

## INTERVIEW: JOCHEN RATJEN, SHL GROUP

As the momentum of self-administrated injection trends continue to increase, auto injector devices are no longer a foreign concept to many patients and device designs have since shifted towards a user-centric approach. The application of human factors and usability engineering is thus necessitated to minimise user-related risks, enhance ease-of-use and, ultimately, allowing them to use the device safely and effectively.

Early involvement of targeted patient groups in user studies during the research and development stages helps engineers not only to understand patient dynamics better, but also to ensure patients' needs are fully integrated into the design of the device. For example, patients with rheumatoid arthritis (RA) may have serious dexterity issues that hinder their ability to uncap or grip a device and properly administer the injection. Thus, a device with customised uncapping or grip options and an exterior that provides additional friction is an example that can prove to be an enhancement for this patient group.

Here, SHL Group's Director of Industrial Design, Jochen Ratjen, shares his insights when approaching the design and development of user-centric auto injectors.

**Q: What are some of the key industrial design considerations for an auto injector?**

**A:** As a device partner to biopharmaceutical companies in the design of autoinjectors, communication is key, especially during the early stages of the design process. It is important for us to understand who our targeted users are, what kind of treatment they require, what environment the auto injector will be used in and any associated limitations. These could range from dexterity issues or impaired vision as a result of chronic diseases to simple, intuitive devices that the patient feels comfortable self-administering. Other essential considerations include storage of the device, expected delivery timelines and design requirements, such as whether or not the device should be based on an existing platform or created as a completely new system.

**Q: Why is human factors engineering (HFE) important for medical devices like auto injectors?**

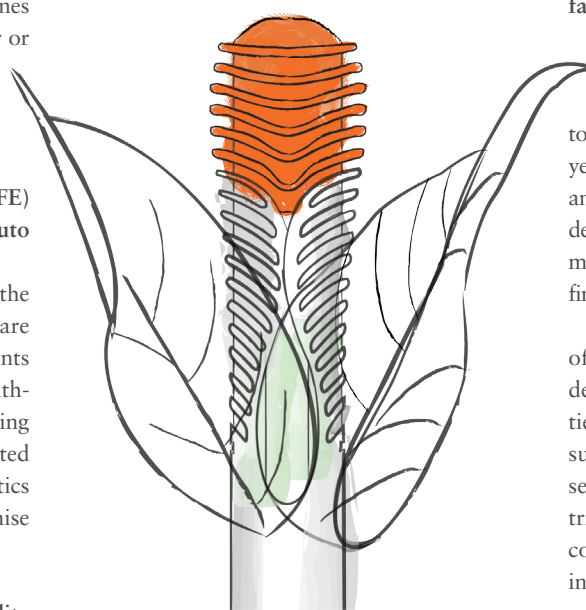
**A:** Auto injectors are intended to assist the end-user with the injection process and are most often self-administered by the patients themselves (as opposed to trained health-care professionals). Consequently, applying HFE principles is crucial as incorporated physical and psychological characteristics minimise user-related risks and optimise user compliance.

**Q: How do you apply HFE and usability engineering to an auto injector?**

**A:** HFE and usability engineering are applied throughout the entire product development

process and assist us with key design decisions; this is certainly not a factor for consideration solely at the end of the project. Depending on the nature and stage of the project, various usability tools are applied to the process, including but not limited to user-performance studies, interviews, on-site visits, failure mode effects analysis (FMEA), review of existing ergonomic research, and design guidance.

We further aim to increase user empathy with the goal of improving our understand-



**Figure 1: The surfaces surrounding the Amber™ Auto Injector's viewing window, inspired by overlapping leaves.**

ing of real users' needs. This is accomplished using various approaches, such as sharing our insights from internal user studies with colleagues, or simply showing an online usage video uploaded by the user— all with the goal to gain better understanding of real users' needs and reality.

Ultimately, we strive to broaden our knowledge beyond identifying factors such as the force required to operate a device or the most comfortable grip – we want to understand the user's emotional context. Indeed, while an auto injector may be simple to use and the cap easy to remove, it is an obsolete device if the user is afraid to use it.

