Director, Clinical Operations
Reference 16-29

Posted: August 2016

About us:
At Arbutus we have a vision: to cure chronic Hepatitis B virus (HBV). We have a dedicated and innovative team and we are uniquely positioned to transform the HBV treatment landscape. We are developing a portfolio of drug candidates with multiple mechanisms of action that we believe will result in a combination therapy to cure HBV. Arbutus Biopharma has offices and research facilities in Burnaby, Canada and Doylestown, Pennsylvania, USA.

About the role:
Arbutus has an opportunity for a seasoned clinical research professional to join our team in the East Coast, reporting to the Vice President, Clinical Operations. The Director, Clinical Operations will be responsible for managing global phase I-IV clinical programs, will work closely to mentor junior members in Clinical Development and will oversee study conduct and vendor performance to ensure that clinical studies are completed in accordance with contract specifications and corporate objectives. The ideal candidate will be located either in our Doylestown office, or in a home-office with the ability to travel as required to Arbutus' offices.

If you are looking to join a team with a proven track record in drug discovery and development, and are as passionate as we are, we want to hear from you.

Responsibilities will include:
- Oversee and manage all operational aspects of phase I-IV global clinical trials
- Manage direct and indirect reports, external partners, consultants, vendors and budget to ensure the timely, high quality, and cost effective implementation of clinical trials
- Strategically assess and recommend third party vendors for implementation of clinical development plan. Review and approve contracts, work orders and invoices prior to submission to senior management for approval
- Establish and maintain effective communication and collaboration with functional area peers including, Regulatory Affairs, Data Management, Legal, Development, Project Management, CMC Finance, etc. to meet program goals and support achievement of corporate objectives
- Contributes to the development, implementation and maintenance of clinical processes, SOP's and systems
- Responsible for establishing, maintaining, and reporting clinical program budgets including forecasting and monthly accrual tracking
- Participates in protocol design and amendment recommendations for clinical trials and ensures appropriate clinical study team review of all trial related documents
- Oversees clinical trial recruitment developing, or overseeing the development of strategies to ensure effective patient recruitment
- Ensures Sponsor oversight on all assigned clinical trials in accordance with GCP, all applicable regulatory requirements, and that trials are monitored in accordance to protocol requirements
- Contributes to development of related regulatory documents including CTA's, and IND's
- Provides support for clinical study report interpretation and assists in data interpretation

- In conjunction with Data Management, responsible for data cleaning, line listing review, and study data integrity
- In conjunction with Clinical Drug Supply, responsible for IP and ancillary supply management for assigned studies
- Other related duties as assigned

Qualifications:

- BA/BS/MS and a minimum of 15 years directly related experience in Clinical Operations management
- In depth knowledge and understanding of all aspects of Clinical Operations management, with a track record of successfully managing programs to completion, on time and on budget.
- Sound judgment and excellent conflict resolution capabilities.
- Excellent organizational skills and demonstrated ability to effectively manage project and/or other cross-functional teams.
- Outstanding communication skills with ability to interact with the Executive Team, capability to negotiate extremely difficult matters and to influence decision makers internally and externally.
- Demonstrates a clear understanding of overall company strategy; aligns people to corporate strategy and vision through words and actions.
- Has a track record of taking a leadership role while introducing new ideas that have significant organizational/team impact.
- Possesses a high tolerance for ambiguity; effectively leads and facilitates change. Flexible and highly adaptable.
- A hands on leader, with excellent problem solving abilities and pro-active nature.
- Experience interacting with regulatory authorities and Ethic Committees with expertise in GCP regulations and knowledge of other regulatory guidelines including GLP and GMP.
- Experience in HBV, rare or orphan drug development and working in a fast-paced biotech environment strongly preferred.

Contact Information:

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Doylestown, PA 18902
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web: arbutusbio.com

How to Apply:

We invite you to send your cover letter and resume in PDF format, to careers@arbutusbio.com. Please ensure your submission is in PDF format (ideally in one document) indicating your surname in the filename (**for example: SmithJane-cover-CV.pdf**) and position title and reference number in the subject line of the email (**"Director, Clinical Operations #16-29"**).

About your Application:

At Arbutus we value diversity and encourage applications from all qualified candidates.

We greatly appreciate your interest in being a part of our team; however, because of the volume of resumes received, we are only able to contact you should you be considered for a position. We will keep your resume in our database for one year, and contact you should a position that matches your skills become available.