Nelly Myrtil

Senior Supply Chain Consultant

Core Competencies

- Clinical Supply Management
- cGMP Labeling
- Supply Forecast
- IRT Systems
- Pacakging Design
- Centralized Services
- Large Global Trials
- RFP and Bid Defense
- Supply Reconciliation

Professional Summary

Ms. Myrtil is a Clinical Supply Chain professional with over 20 years of pharmaceutical, medical device, and biotechnology experience. She is a proven leader with expertise in all facets of operations, supply chain, logistics, vendor management, sourcing, and team engagement in support of ongoing clinical trials and research at global pharmaceutical firms. She is skilled in collaborating with key decision makers of the organization to achieve business and financial objectives, and is instrumental in streamlining processes, enhancing productivity and implementing strategic solutions using continuous improvement methodology.

Nelly has strong knowledge of FDA, cGMP and GCP standards. Constantly promoted from within to positions of increased responsibility, she is an adept manager of Clinical Supplies with executive level understanding of global pharmaceutical development, quality assurance and regulatory oversight and control. She is also an expert negotiator and presenter, and is comfortable making the hard decisions.

Education

B.A.	French Literature, Computer Science	William Paterson University

Professional Experience

Design Space InPharmatics, LLC **2021 - Present**

Senior Supply Chain Consultant

- Forecast and manage the clinical trial materials supply chain including API, bulk & packaged drug,
- IRT vendor selection, development, testing and implementation,
- Understanding of the design of various types of clinical labels and required text for USA, EU, Asia and ROW including vendor management for translations,
- Maintain relationships and negotiate contracts with suppliers.

Ipsen Biopharmaceutical **2020**

Clinical Supplies Consultant

Represent clinical trial supplies as a core member of the Clinical Trial Team (CTT), and define and advise the CTT on the optimal clinical trial supply strategy in terms of, but not limited to, packaging design, technical and timeline feasibility, efficiency, and risk management. Review all clinical trial protocols and protocol amendments providing inputs to develop optimal packaging design, clinical trial supply design and visit schedule (key study parameters and milestones, patient screening and enrollment projections, with appropriate overage). Create and drive finalization of the packaging design and generates labels that comply with global regulatory agencies for investigational new drugs.

- Provide interpretation of regulatory guidance documents, regulations and directives and advice regarding their applicability and impact on internal labeling runs,
- Participate in the selection, evaluation, and approval of third-party contractors for packaging, labeling and distribution activities,
- Provided input to IRT/CTMS systems user requirement specification of investigational product and clinical supplies management modules as needed,
- Managed day to day depots and sites inventory in IRT, reviewed the IRT strategy ensuring the strategic supply plans are supported and IRT settings are adjusted as necessary to optimize the supply chain,
- Manage internal and third-party deviations, customer complaints, and change controls to support cGMP labeling and distribution activities,
- Develop, maintain, and execute an optimal resupply strategy with proactive planning, appropriate lead-time and replenishment quantities to ensure compliance and continuity of clinical supplies, including proactive expiry management of clinical supplies,
- Identify, assess, and proactively communicates supply risks to all relevant stakeholders along with appropriate mitigation strategies to ensure supply continuity,
- Collaborates with all relevant functional departments including Clinical Operations, QA, CMC, Regulatory, product development, Sourcing, finance, Distribution, Packaging, and medical to develop optimal supply strategy,
- Ensure adequate documentation, processes and systems are available and followed for labeling, distribution, returns, reconciliation, and destruction of clinical trial materials activities (SOPs / Protocols review /approval).

SK Life Science **2019 - 2020**

Associate Director, Clinical Supplies

Manage packaging and labeling operations for global clinical studies. Manage activities related to the inventory management and distribution of Investigational Medicinal Product (IMP) in compliance with internal procedures and GxP requirements.

- Worked closely with, and collaborate with, internal departments, third party vendors (including, but not limited to, Contract Manufacturing Organizations (CMOs), Contract Research Organizations (CROs) and shipping agents) and clinical study site representatives to ensure the availability of IMP at clinical study sites globally,
- Provided input to IRT/CTMS user requirement specification of investigational product and clinical supplies management modules as needed,
- Performed user acceptance testing as required; managed day to today depots and sites inventory in IRT,

- Reviewed the IRT strategy ensuring the strategic supply plans are supported and IRT settings are adjusted as necessary to optimize the supply chain,
- Created initial study drug projections and supply plan for clinical supply needs throughout life of study including multiple drug campaigns and appropriate drug strategies,
- Responsible for leading the activities related to the sourcing of clinical services to Clinical Research Organizations (CROs) and other service providers for assigned clinical programs in various stages of development. Also responsible for developing and executing sourcing strategies, managing the RFx process, establishing supplier relationships, negotiating MSAs,
- Managed the execution, oversight, and accuracy of contract agreements, (MSA and RFP) the invoicing and purchase order processes related to IMP inventory management and distribution.

