMS to ensure overall compliance to quality standards while improving overall cost of goods.

Associate Engineer, Process Development (Syracuse, NY)

1993–1997

- Optimized chemical manufacturing processes for the preparation of intermediates and API's to support clinical trial programs through PII and PIII. Generated documentation in support of CMC filings. Supported enzymatic process evaluation and scale up, including enzyme fermentation, separation and isolation/immobilization and subsequent use in commercial applications. Transferred technology to manufacturing facilities for commercialization. Assisted in troubleshooting for commercial products at various manufacturing locations. Managed production for Butorphanol Tartrate (commercial API) and BHBA (commercial intermediate) which were manufactured in the Syracuse pilot plant. Managed process operator allocations across multiple projects and maintained training and development records



Joan Connolly

INDUSTRY ASSOCIATIONS

DCAT Association Executive Committee – Sr. Vice President and Dinner Chair 2011

EDUCATION

Queen’s University, Kingston, Ontario, Canada B.Sc. (Honors) Engineering Chemistry
Recipient – Queen’s National Scholarship

Institute for Supply Management, Phoenix, AZ Certified Purchasing Manager (1999)