DEVELOPING EFFECTIVE TRAINING DEVICES FOR THE PULMONARY HEALTHCARE MARKET

Pulmonary drug delivery is an effective route of pharmaceutical administration but research has shown that a large majority of patients fail to use their devices properly. To address this problem, training devices can help patients learn how to administer the drugs correctly. Joe Reynolds, research manager at Noble looks at the design challenges that need to be addressed as well as some of the latest features that can be incorporated to develop optimal training devices for patients.

Over the years, many industry stakeholders and pharmaceutical manufacturers have come to realise the importance of training and the role it has on promoting healthy patient outcomes and effective disease management. Many studies suggest that without proper training during the onboarding process, or the first 30 to 90 days of treatment, patients are more likely to drop off from therapy or incorrectly use drug delivery devices, such as metered dose inhalers (MDIs), dry powder inhalers (DPIs) 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 a viable alternative to more invasive routes, with future growth potential across new therapeutic areas. These products are often marketed as combination therapies, consisting of active pharmaceutical ingredients and drug delivery devices.

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DRAWBACKS OF PULMONARY DRUG DELIVERY DEVICES

When properly used by patients, these devices are effective in delivering a prescribed dose to the lungs; however, user errors can result in, partial delivery and suboptimal therapeutic outcomes for patients.

According to a study conducted by the University of Texas Medical Branch at Galveston (UTMB), US,[1] 93% of MDI patients failed to use their devices properly, with more than half missing three or more steps.

The most common mistakes patients made were:

- Failing to prime
- Exhaling
- Coordinating actuation with the necessary timing, force and duration of inhalation.

In addition to traditional instructions and package inserts, healthcare providers are often leveraged as learned intermediaries 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 both with these training methods and patients' ability to retain this information and

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apply it successfully to the use of their delivery system.

Further research demonstrates 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 of device training solutions on patients using MDIs. The study examined five different training solutions, ranging from the common Instructions for Use (IFU) to smart error-correcting training, in an effort to better understand how training technology can reduce device errors.

The survey showed that 82% of users said they would feel most confident when training with a device that detects errors. Additionally, 76% of users prefer some form of error detection to help overcome 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 often use 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, there are numerous design and engineering challenges that need to be met.

DEVELOPMENT OF TRAINING DEVICES

Pulmonary smart training devices are designed to monitor patient behaviours and provide corrective feedback during the onboarding experience, which are the early stages of the learning process.

Engineering these devices for manufacturability and repeatability is a delicate balance. Fully understanding device development and mechanical design is one of the first steps in creating robust solutions.

Throughout the design process, human factors are taken into consideration to ensure that training devices align with the physical, cognitive and emotional needs of users. Thus, 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).

While there are many variables that influence the deposition of pulmonary therapeutics (e.g. 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 inhalers effectively. How the patient interfaces with the delivery device plays an important role in drug deposition and full absorption.

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
6	Exhale, away from the device	High
7	Place device in mouth	Medium
8	Actuate dose	High
9	Inhale with the appropriate force, duration & sequence	High
10	Hold breath (as specified in IFU)	Medium
11	Repeat dose as prescribed	Medium
12	Clean and store device as prescribed	Medium

Table 1: Use steps of a MDI and their associated risk of error.

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 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.

EXTERNAL AND INTERNAL DESIGN OF THE TRAINING DEVICE

The exterior of the device should emulate the real drug delivery device so that patients become familiar with key features and physical characteristics such as the look, feel and weight of their commercial delivery devices. Characteristics of the inhaler such as the shape, mouthpiece, size and shape of the canister and dose indicators all need to be accurately matched.

Although making the device look like the real product externally may appear simple, it does present its own 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". Though in every other regard, the trainer appears exactly the same: size, shape, textures and Pantone-matched colour schemes (or complimentary colours to denote that it is a trainer).

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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 like talking packaging, sensor-based error-correction, smart device application or a combination of these features.

The interior design of the devices needs to be meticulously engineered to provide a proper training experience. It also needs additional mechanisms to allow the device to be used multiple times.

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 targets will be met on the final assembly stage, thus reducing scrap rate and ensuring a high quality product.

Critical functions like activation forces and the auditory feeback of calibrated whistles are tested at several points during design, development and manufactuirng. During pilot runs, many other tests are also performed to evaluate the function and conformance of trainers with 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

In order for training devices to work efficiently, it is necessary that devices are tested to stringent standards. As training technology becomes more prevalent in the pharmaceutical industry, the design and capabilities of these devices will continue to advance, requiring a more complex 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.

Patients need to familiarise themselves with a device in order to learn and anticipate the steps necessary for proper drug administration. This requires training devices to replicate the ergonomics, interaction and required forces of the actual device accurately.

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 use their devices, will continue to benefit through competitive advantages and the value they create within the industry.

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.

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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Device training happens here.

There's life beyond chronic conditions. Distractions, anxiety and understanding correct administration technique can all affect compliance. Studies suggest 61% of patients don't completely read the IFU[1] and 12% of patients have proficient health literacy.[2]

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