Packaging Patient Needs

Joining the growing trend towards personalised offerings is the auto-injector market, bringing a unique set of advantages. Improved relationships with drug delivery services in particular can help exceed customer expectations in terms of device design and functionality

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When considering the most effective way to deliver parenteral medication to a patient, pharmaceutical companies typically look to external partners for customisable drug delivery technologies that best meet the needs of their patient population. This marks the beginning of a crucial journey, where each party brings their own expertise and knowledge to the table with a simple objective in mind – creating the best possible combination product.

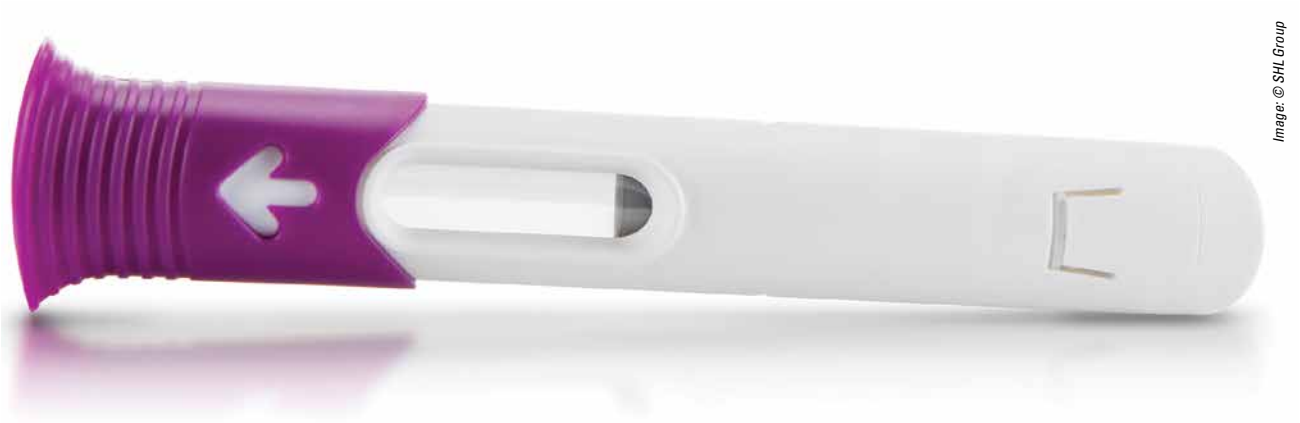
The goal is simple, but the process is often not. Challenges can arise from any number of internal or external factors, and the stakes are high: failure could impact the health of patients, reduce market acceptance of novel drugs and decrease a listed company´s market valuation. To minimise these risks, pharma companies typically look for more than just a device supplier. They seek experienced, long-term device partners that can be trusted to package and deliver their valuable drug products, which, at this stage, have likely cost hundreds of millions of dollars to develop.

The Biotech Challenge

With the current generation of large molecule biotech drugs comes a formulation challenge, which either pushes drug viscosities up – or moves towards larger dose volumes. Both of these trends present hurdles for traditional drug delivery systems that were originally designed to offer smaller volumes of low viscous drugs. This is being compounded by the desire to have thinner needles for patient comfort and market differentiation. Additionally, a number of extremely successful originator drugs have, or are soon,

- Patient performs injection
- Connected injection device sends injection data to smartphone
- Smartphone sends injection data to secure cloud
- Injection data can be safely retrieved by different devices
- Customised information can be provided to different stakeholders

Figure 1: Connectivity concept



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Large volume auto-injector that accommodates a 2.25ml syringe

due to come off-patent, causing a rise in the number of biosimilars.

The drug delivery device is an important component within the biosimilar strategy, with some companies seeking to include new features and innovations on their selected drug delivery systems, while others are simply looking for low-cost solutions to ensure market competiveness. These developments are putting heightened pressure on device businesses to not just generate new technical solutions, but provide more of them in different segments.

As the demand for devices increases, so does the number of new companies offering device concepts and services in this field, making it difficult to identify the most suitable partner. When evaluating potential device partners for a combination product, pharma businesses conduct a thorough tendering process, seeking to identify compatible partners that are experts within their field. By definition, an expert has a high level of knowledge or skill in a given subject; however, due to the multi-disciplinary nature of these projects, pharma companies should be looking for a high level of knowledge or skill in various subjects. This would be especially applicable in the case of auto-injectors – a segment of the drug delivery market that has seen significant growth over the last decade.

Identifying the Experts

The auto-injector has become a highly desirable method of delivering medication to a patient in a home setting due to its convenience, safety, and ability to reduce the physical and financial burden of doctors and nurses who would otherwise have to perform routine injections for patients of chronic diseases. Internally, however, the auto-injector is a complex system with many variables that can impact the design and performance.

