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AUTO INJECTORS & PEN INJECTORS: A USER-CENTRIC DESIGN APPROACH

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Abstract:
Pens and autoinjectors are mainly used for the subcutaneous delivery of biopharmaceuticals, primarily for self-administration by the patient. The ability to self-inject has been the core driver for their development and made them such an important part of the world of drug delivery devices for more than 25 years. With the worldwide increase in diabetes as well as the trend towards biological drugs which cannot be administered orally, their importance continues to grow. This chapter provides an overview of the different types of injection devices as well as what the development of such a device entails. Firstly, the landscape of injection devices is presented including a brief review of the different primary containers around which the devices are designed. The different types of pens and autoinjectors are described in some detail before reviewing the development process. The development sections outline the applicable regulatory requirements, provide examples of useful development tools, and then describe the different steps involved in injection device development and industrialization.

Key words: *Auto injector, The needleless Molly® trainer, Penny™ Adjustable Multi-Dose Injector.*

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INTRODUCTION:

With the momentum of self-administered injection trends quickly increasing, devices for self-injection, like auto injectors and pen injectors, are no longer a foreign concept to many patients. Device designs are thus now focused more than ever on a user-centric approach – with the application of human factors / usability engineering crucial to minimise user-related risks and enhance ease of-us. 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 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. An example of an auto injector designed to address such needs is SHL's Amber® Auto Injector, a device with customised uncapping or grip options and an exterior that provides additional friction for an easier grip (Figure 1).

Another example of a user-centric device that has experienced much market success is the Emerade® Auto Injector, an intuitive disposable two-step auto injector designed to deliver adrenaline for emergency use via intramuscular injection. A usability study of the accuracy of Emerade® device use in a simulated emergency demonstrated that all of the participants successfully administered the injection as per the labelled instructions.

Figure. 1

Figure 1: A rheumatoid arthritis patient handles the Amber® Auto Injector and provides positive feedback to SHL design engineers. SHL's Amber™ Auto Injector is a simple ergonomic two-step auto injector that leverages SHL's market-proven Pushclick® technology.

HUMAN FACTORS, ERGONOMICS AND USABILITY ENGINEERING

The role of an industrial designer (Figure 2) is to create and execute design solutions for problems of form, usability, and the general physical ergonomics. The industrial designer's contributions should be seen as improved service for the patient to self-administer the medication. Equally important, good design is for everyone; understanding user needs is essential to offer users the most suitable drug delivery design available.

Specific patient characteristics, including age and strength, which may impact physical and cognitive capabilities, should be considered when choosing a device design. Precise communication between the device partner and the biopharmaceutical company is thus paramount, especially during early stages where design input requirements are specified. Aside from understanding the targeted user group, the designers also need to gain knowledge of the anticipated usage environment as well as anticipated 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.

Figure 2: An SHL Industrial Designer sketches a conceptual design of an auto injector.

Various aspects for optimising device performance – like portability, identification, safety and effectiveness – should always be considered during early design phases. For a device to be portable and identifiable, the device engineer has to think about size, shape, colour and labelling, whereas device safety and reliability may require fool-proof safety designs such as trigger-locking and automatic safety locking features to prevent injury after use. User-friendliness and effectiveness can depend on optimal grip designs tailored to specific patient types or just size in general. The overall design should be based on a mixture of proven design features and current user study results, and iterated to ensure that the most optimal design is outputted before entering manufacturing stages. Figure 3 summarises functionality and usability considerations for auto injector design.

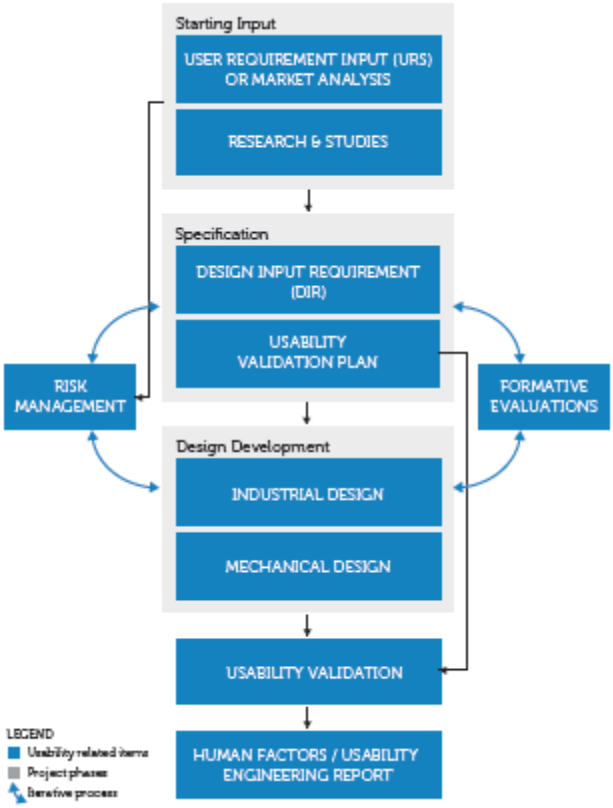

Figure 3: A simplified functionality usability flowchart for the design and development of auto injectors.

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. Requirements include but are not limited to accommodating various primary containers as well as increased agent drug viscosities or volumes.

Auto injectors and pen injectors are intended to assist the end-user with the self-injection process and are often self-administered by the patients themselves. Consequently, applying Human Factors Engineering (HFE) principles is crucial as incorporated physical and psychological characteristics minimise user-related risks and enhance user compliance.

