



DEVICE TRAINING AND ONBOARDING CONSIDERATIONS FOR ON-BODY DELIVERY SYSTEMS

New delivery systems for larger volume and more complex drugs, such as wearable injectors, are revolutionising patient treatment. However, research has shown that patients need to receive quality training and onboarding to ensure they use the devices properly and retain the information. Joe Reynolds, Research Manager at Noble, explores the factors that need to be considered in developing optimal training devices for patients.

While still a younger segment in the broader scope of health care and medicine, the market for biopharmaceuticals and complex chemical entities has revolutionised the practice of modern medicine and significantly improved the quality of life of millions of patients worldwide. From its early origins in the 1980s and the US FDA's approval of Humulin, the first recombinant pharmaceutical product marketed in the US, advancements in science and our understanding of disease mechanisms and pathways have supported the discovery and development of a broad portfolio of currently marketed biotherapies and a robust pipeline of future innovative medicines.¹

According to statistics from The Pharmaceutical Research and Manufacturers of America (PhRMA), there are currently over 6,300 biological compounds in clinical development globally, the majority of which (~74%) are described as having novel clinical

profiles that could provide first-in-class pharmacological and therapeutic benefits to patients.²

In addition to serving as a strong base for future therapy, many of these products leverage innovative scientific approaches such as gene/cell therapy, conjugated antibodies, nanotechnology and other pioneering techniques seeking to advance the field of medicine and address the unmet patient, clinical and economic needs of society. While these medications have the potential to augment and enhance the prognosis of rare, debilitating and underserved conditions, novel approaches to drug delivery are often required to ensure that patients realise the full therapeutic benefits of these innovative compounds.

Due to the structure and clinical properties of biologics and other large molecule compounds, many of these substances are administered through parenteral routes, including intravenous (IV), intramuscular (IM), subcutaneous (SC), intradermal (ID) or other injectable methods for localised or systematic effect.

While numerous factors influence the final dosing route and delivery method of a therapy, subcutaneous injections, many of which are marketed for at-home administration by patients, have historically been administered using pre-filled syringes, safety systems, injection pens, autoinjectors or other conventional device platforms. Over the years, these delivery devices have



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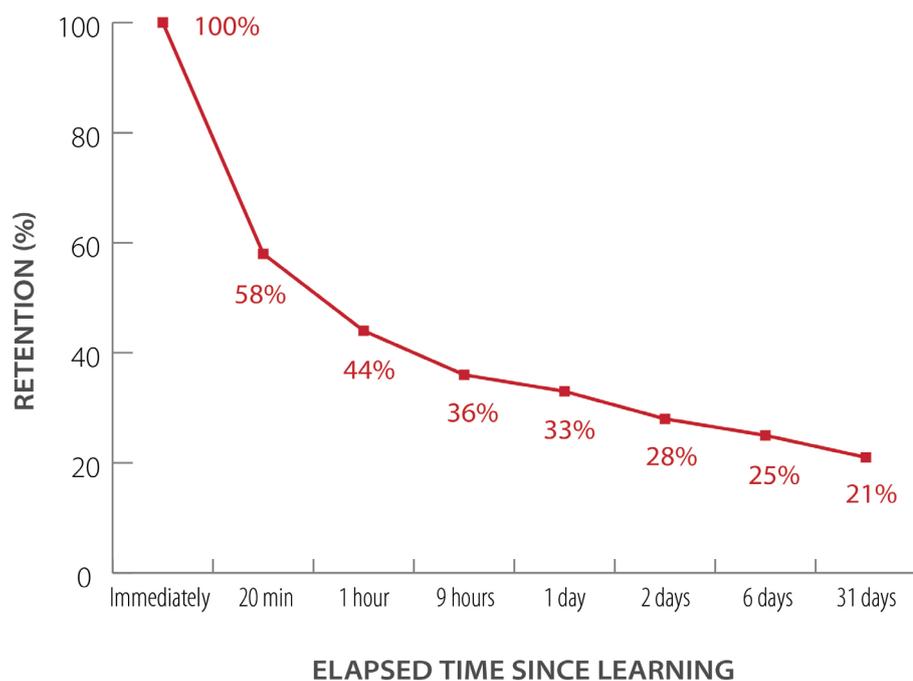


Figure 1: Forgetting Curve theory illustrating the decay in training and treatment information over time.

significantly improved user experiences and safety; however, they also present technical constraints and limitations for drug developers, particularly associated with dosing characteristics such as volume, concentration and viscosity.

WEARABLE INJECTORS

To address the limitations of conventional delivery systems, a new segment of the device delivery market was established for larger volume and more viscous medications, many of which are not suitable or feasible for use with traditional delivery technologies.

Commonly referred to as on-body, wearable or bolus injectors, these new delivery systems are typically adhered to a patient's body where they are intended to remain until a prescribed dose has been successfully administered. In addition to adhering to patients' bodies, these new delivery devices also introduce new behaviours and protocols into the patient experience that increase the need and importance of patient training and onboarding.

THE ONBOARDING PROCESS

Within healthcare and drug delivery, the onboarding process is commonly viewed as patients' first 30, 60 or 90 days of therapy and where their initial treatment attitudes and behaviours are first established. While the

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duration and key onboarding considerations vary across therapies, research suggests that the strength and retention of training and treatment information increases through experience and repetition overtime.

