DESIGNING FOR USABILITY IN EMERGENCY-USE COMBINATION PRODUCTS

In this article, Thomas James, Lead Mechanical Engineer at Key Tech, highlights the importance of early user engagement, as well as continuous refinement of information and workflow design, for efficient development of drug-device combination products for emergency use.

Designing a drug-device combination product can be exceptionally difficult, and reliability is one key aspect that must always be considered and refined in any proper risk management programme. Reliability becomes more important still when a combination product is intended for emergency-use scenarios. Although that bar is high – 99.999% high, to be precise – for any given critical-to-function technical requirement, performance against that bar will be (conveniently) both measurable and verifiable from relatively early on in the development process.

However, when it comes to the usability of these devices, whether they are autoinjectors for administration on the playground, dosing aids in a sterile field or novel delivery devices being used at the bedside, a deep understanding and consideration of the wide range of use-risk scenarios needs to be established long before formal development begins to ensure a commensurate degree of use-related reliability. Unfortunately, these variables can be a bit more complicated to bench test.

The importance of early application-specific user engagement is essential to a successful emergency-use device development programme. Looking past the user's physical capabilities and into their preferences, instincts and expectations can help the development team understand exactly what

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the most sensitive use steps are – and how to best get ahead of those opportunities for error. By widening the view to the full drug delivery journey, from unboxing to disposal, it quickly becomes evident just how valuable each user touchpoint is along that journey. Furthermore, pointed iteration around information and workflow design can play a surprisingly significant role in conveyance of safe and effective device use to the end user, even in these high-stress scenarios.

USER CHARACTERISTICS: BEYOND THE NUMBERS

Understanding the foreseeable user groups, including both patients and caregivers (often one and the same) is a first step towards establishing a human-factors-based starting point for device requirements. Fortunately, published sources covering generic demographic capabilities may guide the technical requirements, such as activation forces or grip diameters. In many cases, however, they do not provide enough insight into creating requirements or informing design strategies that are tailored specifically towards those populations. In these cases, a dedicated, well-designed investigation may be necessary to better understand user preferences and intuitive, population-specific administration practices. As an example, in patients with decreased mobility, an assessment of self-injection location preference and instinctive device handling techniques would be a valuable set of inputs to guide downstream architecture exploration and definition.

User Literacy and Device Use

User characteristics encompass more than physical measurements and force capabilities. Assumptions about user literacy can be particularly risky in emergency-use products. For example, an impaired user administering naloxone or a child with a

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rescue inhaler may not fully comprehend written on-device instructions, particularly those with precise clinical language. In fact, reading comprehension of even the most well-read, measured and methodical users can be greatly impacted by the stress of an emergency scenario. Although it would be highly valuable, it is very difficult to recruit for a formative study with exclusively <5th percentile participants in the "performance under pressure" category. Whilst it is a nuanced scenario, on-device symbols and co-ordinated colour motifs can often help guide correct use among (even temporarily) mixed-literacy users.

User Expectations and Instincts

Expectations around device usage and workflow are a double-edged sword in emergency settings – and often in unexpected ways. Frequently, the lay caregivers with the least device experience can, in fact, be some of the most successful users, as they have very little in the way of preconceived notions of intended workflow. When healthcare professionals (HCPs) are involved, there is a high risk of use-step transference from other devices they have previously encountered. Developers must carefully consider product appearance, workflow and use setting to avoid this potential pitfall. If a product looks like an inhaler but does not work like an inhaler, it should be no surprise to the development team when use errors are encountered in early HCP engagements and formative studies.

Counterintuitively, intentionally manipulating the device form and workflow away from HCPs' expectations can be an effective approach to improve correct use, as it helps to keep the users on their toes during the workflow. Of course, taking that strategy to an extreme can be dangerous, as users can often be intimidated during their first use of an unfamiliar device.

In instances where user instincts play a particularly significant role in device interactions, dedicated handling models with distinct forms or functions can help

inform which specific device concept characteristics are driving those transference behaviours. From there, the development team can thoughtfully consider how best to either avoid or leverage those user instincts for successful device use.

UNDERSTAND THE DRUG JOURNEY – AND OPTIMISE ALL OF IT

A comprehensive understanding of the entire drug delivery journey, from preparation to administration and disposal, is crucial to ensure that emergency-use combination products effectively capitalise on every moment of user interaction. To achieve this, developers must document and analyse each step along this journey, challenging the interface points and identifying any unique environmental or use considerations specific to each step.