Sanofi Pharmaceutical **2015 - 2019**

Global Sr Clinical Supply Chain Operations Lead

Ensured drug supply and inventory controls to support ongoing global clinical drug studies including management of temperature excursions to resolution. Maintained site supply in partnership with the Clinical Operations team to address any supply issues and uninterrupted study progress. Manage IP distribution settings in IRT to ensure adequate and timely supply to clinical sites; solicit, review, and manage CMO quotations and work/purchase orders, and approved vendor invoices.

- Created initial study drug projections and supply plan for clinical supply needs throughout life of study including multiple drug campaigns and appropriate drug strategies,
- Responsible for managing CMO relationship, packaging design, Master Label Text creation and translation,
- Provided input to IRT/CTMS systems user requirement specification of investigational product and clinical supplies management modules as needed,
- Performed user acceptance testing as required; managed day to day depots and sites inventory in IRT; reviewed the IRT strategy ensuring the strategic supply plans are supported and IRT settings are optimized.

Allergan **2017 - 2018**

Manager, Global Clinical Supplies Operations

Directed clinical supply operations to support clinical studies by understanding clinical study protocols, design of clinical labels, preparation of packaging and labelling contracts, and forecasting and supplies ordering requirements in coordination with clinical trials stakeholders across the supply chain. Forecasted yearly supply plans, served as project manager, monitored IP for duration of study and ensured appropriate stock level availability. Reviewed & updated SOPs and established new procedures.

- Developed and implemented the initial timeline, budget, drug supply forecasts and component requirements needed for preparation of the Clinical Supply Master Plan for Phase I through IV clinical protocols Oversight: No oversight,
- Initiated process to optimize or improve IP planning and calculation,
- Provided input to IRT/CTMS systems user requirement specification of investigational product and clinical supplies management modules as needed,

- Performed user acceptance testing as required; managed day to today depots and sites inventory in IRT, reviewed the IRT strategy ensuring the strategic supply plans are supported and IRT settings are optimized.

Sanofi Pharmaceutical **2015 – 2017**

Clinical Supply Chain Project Lead

Ensured managed clinical research studies and provided managerial support to the Outsourcing Team with focus on streamlining outsourcing functionality and processes. Maintained accountability for Clinical Supplies key projects deliverables including forecasting for resources and costs, managing variances, building supply assumptions, capacity and inventory management for IP, DP, DS, API, bulk, finished products, comparators, and devices. Built relationships with key vendors to ensure standardized contracting practices across all relevant providers.

- Assisted in the selection of principal investigators, negotiating contracts, and monitoring milestones,
- Worked cross-functionally with external vendors and internal teams to coordinate the packaging, labeling, storage, distribution, final accountability and invoicing activities for clinical studies,
- Championed a patient centricity project to align Global Clinical Supply division with top corporate goal initiatives; rolled out a patient and site experience survey to assess patient satisfaction and loyalty,
- Conducted extensive research with the clinical team to develop patient friendly protocols by involving patients during the design phase,
- Leveraged digital innovation solution, smart labeling, internet of things, just in time packaging, smart stock, Direct to Patient & Home Trial Support resulting in reduced time-to-market & improved patient outcomes.

Convatec **2012 - 2015**

Associate Director, Logistics Operations

Led daily operations of the US Fulfillment Center and nurtured Fulfillment Center Team to deliver high-level, customer-centric support. Developed yearly and long-term procurement plans and held responsibility for the Transport, Warehousing and Packaging, regional sourcing strategy and implementation.

- Negotiated contracts to realize savings and improved cash flow; built category subject matter expertise to ensure best sourcing decisions and based on a strategy of continuous improvement,
- Managed medical device clinical trials and lead a team of 5 employees,

GE Healthcare **2008 - 2012**

Sr. Global Strategic Business Development, (2010)

Promoted into position to drive overall global business representing 6% of compound annual growth rate by assessing the divisions operations and devising strategies to optimize efficiency and productivity across the business. Managed day to day operations, financial P&L performance, and customer relations across multiple regions.

- Spearheaded new business opportunities and expanded markets in North America, Asia, Latin America, and Europe by designing business models and strategies to maximize competing market platform adoption,
- Collaborated with Product Management, Manufacturing, and R&D to develop new products and work with Sales to develop a go-to-market strategy and sales operation plan.

Sr. Global Supply Chain Operations Manager

Directed logistical operations including purchasing, order fulfillment, product and inventory management, planning, purchase of raw material & packaging supply for multiple sites throughout Europe, Asia, and North America. Managed global commercial R&D projects and shipping and delivery functions.

- Delivered $200M on a $4M goal as part of a new business to penetrate the forensic market initiative,
- Led all staff training, performance coaching, compensation, and succession planning initiatives for 25 staff members and 9 direct reports.