

Scaling Production of the First e-Connected Mobile Diabetes Management System

Case Study



The Challenge

The inspiration for the world's first e-connected mobile diabetes management system came from the most unlikely of places: space.

Dr. Julian Shapley, Cellnovo's founder and Chief Scientific Officer, was working with astronauts at NASA in the United States when he became intrigued by the properties of a paraffin wax pump used in satellites.

Its high level of accuracy and precision in the delivery of fluids seemed well adapted for use in healthcare applications. After much research and experimentation, Cellnovo was created with a mission of using leading-edge technology to help people with diabetes to take control and live their lives to the fullest.

"In founding Cellnovo I wanted to use modern technology to change the paradigm of medical devices," said Dr. Shapley.

Scaling from start-up volumes to mass production is a test many young companies face, and it is exactly this challenge that the Franco-Welsh medical device company was confronted with in 2014.

Cellnovo originally set up a production facility in South Wales. Quickly, demand outstripped supply and the company struggled to keep pace with orders for its product. After a successful IPO in Paris in 2015, Cellnovo set its sights on industrializing production to enable it to meet this growing demand. Being able to reliably supply the disposable insulin cartridges in greater volumes was key to success.

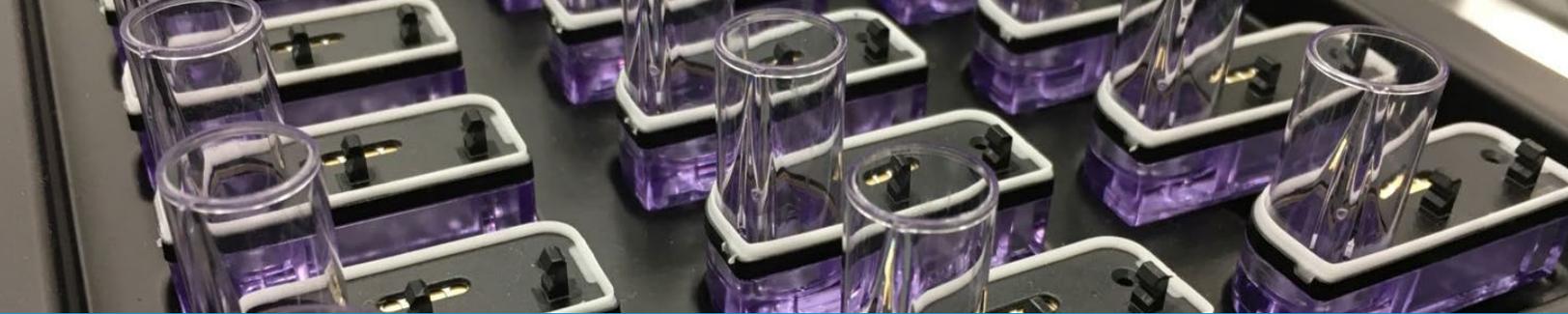
COMPANY Cellnovo

PRODUCT: Insulin Pump

SECTOR: Drug Delivery

SKETCH-TO-SCALE SOLUTIONS

- Design
- Engineering
- New Product Introduction
- Precision Plastics – Molding and Cleanroom Facility
- PCBA and Box-Build
- Supply Chain Management
- Volume Manufacturing



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The Solution

Cellnovo's go-to-market strategy involved outsourcing production to a larger, more industrialized manufacturing partner as volumes grew.

“We looked at the big names in the industry and it became very obvious that Flex was on the very top of our list. They were sizable, and they had the right reputation. They were already successful in the MedTech business. We knew that they knew how to make it happen.”

— **Sophie Baratte**,
Chief Executive Officer, Cellnovo

With precision plastic molding capability in a cleanroom environment, assembly capability and an extensive supply chain, the partnership with Flex would allow Cellnovo to achieve the exponential growth they wanted, but without the overheads or time requirements of doing it themselves.

