Medical Product Development Program

PROJECTS 2010 - 2012

bioalberta
Association for Life Sciences Industry

Medical Product Development Program
The Medical Product Development Program (MPDP) is administered by BioAlberta and jointly funded by Western Economic Diversification Canada and the Government of Alberta through the Canada-Alberta Western Economic Partnership Agreement. The MPDP helps Alberta companies develop and commercialize new medical devices and applications.

BioAlberta is the central voice and organizing hub for the life sciences industry in Alberta. It is a private, not for-profit industry association, representing more than 140 member organizations in the province's growing life sciences sector.

www.bioalberta.com/mpdp

Back in 1998, when the predecessor to the Medical Product Development Program (MPDP) was launched by the Governments of Canada and Alberta, Alberta's medical device sector was a largely unknown segment of the life sciences industry. Medical research and pharmaceutical development tended to get the lion's share of attention.

Yet in recent years, the sector has flourished. According to Life Sciences in Alberta, State of the Industry 2011, 44.9 per cent of respondents in the medical technology and device sector have a product already on the market; another 16.3 per cent have lead products in research and development.

In 2008, the government funders of the MPDP approached BioAlberta to administer the program on their behalf, in order to expand the program's reach and give it a higher profile, and to develop and implement new processes that would improve program delivery.

Under BioAlberta's stewardship, the MPDP has succeeded by applying a needs-based approach to medical product development. We fund companies developing products that solve specific problems.

We have honed a formal process for determining support and assembled a top-calibre review panel. By also ensuring that students are involved as part of multi-disciplinary teams, the MPDP helps provide companies with gateways to academic institutions, which strengthens their access to specialized equipment, laboratory space and potential future employees.

BioAlberta remains committed to working with government and other partners to ensure that the MPDP continues to meet the needs of our companies and supports the growth of the medical technology sector in Alberta.

Ryan Radke, President, BioAlberta
How the MPDP Works

The fact that BioAlberta’s Medical Product Development Program (MPDP) always answers Travis Colley’s question from the outset is why it has quietly become an impressive success — for the people with interesting new ideas, for the medical technology industry, and for the taxpayers of Alberta who have invested $1.8 million in the program since 2010.

The MPDP helps Alberta companies involved in the development of medical and assistive devices take innovative new products and technologies to market. But its rigorous product-development process actually starts well before companies are approved for financial assistance.

Once BioAlberta launches a call for proposals and receives short expressions of interest from companies requesting aid, its MPDP technical directors offer to guide the company through a four-phase process that vets a concept, and then proves that the company developing it can go forward competently if it’s approved for funding.

The process is a detailed roadmap designed so that companies spend as little money as possible during its first four phases and save their funds for the production phase, says Darren Jaka, an industrial designer and kinesiologist who is one of the MPDP’s two technical directors. He and Colley, the other technical director, don’t “advise” companies, but act as sounding boards, throwing out hundreds of questions and providing information. “We ask, ‘What’s the big hurdle holding you up, what’s the big question we can get answered to move you down the road?’ ” says Jaka.

“In our business, everyone’s got an interesting idea — but is there really a need for it?”

Travis Colley, industrial designer and a technical director with BioAlberta’s Medical Product Development Program
The MPDP’s first role is to help companies choose the most appropriate project from the various product opportunities they’ve identified. It must be one that can benefit from just a year of MPDP assistance in what is likely to be a five to 10-year span of product development. It must also be useful. “They have to demonstrate that there’s a need, and that they have a solution,” says Colley.

In the second phase, companies make sure the product appeals to the people using, manufacturing, selling and buying the product. Jakal and Colley urge companies to gather research insights by talking to people who have the condition that the device is meant to assist. (See Case Study: Phase 2) They point out that by invoking BioAlberta and the MPDP’s names, “you can phone experts and they’ll talk to you,” says Jakal.

Next, the development plan suggests the company thoroughly examine its “search space” to learn about every existing, potentially competitive product, and all the possible ways of fixing the perceived problem. This helps ensure that the company chooses the most enduring solution and avoid a common pitfall. (See Case Study: Phase 3) “People often find a good market and come up with one solution and then their competitor sees the market and says ‘We can do it better,’ ” says Jakal. “So you end up doing the basic research for others and don’t reap the benefits.”

In the phase dedicated to conceptualizing the opportunity, the technical directors suggest making quick and dirty, pre-prototype models that the company can get into the hands of the user or expert for critical feedback.

