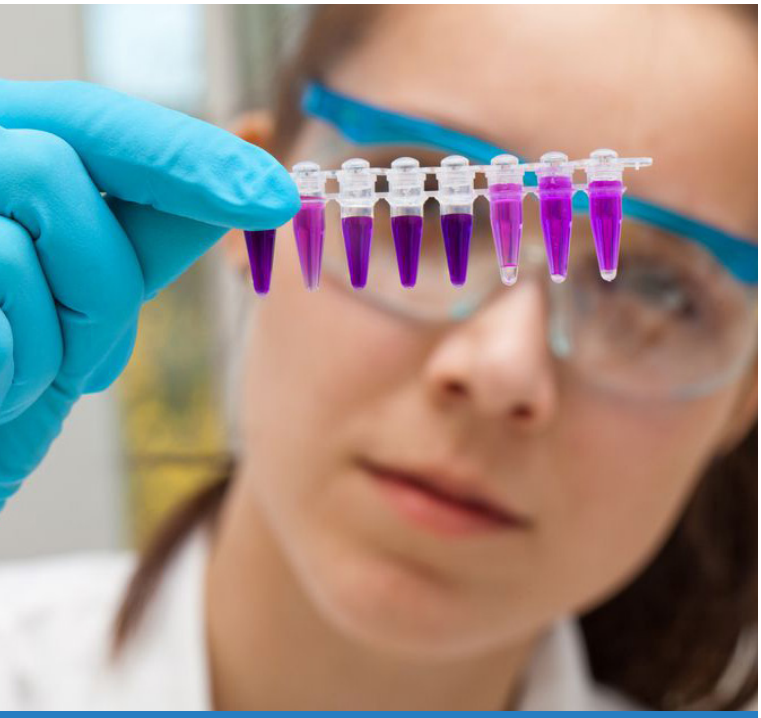
GLIDE TECHNOLOGIES PARTNERS WITH NYPRO HEALTHCARE TO PRODUCE INNOVATIVE PATIENT-CENTRIC MEDICAL DEVICE



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Tony Mills,
Chief Business Officer, Glide Technologies

NYPRO
A JABIL COMPANY

Case Study

Glide TECHNOLOGIES

Company	Glide Pharmaceutical Technologies
Industry	Healthcare
Country	United Kingdom
Employees	23
Websites	www.glide-technologies.com

CHALLENGES:

- Small specialty pharmaceutical company needed help in bolstering core competencies to bring a novel medical device to market
- Additional assistance required to refine device design as well as address human factors studies, clinical trials and regulatory requirements
- Scaling to mass commercialization required engineering, supply chain and manufacturing support

SOLUTION:

- Jabil Nypro Healthcare was selected for its end-to-end services and core competencies in managing core technical, regulatory, commercial and logistical challengess

BENEFITS:

- Sophisticated medical device expertise proved instrumental in refining device design while elevating stability, reliability and durability
- Use of advanced analytics identified and alleviated potential operational risks to ensure highest levels of user adoption
- Rapid prototyping reduced design time and costs while providing potential pharmaceutical partners with a ready supply of samples to expedite decision making
- Flawless service delivery drove success of each phase on the path to commercialization while setting the stage for scale-up manufacturing

Glide Technologies is a specialty pharmaceutical and medical device company focused on developing products for easy, safe and convenient delivery of therapeutics and vaccines. The company's dedication to improving patient comfort, adherence and persistence with injectable drug therapy has led to the creation of both novel drug formulations and device technology.

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Mark Carnegie-Brown, CEO, Glide Technologies

Based in Oxford, England, Glide discovered that many drugs and vaccines, normally injected in liquid form using needles and syringes, could be delivered instead in solid dose formulations. Solid dose formulation offers greater drug stability than liquid formulation, removing the need for refrigerated drug storage. It has the potential, therefore, to increase product shelf life, as well as increasing the convenience for patients who have to self-administer injections, sometimes more than once a day.