Inversely, patients that receive suboptimal training and onboarding may be more likely to misuse drug delivery devices or experience lapses in treatment. According to this research, it is estimated that after one day of training, patients retain and are able to recall only 33% of the information they successfully perceived and encoded. After six days, recall decreases to 25%, where it continues to erode and decay over time (Figure 1).³

To address these adherence barriers and support the proper use of on-body systems, Noble applies a number of supporting learning theories and methodologies to develop the most optimal training devices and onboarding experiences for patients of on-body and other

forms of drug delivery. Ultimately, the goal of Noble's on-body training devices, and other onboarding solutions, is to provide patients with the skills and knowledge required to manage their treatments confidently, successfully use their delivery systems and achieve an improved quality of life. To support this goal Noble applies a number of best practice design, development and manufacturing methodologies throughout its process, ensuring that every patient receives a consistent and meaningful onboarding experience.

DEVELOPING TRAINING DEVICES

Similarly to developing training solutions for other forms of drug delivery, engineering large volume and wearable trainers for manufacturability and repeatability is a delicate balance. Fully understanding device development, mechanical design and other technical disciplines is one of the first steps in engineering robust training device solutions for on-body devices. To be most effective, training devices must replicate the complete user experience and delivery process, with the exception of containing a real needle or liquid, to ensure that patients understand the operating requirements of their delivery systems and are properly onboarded.

External features

The exterior of a trainer should emulate the commercial injection device so that patients become familiar with key features and physical characteristics such as the look, feel and weight of their device. For on-body trainers this commonly includes unique features such as adhesive patches and multisensory user feedback, which are less prevalent in conventional delivery devices. Characteristics of the injection system, such as the dimensions, viewing window, actuation method, surface finish and other external features, are all accurately matched so patients can familiarise themselves with the complete user interface and task flow.

Internal mechanics

In addition to external details, internal mechanics are also crucial to the design and engineering process. To incorporate all of these necessary components, the interior design of training devices needs to be meticulously engineered in order to provide a proper training experience for patients and other stakeholders. To accomplish this, human factors are taken into consideration throughout the design process to ensure



Figure 2: West Pharmaceutical Services Inc. and Noble have worked together to offer a multisensory-based educational and training solution for the SmartDose technology platform to pharmaceutical and biotechnology customers.⁴

that training devices align with the physical, cognitive and emotional needs of users.

In addition to understanding user needs, Noble leverages numerous design inputs to prioritise design requirements for training devices and maximises training value for targeted user populations. Though in some cases mechanisms similar to commercial devices are used, ground-up mechanical design is usually employed to integrate all necessary functions in a resettable and reusable training device. This means that the trainer will look the same on the outside; however, internally it will be vastly different.

Adhesive simulation methods

From a user experience standpoint, one of the most distinguishable differences between on-body systems and conventional injectors is that they are held in place on a patient's body using adhesives.

Incorporating these features into reusable training devices requires careful consideration for sanitation, biocompatibility and other design trade-offs that must be evaluated when determining requirements for on-body trainers. To assist manufacturers through this process, Noble has developed a number of proprietary adhesive and alternative simulation methods that balance these trade-offs and optimise training. This is done so that patients can realistically learn how to adhere and remove devices from their body and experience the sensation of how long it takes the medication to deploy and be fully delivered.

In addition to addressing device adhesion, all functions requiring force application by the user must accurately represent the real device. Force profiles can also play a significant role; some forces may ramp up slowly while others have a fast onset for activation. Within the on-body market, there are also devices that have unique steps for loading, priming, unlocking and other functional features that need to be replicated by a trainer.

Other considerations include representing the audible and haptic feedback levels that

are present and integrating tactile feel elements, such as subtle internal vibrations associated with drive elements. In addition to these items, along with the fact that it needs to be easily resettable versus just a single-use product, the trainer must also maintain a 1:1 size ratio i.e. it cannot get any larger than the real drug delivery device.

NOBLE'S TRAINING DEVICE PORTFOLIO

To address the demand for this emerging market, Noble has developed a broad portfolio of on-body training solutions and platform technologies which can be leveraged by manufacturers to meet the onboarding needs of patients and other stakeholders. Designing the most optimal training device comes down to the unique needs of patients and other user populations.

Knowing this, Noble's development process and proprietary portfolio of multisensory, error detecting, wireless, smart and other technologies support manufacturers in prioritising requirements and developing solutions that maximise training value for patients and other stakeholders (Figure 2).

CONCLUSION

As innovative on-body therapies continue launching and diffusing in the market, onboarding and training will continue influencing patient acceptance, confidence, satisfaction and outcomes with therapy.

ABOUT THE COMPANY

Noble is a full-service, user-centered, advanced drug delivery training device and patient onboarding company. Noble works closely with the world's leading drug delivery device original equipment manufacturers and pharmaceutical companies to develop educational and training solutions designed to provide positive patient onboarding experiences, reduce errors and improve patient outcomes.

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ABOUT THE AUTHOR

Joe Reynolds is Research Manager at Noble, where he leverages his knowledge and experience to develop and implement strategies that improve the patient experience and maximise value for stakeholders. His experiences include commercial, managed care and product development initiatives with leading medical device, pharmaceutical and biopharmaceutical manufacturers. Mr Reynolds earned his Bachelor of Science in Business Administration from the University of Central Florida, a Master of Science in Marketing from the University of South Florida, and a Master of Science in Pharmacy and Master Certificate in Drug Regulatory Affairs from the University of Florida.

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AGITATOR



ENCASED



BALL TIP

*Magnified to reveal detail



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- Needle Force & Feel Simulation*
- Reusable Safety Systems*
- Plunger Force / Viscosity Simulation*
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- Pad Printing
- Finger Flange

+BD UltraSafe™ devices are single use medical devices. Noble's demonstrators are multi-use.
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