Combination products: Common use errors and design considerations

Human Factors Research & Design

Richard Featherstone
Research Director
Human Factors Research & Design
richard.featherstone@ul.com

Linda Giesselink
Managing Human Factors Specialist
Human Factors Research & Design
linda.giesselink@ul.com

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Executive Summary

Combination products, such as injection devices, inhalers, nebulizers, and drug patches, are increasingly being used by laypeople for self-administration at home. Regulators such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) want to ensure that all users – and laypeople in particular – can administer the correct dose at the right time to the right part of their body. Manufacturers have a responsibility to predict likely use errors and, wherever possible, to "design out" the error such that the user automatically uses the product as intended. Designing the user interface such that use error is impossible, or unlikely, is the preferred and most effective approach to reducing use-related harm. The weaker alternative is to rely on instructions and training to avoid use errors; labeling and training are also valuable risk mitigations but should not be the primary ones.

Understanding use errors

The US FDA defines use errors as:

- User action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user and (2) was not caused solely by device failure and (3) did or could result in harm.

The agency calls on manufacturers to apply usability engineering methods to:

- ensure that the device user interface has been designed such that use errors that occur during use of the device that could cause harm or degrade medical treatment are either eliminated or reduced to the extent possible.[1]

Likewise, the European Medical Devices Regulation (MDR) requires manufacturers to ”eliminate or reduce the risks related to use error through a process of designing for patient safety”.[2]

The international standard on usability engineering for medical devices (IEC 62366) provides some helpful further considerations regarding use errors:[3]

- Use errors include the inability of the user to complete the task.
- Use errors can result from the mismatch between the characteristics of the user, user interface, task, or use environment.
- Users might be aware or unaware that a use error has occurred.
- A malfunction of a medical device that causes an unexpected result is not considered a use error.

Accordingly, a use error occurs when the user does not – for whatever reason – complete a task in the way that is intended by the manufacturer.

Common use errors with combination products

As previously mentioned, many combination products are used by laypeople at home. Some of these people might initially have a limited understanding of drug delivery concepts such as “dosage” or injection techniques such as “subcutaneous.” Indeed, when we test drug delivery devices in our usability tests, we frequently see lay participants struggle with some of the critical tasks required for accurate and safe dose delivery. Clear trends in use errors emerge. Some of the most common among these are described below.

Notice anything? Correct – the most important errors are those related to drug delivery. That’s not surprising. Being able to administer the correct dose at the right time to the correct site on the body will always be a critical task. Therefore, use errors that could cause under- or overdosing will almost always be the primary focus for your risk reduction strategies. Even for drugs that do not cause severe harm with overdosing (such as growth hormone or fertility treatments), FDA would still consider any misdosing to represent “compromised care” and hence a focus of concern.

Don’t blame the user

It is a well-established principle in human factors engineering (also known as usability engineering) that you do not “blame the user,” acknowledging that the source of use errors lies somewhere between the user and the user interface. So, rather than stating the cause of a problem as “user error,” human factors specialists instead use the term “use error.” However, it is easy to slip back into the mode of blaming the user. Consider the example of setting a dose selector on a pen injector. The task is to dial the correct dose by twisting the selection knob until the desired dose is shown in the numerical display window.

Let’s imagine that you observe the user selecting the wrong dose. When questioned, she says it was difficult to understand the numbering system on the dial, and that she was not sure whether she selected the correct number. So, you would write up the root cause as “the user was confused about the numbering system.” But you have in effect blamed the user – you have said that the error occurred because she was confused, and hence selected the wrong dose. More correctly, you should have stated the root cause as “the dose indicator (i.e. the user interface) did not clearly communicate the dose selected.”