For patients afraid of needles or caregivers wary of accidental needle sticks, adherence can be a daunting issue. In response, Glide developed the Glide SDI®, a proprietary solid-dose injector, which offers the potential to dramatically improve adherence and persistence in long-term drug therapies while enhancing immune responses to vaccines. The reusable SDI actuator, which has no needle, can deliver the solid dose subcutaneously in a fraction of a second. Glide's platform clearly has the potential, therefore, to make the administration of injectable drugs a more comfortable and convenient procedure, with an improvement in adherence to drug regimens that physicians will welcome.

According to Mark Carnegie-Brown, CEO of Glide Technologies, the SDI has been designed to be extraordinarily intuitive to use. "Simplicity allows us to have a competitive advantage both in adoption of the Glide SDI and in terms of cost of goods," he explains. "Where other actuators require double-digit steps to use, the Glide SDI administers a drug in four easy steps, which we believe will greatly improve the patient experience."

Creating New and Improved Drug Delivery and Device Experiences

The company's current pipeline of therapeutic products includes octreotide for the treatment of carcinoid tumors; teriparatide for the treatment of osteoporosis; and exentide, a GLP-1 agonist targeting Type 2 Diabetes. Additionally, Glide's pipeline of vaccine candidates includes an anthrax vaccine developed in collaboration with Pfenex Inc. and an influenza vaccine from collaboration with Cilian AG.

The Glide SDI, a highly innovative

drug and vaccine delivery system, is very different from other technologies. The reusable injector uses a spring mechanism to administer a tiny, solid dosage below the patient's skin, where it dissolves and releases the pharmaceutical. "It's a well-known fact that patients don't like injecting themselves, so we focused on finding a more patient-friendly solution," says Tony Mills, chief business officer of Glide Technologies. "Our drug-device combination is an exquisite match of solid dose material, which gives the drug greater stability, and the use of an innovative device for extremely simple and rapid injection of that solid drug into the skin."

Starting in 2012, Glide completed early investment rounds to fuel development of solid drug formulations and its highly unique device delivery system. In designing the device, ensuring patient comfort was a top priority. "The auto-injector has to work each and every time without fail, so reliability was a major design criteria," recalls David Grant, technical leader at Glide Technologies. "It's an immensely sophisticated device with a design that doesn't show any of the working parts. There's a lot of physics and engineering that goes into the device that you don't see."

With a working prototype of the device, Glide set out to find a manufacturing partner to help optimize design, complete clinical trials and ramp production. Equally imperative was selecting a company that complemented Glide's small yet highly focused team. "We have 20 employees, so it was very important to choose a partner that could address the whole solution—from supporting early-stage design work and complex regulatory requirements to helping us prepare for large-scale manufacturing and commercialization," Grant adds.

Glide evaluated five potential manufacturing partners as part of its conventional selection process. This list was whittled to two finalists that were assessed for overall capabilities, experience and cultural fit. "Jabil's Nypro Healthcare stood out with their proven ability to handle all of our early-stage design work while maintaining a view to our future and what it would take to achieve mass commercialization," explains Grant. Additionally, Nypro's customer-focused services offered significant strengths in product ideation, human factors analysis, regulatory support, engineering, supply chain optimization, manufacturing and device assembly operations.

Additionally, Nypro's development team was embedded within the company's industrialization group to ensure that device design was continually taken into consideration during each step of the commercialization process. "As a recognized leader in the development and manufacturing of precision devices, Nypro was the perfect partner to help us advance our novel delivery system," says Carnegie-Brown. "From the onset, we found the Nypro team to be extremely responsive to our needs. There was common ground with a mutual can-do attitude and proactive engagement."

Putting Patients First: Perfecting Device Design

Nypro worked closely with Glide to refine prototypes to optimize device ease of use, durability and quality. As part of this process, the collective team worked diligently to identify, address and eliminate potential device risks. Nypro followed a structured Failure Mode Effects Analysis (FMEA) to assess the strengths and weaknesses of different design concepts to address and eliminate risks as early as possible in the process.

