Anatomy of a Good Use Error Risk Assessment

Phillips-Medisize, LLC and Usensus, LLC
March 2018

Phillips Medisize
a molex company

As Human-Centered Design (HCD) continues to drive development of smaller, smarter next-generation drug delivery devices, it is becoming increasingly important for biologics manufacturers to apply human factors engineering (HFE) principles to their selected delivery method or platform. Done successfully, this strategy can lead to safer, more desirable devices that improve patient adherence, save time and money in the manufacturing process, and in many cases give the product a competitive boost.

The Use Error Risk Assessment (UERA) is a critical component of the HFE process. Its content and structure can significantly affect downstream product development and testing activities, including study design for the summative user interface validation. However, structuring a good UERA can be easier said than done, given the minimal guidance available on UERA best practices from FDA, AAMI and other industry sources.

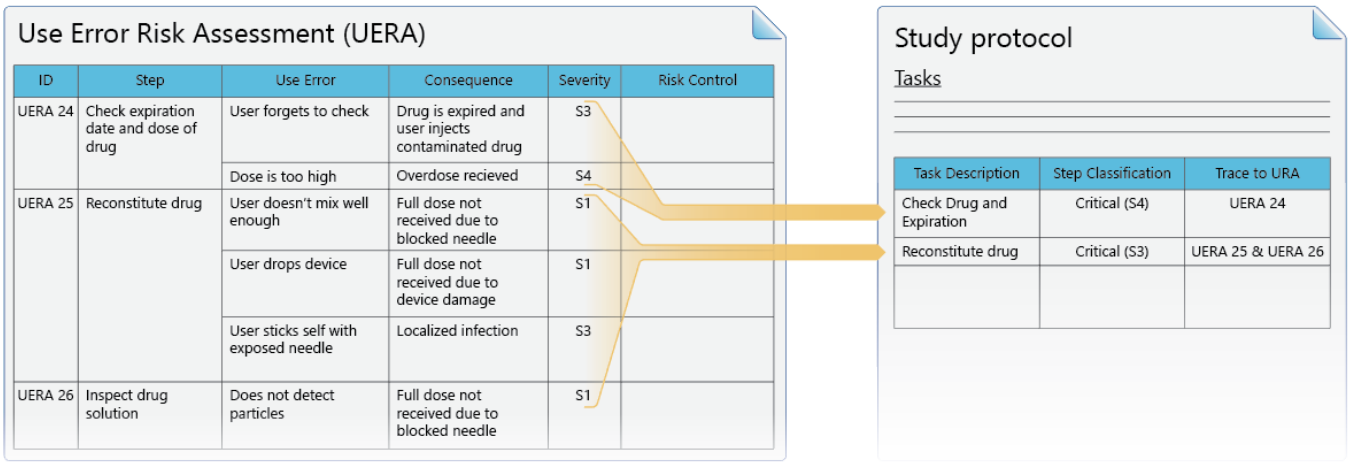
To help manufacturers design a high quality UERA that supports their HFE goals and reduces business risk, this paper identifies commonly encountered challenges and offers proven solutions in four key areas:

1. Tracing inputs from UERA to the summative study plan.

Manufacturers often struggle to show the connection between the UERA and the tasks included in the summative protocol, per the FDA's guidance Applying Human Factors and Usability Engineering to Medical Devices. As stated in Section 8.1.2: "The human factors validation testing should include all critical tasks identified in the preliminary analyses and evaluations…Critical tasks or use scenarios involving critical tasks that have a low frequency of occurrence require careful consideration and those tasks should be included in testing as appropriate to risk severity."

To comply with this guidance, it helps to clearly and straightforwardly trace inputs from the UERA to the study protocol. That means it can be helpful to link each summative task to specific hazardous use scenarios from the UERA. One way to accomplish this is to add a "Trace to UERA" column to the study protocol task table, which should also include "Task Description" and "Step Classification."

Figure 1: Tracing inputs from the UERA to the summative study protocol.



The "Step Classification" column indicates the highest severity risk associated with a task, while the "Trace to UERA" column shows the hazardous use scenario ID from the UERA, as illustrated in Figure 1.

This approach increases the impact of the UERA activity and provides direct visibility to use-related risks in the user interface design, generating fewer questions during the FDA submission and inspection process.