Once the company finalizes its MPDP project concept, it submits a formal project proposal to BioAlberta to apply for funding. The project proposal is then submitted to an external-expert review panel. The panel assesses it for innovation, market opportunity, business strategy, commercialization capability, technical feasibility, intellectual property position and ability to meet the problem addressed.

Why Companies Like MPDP

• Simplified application process
• Streamlined paperwork and reporting requirements
• Flexibility — if a company learns something early on that changes the scope of the project, it can often be redefined

CASE STUDY: PHASE 2 – UNDERSTANDING THE OPPORTUNITY

“Innovative Trauma Care came to us with a very early model,” says Jakal, referring to the company’s ingenious idea for a quickly operated, wound-closure device that even non-professional first-responders could use. The ITClip™ was dreamed up by a former military trauma surgeon with expert understanding of hemorrhage control, but as often happens in product development, initially it wasn’t that user-friendly for non-experts. The company used its MPDP funding to refine the product’s design and usability, and develop a new and improved prototype.

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Each company that submits a shortlisted project proposal also gets a chance to pitch its project to the review panel in person, in a “Dragon’s Den”-style format. The panel’s extensive experience in business, financing and product commercialization gives the company another vetting point in the development plan. Based on how each project stacks up against the evaluation criteria and competing projects, the review panel then selects projects for approval.

If the proposal is approved, the technical directors continue to check in with the company as it completes its project, offering information and contacts.

The MPDP’s focused process allows new product development to occur more quickly, with money spent in a controlled manner, a rarity in many development experiences, says Jakai. “What normally happens is people start at zero, spend a little time and energy, and it’s a long slow bleed over the years. Lots of things will get lost, they’ll duplicate things, and over time it will cost a lot of unknown dollars and not get anywhere. Or, if they do, they might see some sales, only to have competitors see the space and overtake them.” In contrast, says Colley, “this program is well-managed, fairly lean, with extensive due diligence.”

Efficient delivery of the MPDP to companies was precisely BioAlberta’s goal when it took over the program and asked project manager Charlene Navarra to develop and implement a straightforward process. “Working with the technical directors helped to ensure that product development remained at the core of the program, while its administration was smooth,” says Navarra. While she continues to fine-tune its operation, “I think we have a solid program that is building a track record of contributing to company successes.”

The results for the 20 MPDP projects to date bear out this assessment. As of May 2012, close to 80 per cent have applied for patents; most are either already in or going into testing; several, such as XSENSOR Technology Corporation, Circle Cardiovascular Imaging Inc., Cleankeys Inc. and DriveABLE Assessment Centres Inc. are already selling their products, while several more, including IMBiotechnologies Ltd. are poised to enter the market.

CASE STUDY: PHASE 3 – CONCEPTUALIZING THE OPPORTUNITY
XSENSOR Technology Corporation faced a dilemma when developing pressure sensor pads. It had two options for an advanced method that hadn’t been attempted before, and each had large technical issues. The company was unsure of which project to choose, knowing that it might spend money on something that wouldn’t pan out. “The program allowed them to try both ways, to go to a variety of different suppliers and get ideas, and run both of those ideas through,” says Darren Jakai, one of MPDP’s technical directors. “Without the program, they wouldn’t have had the money to try it both ways.”

CASE STUDY: PHASE 4 – REALIZING THE OPPORTUNITY
In 2010, IMBiotechnologies Ltd., which develops medical devices that cut off blood flow to malignant and non-malignant tumours, used MPDP assistance to conduct product quality control tests. That same year, it became the first company to obtain U.S. Food and Drug Administration marketing clearance for a biodegradable embolic.

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BioAlberta’s Medical Product Development Program helps Alberta companies involved in the development of medical and assistive devices take innovative new products and technologies to market. MPDP provides support for incremental product development project costs, from materials to new project personnel.

As of April 2012, the program has completed three rounds, and assisted the following 20 companies.

**MPDP Project Recipients**

**BERTECH PHARMA LTD.**
Edmonton's Bertech Pharma Ltd. is focused on the development of effective cancer diagnostics. Its lead technology is a biomarker with high sensitivity that can be used in a blood test to detect early-stage colorectal cancer. It does so by identifying an enzyme that is expressed at high levels in colorectal cancer patients.

Colorectal cancer is the second-leading cause of cancer death, but when it's caught early there is a survival rate of 90 per cent. Currently, the common methods of identifying this cancer are inaccurate (fecal occult blood tests have only a 50 per cent accuracy rate), or the methods are intrusive and costly (a colonoscopy must follow a positive fecal occult blood test or be used based on a patient’s symptoms.)