Nypro also teamed with Glide on several human factors studies. Together, they worked with potential users to determine how people would interact with—and potentially misuse—Glide's SDI device. Nypro leveraged advanced predictive design tools, such as Finite Element Analysis, to further guide device design in a number of key areas. For example, both computational and analytical modeling were used to assess and validate the accuracy of loading drug doses into the device.

During the first human factors study, the team discovered issues around incorrect operation, which led to important design changes. Based on the initial feedback and risk analysis, Glide and Nypro made further refinements, which

streamlined operation while increasing safety and ease of use. "Thanks to our collective efforts, users gave the device very high scores in a follow-up human factors study," says Grant. "There was an overwhelming preference for the Glide SDI over standard needle-and-liquid injectors."

Throughout the process, both sides met regularly to brainstorm ideas and collaborate on how best to prepare the SDI prototype for clinical trials and mass commercialization. Nypro managed all the design history files in keeping with regulatory requirements while ensuring all regulatory filings met ISO-13485 standards for design and manufacture of medical devices. "Nypro was intricately involved in all the key aspects of improving our technology to take the design to where it is today," says Carnegie-Brown. "The partnership gave us confidence in being ready to move to the next level and get ready for commercial production."

Bridging the Gap between Prototype and Scale-up Production

To speed design iterations and prepare the Glide SDI for industrialization, Nypro uses rapid prototyping with advanced 3D printing capabilities. "Nypro can quickly produce a 3D-printed prototype—sometimes with same-day turnaround," says Grant. "This enabled us to shorten design times considerably as we can quickly see how all the moving parts actually work."

Not only does this expedite device design modifications, it ensures that Glide has readily available samples to share with potential partners. "Prospective pharmaceutical partners are usually blown away by both the simplicity and elegance of the design," says Mills. "It's very easy for them to see the power of this device in enabling patients to safely self-administer drugs."

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>
> **David Grant, Technical Leader, Glide Technologies**

As a result, Glide is poised to change the game in drug self-administration by elevating compliance rates. "Patients hate needles and by doing away with them, we're optimistic about boosting compliance in ways that physicians will want to see," Mills says. Device durability and the success of initial clinical trials for osteoporosis and Type 2 diabetes treatments have opened the door for other applications, such as the collaboration with Pfenex on the anthrax vaccine. "The stability of the device lends itself to stockpiling vaccines in a bio-defense scenario, where large groups of people need to be vaccinated in a short amount of time," adds Mills. "I am personally grateful for Nypro's input on design and ideas for different uses of the device."

Glide also is appreciative of Nypro's prowess for readying the SDI for the next stages of commercialization. "The level of risk analysis, device prototyping and simulation as well as patient computational modeling ensure we're on the right path to commercialization," says Grant. "Nypro shares our unwavering commitment to getting this product to market."

To help Glide navigate the vital manufacturing phase, Nypro is assisting with a funding proposal for the European Union, outlining next steps to bridge the gap between prototype and scale-up production. "There is definitely a level of confidence that comes from working with a partner like Nypro," concludes Carnegie-Brown. "As a small company, we can't have all the competencies under one roof. With Nypro, we can cover the bases while easily and quickly ramping manufacturing as we move forward."

About Jabil

Jabil is an digital product solutions company providing comprehensive electronics design, production and product management services to global electronics and technology companies. Offering complete product supply chain management from facilities in 27 countries, Jabil provides comprehensive, custom solutions to customers in a broad range of industries. Nypro, a Jabil company, specializes in medical devices, with a global footprint of ISO13485 and FDA registered facilities, manufacturing many of the most recognized medical brands for major healthcare and wellness companies. Jabil common stock is traded on the NYSE under the symbol, "JBL". Further information is available on Jabil's website: jabil.com.