Experienced device experts have developed a deep understanding of the three stakeholders that need to be satisfied:

- The patient, who may be impacted physically and/or cognitively as a result of their illness
- The pharma partner, who has high expectations for the performance and flexibility of the device and its ability to handle a range of drug properties
- The payers, who may have different expectations or metrics for price, efficacy and safety

With these stakeholders in mind, the device partner will be able to offer a range of proven solutions that are both adaptable to a number of different therapeutic areas and drug formulations. The partner will be well positioned to guide their customers in selecting the most appropriate design for their project, and identifying the functions that will create value for their patients and help them stand out against the competition. Through time and experience, capturing stakeholder needs correctly can turn into valuable foresight that allows device companies to better anticipate market trends and secure intellectual property early.

When evaluating the device company's production capabilities, the pharma business will be looking for operational excellence as a result of continuous improvement. This covers component production and assembly, but goes far beyond that with audits of the design process, supply chain, quality system and a growing expectation for the device company to support regulatory interactions and submissions. These growing expectations and demands have to be supported by the availability of the core device team – preferably in the customer's region, time zone and language.

Auto-Injector Design

At the heart of a well-designed auto-injector is a deep understanding for the end user, who will be interacting with the product. The device must be intuitive, easy and ergonomic for patients or caregivers to use within the relevant environments and usage context. It should perform its core functions consistently and reliably. It should be aesthetically pleasing and portable, so that patients never feel embarrassed or find it difficult to carry their medication.

The device's intuitiveness and ease of use is the direct result of active human factor engineering. A comprehensive design approach would involve formative studies to understand

A well-designed auto-injector should have the end user's needs in mind

user context, preferences and needs; summative research is then carried out to validate the design. Creating an intuitive device adds intangible value to a product, which leads to increased user satisfaction and improved quality of life.

A well-designed device is comfortable to both handle and operate. Deep consideration is applied to the user demographic, and special attention must be paid to patients who have diminished physical and/or cognitive ability. Multiple iterations of industrial designs will be tested via handling studies. A good design is the simplest possible working solution, unburdened with non-essentials. Indeed, it should follow all of the ten principles of the German industrial designer Dieter Rams, who said: "Only well-executed objects can be beautiful. The aesthetic quality of a product is integral to its usefulness, because products used every day have an effect on people and their well-being."

Consistent and reliable performance is achieved by a robust and verified design, which is manufactured and assembled using validated processes. This has motivated several device manufacturers to in-source their manufacturing operations in a bid to have a tighter control over quality. Collaboration and good communication with other sources that can influence device performance is also essential; this may include the primary container supplier and the contract manufacturing organisation used for filling. A relevant example is the type/distribution of silicon oil within the primary container; a robust testing programme that measures this helps to ensure that the end product performs as good in the market as it did in the lab.

Adding Connectivity

With the Internet of Things assuming a greater role in everyday lives,

Data centres enable device manufacturers to be better connected to patients and stakeholders

connectivity has now become a viable means to satisfy the need to capture data, then analyse, communicate, predict, store and transfer relevant information. For a healthcare industry facing many challenges, this can bring value from several different perspectives.

One of the biggest hurdles is low adherence to medication therapy, which is damaging in many respects. First of all, it contributes to unnecessary suffering for both patients and their families. It also results in large but avoidable healthcare expenses, as well as significant financial loss for the pharma industry. A connected drug delivery device enables patient support programmes to be more effective by providing real data to analyse; this information can be used to personalise the patient experience and support.

Those device companies that hold a greater understanding of the core functions of a drug delivery system and the related stakeholder needs will have the advantage when looking to add connectivity. Furthermore, those that have invested time to explore how connectivity can best be applied in the relevant stakeholder context will be better positioned to develop and deliver entirely new solutions and services. If those products and services bring real value to the stakeholders involved, there is a real opportunity to completely change the landscape for self-treatment of chronic diseases.

Collaboration

Today's healthcare organisations need partners who can help them overcome current biotech formulation challenges, and introduce solutions that deliver care effectively and efficiently amid evolving reimbursement structures. They should seek experienced device companies that have a history of successful product launches that showcase their ability to leverage on a fundamental understanding of different stakeholder requirements.

When approaching the device design, consider ways of not only delivering medication, but also offering satisfaction to the user. Be aware that despite the risks, hurdles and complexities of managing a successful auto-injector launch in an increasingly competitive environment, the goal is simple and the rewards are high. By working together in a collaborative relationship, both healthcare organisations and device manufacturers will be able to master the challenge of packaging patient needs.

About the author

Rasmus Renstad is Director of Research and Innovation at SHL Group, the world's largest privately-owned designer, developer and manufacturer of advanced drug delivery devices, such as auto-injectors and pen injectors. For the last 12 years, Rasmus has been working for SHL, specialising in product development and design engineering for medical devices. He holds a PhD in Polymer Technology from KTH Royal Institute of Technology, Sweden, and a BSc in Business Administration and Economics from Stockholm University.

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