BEST PRACTICES AND CONSIDERATIONS IN DEVELOPING EFFECTIVE TRAINING DEVICES FOR THE PULMONARY HEALTHCARE MARKET

In this article, Joe Reynolds, Research Manager at Noble, discusses the current state of pulmonary drug delivery device trainers, including their value to patients, the complexities of modern design and the stringent requirements on ensuring their quality.

Over the years, many industry stakeholders and pharmaceutical manufacturers have come to realise the importance of patient training and the role it has on promoting healthy outcomes and effective disease management. Many studies suggest that without proper training during the onboarding process (the first 30 to 90 days of treatment) patients are more likely to drop off from their prescribed therapy or incorrectly use drug delivery devices, including metered dose inhalers (MDIs), dry powder inhalers (DPIs), nebulisers and other forms of self-administration.

Designed primarily for at-home use, pulmonary drug delivery is an effective route of administration for localised and systemic uptake of pharmaceutical products. As a result, pulmonary administration is often a viable alternative to more invasive routes, with future growth potential across new therapeutic areas. These products are frequently marketed as combination therapies, consisting of API and a drug delivery device. When properly used by patients, these devices are effective in delivering a prescribed dose to the lungs. However, user errors can result in injuries, partial delivery and suboptimal therapeutic outcomes for patients.

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According to a study conducted by the University of Texas Medical Branch at Galveston (UTMB),[1] 93% of patients prescribed an MDI failed to use their devices properly, with more than half missing three or more of the required use steps (Table 1). The most common mistakes were failure to prime, exhaling and co-ordinating actuation with the necessary timing, force and duration of inhalation.

As an addition to standard instructions for use (IFU) and package inserts, healthcare providers are often expected to onboard patients and provide access to training and education. While these training strategies can be very effective, research suggests that there is often a great deal of variability and inconsistency in the effectiveness of such training and in patients' ability to retain the information and apply it to the successful use of their delivery system.

Further research has shown that many patients are looking for increased access to education and support for self-administration. A study conducted by Noble surveyed patients and examined the impact that device training solutions had on patients using an MDI. The study examined

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Step	Description	Risk of Error
1	Prepare device	Low
2	Remove mouthpiece	Low
3	Inspect the mouth piece for obstructions	High
4	Prepare dose	Medium
5	Exhale, away from the device	High
6	Place device in mouth	Medium
7	Actuate dose	High
8	Inhale with the appropriate force, duration & sequence	High
9	Hold breath (as specified in IFU)	Medium
10	Repeat dose as prescribed	Medium
11	Clean and store device as prescribed	Medium

Table 1: Required use steps for MDIs and risk of error.

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five different training solutions, ranging from standard IFU to smart error correcting training, in an effort to better understand how training technology can reduce device errors. 82% of users said they would feel most confident with a training device that detects errors. Additionally, 76% of users said they would prefer some form of error detection to aid in overcoming anxiety about administering treatment. For example, one device that was tested included IFU and would whistle if used incorrectly.

To address the common gaps in patient onboarding, training devices are often used to create consistent experiences for patients through the use of novel technologies and mechanisms that fully simulate the mechanical aspects of the drug delivery experience. While these devices appear to be fairly simple at first glance, numerous design and engineering challenges must be addressed in order to successfully develop authentic training devices and other onboarding solutions.

INTERNAL DESIGN AND TECHNOLOGY OF TRAINING DEVICES

Engineering training devices for manufacturability and repeatability is a delicate balance. Fully understanding device development and mechanical design is one of the first steps in engineering robust training device solutions. The exterior of the device should emulate the real drug delivery device as closely as possible, so that patients become familiar with key features and physical characteristics, such as the look, feel and weight of their commercial delivery devices. The interior design of training devices also need to be meticulously engineered in order to provide a proper training experience. To accomplish this, human factors must be taken into consideration throughout the design process to ensure that training devices align with the physical, cognitive and emotional needs of users.

In addition to understanding user needs, Noble has analysed a variety of on-market delivery systems to understand their handling requirements and critical functions. Though in some cases mechanisms similar to commercial devices are used, ground-up mechanical design is usually employed to integrate all necessary functions into a resettable and reusable training device. This means that the training device will look the same as the real thing on the outside, however, it will be vastly different internally. Once human and environmental factors have been taken into consideration, design inputs can be documented and prioritised to mitigate user errors and maximise the value to pulmonary drug delivery device training.

