

OBJECTIVE

Entrepreneur-minded pharmaceuticals professional with a broad view from both pharmaceutical companies and Clinical Research Organizations. Be it commercial or clinical world, I strive for smart solutions for pharmaceutical business with a patient-centric approach.

EXPERIENCE

Founder/ | Pharmansard Oy, Espoo, Finland

08/2024- PRESENT

- I provide consulting and contracting to pharmaceutical companies: project management, supply chain management, change management, operative planning, strategic planning, production- and work methods improvement, risk management, renewing processes, continuous improvement
- Subject Matter Expert services in Clinical Supply, Interactive Response Technology (IRT) and Randomization and Trial Supply Management (RTSM)

Senior Clinical Supply Specialist/ IRT and Medication Manager | ICON plc, Espoo, Finland-remote

01/2021-08/2024

- Led the IRT (Interactive Response Technology) system cross-functional sub-team under the Clinical Team and set up and maintained the IRT System used in phases I to IV
- Implemented optimal IRT supply strategies for smooth dispensation of IMP
- Guidance and oversight of IMP handling following the SOPs, GMP, CCP and ICH guidelines
- We implemented Sponsor's freshly established IRT Standards to her studies during the 3-year assignment to reduce costs and full testing needs
- Subject Matter Expert for outsourcing studies to IRT vendors and trained the IRT & Medication Manager Group

Senior Clinical Supply Manager | Grünenthal GmbH, Aachen, Germany

10/2019- 12/2020

- Oversaw and managed vendors to deliver an uninterrupted clinical supply chain of IMP
- Hired CRO/CMO to execute Clinical Studies for Grünenthal
- Oversaw setup and implementation of trial-specific IRT systems with selected provider
- Managed vendor to compile Product Specification File and review of all GMP-relevant manufacturing documentation for clinical trial supplies to facilitate final release by the QP
- Reviewed and monitored budgets of Clinical Trial Supplies
- Contributed as an Auditor/ Subject Matter Expert to the GxP qualification of external Clinical supplies service providers during audit planning, execution and close-out

Clinical Supply Manager | Grünenthal GmbH, Aachen, Germany

07/2017- 10/2019

- Provided operational expertise and interdisciplinary project management ensuring an uninterrupted clinical supply chain of Investigational Medicinal Products
- Translated the requirements from clinical trial protocols into optimal packaging designs ensuring robust processes for clinical trial supplies supply chain with suppliers, e.g. CMOs, depots, couriers, IRT software
- Setup and implementation of trial-specific IRT systems with selected vendor

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- Compiled and reviewed GMP-relevant documentation and provided guidance regarding IMP to ensure GMP-compliance
 - Planned and monitored budgets of Clinical Trial Supplies
 - Liaised with a new supplier offering trial supplies- related simulation and forecasting software to explore new and innovative solutions for supply strategy optimization

Supply Chain Coordinator | Santen Oy, Tampere, Finland

08/2014- 05/2017

- Project management, planning and communicating supply chain matters on US and Asian diagnostic products: inventory levels, logistics, and forecasts within a global corporation
- Procured raw materials, primary, secondary materials and also Finished Goods accordingly from purchase order to invoicing
- Contacted and scouted new potential material or service providers
- Vendor management: contracts, pricing, KPIs, BRMs
- Project management in a (MAH) Marketing Authorization Holder Transfer project: US-APAC-EMEA

R&D Pharmacist | Santen Oy, Tampere, Finland

08/2008- 07/2014

- Oversaw Clinical Supplies packaging, labelling and shipping activities
- Member of a team that provided released sterile IMP batches for open-label/ double-masked/ randomized/cross-over studies to EU, US, Japan, and Russia to Phases I-IIIb
- Managed Inventory levels, accountability, procuring of e.g. comparators, ancillaries, labelling and packaging materials
- Study label & packaging design experience for EU and US Studies complying with GxP, ICH and FDA regulations
- Provided Commercial Product Support, process validation, stability study planning and conduction
- Managed the lifecycle of Clinical Supplies from Trial Kick off to archiving Study documentation (PSF) and destruction of IMP.

EDUCATION

B.Sc. of Science, Pharmacy | University of Eastern Finland (former University of Kuopio)

Kuopio, Finland

2004-2007

SKILLS

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|-----------------------------------------------------|----------------------------------|---------------------------------|
| • 16 years of global pharmaceutical work experience | • Risk based approach and QbD | • Project Management |
| • GxP and ICH knowledge | • MS Office | • Budgeting and invoicing tools |
| • Troubleshooting | • SAP ERP, Veeva, Master Control | • Software lifecycle management |
| • Teamwork | • Outsourcing, vendor management | |

ACTIVITIES

English: Fluent

Finnish: Native

Swedish: Intermediate

German: Good

Spanish: Beginner

Webinars, sports, travelling, writing fiction, reading
