From Bench to Business

The future's bright with emerging opportunities in regenerative medicine and stem cell businesses

hen she graduated from St. Lawrence College with her medical laboratory technology diploma in 1984, Lianne Witt never imagined she would end up working in one of Canada's hottest scientific fields. Today, she is technical director of laboratory and client services at Insception Lifebank, Canada's largest private cord blood bank.

"It's an incredible opportunity to be involved in regenerative medicine, using cuttingedge technology to work with stem cells from cord blood and cord tissue," says Witt. Cord blood stem cells are used to treat more than 80 life-threatening conditions such as cancers genetic diseases, immune deficiencies and blood disorders. To date, there have been more than 30,000 transplants of cord blood stem cells worldwide.¹

Regenerative medicine involves the repair, regeneration or replacement of diseased cells, tissues and organs, using stem cells, tissue engineering or biomaterials. Discoveries promise to treat a wide variety of life-threatening illnesses and chronic conditions including heart disease, diabetes, multiple sclerosis, spinal cord injury, cerebral palsy, vision impairment, and severe burns. Globally, the regenerative medicine field is growing fast. The market currently stands at USD\$19.3 billion and is forecast to more than triple in size and reach USD\$67.6 billion by 2020. The global market for cell therapy is USD\$5.1 billion, estimated

to reach more than USD\$8 billion by 2018.²

Right now, there are more than 1,900 active cell therapy trials underway across the globe, investigating new treatment approaches that may one day become commercial cell products or standard of care therapies. One exciting example is the recent addition of a human clinical study test site in Edmonton, Alberta, for a breakthrough long-term diabetes treatment. The VC-01TM made by California-based ViaCyte Inc., is an implantable pouch that holds pancreatic progenitor cells derived from human induced pluripotent stem cells (iPSCs), (See Stem Cells 101 on next page). Once implanted, the cells mature and secrete insulin, promising to free people with



Type 1 diabetes from dangerous blood sugar highs and lows and the need to monitor or take insulin injections.³

As the cell therapy and regenerative medicine fields grow quickly, new job opportunities are emerging for medical lab technologists looking for careers beyond traditional hospital labs. Positions in these organizations are ideal for those who want to work with leading-edge technologies, thrive in a fast-paced project-focused setting and are motivated by unique leadership and professional development opportunities.

Insception Lifebank is one of 46 member organizations that belong to the Centre for Commercialization of Regenerative Medicine (CCRM), a Toronto-based, notfor-profit organization launched in June 2011. CCRM operates as a global industry consortium at the intersection of academia and business, focusing on accelerating the commercialization of stem cell and biomaterials-based discoveries. Both Insception and CCRM have medical lab technologists on staff. All training happens

technologists on staff. All training happens on-the-job since there are no formal education programs that offer instruction on how to

At Insception, the eight technologists on staff are involved with the production of stem cell products from cord blood and cord tissue from start to finish. They process units for cryopreservation, conduct culture and sensitivity testing on samples with a BacT/ALERT instrument, perform flow cytometry to analyze stem cells, and participate in product releases when transplant requests are received. "We look for people with a track record of a high level of accuracy, because with our samples, we have one chance to get it right: we can't go and get a repeat sample," says Witt.

use the highly specialized and often proprietary equipment not seen in hospital labs.

Technologists at CCRM are involved in all three of the organization's areas of focus: cell reprogramming and engineering, cell manufacturing and biomaterials. They keep cells growing in culture, perform analyses and run experiments such as seeding cells on biomaterials or inducing cell reprogramming. The Microsquisher, developed by CellScale of Waterloo, Ontario, is one example of the highly specialized equipment operated by technologists at CCRM. It is used to determine stress-strength properties of biomaterial scaffolds, tissues and cells. Technologists also beta test new bioreactor equipment for stem cell expansion and provide feedback to manufacturers. Emily Titus, BASc, PhD, hiring manager, lab supervisor and project manager for CCRM's product and process development lab says, "Their feedback is always critical because they are often the ones doing the daily hands-on manipulation of the equipment." She leads a team of five scientists, one lab manager and five technologists.

