Frequently Asked Questions: Demystifying the Use-Related Risk Analysis (URRA)

This FAQ provides additional guidance on common questions related to use-related risk analyses (URRAs), human factors (HF) validation programs, and U.S. Food and Drug Administration (FDA) expectations.

When should a URRA be submitted to the FDA for review?

The final URRA should be completed in correlation with the Instructions for Use (IFU). The URRA is then included in the HF validation study protocol when it is submitted to the FDA for approval prior to completion of the study. It is then also included as part of the HF validation study report after the study is complete.

The URRA can also be submitted to the FDA along with other documentation to support the position that a HF validation study is not needed.

How should the URRA for an independently cleared device be addressed if that device is later used as part of a combination product?

The information from that URRA can be used to support development of the URRA of the combination drug product.

Can the existing device URRA be used with supplemental information specific to the drug delivery context?

Yes, but it's more accurate to say that the previously created device URRA should be folded into the combination drug product URRA rather than the other way around.

Other than IFU mitigations, how are other mitigation measures, such as device design, evaluated during the HF study?

The performance results indicate how well the design supports successful use. For example, you can evaluate the grip properties of an auto-injector by observing if anyone drops it or if there is a need for people to regrip it during use.

If the device packaging or labeling changes, are updates to the URRA required? Could this change require an HF study to validate the modified packaging or labeling?

For the first question, yes. Update the URRA and add the mitigation of the new or changed package or labeling. Then, determine and communicate to the FDA if the residual risk has changed. That will drive whether or not a revalidation is required.

Can the URRA provide justification for not performing an HF study?

Yes. If there are not significant residual use-related risks for the product—or the product has no critical tasks—then a URRA report along with other supporting documents can be used as justification for not performing an HF validation study.

The FDA has new guidance that speaks to the issue of how to justify not conducting a human factors validation study using a decision tree and risk analysis approach.

What is the relationship between the URRA and a use failure modes and effects analysis (UFMEA)? They seem to share similar information.

The URRA is its own tool with the FDA. It may have some overlap with the UFMEA, but it is important to approach them separately. Develop the URRA using the IFU; other documents should not influence construction since the guidance and definitions are very different.

If a team already has a detailed UFMEA for a medical device, are there any best practices for mapping that into a URRA rather than recreating the analysis from scratch?

Ultimately, mapping becomes more complex and time-consuming than creating the URRA from scratch. Best practice is to approach the URRA as a unique document.

Additionally, as they are created following different guidance standards, they are not likely to match or correlate with one another.

Is there a relationship between the requirements for the URRA and the ISO 62366 standard?

Not exactly. There are general properties that do relate, but the URRA is a stand alone tool subject to the FDA's HF process guidance.

Could the FDA issue a finding for not creating a URRA when a manufacturer already has a UFMEA in place?

Yes, and they often do.

If a patient-facing one-pager implies patient actions (such as keeping the device plugged in), do patient actions need to be included in the URRA if the health care professional (HCP) is the intended user?

Yes. If there are any tasks performed by the patient, then those should be included in the URRA.

Serious Harm is defined in 21 CFR 803 as "necessitates medical or surgical intervention." At what point would a delay of treatment become a serious harm?

In the context of combination products any harm is considered critical. For medical devices, if the delay results in a serious impact on the patient, then it would be critical. Be careful of interpreting the definition too literally. Consider serious outcomes that may not be remedied by intervention. Defibrillators are a good example—ANY delay of treatment would result in serious harm up to and including death.

What are examples of non-critical tasks for combination products?

Non-critical tasks for combination products are rare. Two examples come to mind:

- Instructions for injection devices generally require pinching the skin, inserting the needle, and releasing the pinched skin. The timing of releasing pinched skin usually has minimal to no impact, so it is often not critical.
- Refrigerated medications usually call for the user to allow the medication to warm to room temperature prior to use. This step is often not critical because it is for patient comfort. Not allowing the medication to come to room temperature may not cause harm for a particular drug.

How do you capture use errors for treating a patient outside of the indicated patient population?

You don't. In the URRA, you do not have to deal with every type of error, misuse, or off-label prescribing. Those are addressed in other risk management documents and processes, so they don't have to be in the point-of-use context of a URRA for an HF validation.

If you have additional questions regarding URRAs, please contact us: https://interfaceanalysis.com/contact

Related Resources

Applying Human Factors and Usability Engineering to Medical Devices

U.S. Food and Drug Administration, 2016; https://www.fda.gov/media/80481/download

Application of Human Factors Engineering Principles for Combination Products: Questions and Answers

U.S. Food and Drug Administration, 2023; https://www.fda.gov/media/171855/download

Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products (Draft Guidance)

U.S. Food and Drug Administration, 2024; https://www.fda.gov/media/179858/download

Content of Human Factors Information in Medical Device Marketing Submissions

U.S. Food and Drug Administration, 2026; https://www.fda.gov/media/163694/download

ISO 14971: Medical Devices—Application of Risk Management to Medical Devices

International Organization for Standardization (ISO), 2019; https://www.iso.org/standard/72704.html

ISO 62366-1: Medical Devices—Application of Usability Engineering to Medical Devices

International Organization for Standardization (ISO), 2015; https://www.iso.org/standard/63179.html

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