PRODUCTION MANAGER – BSRI-Denver

Description

Blood Systems Research Institute, the research division of Blood Systems, Inc., is growing a world class translational medicine research and development program focused on blood and related transfusion medicine products. A range of cGMP manufacturing development and implementation activities include early feasibility and prototyping, support of preclinical studies, larger scale manufacturing to support clinical trials through Phase 3, and commercialization implementation following regulatory approvals. The projected scope ranges from classical blood products to novel biologics to emerging cellular therapy applications. The Production Manager will manage overall production readiness, execution and product delivery. The candidate must demonstrate excellent organizational and project management skills across diverse and complex projects. Working together with team members within the institute as well as study/project sponsors is essential. This position reports directly to the Director of BSRI-Denver.

Specific duties and responsibilities will include:

- Oversight and project management of all aspects of cGMP manufacturing
- Day to day management of cGMP production
- Initiates timely resolution of deviations and change controls associated with manufacture of product and finished goods
- Authors, reviews, and/or approves pertinent SOP's, manufacturing process instructions, specifications, validation protocols
- Authors or reviews pertinent CMC sections for regulatory submissions
- Identify continuous improvement and process improvement opportunities
- Strategic input to the overall product development plans
- Ensure availability of Standard Operating Procedures, Qualification and Validation protocols and reports sufficient to ensure robust, reproducible product manufacture and testing, meeting or exceeding regulatory requirements and expectations.
- production for preclinical research purposes
- development of critical assays
- manage the overall production readiness, execution, and product delivery
- Understand and oversee process qualification criteria including formulation
- Provide troubleshooting support, and identify and implement improvements to equipment, instruments, techniques and processes.
- Oversees the hiring, development, retention and optimal performance of staff for the leadership and execution of manufacturing operations. Develops comprehensive operating plans and budgets and monitors achievement of business and financial goals

REQUIRED QUALIFICATIONS

- BS in chemistry, biology, or closely related disciplines - graduate degree preferred
- 3 yrs of experience in all aspects of pilot or commercial biologics manufacturing process in a pharmaceutical or biotechnology environment
- Two (2) years in a project management and/or leadership role
- The candidate should have a good working knowledge of manufacturing operations, biologics drug substance manufacturing, drug product manufacturing (oral solid dose and/or parenterals,) pharmaceutical packaging, CMC regulations, cGMP, and sterility assurance techniques.
- The candidate should have demonstrated written and oral communication skills and ability to work in a cross functional team environment.
- Knowledge of aseptic operations and support systems is essential. A strong working knowledge of the regulatory compliance requirements for the production of biologics used in clinical studies and commercial manufacturing are essential. Demonstrated managerial skills, written and communication capabilities, and inter personal skills is necessary. The Manufacturing Manager must remain current regarding technical manufacturing requirements and must be able to develop/modifies production methods to fully address such issues. The Manufacturing Manager prepares validation protocols, SOPs, and master batch records. The Manufacturing Manager manages manufacturing operations assuring compliance with appropriate regulatory standards
- Working knowledge of cell culture, aseptic and scale-up operations
- Thorough knowledge and understanding of cGMPs, GLPs and familiarity with FDA guidelines

LANGUAGE REQUIREMENTS

- Fluent English

EEO/Minorities/Females/Disabled/Veterans

Our organization is an equal employment/affirmative action employer. If you need accommodation for any part of the employment process because of a medical condition or disability, please send an e-mail to accommodation@bloodsystems.org or call 1-844-220-2612 to let us know the nature of your request. A representative will respond to accommodation requests within two business days. Please note that this email/phone number is for medical/disability accommodations only and any other inquiries will not receive a response.

To express your interest please submit your CV and cover letter by August 31, 2017 using the following link:

https://bloodsystems.taleo.net/careersection/bsi/jobsearch.ftl?lang=en&radiusType=M&searchExpanded=true&organization=56200100500&radius=1
Enter Job Number 17000900 into the search field.