Medeor Therapeutics, Inc.
611 Gateway Blvd, Suite 120
South San Francisco, CA 94080 USA

Position Description:

Director of Biopharmaceutical Operations / Manufacturing

Summary: The ideal candidate will have extensive experience in development and clinical manufacturing of cell therapy products in a GTP/GMP environment, as well as relevant industry experience in the conduct of clinical trials for investigational products. Excellent communication, organizational abilities and problem-solving skills are a must.

The Director shall represent Medeor at CMO meetings and provide leadership and manage day-to-day manufacturing and testing at the CMO. Be fully aware of contractual terms and implement controls as required and under the direction of the Head of Biopharmaceutical Operations. Track progress and support multiple programs at the CMO. Serve as a technical expert to the CMO participating in Medeor's clinical stage cell therapy programs. Demonstrate technical expertise and leadership in the development and manufacturing of cell therapy products, producing tangible and timely results as products progress from development toward registration and commercialization. The primary role of this position is to support clinical trial requirements from the CMC/Operations arena.

Essential Duties and Responsibilities

- Perform, oversee and lead a range of activities focused on clinical manufacturing operations, process development, tech transfer and implementation of manufacturing at contract manufacturing organization (CMO).
- Oversee and lead the development and transfer of manufacturing processes and assays to the CMO.
- Provide training and onsite technical support to CMO staff.
- Monitor and troubleshoot manufacturing performance through onsite support and supervision as well as review of process performance data.
- Establish and maintain productive working relationships with internal organizations such as Clinical Operations and Quality/Regulatory.
- Ensure that industry standards and best practices are effectively applied.
- Execute and oversee technical investigations of deviations. Identify CAPA and implement/design/lead process development studies to address.
- Perform FMEA and other risk analysis on manufacturing process. Lead DOE efforts, identify CQA and CPP, develop studies to determine acceptable ranges, implement validation studies in support of IMPD, Master File and license applications.
- Establish and maintain relationships with key equipment and material suppliers.
- Identify backup suppliers and processes to make certain supply chain risks are analyzed and adequately mitigated.
- Identify labs and lead and oversee leaching and extractable studies on all product contact materials as needed.
- Develop GMP data systems for manufacturing data, perform data analysis and CMC portions of Annual Product Reports to FDA as required.
- Review and update batch records and lead efforts to streamline batch records to reduce deviations.
- Review and approve Statement of Work and other commercial contracts.
- Review and approve departmental and project invoices.

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- Ensure departmental budget is maintained.

Qualifications

- B.S. or advanced degree in Life Sciences, Medical Technology or relevant field
- Minimum of 10-15 years of experience in cellular therapy product manufacturing in academic, hospital or industry setting
- Minimum 5-7 years of experience in manufacturing cell therapy products for clinical trials
- Expertise in ex vivo cell processing, cryopreservation, and testing (cell counting, flow cytometry, clonogenic assays) for hematopoietic stem cell products
- Experience with aseptic processing and use of automated closed system devices
- Understanding of FDA regulations, including cGTPs and cGMPs
- Experience with qualification and validation activities for equipment, assays, methods, and manufacturing processes