ExCellThera Inc.

Director of Manufacturing

Background:

ExCellThera is an advanced clinical stage biotechnology company delivering engineered cell therapies using proprietary molecules and bioengineering systems to expand blood stem and immune cells for therapeutic use. ExCellThera's lead technology, ECT-001, combines a proprietary small molecule, UM171, and an optimized culture system. In pursuit of better treatments for patients, the company is building out its portfolio of living cell products, supported through best-in-class clinical trials, and an emerging commercial manufacturing strategy.

ECT-001 technology is capable of expanding the number of stem and immune cells exponentially in as little as seven (7) days, and is used in novel curative re-engineered cell therapies for patients with blood malignancies and other diseases, allowing more rapid engraftment, greatly reduced incidence of transplant-related mortality, low risk of chronic graft-versus-host disease and low risk of relapse, resulting in better outcomes for patients.

The FDA has granted ECT-001 orphan drug designation (ODD) for the prevention of graft-versus-host disease and regenerative medicine advanced therapy (RMAT) designation in the treatment of hematologic malignancies.

Various clinical studies using ECT-001 are currently ongoing and about to begin in Canada, the U.S. and Europe in the treatment of multiple myeloma, high-risk leukemia, sickle cell disease and other hematologic indications. In addition, ExCellThera plans to initiate additional clinical trials, including a pivotal licensure-enabling trial in the U.S., Europe and Canada, in the coming months.

The ECT-001 cell therapy product is currently manufactured in Montreal and its production process is being further automated and scaled for commercial production at a development site in Toronto. ExCellThera has recently entered into a manufacturing and collaboration agreement with New York Blood Center to increase output capacity. In addition, the company is in discussions with several world-class partners and CDMOs with respect to activating additional sites to further increase production capacity.

ExCellThera is at a pivotal point in its development and looking to grow its leadership team. The company is seeking a Director of Manufacturing to lead the growth and maturation of ExCellThera's process development and manufacturing activities. This is an exciting opportunity for a talented technical expert and leader to guide the manufacturing strategy and to build a manufacturing team for a fast-growing biotechnology company, and further their career experience in cell and gene therapy.

The ideal candidate has a technical background in bioprocess engineering, cellular therapies or a related field, and leadership experience in the cell the gene therapy industry, preferably in the context of a clinical or commercial stage therapeutics company. A broad understanding of CMC needs, stage appropriate technical operational requirements, and leading teams is a highly dynamic environment are highly desirable.

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Position Description:

- Lead commercial development and manufacturing strategy for ExCellThera's clinical stage pipeline through pivotal trial and registration.
- Build a manufacturing team and provide leadership, mentorship, and subject matter expertise to a growing team of development scientists, engineers and operators.
- Develop a strategy for and liaise and foster relationships with external manufacturing partners including CDMOs, supply chain partners and enabling technology providers.
- Lead the preparation, review and approve development plans, standard operating procedures, batch records and other process documentation.
- Advise and lead in strategy and preparation of CMC sections of regulatory applications (including BLA).
- Serve as a critical member of a dynamic leadership team by interacting closely across the leadership to grow and develop the company.
- Act as KOL and external technical leader for ExCellThera by interacting with the cell and gene therapy field to stay abreast of new technologies and developments and expand ExCellThera's network of manufacturing advisors.

Qualifications:

- Advanced degree (Ph.D. or M.Sc or equivalent) in biological engineering, chemical engineering, biological sciences, or similar.
- Minimum of 3+ (ideally 5 to 10+) years industry experience in process development and/or manufacturing in the cell and gene therapy, regenerative medicine or related field.
- Minimum of 2+ (ideally 5+) years team leadership and mentoring experience.
- Familiarity with clinical and commercial manufacturing, CDMO relationships, and CMC regulatory aspects.
- Hands-on involvement in progressing a therapeutic through the clinical pipeline.
- Ability to plan, guide, and lead teams in a dynamic environment, excellent organizational and problem-solving skills.
- Strong English oral and written communication skills.
- Familiarity (ideally direct experience) with CMC regulatory submissions, process development, GMP manufacturing, and/or technical operations.
- Familiarity (ideally direct experience) with a commercial manufacturing environment.
- Familiarity (ideally hands-on experience) working with human primary and/or stem cell cultures.
- Proficiency with relevant software and a range of technical applications (e.g. MS Office, statistical software, programming, data analysis).

Other:

- Full-time position based in Montreal (oral/written French is an asset).
- Significant advancement possibilities in a fast-growing biotechnology company.
- Competitive remuneration package and benefits (including relocation package if necessary).

Contact: submit your CV or enquires to david.millette@excellthera.com and peter.zandstra@ubc.ca.