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Conceptual rendering of research device. Product is under development and is not available for sale in the United States.

Bigfoot Biomedical Customer Case Study

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This case study explores how medtech startup Bigfoot Biomedical selected and implemented codeBeamer ALM to support their medical device development processes. The company, founded by fathers of children with Type 1 Diabetes, is building a connected ecosystem of medical technology that aims to significantly reduce the burden of managing diabetes care.

With product components including a glucose monitor, an insulin pump backed by an AI-supported control algorithm, and a smartphone app for ease of use, Bigfoot's development team is building an innovative Class 3 medical device that has the potential to create a revolutionary shift in the everyday lives of patients living with diabetes.

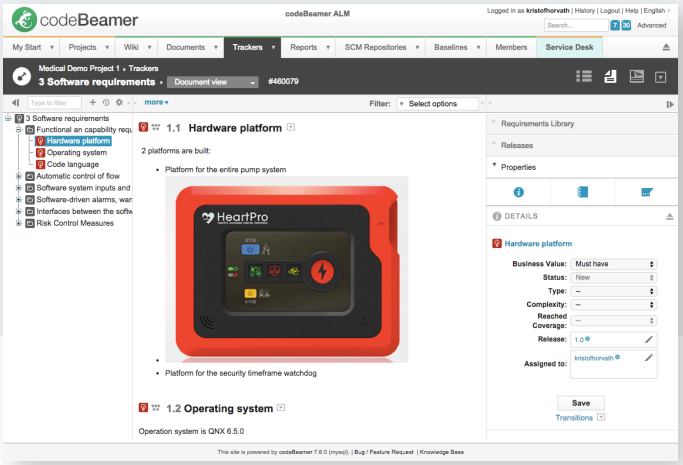
Led by Senior Director of Software Engineering Alan Schachtely, Bigfoot's development team is supported by codeBeamer ALM in their efforts to deliver first of its kind, cutting edge medical technology that promises to take the headache out of managing diabetes.

ALM for Medical Device Development

Traceability | Review | Compliance

As the best medical Application Lifecycle Management tool on the market, codeBeamer ALM efficiently supports product development and compliance in healthcare innovation. It guarantees traceability across the lifecycle, supports the use of mature development and risk management processes, and greatly facilitates compliance with medical standards.

Intland's Medical IEC 62304 & ISO 14971 Template provides preconfigured processes and artifacts to reduce the time and costs of audits, while Intland's Tool Validation Package Template reduces the burden of qualifying codeBeamer ALM for use in safety-critical development. Learn more at **www.intland.com**.



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Bigfoot Biomedical: The Story

Bigfoot Biomedical Inc., a company started in 2014 and now based in Milpitas, CA, is a medical technology startup working on a disruptive product that has the potential to revolutionize diabetes care. The integrated medical device ecosystem the company is developing promises to dramatically reduce the cognitive, emotional, and financial burden of insulin-requiring diabetes.

In a medical technology sector largely driven by top-down development projects by large corporations, the company's story is a particularly inspiring one.

It all started in 2011 when Sam, the 5 year old son of Bryan Mazlish, one of Bigfoot Biomedical's founders, was diagnosed with Type 1 Diabetes (T1D). Like so many other parents of children with T1D, he was faced with the difficulties of the day-to-day management of diabetes care: the constant monitoring and tedious logging of blood sugar levels round the clock, all on paper forms. And if Sam was out of the house, along with all the data recorded by his glucose monitoring device? Bryan could always cross his fingers and hope his son would be alright…

Frustrated by the limitations of commercially available products, he went on to hack his son's glucose monitoring system to export glucose data and feed it right into the cloud. Making this data available for patients and caregivers in real-time is proving to be a game-changer in diabetes care.

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About Alan Schachtely

Sr Director Software Engineering, Bigfoot Biomedical

Alan received training as a Medical Specialist and Emergency Medical Technician and spent time in the US Army before joining the National Guard Service. He spent more than 6 years working at GE Energy and GE Software before joining Bigfoot Biomedical in mid-2015.

An energetic and charismatic Agile leader, Alan has and continues to play a key role in building and scaling Bigfoot's development capabilities. These capabilities to develop high quality medical products enable the company to realize their vision of transforming the everyday lives of patients living with insulin-requiring diabetes.

Alan drove the evaluation and implementation of codeBeamer ALM at Bigfoot. It wasn't long before he became a champion happy to share his experiences with the platform both as quotes in this case study, and in discussions with potential users of codeBeamer ALM.

Fast forward to 2018, Bryan joined together with a team of people with personal touch points with T1D to form Bigfoot Biomedical, and the company is hard at work to design systems to optimize the dosing and delivery of insulin for people with insulin-requiring diabetes. Their two investigational systems in development include an automated insulin delivery system consisting of a connected glucose sensor, and an insulin pump with a proprietary control algorithm supported by Artificial Intelligence to adjust the amount of insulin with the intent to keep glucose levels in range, and a connected insulin pen-based decision support system for people who take insulin injections. These systems, each of which integrate with a smartphone app, are intended to reduce the burden of living with Type 1 and insulin-requiring Type 2 Diabetes.