When looking at the case for pulmonary smart training devices, they are designed to monitor patient behaviours and provide corrective feedback during the early stages of the learning process. While there are many variables that influence the deposition of pulmonary therapeutics, including timing, force, volume and muscle memory, trainers should be developed to support patients in establishing motor and muscle skills, along with the appropriate level of force required to use their inhaler effectively. How the patient interfaces with the delivery

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device plays an important role in drug deposition and achieving full absorption. When designing a device it's important to understand the sequence of steps patients go through and the risk of error associated with each (Table 1).

EXTERNAL DESIGN OF THE TRAINING DEVICE

As mentioned previously, external details are also crucial to the design and engineering process. Characteristics of the inhaler, such as the overall shape, mouthpiece, dose indicators and size and shape of the canister, are all accurately matched to the real device so that patients are able to familiarise themselves with its look and feel. However, this is a complex task, due to the fact that the interior of a training device contains additional mechanisms which allow the device to be used multiple times.

One of the most seemingly simple design requirements is to make the device look like the real product externally, which presents its own set of challenges. For example, if the trainer looks exactly like the real device one may mistakenly use a trainer in an emergency or vice-versa. This is typically addressed with optimised packaging, labelling and graphical training instructions. Trainers usually have large labels which read "Trainer, This Device Contains No Drug". In every other regard, the trainer appears exactly the same, in terms of size, shape, textures and Pantone-matched colour schemes (or complimentary colours to denote that it is a trainer).

Other considerations that must be prioritised include ancillary training features like augmented auditory and/or video-based training instructions. Many of the trainers currently in development include some form of collateral training, such as talking packaging, sensor-based error-correction, smart device application or a combination of these features.

QUALITY CONTROL PROCESS

Quality design standards are paramount when designing training devices, in order to ensure that every patient has a consistent and accurate training experience. Noble conducts rigorous device testing, taking into consideration each brand's specified requirements. One of the keys to success is utilising optimised standard operating procedures (SOPs) and standard inspection procedures (SIPs) in the assembly process at the factory. Many manual and semi-automated tests and inspections are integrated throughout the process to verify that targets will be met on the final assembly stage, reducing scrap rate and ensuring a high quality product.

Critical functions, such as activation forces and the auditory feedback of calibrated whistles, are tested at several points during design, development and manufacturing. During pilot runs, many other tests are also performed to evaluate that the device functions as intended and conforms to specifications and other design inputs. Some of these include environmental, accelerated ageing/life, shipping, drop-testing and materials compliance. Though not a formally regulated device category, Noble treats the design and manufacturing of trainers much like a regulated product to ensure the highest final quality product.

CONCLUSION

As training technology becomes more prevalent in the pharmaceutical industry, the engineering and capabilities of these devices will continue to advance, creating a more complex and intricate engineering process. These advancements are necessary, as they will allow patients to become more confident in their treatments, overcome treatment barriers and ultimately lead healthier lives.

In order for training devices to work efficiently, it is necessary that devices are tested with stringent standards. Patients need to familiarise themselves with the device in order to learn and anticipate the steps necessary for proper drug administration. This requires training devices to replicate the ergonomics, interaction and injection time of the actual device accurately.

In today's market, a growing number of patients are being prescribed self-administered treatments. Pharmaceutical companies that prioritise the patient experience, using training technology to help these patients properly onboard to therapy will continue to benefit through competitive advantages and the value they create within the industry.

ABOUT THE COMPANY

Founded in 1994, Noble® is a leader in medical device training solutions, patient onboarding strategies and multisensory product development for the world's top pharmaceutical brands and biotechnology companies. Focused on driving innovation, Noble works closely with brand, device and commercialisation teams to develop turnkey solutions that improve onboarding and adherence, bringing value to clients and patients alike.

REFERENCE

1. *Bonds RS, Asawa A, Ghazi AI, "Misuse of medical devices: a persistent problem in self-management of asthma and allergic disease". Ann Allergy, Asthma Immunol, 2015, Vol 114(1), pp 74–76.*

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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