



Lionbridge
LIFE SCIENCES
CASE STUDY

LIONBRIDGE LIFE SCIENCES & ATCOR MEDICAL

When strategizing their next generation medical device technology, AtCor Medical sought external software engineering expertise to ensure a world-class user experience.

The Challenge: Successful Development and Testing of a Global-Ready Platform

AtCor Medical, with its SphygmoCor® technology, pioneered the gold standard measurement for central blood pressure measurement, performed noninvasively, enabling unprecedented clinical insight.

In developing its next-generation technology, the AtCor Medical team wanted to ensure that the user experience was optimized to provide clinicians with:

- Enhanced accuracy and speed over first generation technology
- Simple patient intervention
- Easy access to pertinent clinical information through a simplified graphical user interface (GUI) and optimized system logic to accurately capture, manage, and utilize recorded patient data



In consideration of concurrent commitments and highly focused technical expertise among AtCor's existing internal product engineering team, AtCor's management saw the need for partnering with a credible technology engineering provider to complement its capabilities as product go-to-market timelines loomed.

The Right Choice: Lionbridge Life Sciences

After a rigorous evaluation of several service providers, AtCor Medical turned to Lionbridge Life Sciences and its highly credentialed team of Project Managers, Software Architects, and QA Specialists.

Through its Global Development and Testing (GDT) unit, Lionbridge Life Sciences' value-proposition to AtCor included:

- Substantial healthcare experience within highly regulated environments
- Well-developed software development process fully compliant with IEC 62304
- Substantial reduction of maintenance by migrating to .NET

INDUSTRY:

Medical Device

CUSTOMER PROFILE:

An Australian-headquartered company with a U.S. subsidiary, AtCor Medical develops innovative, non-invasive products for the assessment of cardiovascular system functioning.

OVERVIEW:

In preparing to launch its next generation technology, AtCor Medical wanted to ensure that the user experience was optimized to provide fast, accurate and easy-to-administer measurements as well as easy access to pertinent clinical information.

With its substantial healthcare experience in highly regulated environments and software development processes fully compliant with IEC 62304 requirements, AtCor tapped Lionbridge Life Sciences for the important effort. Lionbridge applied distributed agile co-development and the Plus-One customer satisfaction program, delivering within stringent timeframes and supporting a successful, on-time product release.

- Ability to accommodate future localization and language needs in layered software architectures
- Project teams committed to delivering high quality, timeliness and budget discipline

The Solution: A Quality-Focused, Agile-driven Process

Lionbridge Life Sciences applied three of its strongest features to the project:

- Distributed Agile co-development: A framework emphasizing incremental tasks, close collaboration, adaptable planning and rapid delivery
- The Plus-One customer satisfaction program: A continuous improvement initiative within Lionbridge Life Sciences designed to encourage employees to find ways of delivering beyond the expectations of the original scope of work
- Experience in regulatory requirements for medical devices: Protocols designed to ensure strict compliance with the IEC 62304:0606 standard in software acceptance criteria including detailed design, coding activity, unit testing, integration testing and performance verification

Lionbridge Life Sciences and AtCor Medical developed a detailed work scope for the project addressing:

- Presentation layer (GUI), data layer and common functionality
- Tools and technologies to be used, with Agile development milestones
- Specifications for automated unit testing, integration/performance testing and user acceptance testing
- Architecture and technical approach
- Scripts for migrating legacy user data into a new, centralized database
- Progress and bug tracking
- Requirements for regulatory compliance
- Acceptance criteria and change control

The resulting collaboration between the teams led to predictable release planning with consistent delivery, upward-trending velocity with downward-trending spend, repeatable processes and a trusting partnership over a multi-year project.

“ We have been pleased with our customers’ enthusiasm regarding SphygmoCor’s clinical value and their very favorable response to the graphical user interface. I give high marks to the Lionbridge team for their

STRONG COMMITMENT TO QUALITY,

their continued responsiveness throughout the development cycle, their ability to work within stringent regulatory parameters, and their strength in software engineering. We considered them an extension of our product development team. ”

- Lawrence Chan
Product Development
and Technology Manager
AtCor Medical



The Result: Regulatory Clearance Received, Highly Favorable User Response

The joint efforts of both teams resulted in AtCor Medical being able to launch the next-generation SphygmoCor® at the May 2012 annual European Society of Hypertension Congress in London. In November 2012, AtCor received U.S. Food and Drug Administration (FDA) clearance to market the SphygmoCor XCEL system in the USA, its largest market. The successful market uptake of this revamped flagship product was clearly reflected in AtCor's 2013 financial performance with a Y-o-Y sales increase of 41%.

Today, more than 3,200 SphygmoCor systems are in use in 39 countries, following approval in Canada and China in 2014. In 2012, AtCor was awarded a coveted Australian International Design Award by Good Design Australia. Articles on the SphygmoCor XCEL system have appeared in Proceedings of the 34th Annual International Conference of the IEEE EMBS (2012) and Journal of Hypertension (2013).

An extremely positive user experience has been a large part of the technology's adoption success, thanks in part to the valued contributions of the Lionbridge Life Sciences team.

SPHYGMOCOR XCEL SYSTEM:

- Improved graphical user interface
- Easy access to key clinical information
- Regulatory-compliant functionality
- Positive user experience

“As they say, great customers make for great outcomes, and in working with AtCor Medical, this was definitely the case. The entire AtCor team was

EXTREMELY COLLABORATIVE AND EASY TO WORK WITH.

They provided great insight and brought deep experience and commitment to the project. Clear, consistent communications helped us to work through some unexpected challenges together, which in the end made for an even stronger outcome. On behalf of the Lionbridge Life Sciences team, we were pleased to be a part of this important effort and look forward to maintaining a positive and productive relationship in the future with AtCor Medical.”

- Kelvin Chan
Head of Sales
South Asia, Lionbridge

ABOUT ATCOR MEDICAL

AtCor Medical develops and markets products for the early detection of cardiovascular risk and management of cardiovascular disease. Its technology allows researchers and clinicians to measure central blood pressure non-invasively. AtCor has operations in Australia, the United States and Europe. For further information, please visit www.atcormedical.com.

ABOUT LIONBRIDGE LIFE SCIENCES

Lionbridge Life Sciences is a specialized business unit within Lionbridge Inc, providing translation and globalization services exclusively to Medical Device and Pharmaceutical companies, Clinical Research and Healthcare organizations. Lionbridge serves to maximize global communication effectiveness within the boundaries of a highly regulated, complex and always-challenging life science environment. For more information, please visit lifesciences.lionbridge.com.