Having received financing of over $70M+ from investors including the Juvenile Diabetes Research Foundation, Bigfoot's co-founders (each a father of children with T1D) are creating what the NYTimes simply dubbed "A Do-It-Yourself Revolution in Diabetes Care".

Bigfoot Biomedical is leveraging smart technology and Agile practices to develop high-tech Class 3 investigational systems intended to greatly improve patient experience for those affected by insulin-requiring diabetes. In 2016, the company chose the codeBeamer ALM tool as part of their Quality Management System to support their medical device development processes, which are compliant with relevant medical regulations.

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Challenges of Agile Development in MedTech

Led by Alan Schachtely, the team at Bigfoot runs a rigorous lean Agile shop. Their software and IT teams, numbering about 20 team members altogether, follow Agile practices to define, design, develop, and test their product's software components.

Being a startup company, Bigfoot Biomedical was aiming for a cost-conscious approach to ensuring efficiency in development and compliance. Following recommendations, they had implemented Jama for requirements management and JIRA for scrum management.

Using Jama to develop and trace requirements and JIRA to track the process of work, the Bigfoot team needed the two tools to integrate seamlessly in order to maintain traceability. However, the bi-directional sync between their chosen platforms was problematic: some items would simply disappear, leaving developers perplexed and making traceability impossible to achieve.

After about a year or so of struggling with this toolset, like many other companies, they reverted to that method so dreaded for its inefficiency by software teams worldwide: using spreadsheets to trace work items across their software tools.

> **"Our product management team was using Jama to develop our requirements and track their relationships. Jama was supposed to integrate with the Jira boards the development team used to track progress in implementing those requirements, but we ran into issues with the bi-directional integration. We ended up using spreadsheets to capture trace across the two systems. This was an extremely tedious manual process that we knew wasn't going to work long-term."**

With compliance needs including IEC 62304, Title 21 CFR Part 11, ISO 14971, and ISO 60601, the lack (or troublesome manual logging) of traceability was a crucial issue.

The Bigfoot team faced another challenge when trying to provide data for their Word-based Quality Management System. Jama's export functionality failed them, making it difficult to use with the QMS that Bigfoot had in place.

These key pain points of traceability and QMS compatibility sent them searching for a new tool that, ideally, would have combined solutions for all their needs in one platform.

> **"Our goal was to have a fully featured, integrated digital system of record that enabled the capture of our cascade of documentation needed for product development and regulatory submissions as well as faciliated the rituals and patterns that drive the product development cycle."**

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Evaluating ALM Tools

Bigfoot Biomedical started their evaluation of ALM tools in Oct 2016. During the 4-6 weeks of investigation, Alan Schachtely's team researched and analyzed the capabilities of a set of development tools. Key evaluation criteria included full ALM integration (from requirements through testing and team management), workflows, platform adaptability, cost per user, and platform maturity.

Eventually, none of the below tools really convinced them during the bake-off:

- **Jama:** The Bigfoot team was disappointed over the quality of Jama's JIRA integration for team tracking, and the lack of integration with test tracking.
- **JIRA:** They believed JIRA was good for team rituals, but were challenged by its lack of integration and tracking.
- **IBM Rational DOORS:** DOORS was ruled out due to negative historic experiences, shortcomings of the user interface, and the tool's limited adaptability.
- **Test Track:** The Bigfoot team liked Test Track for test management, but it was not easily integrated with requirements management, prohibiting its use in a development environment where traceability was key.

codeBeamer ALM was referred to Bigfoot Biomedical by a consultant via Medtronic (head over to **intland.com/medtronic** to download our Medtronic case study). As Alan puts it, codeBeamer came as "the right tool at the right time". They were happy to find a one-stop shop for all their development needs: the tool included Scrum management, requirements cascade, relationships between work items, and solid document management capabilities – and more.

The evaluation team at Bigfoot was thrilled to find that they were able to fully adapt codeBeamer ALM to their processes. In addition to offering the good document support and solid importing and exporting of Word files that their QMS needed, codeBeamer enabled the Bigfoot team to link requirements to sprints, tasks, test cases, and all other artifacts. This gave them the ability to trace all items across the entire lifecycle.

They also found that all test activities could be linked and logged in codeBeamer ALM, completing the Bigfoot team's digital design history file all in one place. This allowed them to use their Application Lifecycle Management tool as a digital system of record to feed their Quality Management System.

> **"Essentially, what tipped the scale was codeBeamer's strengths of a fully integrated ALM with execution management."**

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A DIY Approach to Rollout & Process Configuration

The team at Bigfoot Biomedical took an independent approach in implementing codeBeamer ALM. They chose to go without training or consulting, aiming to roll out the system on their own.