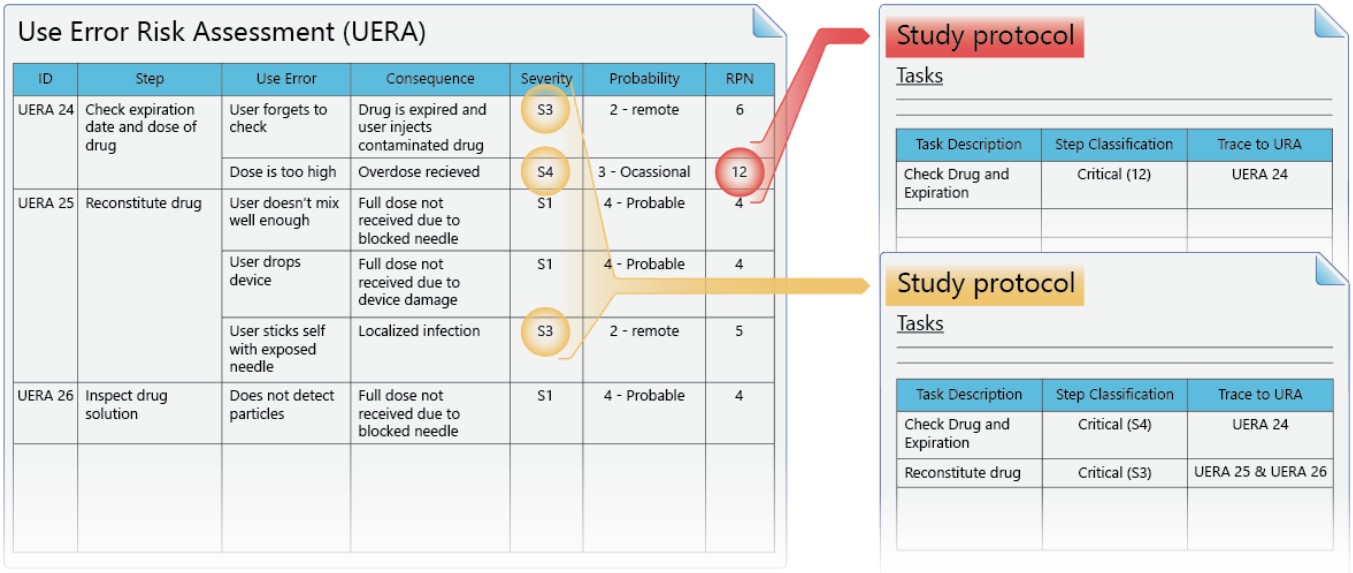
2. Prioritization of tasks included in the summative study.

Another challenge manufacturers frequently face is that using probability-of-occurrence-based prioritization schemes, such as risk prioritization numbers (RPN), can exclude some hazardous use scenarios from the summative study. This is potentially problematic, based on expectations described in the FDA guidance.

Clients often employ the same risk prioritization schemes they use to satisfy ISO 14971 to the selection of tasks for the summative study. However, IEC 62366 – which reflects the the FDA's guidance – states in Section 5.5: "The manufacturer shall elect either all hazardous use scenarios, or the subset of the hazard related use scenarios based on the severity of the potential harm that could be caused by the user." In this case, manufacturers are directed to select summative tasks based on severity no matter the probability of occurrence.

Therefore, all use scenarios that could lead to serious harm should be tested. While both harm severity and probability can be used for overall risk assessment, harm severity alone should be used to identify tasks to include in the human factors summative study. For example, in Figure 2, testing based on an RPN that incorporates severity and probability would lead to testing the task "Check Drug Dose and Expiration." However, focusing only on harm severity would lead to testing the "Reconstitute Drug" step as well as the other task.

Figure 2: Prioritization of tasks included in the summative study



In addition to complying with FDA guidance, testing all high severity scenarios is a more inclusive approach that ensures comprehensive validation of risk control measures.

3. Methods affect identification of risk control measures.

Some UERA methods, such as PCA (Perception, Cognition, Action), may limit the identification of hazardous use scenarios to behaviors that occur within the bounds of the expected step sequence. Unfortunately, this approach may fail to consider unanticipated use errors outside of that expected sequence, leading to a different, likely more limited, set of risk control measures.

A PCA approach is ideal for the early step identification necessary to build a foundation for the risk analysis. But to ensure a robust assessment, it is vital to also employ complementary UERA methods such as "What If" or Haz-Op (Hazard and Operability Analysis). These methods focus on identifying both introspective and extrospective behaviors that can occur outside the bounds of the expected step sequence.

