

Case study – Inside Biometrics ◀

The customer

Inside Biometrics is a healthcare medical technology company that operates in the expanding global markets of diabetes self-testing devices and personal fitness tracking devices for performance and weight management. Based in Dingwall, near Inverness, Scotland, it was founded in 2013 by Dr Selly Saini and a team with extensive experience in the development of healthcare medical technology, personal self-monitoring devices and medical device manufacture. Before setting up Inside Biometrics, Saini worked for Johnson & Johnson Inc. as VP Global Strategic Marketing, VP Research & Development and Worldwide Director for the Diabetes Care business.

The challenge

Inside Biometrics' first product to market was a blood glucose meter that was set to launch in early 2016 in Europe. The product enables diabetic patients to self-measure the level of glucose in their blood, in order to make decisions about medication and food intake. The user obtains a minute drop of blood and applies it to a disposable test strip, which is attached to an electronic meter that displays the test result. While there are many blood glucose meters on the market, the Inside Biometrics product is highly innovative in its ability to collect and analyse the sample, giving users more relevant and valuable information that can be used to avoid short and long term health complications from diabetes. That ability comes from a combination of new strip technology and software within the meter.

The product will be made available through healthcare providers, such as the NHS. However to bring it to market, Inside Biometrics needed to be sure that its product complies with relevant international regulatory requirements for this type of medical device.

This required Inside Biometrics to establish, practice and monitor a well-defined quality management system which is subject to continuous improvement. This was implemented using a combination of internal experts and specialist external organisations providing skills and experience in specific areas for the project.

"It was about bringing in the right people with the right knowledge and experience, who could advise us and put all the pieces together," says Dr Selly Saini. "Alastair and the Lorit team had the right experience to advise us on medical device software. It was a very good fit that proved to be catalytic in achieving our objectives."

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Inside Biometrics

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Inside Biometrics

How Lorit Consultancy helped

Inside Biometrics picked Lorit Consultancy from a range of providers, based on Lorit's breadth of experience. "Alastair's broad background gives him the right perspective to bring these kinds of programmes to fruition," says Saini.

Lorit Consultancy ensured that Inside Biometrics followed the regulations it needed to sit behind the relevant standards.

The two main standards involved were BS EN 62304 and ISO 13485:2003.

BS EN 62304 is a harmonised international standard that specifies life cycle requirements for the development of medical software and software within medical devices. ISO 13485:2003 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

Lorit's role was to take an in depth look at the software controlling the device. The task involved making sure that all the correct documentation was in place, that the design history was appropriate, that the correct risk analysis measures were taken and that appropriate system testing was carried out.

Specifically, Lorit Consultancy carried out the following actions:

- ▶ Defined a documentation structure for the BS EN 62304 Class B software implementation.
- ▶ Defined actions and the nature of activities for the software implementation.
- ▶ Restructured requirements for the blood glucose meter implementing V models for both software and hardware.
- ▶ Linked system, software and hardware requirements to top level product requirements, ensuring all requirements are unique, traceable and verifiable.
- ▶ Generated architectural requirements for both hardware and software.
- ▶ Generated software unit and detailed hardware requirements.
- ▶ Defined supporting documentation for the BS EN 62304 implementation.
- ▶ Successfully presented the documentation to BSI in the ISO 13485 audit.
- ▶ Ran checks on requirement traceability.

Lorit's range of experience meant that the company was well placed to provide the expertise needed for the project. "Alastair was able to bring a wealth of experience from other projects, sometimes in other industries, and bring them to bear on this particular one we are looking at. That broad experience helped to accelerate the pathway," explains Saini.

"My background in hardware and software development was particularly useful in this project," says Alastair Walker. "I know the demands placed on development teams and that put me in a good position to support Inside Biometrics in what was a fairly time critical project."

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Lorit Consultancy

The outcome

For Inside Biometrics, one of the biggest measurable benefits was how efficiently Lorit was able to proceed through the project. With a projected UK product launch date of early 2016, it was important to hit milestones promptly. "Alastair was able to put in place all the required systems and work synergistically with the internal development and quality teams in preparing the documentation within the quality management system, allowing our organisation to move to the next development milestone," says Saini.

Want to know more? ◀

If you'd like Lorit Consultancy to help you achieve your development milestones by ensuring that you meet appropriate functional safety and quality requirements, please contact us for a confidential discussion about your project at info@lorit-consultancy.com or +44 7708 360023 (UK) or +49 3056 795165 (DE).