Bertech's technology appears to be 80 to 90 per cent accurate, is cost-effective and non-invasive. It will provide increased convenience for patients and diagnostic accuracy for health-care providers. MPDP funding was used to support the creation of a commercial prototype of the product.

**CIRALD SCIENTIFIC INC.**
Calgary Scientific Inc. is a Calgary company developing and commercializing advanced medical visualization and mobile health software. Its target market is industries looking for secure transmission of heavy data, using their existing systems.

The company is developing analysis software for a novel medical imaging biomarker that distinguishes benign cysts in the liver from cancerous ones, when viewed on computerized tomography (CT) scans. The analysis will help radiologists—who see a large volume of scans and have only a few minutes to diagnose the original health concern, let alone others—to quickly and easily determine if these cysts need a biopsy.

The objective of the biomarker is to increase diagnostic accuracy and enable early treatment, resulting in an increased likelihood of patient survival and less cost to the health-care system.

MPDP assistance was provided to create an imaging biomarker for known cancerous tumours and non-cancerous cysts, using existing medical databases of images. The project's other goals were to develop a graphical user interface to visualize the information, and to adapt the tool for broader applications.

**CIRCLE CARDIOVASCULAR IMAGING INC.**
Circle Cardiovascular Imaging Inc. is a Calgary company that develops analytical cardiac imaging software. The software allows physicians to easily access large and complex cardiac MRIs (magnetic resonance images) from a GE, Philips, Siemens or Toshiba scanners, and then navigate and analyze them on any computer, including those located anywhere in the hospital, at a doctor's own office or home, or on a tablet while on the road.

Since its market launch in 2008, the product, which is called cmr42, has evolved to be the most comprehensive software of its kind. It is used in 22 countries, and at many of the world’s top cardiovascular hospitals and universities, including the Cleveland Clinic; the Mayo Clinic Health System; Duke, Harvard and Yale’s medical schools; Royal Brompton and King’s College hospitals in the UK; and the University of Leipzig.

Circle was awarded MPDP assistance to create a client-server model for cmr42 which lets multiple clients connect behind a hospital firewall, manages connections and patient data, and allows for pay-per-use and other creative licensing models. This cmr42 Smartclient solution will increase efficiencies in distributing and analyzing medical images, saving physicians valuable time and leading to higher levels of patient efficacy.
**IMBiotechnologies Ltd.**  
WWW.IMBIOTECHNOLOGIES.COM

IMBiotechnologies is an Edmonton company developing medical device products in the area of embolotherapy, which involves cutting off blood flow to malignant and non-malignant tumours. In 2010, IMBiotechnologies received U.S. Food and Drug Administration clearance to market its lead product, OCL 500, to treat unreatreatable and inoperable hypervascularized tumors such as liver cancer and kidney cancer. The product is a biodegradable embolic device. Unlike existing products, OCL 500 does not remain in the body permanently. After the tumour is treated, the product biodegrades, and the blood flow to the treated tissue is restored. The company received MPDP assistance in order to conduct a series of product quality-control tests necessary to meet FDA requirements.

**XSENSOR Technology Corporation**  
WWW.XSENSOR.COM

XSENSOR Technology Corporation is a Calgary company that develops and manufactures sensor pads for pressure—imaging (a.k.a. a pressure-mapping) to monitor and compare pressure distribution over time. These systems are used in the sleep and automotive industries, and in the fields of patient safety. In patient-safety applications, clinicians, nurses and rehabilitation therapists use them to help prevent pressure ulcers (bed sores), through improved surface selection and patient positioning. XSENSOR’s pressure-imaging systems are used in more than 40 countries, and by clients that include NASA, the U.S. Air Force, multiple car and mattress manufacturers, and the Mayo Clinic. XSENSOR is now developing technology to monitor and measure accumulated pressure on the surface of hospital beds to further aid in the prevention of pressure ulcers. MPDP assistance allowed the company to develop and test improvements in the manufacturing process for the sensor pads. The new product is now on the market.

**Zephyr Sleep Technologies Inc.**  
WWW.ZEPHYRSLEEP.COM

Zephyr Sleep Technologies Inc., a Calgary company focused on the sleep-disordered breathing market.

Sleep disordered breathing affects millions of people and can have severe consequences. In particular, sleep apnea (abnormal pauses in breathing during sleep) reduces oxygen levels to the body and can lead to hypertension, stroke and heart disease. Currently, 90 per cent of patients diagnosed with the most common sleep apnea — obstructive sleep apnea, caused by physical airway blockage — are treated by continuous positive airway pressure machines, or CPAPs. However, CPAPs are uncomfortable and inconvenient; more than 40 per cent of patients give up on them within the first year of use. In contrast, dental-based therapy using an oral device has proven to be a very effective option for 80 per cent of obstructive sleep apnea sufferers. The challenge is that there has been no effective way for determining which individuals will respond to dental-based therapy.

