

SHL GROUP

SAFEGUARDING USER NEEDS: THE LONG-TERM LEGACY OF SHL'S PATIENT-CENTRIC DESIGNS

Despite being founded in an age when medical devices were more about getting the job done than providing optimum patient experience, SHL Group, has from the very beginning placed emphasis on users and usability. At the center of SHL's design hub, safeguarding these fundamental values, is SHL's Director of Industrial Design, Jochen Ratjen. In this article, we talk to Mr Ratjen about his personal experiences, what patient-centricity means to SHL, and how SHL's designs are moving ahead with the changing trends.

Today human factors, patient-centricity, and usability are terms strongly connected with the healthcare sector as well as the development of medical devices. However, just 30 years ago, the idea of focusing on patient-centricity in designs was more of an idealistic concept than a determining factor for the medical industry.

It was not until 2011 that the US FDA, in response to the increasing emphasis on the patient experience, updated its guidelines for applying human factors in medical devices into a new guidebook – “Applying Human Factors and Usability Engineering to Optimize Medical Device Design”.^{1,2} Later, the FDA announced that the document would officially supersede its 2000 predecessor as of April 3, 2016. This marked the shift from simply designing products that work to creating devices that place patient comfort and safety first.

A MAN OF PASSION & PRACTICALITY

Jochen Ratjen started his career in an industrial design consultancy in 1988. He played important roles in award-winning healthcare projects for the elderly and the disabled, and worked on a variety of consumer and medical technology products in different segments. Later in his career, he became more invested in auto injectors, reusable and disposable pen injectors,

pill dispensers, and inhaler systems. It was during that time that he began working with plastic components for mass production, an experience that would lend itself to his expertise working on in-house manufacturing at SHL.

“After all these years participating in user studies, I still find there is always something new to learn.”

In 1995, a more seasoned Jochen Ratjen was approached by SHL's management team to design the company's first auto injector – PenInject 2.25 (Figure 1). This was a time, he notes, when the medical industry focused more on device functionality rather than patient usability, and when terms such as “usability,” “ergonomics,” and “human factors” were not mentioned by pharma companies as they are today. He was, as a result, struck by SHL's passion for industrial design as well as by the company's foresight to involve the end user at the very beginning of the design process.

Prior to becoming an industrial design expert, Mr Ratjen was educated as a precision tool maker in Germany. This experience influenced his interest in as well



Jochen Ratjen
Director, Industrial Design
T: +46 8 462 1800
F: +46 8 462 1890
E: info@shl-group.com