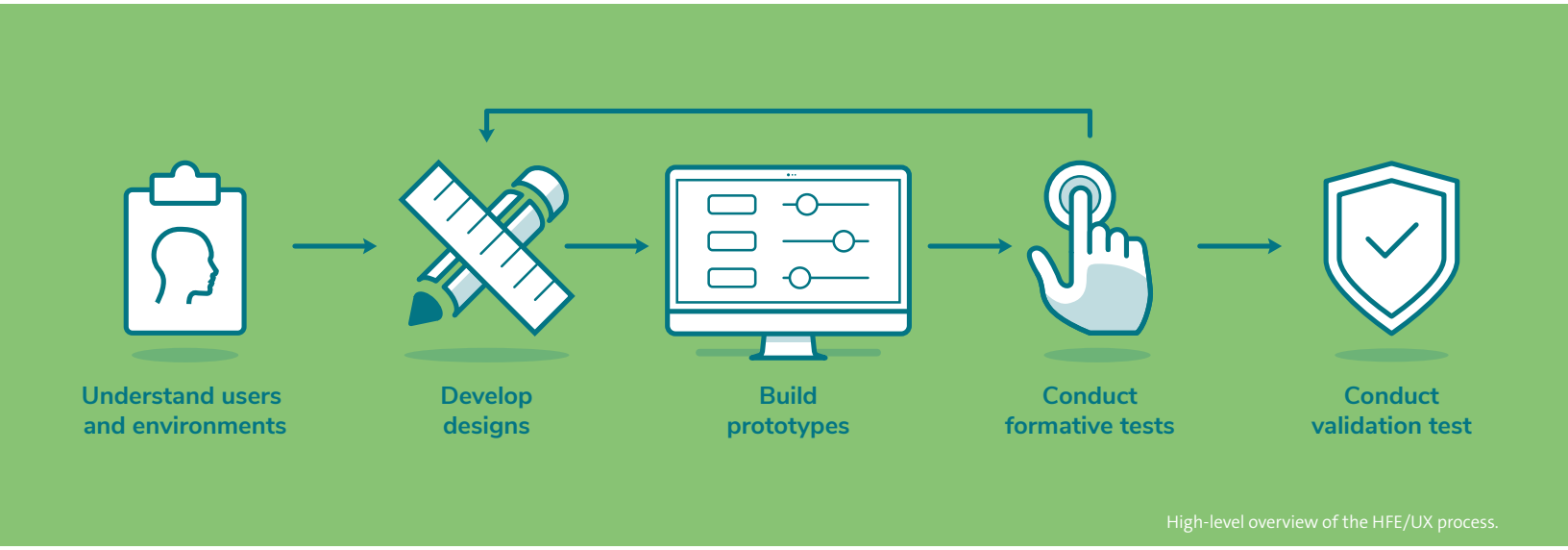
The distinction can be summarized as:

- User error – the user was to blame for the error
- Use error – the user interface was to blame for the error

Why do we put the focus on the user interface rather than the user? Well, it is not a good strategy to expect the user to do all of the hard work of avoiding errors. And, the “blame the user” approach absolves the manufacturer of any responsibility for designing a safe product. Hence, focusing on the user interface provides product designers with the task of getting their product’s user interface right, to guide the user towards safe use and away from harm.