With MPDP assistance, Zephyr has developed an assessment tool that predicts whether oral appliance treatment will be effective, and also what the optimal device configuration should be for the patient. This tool not only gives dentists and patients a time-saving and cost-effective solution, it also brings dentists and sleep physicians together in the effective management of obstructive sleep apnea.

The MPDP project allowed Zephyr to create three prototypes of its tool, and to complete the electrical certification required for regulatory approval. The device will be proven effective in clinical trials, as Zephyr works toward clearance for the tool by the U.S. Food and Drug Administration and Health Canada. In addition, Zephyr was successful in its application for Round 2 funding by the MPDP for another product based on the same platform (see Round 2 descriptions.)

**Cleankeys Inc.**  
WWW.CLEANKEYSINC.COM

Cleankeys Inc. is a Calgary company focused on the disordered breathing market. The device was proven effective in clinical trials, as Zephyr works toward regulatory approval. The device will be proven effective in clinical trials, as Zephyr works toward clearance for the tool by the U.S. Food and Drug Administration and Health Canada. In addition, Zephyr was successful in its application for Round 2 funding by the MPDP for another product based on the same platform (see Round 2 descriptions.)

**Drivable assessment centres Inc.**  
WWW.DRIVEABLE.COM

Drivable produces science-based competence-assessment tools for motor vehicle drivers, which quickly, accurately and effectively predict cognitive competence. These assessment tools meet the need for driver risk and safety management for the health-care industry, the insurance industry, government licensing agencies and fleets. They can be used in multiple ways as a pre-employment screening tool, to make sure current drivers are, and remain fit, to drive over the years; and to ensure employees returning to work after an injury are safe behind the wheel. The tools were developed by Dr. Allen Dobbs, when he was director of the Neurocognitive Research Unit within the Northern Alberta Regional Geriatric Program (Glenrose Hospital), and a professor at the University of Alberta. Dr. Dobbs founded Drivable as a University of Alberta spin-off company to offer the assessment service worldwide. He now serves as the CEO of Drivable. Drivable’s various tools test cognitive abilities in a number of scenarios. With MPDP support, the company is developing a tool specifically for evaluating the cognitive competence of school bus drivers, who may have reduced cognitive abilities due to medical conditions. Product development and testing is nearing completion.

**Innovative Trauma Care Inc.**  
WWW.INNOVATIVE TRAUMA CARE INC.COM

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The Alzheimer’s Innovation Institute Inc. is a privately held for-profit corporation headquartered in Calgary, Alberta. It was founded in 2005 to research, develop and commercialize therapeutic quality-of-life enrichment programs for persons with Alzheimer’s disease and other types of dementia. The Alzheimer’s Innovation Institute is the sole developer of the Ashby Memory Method program (AMM). It is a structured cognitive-exercise program focused on the sleep-disordered breathing market. The project is focused on the Adaptively Controlled Mandibular Positioner, a dynamically controlled oral appliance that monitors breathing throughout the night and adjusts the position of the mandible (the jaw), in response to airway obstruction associated with sleep disorder breathing. The objective of the technology is to provide mandibular advancement therapy to patients only as they need it during the night. The overall goal of the MPDP project is to develop the data interface of the mandibular positioner, with specific emphasis placed on the therapeutic application. MPDP funding is being used to hire a project team to develop the product and materials.

Aquila Diagnostic Systems Inc. is a Calgary early-stage medical device company focused on point-of-care diagnostic testing for blood-borne infectious diseases and cancer. Current molecular diagnostic tests for blood-borne diseases have several qualities that make them unsuitable for use in developing countries, or for specific applications in developed countries. They are either expensive and complex (requiring extensive infrastructure, such as centralized laboratories and highly trained staff), or they are not sensitive enough to be used in point-of-care testing. With MPDP assistance, the company is developing its Domino portable diagnostic platform test kit. It would be a low-cost, robust diagnostic test for blood-borne infectious agents, that could be used by front-line staff in developing and developed countries. The technology encompasses a disposable, micro-fabricated plastic chip and a supporting instrument, which have been successfully used to detect multiple viral, bacterial, parasitic and genomic genetic markers in blood samples. MPDP funding will go towards the industrial design of a rugged, field-ready Domino system.
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