Weilin Tiger Bee

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
- Vendor Management

Professional Summary

Weilin Tiger Bee has twenty years' pharmaceutical industry experience, focusing the last 10 years on clinical supply and maximizing available inventory through international depot planning while minimizing waste and potential obsolescence. He develops and implements clinical supply master plans for all phases of clinical protocols, ensuring timely and continuous drug supply to global clinical studies through timelines, budgets, drug supply forecasts, supplier agreements, etc.

Tiger has managed clinical supply at 170 sites in 44 countries. He supports studies through continuous forecasting, communicating manufacturing needs, packaging, translation and labeling. He has extensive knowledge of the entire investigational product supply chain, IRT requirements and cost drivers to develop creative, efficient, and robust clinical supply chain solutions.

He has worked closely with manufacturers (in China), packaging facilities (in Canada), and depots (in EU and US), and was able to deliver supplies in a timely fashion. He also has a good understanding of customs and value added tax.

Education

M.B.A.	Business Administration	Pennsylvania State University
M.S.	Biomedical Engineering	Purdue University
M.S.	Chemical Engineering	National Tsing-Hua University
B.S	Chemical Engineering	National Chung-Hsing University

Professional Experience

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

Senior Supply Chain Consultant

- Managed 6 late-stage global studies,
- Import/export activities, depots, IRT integration, packaging and labelling,
- IRT design, UAT, and implementation,
- Blinded head-to-head Phase III studies,
- Expertise in both China to/from US customs and import procedures,
- Manging global Oncology and COVID-19 late stage studies.

KLUS Biotech Biopharmaceuticals **2017 - 2020**

US Clinical Supply and Clinical Project Management Head (Director)

- Study Management for Multi-million, multi-year clinical trials,
- Oversight of investigational medicinal product (IMP) supply forecasting/management and study-level IMP reconciliation and recommend appropriate trade-off to balance risks and study execution deliverables,
- Working with internal CMC and external CMOs to ensure tech transfer between manufacturers for biologics, ADC drug products, and linkers,
- Drive study execution utilizing available performance metrics and quality indicators,
- Regulatory Compliance: Proactive identification of potential risks and development/implementation of actions to avoid or mitigate risks with study deliverables and costs,
- Development/management of vendor scope of work (SOW) per contract, quality, and budget,
- Operational and strategic input into study documents such as synopsis, protocol, ICF, CRFs, CRF Completion Guidelines, Study Execution Plans, Clinical Data Review Plan, Clinical Database edit specifications, Clinical Study Report (CSR) development, etc.
- Oversight of TMF set-up, ongoing quality review, and final reconciliation of study documents including review of site regulatory documents/packages and obtaining of appropriate country/site insurance,
- SOP creation for supply chain management, labeling management, temperature monitoring, import export management, deviation reporting, unblinding procedures, etc.
- Proactive management of internal partners/stakeholders including Clinical Research, Project Management, CR&D Operations, and Affiliates and foster partnership across the multi-disciplinary teams.

GlaxoSmithKline **2007 - 2017**

Clinical Study Coordinator / IRT Specialist (2015 - 2017)

- Clinical Operations: Managed 15 multi-national clinical studies (from phases I to III; infection diseases, HIV, respiratory, oncology, immuno-inflammation, etc.),
- Protocol coordination and approval: Reviewed all sections, with special focus on Time-event table, statistical considerations (e.g., randomization strategy, sample size, blinding panel), eligibility criteria (for recruitment and retention). I coordinated all types of study protocols: double blind (with and without cohorts), open labeled and double randomization studies,
- Protocol amendment: For "live" studies, there were several occasions when a major amendment was needed. Responsible for collecting/archiving required documentations/signatures and performing testing on clinical IT systems,
- Data collection: Accountable for study documentations archival to eTMF, including eCRFs, training materials, reports, change controls, etc.
- Contributed to patient reported outcome (PRO) and clinical outcome assessment (CoA),
- Site activation: Collaborated with CRAs, study managers, and IT support to initiate the studies to make sure study protocols are followed and regulatory requirements are met,
- Compliance and deviation investigation: Led investigations of three deviations in 2017 and developed effective CAPAs to mitigate the risk of repeat deviations,

- Supply Chain Management via IVRS/IWRS: Proactively advised on study protocol design to ensure optimal usage of IVRS/IWRS and shipping/inventory systems and achieved 100% on-time delivery for all studies,
- BioClinica IRT,

- Smart Labeling initiative: led efforts to evaluate, design, and implement state-of-art labeling translation and printing platform,
- Coordinated efforts between logistics, packaging, clinical operations to configure initial and resupply strategies in IVRS/IWRS systems to satisfy forecasted supply and demand and reduced stock-outs by 30%,
- Provided a forecast of clinical studies and monitored supplies for each investigational site and depot,
- Led UAT efforts for IVRS/IWRS modernization projects,
- Periodically reviewed supply strategies with clinical operations and schedulers,
- Managed all aspects of the study following activation in the IVRS/IWRS.

Compliance and Process Improvement Lead at Pilot Plants (2014 - 2015)

- Successful implementation of electronic logbook (eLog; part of global GSK IT MES modernization initiative) for two manufacturing sites at US Pilot Plants,
- Process and compliance improvement for primary and secondary manufacturing operations in support of CMC operations: Applied Lean Six Sigma methodologies to drive Gemba and reduce deviations, creating effective manufacturing practices to guarantee on-time delivery of clinical supply,
- Led tech transfer process improvement projects for large molecules and small molecules programs to support a dozen of clinical supply campaigns,
- Worked with Supply Chain and Operations Managers to revise SOPs and training materials, and provide trainings for material handling, manufacturing operations, and packaging personnel,
- Engaged in forecast meetings (4-week out) and implemented ADP practices into daily activities to ensure zero delays in clinical supplies,
- Led After-Action Reviews (AARs) for 30+ manufacturing and packaging batches,
- Coordinated investigations and drove Corrective Actions and Preventive Actions (CAPAs) on 20+ compliance and quality deviations for clinical supply, packaging and labeling.

Senior Scientist and SME in Cellular Imaging Assay Development (2007 - 2013)

- Seven years of dedication in assay development, high throughput screening, and lead optimization: Delivered more than 20 screening assays every year to support major therapeutic,
- Led assay development effort for average 4-5 pre-clinical program teams every year,
- Strategically initiated high content screening efforts,
- Globally strengthened drug discovery capability by implementation of High-Content Screening (HCS),
- Standardized policies and workflows to ensure data quality and integrity in the areas of cellular imaging and cytometry.

Research Assistant, Purdue University, (2005 – 2007)

Research Affiliate, Massachusetts Institute of Technology (MIT), (2004 – 2005)

Bioinformatician, Proteomics Core Facility, Academic Sinica, (2003)