Jazz Pharmaceuticals
Innovation that performs

DATE WRITTEN/REVISED: ***25 Sep 2018***

Job Description

JOB TITLE:	***QA Manager, Development Projects***	COUNTRY:	***Ireland***
LOCATION:	***Dublin***	ALT LOCATION:	***Enter City, State of Alternative***
DEPT NAME:	***Quality***	DEPT NO:	***10500***
REPORTS TO:	***Ann O'Connor***	FLSA STATUS:	***Choose Drop Down***
JOB TYPE:	***Full Time***	WORK LOCATION TYPE:	***Office***
IS POSITION SUPERVISORY?	***YES***	BUDGET NUMBER:	***Enter Budget Number***
% OF TRAVEL:	***10% to 20%***	TRAVEL TYPE:	***Both US/International***

The purpose of this description is to provide a statement of the essential functions and requirements for the position and to organize and present the information in a standardized way. It is not intended to describe all functions, knowledge, skills, abilities, or working conditions that may be required for this position, nor should it serve as the sole criteria for personnel decisions and actions.

Brief Description:

Quality lead on Jazz development project teams. Responsible for Quality oversight of contract manufacturing organisations (CMOs) and material/service suppliers to ensure that all operations are fully in compliance with current international standards for cGMP. Specifically, this position is responsible for Quality oversight of CMOs/vendors of Jazz Biologics Investigational Medicinal Product across all phases of the clinical development lifecycle. Reporting directly to Director, Quality Development Projects.

Essential Functions:

Responsible for, but not limited to:

- Quality oversight of Biologics DS and DP process/product development and clinical manufacturing/analytical testing/packaging.
- QA Lead on internal Jazz and external CMO cross functional teams for development projects
- Quality oversight of process and analytical qualification and validation in accordance with phase appropriate regulatory requirements
- Monitoring operations at the contract site including batch review and disposition, review of stability data, deviations, OOS investigations, change controls, and other quality systems.
- Provide QA support to project teams and participate in strategies for product development and obtaining regulatory approval.
- Collaboration with contract manufacturers, packagers and testing laboratories to resolve any quality issues.
- Collaboration within Jazz cross functional CMC teams to resolve any quality issues.
- Ensure compliance with the GxP vendor qualification programme including initial and ongoing qualification
- Conducting vendor audits and vendor site visits as required
- Assisting in internal audits and Jazz or CMO regulatory agency inspections
- Support the product stability program for IMPs

- Contribute to the development of quality policies and procedures as required
- Generate and maintain Product Specification Files (PSFs), QP declarations, Supply Chain Flows
- Review and approval of IMP product artwork/labelling
- Support the execution of the internal Quality Management System (QMS) to ensure compliance to all relevant standards within the company.
- Support supply chain with on time Quality review and approvals to ensure timely supply of clinical material to trial sites.
- Contribute to regulatory submissions
- Build authentic relationships with critical suppliers and contract manufacturers and maintain all product-related Quality Technical Agreements (QTA's).
- Participate in and provide critical analysis of business diligence visits.
- Work closely with other members of Technical Operations group to ensure delivery of key project objectives and timelines
- Foster a positive employee relations environment and a culture of continuous improvement and teamwork through the use of good and consistent management principles.

Required Knowledge, Skills, and Abilities

- Significant QA experience (5-10 years) working in biologics/sterile manufacturing.
- Eligibility to act as a licensed Qualified Person is extremely desirable
- Working knowledge and experience of CMC regulatory and quality requirements for phase 1 through post approval, both US and EU.
- Thorough understanding of Quality Systems and phase appropriate cGMP's.
- Experience leading third party vendor audits
- Interpersonal skills and professional skills to interact at all levels including senior executives, contractors, and colleagues.
- Experience working with contract manufacturing
- Experience interfacing with regulatory bodies or working on regulatory submissions
- Highly organised, with exceptional time management and prioritisation
- Critical thinking and evaluation of process problems
- Excellent verbal and written communication skills
- Patient and results focused
- Good Leader, decision maker and highly motivated.
- Collaborative team player
- Strong work ethic with a flexible and adaptable approach

Required/Preferred Education and Licenses

- Bachelor's degree in chemistry, biology or a related discipline
- Eligibility to act as a licensed Qualified Person is extremely desirable
- GMP lead auditing certification is desirable

Description of Physical Demands

- Responsibilities may require working outside of "normal" hours, in order to meet business demands.
- Requires international travel for oversight of manufacturing/packaging activities at the contractor site as Jazz QA person in plant.