# Keeping The Patient At The Center Of Drug Delivery Devices

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Healthcare is increasingly moving out of the hospital and into the home as self-administration of medications becomes more cost-effective. As the population ages and people live longer with chronic conditions, the need for safe and effective drug delivery devices will continue to increase.

However, developing the best delivery platform for your medication brings many challenges. For one, there are physiological and chemical aspects to consider beginning in the early formulation stage of drug development that should be considered when thinking about the safest and best delivery for the patient. So understanding the best method of administering the drug, and how it will interact with the patient to improve lifestyle and condition, are very important. A second challenge is the differences in patient strength, body size, dexterity, education, literacy, state of health, lifestyle, gender, culture, and cognition, which all impact a patient's ability to successfully use a drug delivery device. A patient's inability to correctly administer medication, or not take the medication at all, could result in potentially serious or life-threatening consequences.

Reports show that patient non-adherence accounts for billions of lost revenue for pharma; an estimated $188 billion is lost in the United States and almost double that globally. We've all either been there or had a family member who was prescribed medication and either refuses to take the recommended doses, forgets due to lifestyle habits, or may not comply due to lack of knowledge. In the U.S., there are almost 4 billion prescriptions written every year, yet more than half of them are taken incorrectly or not at all. Studies have also shown that patient non-adherence can also affect clinical trials. In some cases it wasn't the drug that failed but the method of delivery. This can result in potentially millions of dollars in lost drug and biologic development costs and future sales.

Take for example the treatment of COPD through inhalers. According to the World Health Organization (WHO), currently 210 million people have COPD and 3 million people died of COPD in 2005. The WHO predicts that COPD will become the fourth leading cause of death worldwide by 2030 (COPD 2007). COPD is incurable, but management of the disease provides the patient with better quality of life and slows the progression of the disease. Patient non-adherence is still one of the biggest problems with effectively treating COPD. Many times patients adhere to the prescribed dosing schedule, but they may use the inhaler improperly. An inhaler's design features play a big role in the patient's adherence to treatment. A good example of that was an evaluation of inhaler use in 316 patients suffering from asthma or COPD which found that 89% of the patients made at least one mistake in the inhalation technique. Patient skill errors contributed to non-adherence. Almost 70% of patients did not continue to inhale slowly after actuation of the inhaler. And 66% of patients did not exhale before inhalation.

In a recent comparison of inhalers, the Diskus® inhaler (DK) by Advair and the Handihaler® (HH) by Spiriva, regarding preference and ease of use, more patients

preferred the DK. Although there was no difference in the number of instructions needed for both inhalers, 90% of patients found the overall feel and function of the inhaler as the most important factor contributing to their overall preference.

Due to concerns for patient safety, the FDA expects human factors and usability studies to be part of the overall risk management process for new drug delivery and medical devices, as well as existing devices being used with new drugs or new populations. Drug delivery device designs are increasingly utilizing the results of human-centered design and patient-preference research, driving significant improvements in patient adherence and the usability of medical devices over the past decade.

## Human-Centered Design Ensures Usability, Saves Money

As biopharma manufacturers think about developing proprietary drug delivery devices for new or existing drugs, evaluating the most efficient and safe delivery method along with patient lifestyle needs and preferences is crucial. Not only has it proven to save time and money, but in many cases it helps give a competitive edge. Human-Centered Design (HCD) brings together specialists in industrial design, cognitive science, and other related science and engineering disciplines to design medical devices built with user needs and capabilities in mind. Applying HCD principles early in the design process can ultimately save time and money for biologics manufacturers by ensuring that devices will perform well in usability and human factors testing. Whether the pharmaceutical product is an injectable, an inhalable, or a solid dose, the development of the delivery device will benefit from integrated HCD. A human-centered approach should be adopted early in the drug delivery development process and embedded into the culture of the biologics manufacturer. When designing a drug delivery device, engineers should consider key principles such as confirming if the product is:

- **Useful** — meets a specific need within that targeted therapeutic area
- **Usable** — is easy to understand and manipulate without being complicated or cumbersome
- **Desirable** — is appealing to the patient administering the medication
- **Manufacturable** — is efficient and reliable to produce without having to make multiple changes to the original design

The three elements of HCD are:

1. **Design Research** — This process establishes a firm foundation for future development work. Design research activities should be conducted at the beginning of development, focused on the end user needs derived from interviews, contextual observation, and participatory workshops. Additionally, the focus should be on the environment in which the final design will be used.

2. **Industrial Design** — This builds upon the foundation of design research, translating those discoveries into tangible concepts using 3D computer-aided design and physical modeling. The user interface, ergonomics, material selection, and aesthetics are determined at this stage.

3. **Human Factors Engineering (HFE)** — This focuses on product safety and efficacy. Key benefits are user interface optimization and risk mitigation. HFE activities may include product-handling studies, use error analysis, usability testing with representative users, and usability validation studies to satisfy regulatory expectations.

## The FDA's Recommendations For HFE

The FDA encourages manufacturers to reference standards such as HE-75:2010; IEC 62366-1:2015; and the newly released FDA guidance document, "Applying Human Factors and Usability Engineering To Medical Devices". The recommendations in these documents are intended to improve the usability of devices to reduce or eliminate user error which could lead to patient harm.

To gain an understanding of the user interface dynamics of a particular medical device, the FDA recommends thorough consideration of the following:

1. **Device users** — Evaluate and understand essential characteristics of all intended user groups:
    - the end users of the device (e.g., patient, family member, physician, nurse, professional caregiver)
    - the level of training users will have and/or receive
    - user characteristics (e.g., functional capabilities, attitudes and behaviors) that could impact the safe and effective use of the drug delivery device
    - ways in which users might use the device that could cause harm

2. **Device use environment** — The environment in which medical devices are used may present a range of complexities. Medical devices may be used under variable conditions involving environmental attributes, such as space, lighting, noise levels, and activity:
    - hospital, surgical suite, home, emergency use, public use, etc.
    - special environments (e.g., emergency transport, mass casualty event, sterile isolation, hospital intensive care unit)
    - interoperability with other devices

3. **Device user interface** — The user interface includes all components of a device with which users interact while using the device, preparing it for use, or performing maintenance:
    - functions, capabilities, features, maintenance requirements
    - packaging, labeling, and instructional materials

## HFE Verification

As part of HFE/UE studies, the FDA emphasizes formative usability evaluation and summative user interface validation. Formative usability evaluations allow representative users to interact with prototype devices, highlighting potential use errors and identifying opportunities for design optimization. For instance, if a device will be used

by elderly users with hearing disabilities ranging from normal to moderate impairment, formative usability evaluations would likely examine the points of user interface that enable the device's alarm volume to be adjusted by a patient.

The summative human factors validation test demonstrates that the intended users of a medical device can safely and effectively perform critical tasks for the intended uses in the expected use environments. It is particularly important during HFE validation testing to use a production version of the device, representative device users, actual use or simulated use in a realistic environment, and to address all aspects of intended use.

The test results should provide evidence that all known risks have been mitigated to an acceptable level or eliminated. The results should also facilitate identification and understanding of the root causes of use failures or problems that may occur.

## Conclusion

As biologics manufacturers look for new delivery platforms, incorporating a patient-centric strategy to their selected delivery method or platform will become increasingly important. The HCD approach has been driving the trend toward development of smaller and smarter, next-generation devices. When successfully executed, the process will produce devices that are more useful, safe, and desirable than current-generation devices. Applying human factors engineering principles will help not only develop a strong proprietary delivery product and improve patient adherence, but can also save time and money in the manufacturing process.



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