Human Factors Considerations in Combination Product Design and Development

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FDA recently released a draft guidance for the Industry and FDA staff regarding Human Factors and Related Clinical Study Considerations in Combination Product Design and Development (February, 2016). This guidance underlines principles of human factors (HF) studies during the development of combination products, which are comprised of a drug or biological product and a device, for investigational or marketing applications. The guidance clarifies the different types of HF studies, the recommended timing and sequencing of HF studies, and how HF studies are part of the process to maximize the likelihood that the combination product user interface is safe and effective for use by the intended users, uses, and environments.

Risk Based Approach

For medical devices, the use of human factors and usability engineering (e.g., applying the knowledge of human behavior, abilities, and limitations to the design of a medical device) plays a key role. A risk based approach should be used by the device manufacturers to identify and analyze potential use-related hazards, including lessons learned from reported errors with similar products, and as appropriate, incorporate and validate design features that mitigate or eliminate these hazards. This assessment informs the device design development to eliminate or minimize use errors that could cause harm or compromise medical treatment.

Critical Tasks

The use-related risk analysis should identify critical tasks. Critical tasks are user tasks that, if performed incorrectly or not performed at all, would or could cause harm to the patient or user, where harm is defined to include compromised medical care. The FDA expects the risk analysis for the combination product to include an identification of all the critical tasks required for using the combination product, the consequences for failing to perform each critical task correctly, and the strategies that have been applied in the design of the user interface to eliminate or reduce risks to acceptable levels.

Human Factor Studies

The HF study should be conducted with representative users to assess the adequacy of the combination product user interface design to eliminate or mitigate potential use-related hazards. The study evaluates the ability of the user to:

- Perform critical tasks, and
- Understand the information in the packaging and labeling, such as product labels or instructions for use.

HF studies on a combination product are conducted as part of the product design controls process.

Types of HF Studies

HF Formative Studies: HF formative studies are designed to evaluate early combination product prototypes, taking into consideration the identified use-related hazards. HF Formative study results guide prototype design changes to eliminate or mitigate use-related hazards identified during the product development process. The use of iterative HF Formative studies optimizes the design of the combination product user interface for safety, and minimizes the risk of first discovering use problems during later stages of development.

Human Factors Validation Studies: HF Validation studies demonstrate that the final finished combination product user interface would maximize the likelihood that the product will be safely and effectively used by the intended population, for its intended uses and environments. There are two types of HF Validation studies:.

> **Human Factors Simulated-Use Validation Studies**: Simulation methods for these studies vary and may include the use of a manikin, injection pads, placebo, and other elements intended to simulate the patient, the procedure, or the environment of use.
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> **Human Factors Actual-Use Validation Studies:** There are rare circumstances when it is difficult to simulate the conditions of use, physical characteristics of the product, or environment of use. Thus, a HF Actual-Use Validation study may be needed to confirm the adequacy of the user interface design.

For most combination products, FDA expects that a HF Simulated-Use Validation study will be sufficient to assess the adequacy of the user interface.

Changes to the Design After HF Validation

FDA recognizes that combination product design changes may occur premarket or postmarket after HF Validation studies have been completed. Design changes made after HF Validation that relate to identified critical tasks or may result in new use-related errors or hazards that could lead to harm should have new HF Validation study assessments.

Relationship of HF and Major Clinical Studies

The HF Validation study is not sufficient to establish the safety and effectiveness of the combination product for the proposed indication. Specifically, data from the major clinical study(ies) establish the combination product's safety and effectiveness for the proposed indication and the complete labeling summarizes the essential scientific information needed for the safe and effective use of the product. Therefore, ideally, before initiation of major clinical study(ies), the HF Validation study should be conducted on the final finished combination product, including the user interface (e.g., instructions

for use, training materials, and any other user labeling, if applicable). It should be noted that in some cases it may be appropriate to conduct human factors studies in parallel with major clinical studies or after your clinical studies to address modifications to your product.

FDA encourages applicants to request early discussions with them regarding the HF program and the type of HF studies that might be appropriate or necessary in the planned submission.

Reference:

Draft guidance for the Industry and FDA staff regarding Human Factors and Related Clinical Study Considerations in Combination Product Design and Development (February, 2016). http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm484345.pdf