Johanna Hunt Karas

Senior Supply Chain Consultant

Core Competencies

- Supply Chain Forecasting
- Clinical Supply Protocols
- Cold Chain and Sub-zero
- Open Label Supply Chain
- Blinded & Double Blinded
- Unblinded Pharmacist
- Packaging & Labeling
- International Customs
- IVRS
- Global Distribution Chain
- Vendor Management

Professional Summary

Ms. Karas has over twenty-eight years of experience in providing clinical supplies for investigational studies worldwide. Experience includes packaging and labeling, understanding of label requirements for multiple countries, import/export requirements, development of IVR specifications and monitoring systems for duration of clinical studies.

She has coordinated packaging/labeling, monitor repass dates, forecast and review/write packaging section of clinical protocols. Diligently worked with international counterparts to establish international shipping, depots, customs and processes.

A leader for developing and implementing of IRT for all phases of clinical trials including clinical trial designs that affect patient supply. She provides a variety of study experience including open label, blinded and double dummy studies, as well as complex drug packaging such as titration studies. Also, functioned as unblinded pharmacist for large Phase III studies by monitoring randomization of patients and ensuring drug availability.

Ms. Karas is a licensed pharmacist with a B.S. degree from the University of North Carolina at Chapel Hill. She has served in a clinical supply role at PRA, Gilead Sciences and as an independent consultant.

Education

B.S. Pharmacy University of North Carolina at Chapel Hill

Professional Experience

DSInPharmatics **2020 - Present**

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Ms. Karas supports our Clients' clinical supply management production forecasts and forecast models creating strong vendor relationships by managing clinical trial material distribution and cross-functional multi-national teams.

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Clinical Supply Consultant **2018 - 2020**

Senior Clinical Supply Chain Consultant

Represent clients on clinical supply cross-functional teams providing input to the development of IP-related study documents, protocols, study and pharmacy manuals.

- Forecast Investigational Product (IP) supply requirements and manage the IP distribution process for multiple clinical trials,
- Assist in the development of IRT specifications, perform UAT for IRT systems, and manage the IRT system for the duration of the study,
- Provides input into IP-related content for training materials and coordinates training on study procedures,
- Manage shipments of materials to depots throughout the world, work with depots to get materials through customs and have materials delivered to sites in a timely manner.

PRA Health Sciences **2016 - 2018**

Clinical Supply Project Manager

Serve as member of clinical study team and clinical drug supply team managing clinical supply planning and forecasting for study protocols.

- Interpret relevant protocol information to develop packaging/labeling design and/or global distribution strategy,
- Support design and set-up of IVRS system,
- Coordinate the origination, proofing and translation of clinical study labels,
- Monitor global clinical supply inventory at the clinical site level for both IVRS and traditional studies via tracking of specific milestone dates and adjusting drug distribution plan accordingly.

Clinical Supply Consultant **2006 - 2016**

Senior Clinical Supply Chain Consultant

Responsible for planning, implementing, and initiating activities on multiple projects related to the packaging, labeling, and distribution ofclinical supplies to ensure clinical supply study start dates are met.

- Assist in the development of IVR specification and manage IVR systems for duration of study. Address and resolve clinical supply issues for the IVR for duration of study,
- Manage external vendor relationships, negotiate contracts and conduct vendor audits with QA team,
- Manage the international distribution of clinical supplies for large phase 3 study,
- Manage inventory levels at sites and depots for pharmaceutical companies for clinical studies,
- Manage contract packaging and labeling by reviewing quotes, packaging and labeling documentation, scheduling of labeling activities, and requesting distribution of material to sites.

Gilead Sciences **2003 - 2005**

Manager, Clinical Supplies

Manage contractor activities, including selection of contractor to manage clinical supplies, provide timelines, resolve issues, etc. Responsible for forecasting and managing budget for packaging/labeling/distribution and related projects.

- Write/review drug product/clinical supply section of protocols and clinical study reports,
- Write and review SOPs required for clinical packaging/labeling/distribution to ensure GMP compliance,
- Work with Quality Assurance to resolve quality related issues with vendors.

Additional Professional Experience

- Triangle Pharmaceuticals
- GlaxoWellcome, Inc.
- Bryan Drugs
- Burroughs Wellcome