SHL Group
PO Box 1240
Augustendalsvägen 19
SE-131 28 Nacka Strand
Sweden

www.shl-group.com

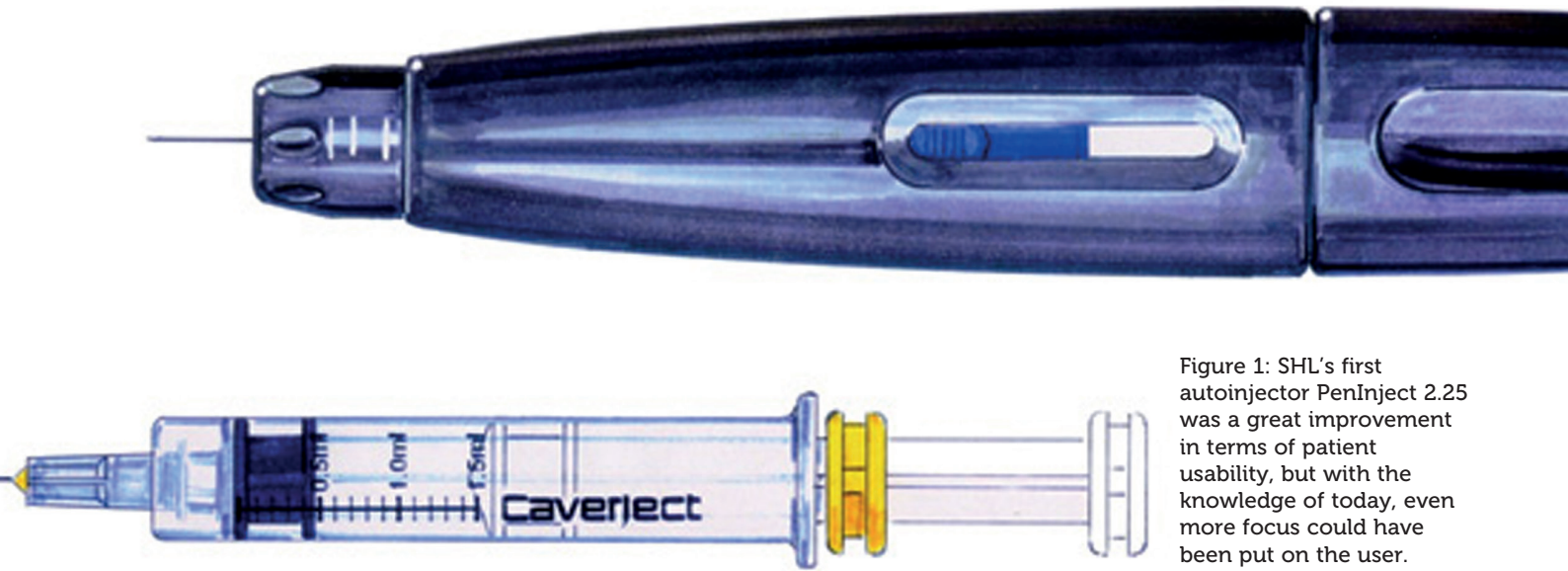


Figure 1: SHL's first autoinjector PenInject 2.25 was a great improvement in terms of patient usability, but with the knowledge of today, even more focus could have been put on the user.

as eye for the mechanical details inside auto injectors and other systems. His training has also allowed him to consolidate the exterior design with the inner components to design products for enhanced user experience.

ALWAYS DEDICATED TO USER NEEDS

Over the years, SHL has participated in an extensive amount of user studies, some led by pharmaceutical partners in collaboration with human factors firms and some within the company involving different target groups. "SHL has from day one been engaged in user experience and user needs studies," says Mr Ratjen. With a smile on his face he adds that such emphasis was "not just so that we adhere to regulations set by authorities such as the FDA".

Participation in user studies is extremely important as it provides new insights into how real patients interact with devices. Since the idea of patient-centricity has changed so drastically, it is now more important than ever to continue investigating the unmet needs of patients. Mr Ratjen notes, "Each treatment is different and each patient is unique. After all these years participating in user studies, I still find there is always something new to learn."

In order to know if a design works, SHL is also invested in getting real user feedback. Personally looking into social media support groups, Mr Ratjen found that a majority of users responded positively to the treatment carried in one specific auto injector designed with high-level usability features.

Further investigation also revealed that there were no complaints made about the

SHL device. Mr Ratjen feels that "the greatest reward as an industrial designer is knowing that your design works and that you have made a positive impact on somebody's life".

With the changing times, SHL's in-house design team has grown significantly throughout the years. Today's team includes individuals with multi-disciplinary backgrounds including mechanical design, industrial design, human factors engineering, and usability research. Now, this group of talented individuals, each with their own range of expertise, works with determination to create better designs focused on the user. With the range of competencies now more comprehensive than ever, Mr Ratjen is confident that SHL is ready to take on the challenges of the future.

CASE STUDIES ARE MORE THAN JUST STATISTICS

SHL also believes in the importance of looking beyond statistics in case studies and paying attention to the unmet needs of the patients, the unsung heroes of patient-centric designs.