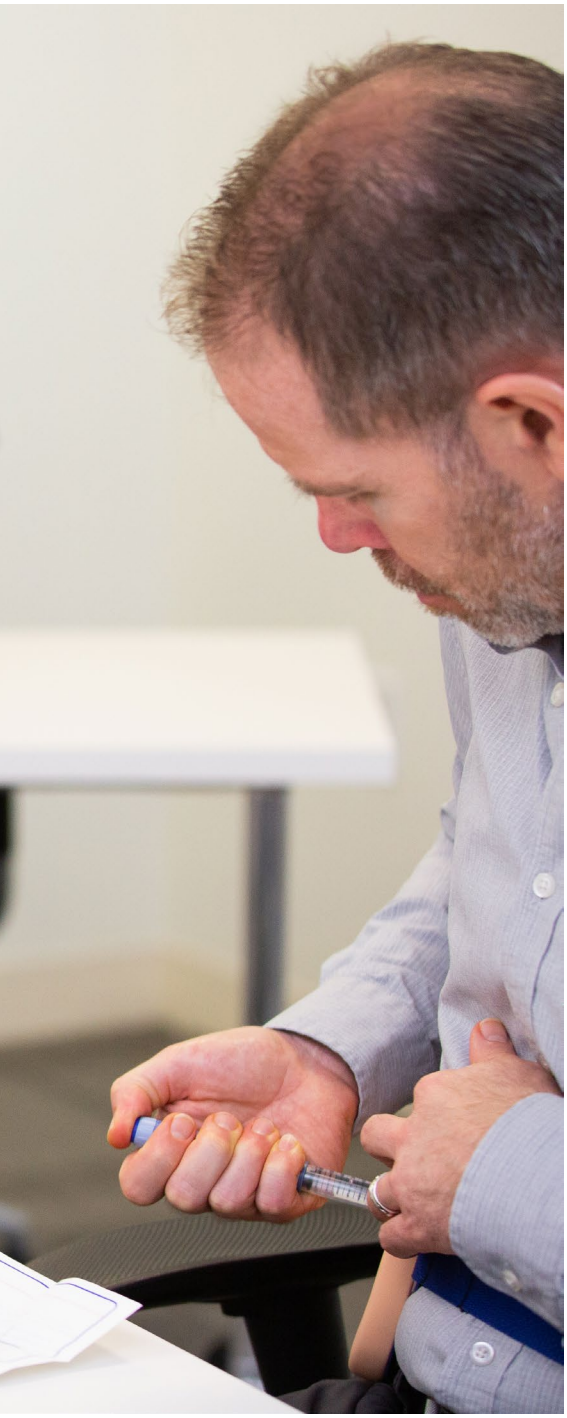
HFE/UX process

The figure below provides an overview of the iterative Human Factors Engineering (HFE) / User Experience (UX) process that medical device manufacturers and pharmaceutical companies utilize to develop their product.



High-level overview of the HFE/UX process.

The process starts with determining user needs and translating those into user interface requirements, extending all the way through validating that the final design is safe and effective in a human factors (HF) validation test. The three steps in the middle, which may be repeated in two or more iterative cycles, are related to the design and evaluation of the device in development. As you develop a product, you will evaluate it via representative prototypes during a formative test with intended users to identify strengths and opportunities for improvements. During this test, you will typically also identify use errors. Based on those findings, you will make changes to the device and then evaluate the design again, repeating the cycle as many times as necessary to arrive at an arguably optimal design. Of course, as you work to improve the user interface, you must document your risk reduction progress in a use-related risk analysis (URRA).



Conducting a use-related risk analysis (URRA)

A URRA presents all the risks associated with using the device. During this entire HFE process, you will develop and update the URRA. It is a living document that evolves over time because each time you identify new use errors, you will add them to the URRA. Similarly, each time you reduce the risk of a use error, you update your URRA. For each of the identified use errors, you will consider what the associated harm is and add a severity classification. This severity classification will determine whether the use error is classified as critical or non-critical, which will then help you to determine the priority in implementing design solutions (i.e., mitigations). Notably, you will also document these design solutions in the URRA.

Identifying use errors

There are several ways to identify possible use errors, so you are not limited to usability testing. Other means to identify possible use errors are observations, interviews, complaint and adverse event reports, field experience, task analysis, hazard analysis, and brainstorming with multidisciplinary team members. All these different methods help to develop a complete URRA and gather as much input as possible to design a device that will be safe and effective to use. After identifying use errors, you will also need to analyze the underlying issue for each of the identified use errors. This process is called root cause analysis (see sidebar).