A broader spectrum of behaviors can be identified by asking questions such as:

- What if the user omits a certain step, such as forgetting to check the drug dosage?
- What if the user completes the steps out of order or at the incorrect time, such as mixing the drug too soon?
- What if the user takes a short cut, such as trying to charge the device while it is in use?

To thoroughly think through all relevant behavioral scenarios, it is valuable to involve a cross-functional team that includes representatives from quality assurance, tech support, design and other relevant departments.

Methods such as "What If" or Haz-Op provide three primary benefits for risk assessments. One, they identify a broader range of risk control measures for implementation. Two, the resulting device will be more robust. And three, they reduce safety-related issues in the field.

Figure 3: Methods affect identification of risk control measures

Introspective Approach

Use Error Risk Assessment (UERA)

ID	Step	Use Error	Consequence	Severity	Risk Control
UERA 54	Power down.	User does not see or feel power button	Short term delay of treatment while user experiences difficulty Long term delay of treatment while user charges device	S1 S3	Device markings identify power button. Button material has different tactile feel than device body material
		User cannot depress the power button	Short term delay of treatment while user experiences difficulty Long term delay of treatment while user charges device	S1 S3	Depression force for button accommodates 95th percentile finger strength Visual and audio feedback provided when device shuts off

Extrospective Approach

Use Error Risk Assessment (UERA)

ID	Step	Use Error	Consequence	Severity	Risk Control
UERA 54	Power down.	User omits turning off the device	Long term delay of treatment while user charges device	S3	IFU instructs users how to turn off the device Device has automatic shut off
		User powers off the device too soon – while device is in use	Short term delay of treatment while user reloads and restarts treatment	S1	Lockout prevents power button from being activated while device is delivering treatment.

4. Documenting design features in the UERA

Many UERAs incorporate design-based risk control features into the task flow, but this approach may result in excluding some hazardous use scenarios from the summative study. For example, consider the task of connecting the medical device to the charger.

If the user attempts to recharge the device while the device is in use, he or she risks receiving an electrical shock. However, if the charging lock-out feature – a design-based risk control measure – is integrated into the use error description, the consequence is a much less severe short-term treatment delay instead.

Clearly, the lock-out feature is highly effective at mitigating the risk severity. But in this scenario, the task priority of the potential hazardous use is underrated, and thus the task may not be selected for summative validation. In addition, the value of the design mitigation feature may not be fully appreciated.

Figure 4: Documenting design features in the UERA

Design Features included in Use Error

Use Error Risk Assessment (UERA)

ID	Step	Use Error	Consequence	Severity	Risk Control
UERA 1	Connect device to charger.	User attempts to recharge while **USB port is blocked** because the drug is loaded	Short term delay of treatment	S1	IFU instructs that device cannot be charged while the drug is loaded
UERA 54	Power Down	User omits turning off the device	**None- Auto shut off saves battery life**	S1	

Design Features included as Risk Control Measures

Use Error Risk Assessment (UERA)

ID	Step	Use Error	Consequence	Severity	Risk Control
UERA 1	Connect device to charger.	User attempts to recharge while drug loaded	Electrical shock if user tries to deliver the drug.	S4	**USB lock out feature prevents drug delivery during charging.** IFU instructs that device cannot be charged while the drug is loaded
UERA 54	Power Down	User omits turning off the device	Long term delay of treatment while device is being re-charged.	S3	**Auto/timed shut off saves battery life**

the design features in the risk control measures rather than integrating them into the task flow. Focusing on solution independence delivers three benefits:

- It ensures risk control measures and tasks related to hazardous use scenarios are validated as part of the summative study.
- It improves the definition of the task itself, taking into account factors such as context, degree of simulation required and moderator observations.
- It documents where a particular design mitigation prevents user harm and clarifies the trace to the design validation.

A good UERA delivers better outcomes

Risk analysis is a vital but time-consuming component of the medical device development process. Designing and performing a well-constructed UERA plays a significant role in helping medical device manufacturers achieve their human factors and usability goals.

Improving the quality of UERAs can help streamline the FDA compliance process by demonstrating that all known risks have been mitigated to an acceptable level or

eliminated. It can also facilitate the identification of summative tasks and understanding of the context of use failures or potential issues.

Bottom line, good UERAs support the development of well-designed, robust products that support better patient outcomes while also minimizing business risk.

phillipsmedisize.com
info@phillipsmedisize.com
877.508.0502