AMANDA B. GOODMAN

Supply Chain Consultant

Core Competencies

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

Professional Summary

Ms. Goodman is an accomplished clinical trials material manager with experience running domestic and international drug development programs for clinical trial phases 1through 3. The clinical trial programs included management of CMC manufacturing of drug substance, drug product, labeling and packaging of clinical supplies and clinical supply distribution.

She has led the developing and implementing of IRT for all phases of clinical trials including development of randomization and stratification criteria, review and development of specifications and user acceptance testing. She is knowledgeable of cGMPs and relevant FDA regulations.

Expertise includes developing detailed electronic diary for use in phase 2 and phase 3 clinical trials for orphan disease working with vendors to develop specifications, specification review, testing script development, conducting and managing testing of the diary and assisting in trouble shooting as issues arose during the clinical trial.

- Established and maintained clinical supply chain to ensure appropriate material delivery in a timely manner for multiple clinical trials,
- Maintain appropriate supplies for clinical sites based on expiry period including management of short expiry periods and limited IMP supply,
- Worked with clinical and CMC to develop robust strategies to ensure clinical trial needs are met,
- Responsible for all IMP labeling activities including development of label content for multiple regulatory agencies and management of translations,
- Establish and modified trial specific distribution agreements,
- Lead person managing vendors and coordination between multiple sites (domestic and international) to ensure project success including managing budgets, contracts, invoices and statements of work,
- Lead person developing and implementing IRT for all phases of clinical trials including development of randomization and stratification criteria, review and development of specifications and user acceptance testing,
- Collaborate with CMC and clinical project teams to develop CTM supply requirements based on materials on hand and clinical needs,
- Manage shipments of materials to depots throughout the world, work with depots to get materials through customs and have materials delivered as sites in a timely manner.

AMANDA B. GOODMAN

Supply Chain Consultant

Education

B.S. Biology, Secondary Education Appalachian State University

Professional Experience

DS InPharmatics **2020 - Present**

Supply Chain Consultant

Ms. Goodman supports our Clients' clinical supply management and supply chain strategy by making a positive impact in their CMC drug development program. She monitors production forecasts and models to forecast the clinical trial material distribution. She manages cross-functional and multi-national teams.

Biocryst Pharmaceuticals **2012 - 2020**

Clinical Trials Material Manager

Responsible for establishing and maintaining clinical supply chain to ensure appropriate material delivery in a timely manner for multiple clinical trials.

- Maintain appropriate supplies for clinical sites based on expiry period including management of short expiry periods and limited IMP supply,
- Responsible for all IMP labeling activities including development of label content for multiple regulatory agencies and management of translations,
- Lead person managing vendors and coordination between multiple sites (domestic and international) to ensure project success including managing budgets, contracts, invoices and statements of work,
- 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.

Becton Dickinson **2012 - 2012**

Quality Engineer

Managed conversion to a new quality program including management of an electronic SOP tracking program, calibration and preventative maintenance program for instrumentation and electronic notebooks program.

Cenduit **2011 - 2012**

Project Manager (IXRS)

- Managed all aspects of designing and development of interactive clinical systems (IXRS) for client's clinical trials,
- Liaison between clinical project teams and engineers.

Fulcrum Pharma Development **2008 - 2011**

Project Manager

Coordinated projects in multiple drug development areas including preclinical, CMC and clinical to meet the requirements of the project team and client including study planning and implementation, study status reports, project timelines and updates.