JOB DESCRIPTION (DRAFT)

Job Title	Head of Clinical Supply & Logistics (Snr Director)
Grade	
Reports to	SVP, Head of Clinical Operations
Department	
Hours	35
Location	London (White City)

About Autolus

Autolus is a clinical-stage biopharmaceutical company developing next-generation, programmed T cell therapies for the treatment of cancer. Using a broad suite of proprietary and modular T cell programming technologies. The company is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognise cancer cells, break down their defence mechanisms and eliminate these cells. Autolus has a pipeline of product candidates in development for the treatment of haematological malignancies and solid tumours.

Role Summary

Responsible for global clinical supply chain management across clinical sites, including qualification and training from apheresis, product delivery and infusion to the patient. This is a key role to ensure the relevant processes and interactions with clinical sites and manufacturing ensures a smooth delivery of the cell management processes. This person will be responsible for building processes to manage the patient cells from apheresis through cell infusion. It will require a background and experience in cold chain management within a global customer facing environment.

The Head will be responsible for global clinical supply chain management for CAR T cell clinical trials, driving supply chain logistics activities, managing service partners and suppliers and processes. He/she will collaborate with cross-functional teams in Europe and US including Technical Operations, Quality and Finance to accomplish Autolus' objectives for product management and lifecycle management.

The position will report into the SVP, Global Clinical Operations and a dotted line to Global Supply Chain Head.

Key Responsibilities

Key responsibilities will include:

- Build the key processes to optimise the management CAR T cell management within the global clinical trial setting
- Build a global clinical supply and logistics team to manage both cells and patients at the clinical trial sites in EU and US.
- Collaborate with manufacturing and logistics suppliers to ensure patient cells move through the supply chain in a seamless and rapid manner
- Identify operational improvement opportunities and lead their implementation
- In conjunction with relevant line functions lead the implementation of an electronic cell management system

- Ensure the clinical supply team manage the day-to-day logistic management tasks and monitor completion of required activities
- Lead and drive continuous improvement
- Work closely with global QA team to ensure GMP compliance in Supply Chain
- Create and develop standard operating procedures (SOPs) as required
- Manage the training clinical site personnel in SOPs and compliance
- Manage logistics investigations, process variances and deviations
- Ensure compliance with current European and US federal and local regulations
- Owner of related business processes and systems
- Lead cross-functional activities
- Develop and implement protocols and practices to ensure effectiveness and efficiency of strategic initiatives on logistics management
- Manage the functional budget

Demonstrated skills and competencies

E – Essential
P – Preferred

Experience

- Preferred qualification in supply chain or related discipline or equivalent qualification
- At least 7-10 years of relevant cold-chin clinical supply chain preferable in pharmaceutical or biotech company
- Working knowledge and understanding of GMP, GCP, GDP, and relevant ICH and FDA guidelines
- Strong knowledge and understanding of pharmaceutical Supply Chains as well as international distribution experience
- Previous experience in Cold-Chain Logistics, Distribution, and Supply Chain preferred
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Qualifications

- BSc, MSc or PhD in related discipline (E)

Skills/Specialist knowledge

- Solid experience working in cold chain logistics in drug development including significant experience with countryregulations
- Good knowledge of GxP quality standards
- Excellent communication skills
- Proven leadership skills
- Excellent written and verbal communication skills.
- Role will have multiple contacts across internal and external groups
- Process-oriented with strong analytical skills for risk identification and management
- Proficient in MS word, Excel, PowerPoint, Outlook and Warehousing software
- Excellent interpersonal, verbal and written communication skills are essential in this collaborative work environment
- Comfortable in a multicultural, fast-paced environment with minimal direction and able to adjust workload based upon changing priorities
- Flexible and approachable, open minded personality, ‘can do’ mentality
- Only candidates with a valid EU work permit will be considered

I have read the above job description and agree that this is a fair and representative summary of the duties and responsibilities of my role.