The team realized right away that codeBeamer was a very flexible tool with powerful capabilities. But, as Alan said, with great power comes great responsibility: they were able to set up codeBeamer the way they needed it to work for their rituals and patterns, but this organic learning process meant an investment of time and effort.

> **"codeBeamer is a tool with a lot of power. But you got to figure out how to wield that power. There's a ton of flexibility, but it's essentially a set of building blocks that fit together to allow you to build up capabilities."**

One of Bigfoot's product owners started playing around with the tool to explore its functionality, and quickly understood that patterns repeated themselves across the platform, dramatically reducing the learning curve of the system's implementation & maintenance side.

Having figured out how permissions, roles, and workflows worked in their new ALM tool, the Bigfoot team sat down to map out their development processes in detail. Once they wrapped their brains around these practices, it was easy for them to configure the system to support those processes. They were able to express the way they wanted to work within codeBeamer ALM, perfectly adapting the system to their needs.

> **"Leveraging the adaptability inherent to codeBeamer to improve our processes and practices is key to our product development model."**

Bigfoot started out with **Intland's Medical IEC 62304 & ISO 14971 Template**, took ideas from it, and integrated them with their incremental and lean Agile processes. codeBeamer ALM is now a key and critical tool for their product development, encompassing everything from requirements and risk management all the way through to automated testing activities. codeBeamer is the digital system of record for Bigfoot's entire process of development, providing valuable input for their QMS tool which helps them assert compliance.

Preconfigured template to support safety-critical compliance

Intland's Medical IEC 62304 & ISO 14971 Template is a preconfigured project template that comes with predefined artifacts, processes, and a wiki filled with medical device development knowledge & best practices. The template helps users leverage the capabilities of codeBeamer ALM to support **compliance with IEC 62304, IEC 60601, Title 21 CFR Part 11 (FDA), and ISO 14971**.

codeBeamer ALM: Licensing, Adoption & Training

The Bigfoot Biomedical team made the transition to codeBeamer ALM independently, climbing the learning curve on their own. In hindsight, the team said they could have accelerated their understanding with some training to help them work out the system's architecture and technical underpinnings.

While codeBeamer ALM is an easy to use platform from the user's perspective, the Bigfoot team felt that its versatile configurability meant a certain complexity on the system's implementation and maintenance side. Yet Alan said the learning process was an ongoing investment they were happy to make: the more the Bigfoot team learned about codeBeamer ALM, the easier it was for them to really leverage its powerful capabilities in support of their lean Agile processes in a safety-critical sector.

> **"Our new-hires can get up to speed within a few days of using the tool, but it takes a while for them to have that "aha!" moment when they realize how valuable it is within the context of our regulated industry."**

Initially, Bigfoot Biomedical purchased a combination of Requirements Management, ALM, and Reviewer licenses for their respective teams, but quickly found that the all-encompassing functionality of ALM licenses better suit their needs. Since 2016, they have expanded their pool of licenses to a total of over 80 codeBeamer users.

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Benefits and Value Realized with codeBeamer ALM

As a true Agile team, Bigfoot's product owners work closely with developers as well as other stakeholders. codeBeamer ALM provides a platform for this collaboration to continue, channelling the process of requirements management and development into a single system. It has simplified the way they write, revise, and implement requirements.

> **"Automation is core to what we are doing at Bigfoot and we see value in having our continuous integration systems funnel test results into codeBeamer in a way that provides immediate trace between a requirement, the test that verifies the requirement, and the latest test result. codeBeamer enables our product development processes."**

As a result of their self-taught approach, Bigfoot enjoys a solid and continued growth of their knowledge of the tool. This process of continuous improvement yields notable improvements in their codeBeamer instance on a regular basis.

codeBeamer ALM's use has greatly expanded at Bigfoot since its implementation. Today, almost everybody at the company uses the platform, and they are investigating what other processes it could support. The Bigfoot team is currently looking into how they could leverage the capabilities of codeBeamer ALM to implement a system of continuous compliance in their ALM platform, enabling them to stay audit-ready throughout the process of development. They also plan to use it in bringing together hardware and software development processes, with the final aim to "use codeBeamer as the center of the universe" in their product development efforts.

> **"We are pleased with the investment made, and we are pleased with the results we made from that investment. codeBeamer is not perfect, but it's better than most systems that I have used. I'm a fan of codeBeamer ALM."**

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codebeamerX

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Start your own free trial of codebeamer X today – no strings attached, no credit card required!

Try codebeamer X

About Intland Software & our solutions

Intland Software offers industry-leading software tools to simplify complex product and software engineering at scale. Our enterprise-grade platforms help accelerate the development of technology products and simplify regulatory compliance.

Intland's solutions are used by leading companies including top automotive, medical, pharma, and life sciences developers worldwide to manage their innovative, compliant product engineering processes.

codebeamer is an Engineering and Application Lifecycle Management (EALM) platform with unique configurability and product line configuration capabilities.

codebeamer X is an integrated platform Engineering Lifecycle Management (ELM) platform for life sciences companies with regulatory process & compliance support.

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