Mr Ratjen remembers being inspired by a group of elderly rheumatoid arthritis patients who had extreme difficulty gripping and holding onto objects. Speaking to them, he learned that the patients had volunteered in quite a few other studies as a way of giving back to society. This drove the SHL design team to work even harder to help them accomplish their mission and design a product that they could really use. After rounds of improvements, the patents were finally

able to handle the device with ease, giving the SHL team more confidence that others could do so too.

Mr Ratjen also recalls one of his first and most heartfelt lessons learnt as a young industrial designer working in medtech. During one of his earliest case studies, he met a young lady in a wheelchair who spoke to him about the devices she was using at home and how she had to manoeuvre them to work in her favour. "It was then that I learnt she was undergoing fertility treatment and was already familiar with self-administered injections. Immediately, I knew that I had made assumptions about her because she was in a wheelchair. Admittedly, I felt guilty for failing to see her beyond her condition," he explained.

Having learned the hard way, Mr Ratjen shares his story to remind himself as well as his team always to look beyond the numbers and statistics in user studies, and treat patients with sincerity and true compassion.

"To stay ahead of the trend, SHL has invested in a brand-new design centre that will include a dedicated interview studio featuring state-of-the-art equipment for recording and documenting patient experience and feedback."

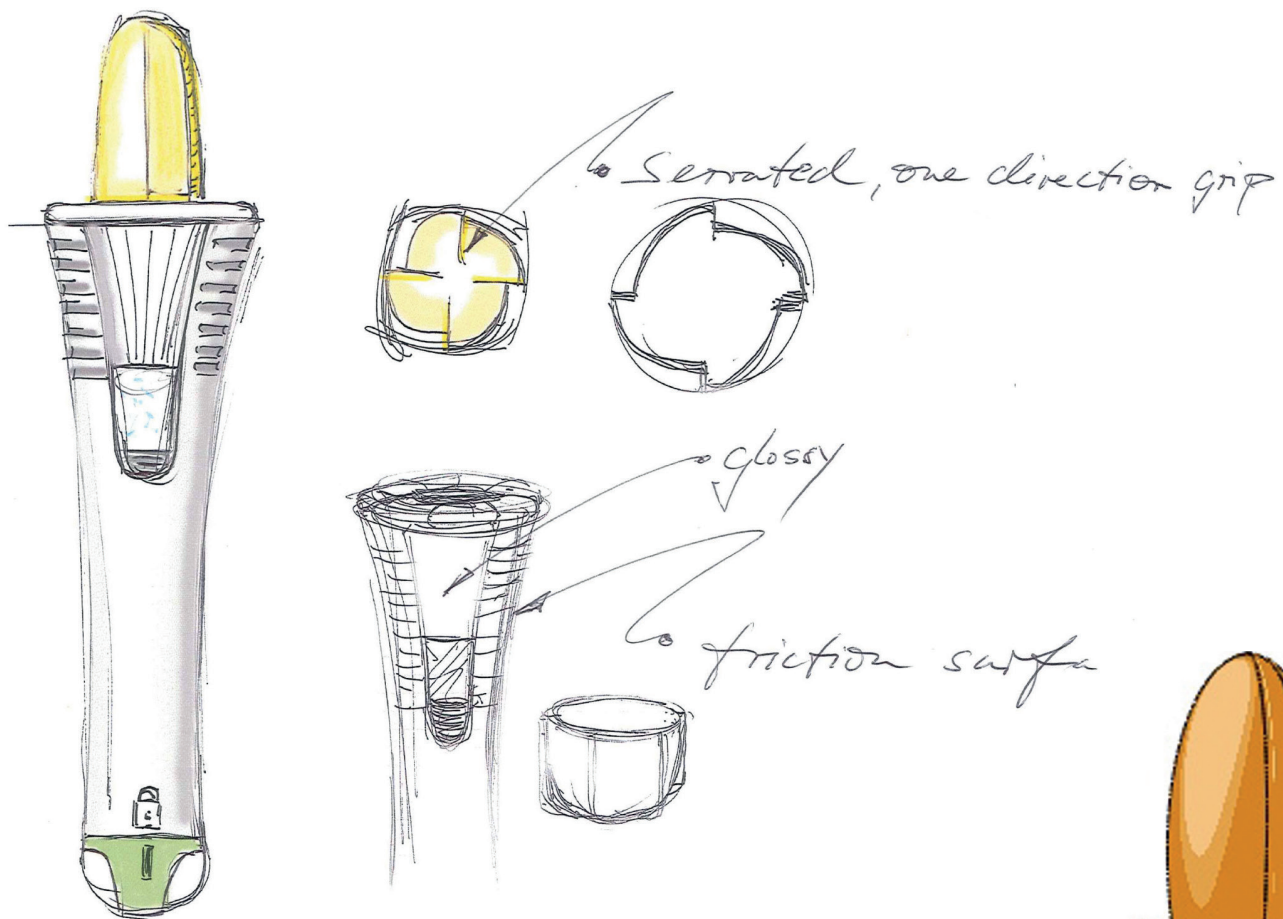


Figure 2: While all patients are different, a good device must be intuitive and self-instructing.

STAYING AHEAD OF THE CURVE

While there is no “one size fits all” method for patient centricity, SHL is able to capitalise on its near three decades of experience when it comes to launching new projects. Building on this foundation, SHL is in the final stages of completing its “usability process,” a project that will standardise the methods in which usability and human factors are incorporated in SHL’s internal design and development process. Once the project is complete, all involved, from design to development to manufacturing, will understand what usability means to SHL and how specific requirements are to be carried out throughout the entire organisation for optimum outcomes.

For this purpose, the company has built a database to help it effectively investigate how different types of treatments using SHL devices or other similar devices are perceived. Data from every project conducted throughout the years are fed into the database so that the experiences can serve as invaluable reference points for improvements when a new project is launched.