Product Retrieval and Unboxing Experience

When product retrieval is part of the emergency-use scenario, understanding the locations and the ways in which the product is stored is critical, as the storage conditions frequently vary greatly from the conditions during administration. Taking an autoinjector as an example, while the administration environment may have one temperature and humidity range, if the product is refrigerated prior to use, it is very unlikely that the user will be able to "let it warm up for 30 minutes" before administration, which is common practice in self-administration for management of chronic conditions. Whilst this readily translates to power-pack design requirements to handle potentially elevated viscosities and deeper characterisation of break-loose glide force, for example, it also elevates the criticality of effective in-process feedback solutions, due to the range of resultant injection times that the user needs to successfully navigate.

Developers must consider scenarios such as the risk of opening the box before use, as can happen with co-packaged drug-device combination products, as the use risk of potentially separating the instructions for use (IFU) from the product quickly becomes relevant. Similarly, in situations where the product requires sterile compounding, ensuring that necessary information reaches the user administering the product is essential, often through on-device labelling. Effective functional packaging, with consistent and targeted information design on the outer carton, IFU and sterile barriers, can help establish correct use practices even

in those unfortunate cases when the user disregards and discards the IFU.

Circling back to the drug delivery journey, it is important to consider each use step not only as a challenge but also as an opportunity. The unboxing and preparation experiences, for example, are often overlooked by engineering teams during architecture development, but they play a significant role in communicating proper device use to the user. In many cases, these "non-critical" steps may take longer than the actual device use. For example, if 30 seconds of interaction with external packaging precedes a 10-second injection, three-quarters of the opportunity to communicate with the user is during the external packaging touchpoints.

There should be a dedicated focus during product architecture development to optimise the information and workflow design of unboxing and preparation to stack the deck in the user's favour. It is incredibly valuable to trial this "full workflow" experience in front of users as well. Evaluating a concept's effectiveness is one obvious reason why but, furthermore, providing realistic device packaging goes surprisingly far towards helping users to settle into simulated-use scenarios, which are notoriously difficult to produce.

In-Process Feedback and Workflow Design

In chaotic emergency-use settings, planning for multiple feedback mechanisms is vital. For example, a single audible feedback source may be insufficient in a noisy industrial environment, so visual or tactile feedback should also be implemented. Fortunately, some features can provide multiple types of feedback – an end-of-dose "click" in an autoinjector often comes with a tactile sensation for free.

In many emergency-use systems, mechanical lockouts are often a necessary feature to mitigate risks such as premature dose delivery. However, not all use steps are tightly coupled to internal mechanisms of the device, and therefore it can be extremely difficult to poka-yoke those steps to mechanically "enforce" correct use.

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For example, consider a dual-chamber injector that reconstitutes at the point of care. Guiding the user through a process such as "confirm that all particulates have dissolved, then invert the pen and continue with a priming step" is not easily handled by internal cams and triggers. In these instances, functional labels that force interaction (e.g. "inspect and then tear along the perforation") can be used to briefly capture the attention of a user who had been racing through the device use steps up to that point. To ensure that that moment of attention is as effective as possible, eye-tracking glasses can help evaluate if on-device labelling and critical features are in line with the user's instincts, which allows the designer to make the most effective use of that high-value on-device real estate.

Functional labels offer the added benefit of rapid iteration and evaluation of different information design strategies, as they can often be revised and reprinted on the fly by a nimble design team. This capability allows for quick adjustments during early use studies and helps calibrate the designer's ability to put themselves in the user's shoes (or scrubs) as the product development cycle continues back at the office until the next in-person device evaluation.

CONCLUSION

Efficient development of drug-device combination products for emergency use demands a deep appreciation of user characteristics, expectations and instincts, as well as a comprehensive analysis of the

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entire drug delivery journey from unboxing to disposal. Early user engagement and continuous refinement of information and workflow design are crucial for guaranteeing safe and effective device use. Focusing on user preferences, instincts and expectations throughout the entire device process allows designers to craft a smooth user experience, significantly reducing opportunities for human error, even in the most stressful settings.

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ABOUT THE COMPANY

Key Tech is an end-to-end product development firm specialising in the design of complex electromechanical devices and systems for medical applications. It is 100% employee owned and located in downtown Baltimore (MD, US). Key Tech employs 75 engineers and designers focused on transforming complex technologies into simple, intuitive solutions.

ABOUT THE AUTHOR

Thomas James is a Lead Mechanical Engineer at Key Tech, where he is responsible for both the innovation and development of novel drug preparation and delivery devices. During his tenure at the company, he has contributed to several in-clinic and at-home infusion and injection systems, ranging from low-cost emergency-use disposables to highly accurate and flexible advanced-functionality delivery systems. Mr James also serves on Key Tech's business development team, focusing on the pharmaceutical and drug delivery industry. He holds a BSc in Mechanical Engineering from the University of Maryland (MD, US).