**Q: How do you balance clients' user requirement specifications (URSs) and the ideal user-centric design?**

**A:** Our biopharmaceutical clients' strengths lie in their injectable drugs and targeted patient groups, while SHL excels in the design, development and manufacturing of the secondary packaging device component of an auto injector. As such, an important part of my job is helping our partners to understand the design concepts we have created, the usability programs we have performed, and sharing our valuable experience from past projects. By doing so, we collectively ensure a balance is met between the URSs and user-centric design considerations.

**Q: What impact does designing for manufacturability (DFM) have on a device such as an auto injector?**

**A:** DFM was in fact one of the main reasons SHL took the strategic decision to establish an in-house design department 14 years ago. This enabled close collaboration and instant communication between industrial design engineers, production teams and project managers. The result is a faster track towards a finalised product for mass production.

Today, one of the valuable products SHL offers is the in-house availability of key design services and manufacturing capabilities for the development of medical devices such as auto injectors. This ranges from services including but not limited to industrial design, regulatory affairs, and quality control systems; to capabilities such as tooling, molding, assembly, and final assembly.

**Q: Where do you get your design inspirations from?**

**A:** This differs across the team and is



Figure 2: SHL's range of auto-injector products.

dependent on the individual. Personally, I find inspiration in non-medical fields. Bionics, for example, is an application that is especially intriguing for me as nature never ceases to surprise us. In fact, the design of the surfaces surrounding the Amber™ Auto Injector's viewing window was inspired by overlapping leaves which adds an organic element and steers away from the look and feel of a typical medical device (Figure 1). Furthermore, I like to explore all sorts of hand-held tools, especially when I travel, as this allows me to explore solution variations across different cultures.

**Q: What does your team do to stay innovative?**

**A:** I believe my team is very privileged to be working in the medical device field, especially in the design and development of self-injection devices like auto injectors, the purpose of which is to improve the

patient's treatment experience and consequently their quality of life. By always bearing in mind that what we do has the potential to help others, we are motivated to remain innovative in the design and

unprecedented design concepts. Our aim is to never idle in the present; a model which I believe will keep us at the forefront of pioneering the development of drug delivery devices.

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development of next-generation devices. In addition, as a company of Swedish heritage with a strong native culture, we are empowered to take creative initiatives and have the flexibility to experiment with

**Q: Can you give us some examples of devices that embody user-centric designs?**

**A:** Integrating user needs has always been discussed, evaluated and prioritised in the development of drug delivery devices. As such, many commercially-available auto injector products have evolved and improved and now show promising user-centric designs, including the range from SHL (Figure 2).

A great example is the Emerade® – an intuitive two-step intramuscular adrenaline auto injector (AAI) for the treatment of anaphylaxis (Figure 3). The design of the Emerade® is the result of a collaborative effort between SHL and Medeca Pharma (Uppsala, Sweden), a pharmaceutical company specialising in allergy therapies.

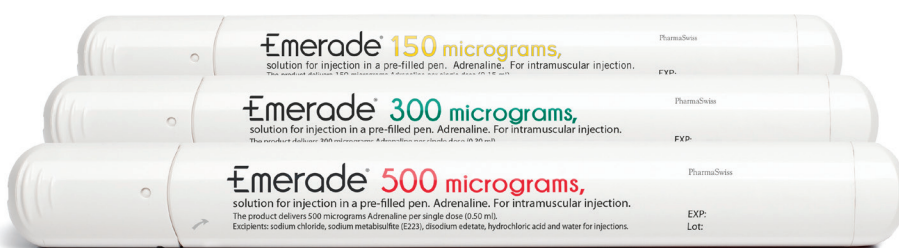
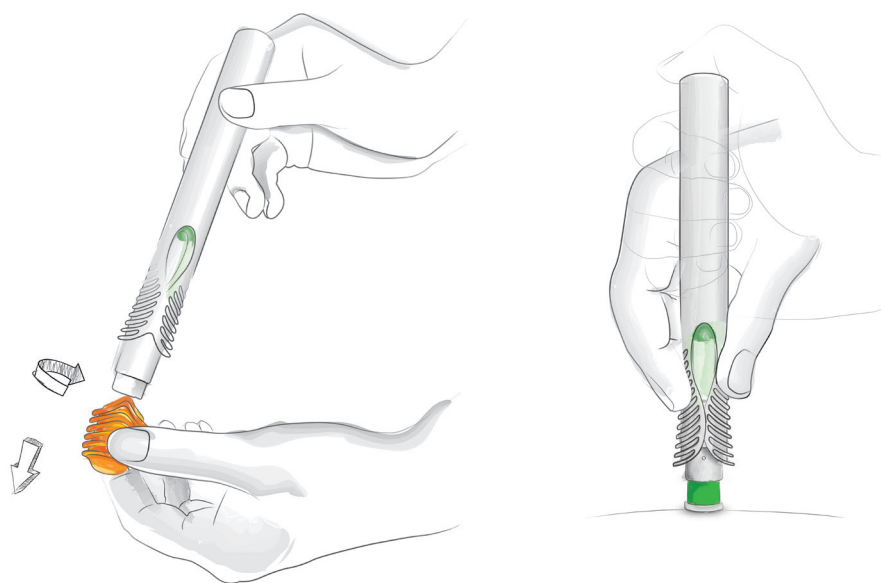


