Suzan R. Lanz

Senior Supply Chain Consultant

Core Competencies

- Clinical Supply Management
- cGMP labeling
- Supply Forecast
- IRT systems
- Pacakging Design
- Large Global Trials
- Global Depot Network
- Global Customs

Products

- Tymlos®
- Arikayce®
- Krystezxxa®
- Refludan®

Professional Summary

Ms. Lanz has over 30 years of pharmaceutical, device and supply chain experience in submission preparation, project management and GMP readiness from clinical supplies management, in-licensing & due diligence; risk analysis to identifying, implementing and validating end to end supply chains, supply planning, labeling design, and development including DSCSA serialization for commercialization.

Her engagements have included organizations developing novel RNA-modulators, novel treatments for ocular melanoma, cancer gene therapy and therapeutics in neuroscience, immuno-oncology and contraception.

She has managed all aspects of clinical supply set up. Ensuring manufacturing timing for consistent IMP supply and ancillaries, retest dating and longevity of the product for the trial, estimating clinical supply needs, timeline & overages based on trial design, develop labeling, support IRT, depot to depot logistics, commercial readiness, label design for US & EU (clinical and commercial), DCSCA & FMD serialization readiness.

Education

M.S.	Global Management	University of Phoenix
B.S.	Chemistry	Fairleigh Dickinson University

Professional Experience

Design Space InPharmatics LLC **2021 – Present**
Independent Consulting

Senior Supply Chain Consultant

- Understanding of clinical study forecasting protocols,
- Open label, blinded and double blind studies, as well as complex drug packaging such as titration studies, childproofing, drug/device combinations, etc.
- Design of various types of clinical labels and required text for USA and EU, including vendor management for translations,
- Sourcing and management of CTM packaging and labeling including RFP's, CMO bid review and recommendations, tech transfer and startup.

Pharmaceutical Operations Consulting **2018 - 2021**

Principal Consultant

- Pharmaceutical Operations Consultant supporting all aspects of drug & device development, clinical and commercial supplies management,
- 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,
- Evaluate CMOs for logistics & labeling providers; manage CMOs, label development and depots,

Radius Health **2015 - 2018**

Sr. Director, Supply Chain

- Develop, set up and implement global supply, distribution, logistics and labeling/packaging activities to support MAA and NDA submissions through commercialization of Tymlos® injectable pen. Provided Tymlos® in-channel 26 days post FDA approval,
- Production planning and scheduling of all GMP processes and products to support the commercial business unit as well and the organization's upstream development program,
- Evaluate and establish CMOs, logistics & labeling providers for commercial and upstream clinical,
- Perform due diligence, negotiate contracts, generate RFPs, participate in Sales and Operation Planning, manage staff & implementation and validate GMP processes and systems (ERP, Serialization).

Insmed **2013 - 2015**

Sr. Director, Supply Chain & Logistics

- Developed a fully integrated supply chain for novel orphan cold chain products (parenterals). Supply management of global Phase 3 clinical trial to support an NDA submission (Arikayce®),
- Supply planning and scheduling all manufacturing and packaging for validation, clinical and commercial use,
- Planning for procurement of critical raw materials, device components and other supplies,
- Manage shipments by all vendors and CMOs in support of the commercial demand forecast, non-clinical/clinical study requirements and product development projects,
- Performed due diligence and audits on potential supply chain partners, CMO, warehouses, third party logistics providers, and clinical suppliers,
- Generated and negotiated RFPs, supply agreements, and contracts,
- Lead Supply Chain & Logistics department staff,
- Generated and managed department budget. Developed labeling and packaging components in collaboration with RA & Commercial teams,
- Developed serialization strategy for US and EU, and GS1 implementation as per DSCSA & FMD laws,
- Prepared, assisted and/or reviewed CMC source data as well as summary documents for regulatory.

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Savient Pharmaceuticals **2007 - 2013**

Director; Global Supply Chain (2011)
Associate Director; Project Management (2007)

- Set up and implemented global supply, distribution, logistics and labeling/packaging activities for clinical and launch activities,
- Delivered ready-to-distribute, Krystexxa® within 5 weeks of FDA BLA approval,
- Completed MAA approval and launch preparedness for EU market,
- Managed forecasts, planning, inventory, and department budget,
- Alliance management of contract drug product manufacturing, packaging and laboratories,
- Co-authored CTD modules. CMC team lead for clinical and commercial penetration into new global markets and indications as well as compassionate use programs and named patient programs,
- Managed all labeling artwork, & packaging. Negotiated MSA contracts, authored SOP's & policies, performed audits, and qualifications. Lead Supply Chain & Logistics department staff.

Schering AG/Berlex **1995 - 2006**

Global Drug Development Project Manager, Oncology (2004)
International Project Manager, Specialized Therapeutics (2003)
Project Coordinator, Cardiovascular, BU Therapeutics (2000)
QA Clinical Supplies Compliance Coordinator (1998)
Bioanalytical Methods Development Chemist II (1995)

- Managed drug development projects in oncology, targeting mostly the treatment of solid tumors with compounds having novel mechanisms of action or having improved characteristics compared to marketed drugs (Histone deacetylase inhibitor, multi-target tumor growth inhibitor, TOCOSOL® Paclitaxel, Bonefos®). These include highly prioritized projects and a total budget supervision of between 20 and 60 million US$ annually,
- Project manager for drug development projects in the area of life cycle management for Betaseron, Schering AG/Berlex' interferon β-1b for the treatment of multiple sclerosis as well as other novel treatments,
- Coordination of all aspects of Drug/Device development from in-licensing or R & D of new chemical entities such as Fasudil, a rho-kinase inhibitor or treatment of angina,
- Life cycle management of the Drug/Devices post market; Refludan for heparin induced thrombocytopenia, Betapace AF for treatment of atrial fibrillation and Lifecor's LifeVest for intermediate-term treatment option for people at high risk for sudden cardiac arrest (SCA).