HFE / Usability Engineering should be applied throughout the entire product development process and assists with key design decisions. 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.

DESIGNING FOR MANUFACTURABILITY

Besides HFE, one of the biggest challenges for the device designer/manufacturer is to develop a device that is easy to understand, intuitive to handle, has a non-medical appearance, and also suitable for mass production. Hence the importance of DFM (Design for Manufacturing) aspects of designing auto injectors and pen injectors, as economic factors will affect the production of the device. This normally would require close collaboration and instant communication between industrial design engineers, production teams and project managers. SHL offers in-house availability of key design services and manufacturing capabilities. The result is a faster track towards a finalised product for mass production. Other services may include industrial design, regulatory affairs, and quality control systems; and capabilities such as tooling, moulding, assembly, and final assembly. Having in-house capabilities accelerates time-to-market for new products and for new features of existing products.

Consequently, a balance must be achieved between the pharmaceutical company and the device manufacturer. It is important for both parties to understand the design

concepts and usability programs clearly, and to also share valuable knowledge from past experiences.

ENHANCE AND IMPROVE USER EXPERIENCE

According to the World Health Organization, "Poor adherence attenuates optimum clinical benefits and therefore reduces the overall effectiveness of health systems." While auto injector designers strive to introduce the most innovative and user-centric device solutions, oftentimes even the most intuitive device cannot overcome a patient's anxiety when faced with their first self-administered injection.

Not only do the considerations of safety, convenience, and ease of use need to be integrated into the device design to begin with, the pharmaceutical company and device manufacturer will need to work together to anticipate potential usage scenarios and prepare supporting documents such as clear instructions for use (IFUs), handling videos, appropriate labelling and training devices. Since injection devices like auto injectors are usually targeted for self-administration, where the patient received the device with drug inside through a distribution channel and takes the injections by themselves without the direct supervision of a healthcare professional, it becomes even more challenging for the biopharmaceutical company to effectively connect with the patient to ensure the proper usage of the device.

SHL provides needle-free trainers, for example the trainer version of Molly® shown in Figure 4, that replicate both the look and feel of the actual device, in order to lessen the impact of patient's psychological barrier. Trainers can prove to be very effective and provide users with an opportunity to practice handling the device without the fear of incorrect administration.

Understanding user needs goes beyond identifying factors such as the force required to operate a device or the most comfortable grip – at times it is the user's emotional status that will make or break the deal. Indeed, while an auto injector or a pen injector may be simple to use, it is an obsolete device if the user is afraid to use it. Therefore, device manufacturers like SHL steer away from the typical medical device look to enhance acceptance level from patients.

Improving patient compliance will ultimately enhance wellness and a better health management. SHL strives to improve adherence, and in doing so must assess the various aspects that surround the everyday concerns of a patient who will be using self-administered injection devices like auto injectors and pen injectors on a regular basis.

Figure 4: The needleless Molly® trainer helps users simulate the two-step operation of the actual auto injector. The trainer is paired with a reset mechanism in the cap, allowing the device to be used as many times as needed until the user is ready to inject with the real device.

NNOVATING TO EVOLVE – "PENNY™ ADJUSTABLE MULTIDOSE INJECTOR"

True user-centric innovation should be based off of proven designs, user study results, or even just market observations – which may include user complaints. By understanding the missing features or possible room for improvement of similar existing devices and leveraging recognised preferences, the designer can truly design to further evolve a device. An example is SHL's latest device – Penny™, a 3.0 mL multi-dose disposable pen injector with a user-centric and simple yet modern industrial design (Figure 5).

Figure 5: Penny™ Adjustable Multi-Dose Injector – a 3.0 mL multi-dose disposable pen injector with a user-centric and simple yet modern industrial design.

While similar pen injector products have been available on the market for many years, Penny™ is designed to stay true to the established mentality of a diabetic user and offers equivalent performance to current leading pen injector products. Internal user studies also showed that the discreet design was preferred and the interface intuitive and easy to use at home (Figure 6).

The business model offered by Penny™ also allows for full freedom to operate (FTO) and a short time to market if a preconfigured device is chosen. The device offers a platform for variable as well as set doses and is designed for large scale manufacturing.

Figure 6: A patient injecting with the Penny™ device in the comfort of their own home.

SHL offers a range of auto injector and pen injector solutions (Figure 7) that can accommodate changing injection needs such as higher viscosity, larger volumes, and more.

Figure 7: SHL's range of auto injector and pen injector solutions that can accommodate changing injection needs such as higher viscosity, larger volumes, and more.

CONCLUSION:

In an industry where long development cycles and time-consuming product approval processes make trends difficult to recognise, a user-centric approach will always be the basis for the industrial design of auto injectors and pen injectors. In the future, a greater number of unadorned, disposable devices with even more simplified performances will become preferred and stay mainstream. In addition, these devices could potentially have the ability to connect to smart communication systems, for improved compliance and potentially reducing costs.

A focus from incident-based treatment and care delivery has been shifted towards continuous disease management, thus patient engagement has become more crucial than ever. Integrating technologies such as connectivity can enhance information sharing, allowing for better management of patient treatments and device tracking. With internet and electronics readily available today and technology penetration apparent and still growing, such solution can be easily adopted. It is thus safe to assume that more technology-integration innovations will be introduced alongside the continuous innovation of the industrial

and mechanical design of auto injectors and pen injectors.

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