Supply Chain Specialist

Reports to: Associate Director of Supply Chain Management

Classification: Exempt

Summary:
This position will be responsible to support the supply chain function for all clinical trials.

Essential Functions and Job Responsibilities:

- Create, review and update clinical supply packaging plans to meet the demands of multiple clinical trials
- Set packaging and labeling schedules; supervise on-time completion at Contract Manufacturing Organizations (CMOs)
- Develop label specification; ensure labels meet country specific requirements
- Work closely with Quality Assurance, Regulatory Affairs and Clinical Operation teams for production input into the supply chain, as well as ensure release of product domestically and internationally
- Plan, schedule, and manage inventory and logistics of clinical studies (secondary packaging and labeling activities)
- Manage Finished Good shipments between international and domestic depots and clinical sites
- Review and resolve all shipment issues (e.g., damage, temperature excursions, non-compliance)
- Plan, schedule, and manage inventory and logistics to help manage supply chains
- Partner with Clinical Operation and Contract Research Organizations (CROs) on site level documentation and processes governing supply
- Manage supply chain timeline and stay abreast on changes by the functional groups or external vendors
- Maintain awareness of product expiration dates as well as supply levels to meet the needs of multiple sites, trials and patients
- Oversee inventory levels at the clinical sites and CMOs
- Project clinical site and CMO inventory levels; proactively ship to maintain supply
- Provide an input to production plans based on inventory projections
- Complete other responsibilities as assigned

Minimum Qualifications:

- Bachelor's degree or equivalent work experience in Logistics or related discipline
- Minimum of 3 years of experience in clinical supply chains in biotech/pharmaceutical industry
- Working Knowledge of cGMP's, GDP's and pharmaceutical industry procedure and regulation
- Problem-solving and decision-making skills
- Flexibility and the ability to manage change
- Strong interpersonal skills and the ability to work independently, as well as a member of a team
- Exceptional verbal and written communication skills, solid organizational, time management and project management skills
- Experience with the following software: Microsoft word/Excel/PowerPoint
- Knowledge of clinical supply demand management/planning tools (e.g. IWRS) and ability to support IWRS set up and maintenance

- Experience with clinical trial material label proof creation, approval process and label controls
- Detail oriented and flexible with the ability to manage change
- Theoretical and practical knowledge of clinical supply forecasting, demand planning and manufacturing capacity management
- Must have exceptional verbal, written, presentation, communication and negotiation skills