Chris Townsend, Chief Operating Officer of Cellnovo, said: “Straight away, Flex's ability and experience were evident. Small improvements in the lead frame and the pinned circuit board immediately led to capacity improvements. Working with Flex has also opened up the supply chain relationship. Their previous regulatory experience in manufacturing medical devices that are FDA approved for the US market was also a huge benefit to us.”

High-Volume Manufacturing

Building a high-volume manufacturing line is complex but can yield tremendous dividends when done properly.

Flex engineers at Althofen in Austria considered improvements in almost every aspect of production. The highly experienced engineering team, working closely with Cellnovo, assessed the suitability of the existing designs for volume manufacture, and where necessary, helped re-design components.

Unit cost was also a major consideration, and the design team's understanding of materials, manufacturing processes and medical device regulations ensured the new specifications were optimized for cost, reliability and performance.

The Cellnovo Insulin Pump

Cellnovo's patented diabetes management system is an example of how real-time data and an innovative insulin-delivery system can be harnessed to deliver a digital health device, and consists of three elements:

- A compact, discreet and connected, wearable micro-pump;
- A handheld touchscreen controller, similar to a smartphone with an integrated blood-glucose meter, and;
- An online portal to allow information about the patient to be shared in real time with healthcare professionals or family members.





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Collaborating on Innovation

One of the innovations jointly developed involved the pinning process for the stacked printed circuit board (PCB). This had been done manually at Cellnovo using a soldering-fixing procedure. Flex helped introduce a fully automated solution, which resulted in higher output and eliminated some of the soldering and all of the manual assembly previously required.

Similarly, enhancements were introduced for a fragile lead frame that needed to be formed in a very specific way. With a diode soldered on both ends to connect two different metal parts, the delicate frame had to be placed into a chamber. Flex engineers modified a machine used in the electronics industry to automate this process and eliminated the need for manual processing.

Precision Plastics Solution

Another critical component was the housing body. Previously this was glued together in Cellnovo's production facility, but was re-designed by Flex to turn a manual process into one involving highly advanced precision plastic molding.

And because the Flex Centre of Excellence for test equipment is also located at Althofen, the entire line could be continually tested and improved until perfected. With every detail of the process documented and verified, the production line can be easily replicated in other Flex facilities around the world to move production closer to the markets Cellnovo serve as their volumes grow.

“The sheer level of technical capability that Flex brings to complement our team was excellent. They’ve given us almost infinite resource.”

— **Chris Townsend,**
Chief Operating Officer, Cellnovo



1 in 11*
adults
worldwide
has diabetes



1st
all-in-one
connected
diabetes
management
system



12
fold increase in
insulin cartridge
production

*WHO: www.who.int/diabetes/global-report



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The Result

Partnering with Flex enables Cellnovo to focus on its core competencies: innovation and the differentiation of its product, and bringing superior value to patients, their families and care teams.

Because Flex produces medical devices to the highest international quality standards, Cellnovo's management team is assured that the production complies with international regulatory and safety standards.

Cellnovo is now capable of delivering a 12-fold increase in the number of insulin cartridges produced per annum. In 2019, a second production line is planned to go live at Flex in Timisoara, Romania, which would dramatically increase Cellnovo's insulin cartridge production.

"After automation, precision plastic molding, and other efficiencies to reduce production time and cost, we analyzed the product lifecycle management plan and overlaid it with a value stream map, so that we could precisely identify areas for cost saving and predict unit cost reduction over the longer term."

— **Hannes Moritz**,
VP Operations, Flex

"Flex allowed us to tap into a knowledge base that is essential for us to scale to the next level of production and deliver value to the diabetes community."

— **Sophie Baratte**,
Chief Executive Officer, Cellnovo

Flex is the Sketch-to-Scale™ solutions provider that partners with customers to innovate, design, and build intelligent products in a connected world, including the design and commercialization of more than 75 regulated medical devices. With over 200,000 employees and 2,500 engineers across 30 countries, Flex accelerates time to market and optimizes resource allocation for efficient, cost-effective solutions throughout the product life cycle. Our approach is supported by FDA-registered and ISO 13485 compliant facilities and a world-class quality system.

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