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Stem Cells 101

A stem cell is a cell that has the ability to divide and differentiate into any cell type. Induced pluripotent stem cells (iPSCs) are adult cells that have been genetically reprogrammed to revert back to an embryonic state. Shinya Yamanaka, MD, Ph.D., won the 2012 Nobel Prize in Medicine for his discovery of a way to reprogram mature skin cells back to stem cells. in teams on a changing roster of projects. Titus says, "Something that defines the technologist position here at CCRM is that we have a diversity of projects and needs change very quickly. We get exposure to new ideas both from industry projects and from exciting academic work that comes through our lab. We have very defined expectations in terms of project milestones and goal setting." Flexibility is key at Insception too: "Things are always changing, even in the space of a year. Our technologists now process cord tissue, a technology we just launched a year ago," says Witt.

Gaining on-the-job specialized skills means that medical lab technologists become subject matter experts, which leads to unique leadership and professional development opportunities. Lab technologists at Insception have the opportunity to become accredited assessors with the AABB (formerly known as the American Association of Blood Banks) and travel to other countries to assess the quality and operational systems of other cord blood programs. The AABB is the accrediting body for cellular therapy labs around the world. Witt participated in the AABB's rigorous Accreditation Assessor Program and has travelled twice to different parts of India, one of her technologists recently went to Dubai, and she knows others who have gone to Brazil, Poland, Thailand, and China.

At CCRM, lab technologists lead the Human Induced Pluripotent Stem Cell (HiPSC) Workshop, providing essential training to other technologists and scientists in the community on how to produce and maintain iPSCs. Participants gain a strong foundation in standardized validation and characterization methods to ensure quality in the production of stem cell lines. "We offer the program on a pay-per-service basis. It is all run by the lead technologist who provides hands-on training in a teaching lab at the University of Toronto, one of our partners. We have trained over 50 people in the past four years," says Titus. This year's workshop was offered in October, in conjunction with the 2015 Till & McCulloch Meetings, Canada's only annual stem cell conference. Technologists attend together with leading stem cell scientists, clinicians and bioengineers as well as representatives from government, health and non-governmental organization (NGO) sectors from around the world. CCRM, the Stem Cell Network and the Ontario Institute for Regenerative Medicine co-hosted the conference this year.

Both Witt and Titus say the ideal candidate for a medical lab technologist position with Insception is someone with transferable skills and a keen interest to learn and work in groups at the leading edge of new discoveries. Witt says, "We look for technologists that have been involved in transfusion medicine. Experience with Canadian Blood Services is a bonus because they are familiar with blood manufacturing and its regulations and standards, and because they're going to have knowledge of some of the equipment we use here. We have hired new grads and we also work with The Michener Institute for Applied Sciences to place students who have completed their first year in our summer internship program. They start as lab assistants and



Emily Titus

can transition to casual labour and full time," says Witt.

At CCRM, all technologists currently on staff have either a bachelor or masters degree in science with a focus on cell biology, molecular biology or bioengineering. "Rather than looking for people with specific skill sets, we are looking people with a specific work ethic, a willingness and

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Canada's Legacy

Canadian doctors, James Till and Ernest McCulloch discovered transplantable stem cells at the Ontario Cancer Institute in Toronto in 1961. Since then, a number of Canadian scientists have been advancing the field. Read more about Canada's stem cell legacy of innovation at http://stemcellfoundation.ca/en/about-stem-cells/canadas-contribution/.

excitement to learn new techniques and work in collaborative team environments," says Titus, "We are open to all applications. I haven't seen someone with a medical laboratory technology diploma applying here yet but it would be very interesting to interview someone with that background to see how they would fit within the context of our overall philosophy."

The future is bright for career opportunities for lab technologists in the regenerative medicine sector. CCRM anticipates tripling their workforce over the next five years, spinning out more companies that will provide novel stem cell and biomaterials-based therapies. Insception plans to introduce new regenerative medicine technologies in the future, technologies that are top secret right now, but ones that technologists will also be involved with.

Working in the regenerative medicine field is a worthwhile career option for medical lab technologists looking for a chance to work with recent scientific discoveries and new treatments that can help people dealing with devastating and costly diseases and conditions. "Technologists here truly embrace and love what they do. There's so much passion! They know that the samples they're working on are golden and that this could be the difference in a child's life," says Witt.



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