Ratjen points out: “As a provider of drug delivery solutions, we often have to

be ahead of our customers in terms of understanding how the administration of injectable drugs affects the patient.” The upkeep of the database is especially important because the knowledge can help speed up a new project’s time-to-market. The data also becomes the foundation of SHL’s solutions for auto and pen injectors.

MOVING AHEAD

According to the FDA, human factors and usability engineering focuses on “the interactions between people and devices,” and in between them is the “device user interface.”³ A well-designed device interface, for Mr Ratjen, is not just about how one grips and holds a device, but also about how the device is understood and accepted by the user. While this will include such basic elements as grip and hold (Figure 2), a truly user-centred device interface will also feature proper visual, audio and tactile feedbacks to help the user understand what is going on both outside and inside the medical device.

In the future, Mr Ratjen believes that industrial design will play an even more important role as the differentiator for injectable drugs. Standardised functions,



Figure 3: All SHL devices are designed to meet various user expectations.

such as SHL's two-step uncap and inject procedure, will be incorporated with more specific patient-centric designs to meet the needs of specific user groups. In other words, the industry will see more product specific designs for injectable drugs and user need (Figure 3).

To stay ahead of the trend, SHL has invested in a brand-new design centre that will include a dedicated interview studio featuring state-of-the-art equipment for recording and documenting patient experience and feedback. The centre, in co-ordination with SHL's usability process and user study database, will allow SHL to continue creating time-tested designs to meet future industry challenges.

Jochen Ratjen concludes that most patients are nervous when they start a treatment, and there is without a doubt always a long way to go before anyone can feel comfortable enough to treat themselves with a self-administered injection. "At the end of the day," he says, "nobody really wants to be sick and need treatment; this is why we try our best to make this scary experience become as easy and comfortable as possible."

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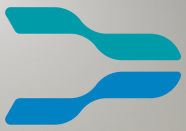
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Feb 2018	Prefilled Syringes	Dec 22nd
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