Figure 3: Emerade®, an intuitive two-step intramuscular adrenaline auto injector for the treatment of anaphylaxis.



**Figure 4: The Amber™ auto injector can be operated in just two simple steps: uncap and inject.**

By incorporating Medeca Pharma's years of experience with clinical allergy specialists and the patients themselves, along with SHL's expertise in design and manufacturing, the Emerade® auto injector truly reflects the end-user's needs and has revolutionised the AAI market. The device features a two-step operation, intuitive industrial design, a longer needle and three dosage options. To showcase this device's user-centric design further, a usability study on accuracy of use in a simulated emergency showed that all participants were able to successfully administer the injection in accordance with the label's instructions.

Another example is SHL's internal device, the Amber™ auto injector – that I mentioned briefly previously – which features a unique, ergonomic design that embodies various grip options both during cap removal and on administration. In addition, unique surface extrusions surrounding

needle and a range of audible, visual and tactile feedback mechanisms.

**Q: What do you consider an upcoming trend in the industrial design of auto injectors?**

**A:** This is an industry where long development cycles and time-consuming product approval processes can make trends difficult to recognise. However, I do believe a user-centric approach will remain the basis for the industrial design of auto injectors. In the short term, we will continue to see aesthetically-pleasing devices with good usability aimed at different therapeutic areas. Five years from now, I believe we will see a greater number of unadorned, disposable devices with even more simplified performances. These could potentially have the ability to connect to smart communication systems, for improved compliance while reducing costs.

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the cap and viewing window extend the area of friction for improved handling. Utilising SHL's Pushclick™ technology, the Amber™ auto injector can be operated in just two simple steps: uncap and inject (Figure 4); and integrates essential safety features, including a permanently hidden

**Q: What other methods can be provided to enhance the user experience of an auto injector?**

**A:** While we strive to introduce the most innovative and user-centric device solutions, we understand that even the most intuitive device cannot overcome a patient's

anxiety when faced with their first self-administered injection. In order to lessen the impact of this psychological barrier, we recommend the use of needle-free trainers that replicate both the look and feel of the actual device. Trainers can prove to be very effective and provide users with an opportunity to practice handling the device without the fear of incorrect administration and should thus be taken into consideration by biopharmaceutical companies at an early stage in the project's lifecycle.

Aside from SHL's comprehensive range of in-house manufacturing capabilities, the company has invested significantly in R&D in recent years, expanding their design and innovation teams in Sweden, Florida, US, and Taiwan. This is in large part to better support our customers with breakthrough devices that provide their products with a strong competitive edge while simultaneously meeting previously unrealised user needs.

SHL designs, develops, and manufactures a diverse range of drug delivery devices to address existing and upcoming injectable needs, including auto injectors, pen injectors, and inhalers. Requirements include but are not limited to accommodating various primary containers as well as increased agent viscosities or volumes. With the goal of improving patient compliance, SHL's comprehensive portfolio offers devices with simple two-step operations, ultra-compact designs, ergonomic exteriors, innovative feedback systems and more.



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