Mitigating against use errors

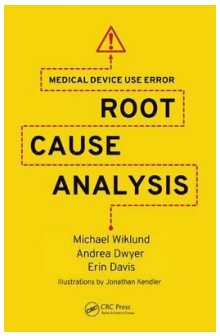
As a next step, you will need to act upon the use errors. Risk management standard ISO 14971[4] provides a hierarchy for mitigations that is adopted by the US FDA in their guidance document on usability engineering[5] and in IEC 62366-1:2015.[6] Manufacturers are encouraged to first mitigate through design. A secondary method would be implementing protective measures, such as adding a needle shield or enlarging the medication viewing window. And, as a last resort, manufacturers may turn to information for safety, such as instructions for use, labeling, warnings, and finally training.

To be clear, instructions for use, labeling, warnings, and training are valuable complements for an inherently safe product. One becomes concerned about the ultimate safety of products that are hazardous in specific ways and rely mostly or solely on the complementary risk mitigations. That is why it is good practice to base risk assessments on the inherent safety and protections built into a product and, out of an abundance of caution, to disregard the benefits of the complementary safety measures. Nonetheless, the complementary measures almost always add value.

Conducting a root cause analysis (RCA)

After identifying use errors, you will need to conduct a root cause analysis (RCA) to identify the underlying reasons for that interaction issue. At a high level, this means that you observe what happened during the use error, interview the participant or user to understand his/her thought process and potential root causes, and study the prototype (for any failures) and the design (for any design flaws). Then, you consider and synthesize that data to determine the root cause of the use error (remember, don't blame the user!).

For more details on how to conduct root cause analysis of use errors, you may wish to consult the book *Medical Device Use Error: Root Cause Analysis*.



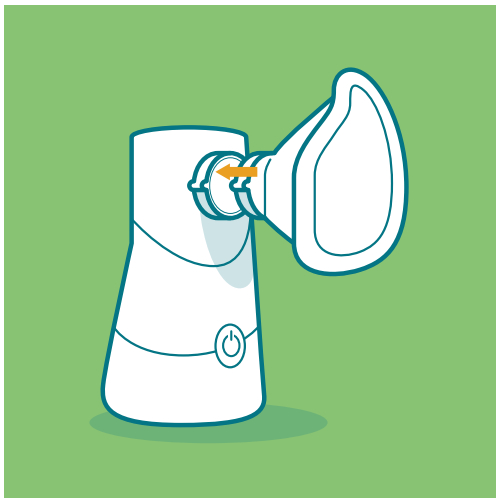
The book *Medical Device Use Error: Root Cause Analysis*[7] provides a detailed method for analyzing medical device use errors.

Use errors are predictable and largely avoidable

Most use errors can be predicted by performing rigorous formative evaluations and by learning lessons from similar products. Most use errors can also be designed out of a product. Carefully identify the root cause(s) for the use error, then get your product designers to work on the user interface; once they have a clear idea of the problem, the solution becomes easier to identify.

Design solutions

There are several design solutions that manufacturers may consider while mitigating against identified use errors for combination products. Based on the trends we observe in our work with combination products, these design solutions are ordered by mitigation hierarchy: device, packaging, label, instructional materials, and finally, training.



Mouthpiece attachment to the nebulizer is guided by shape coding and confirmed via perceptible tactile and audible feedback.

Device - Assembling and preparing the device

For combination products (and basically all products), it is important that users perform assembly correctly. This can be achieved by the following means:

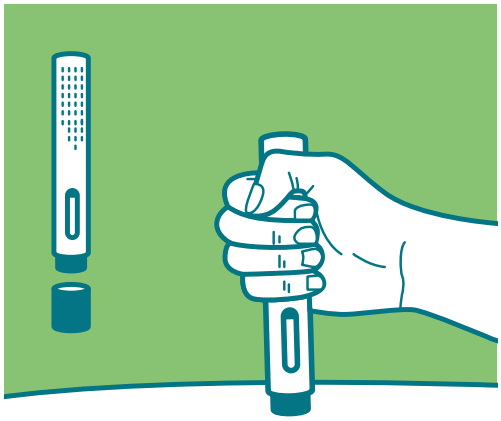
- Shape parts so they only go together one way
- Add color coding to signal which parts go together
- Provide alignment cues to guide proper orientation
- Provide audible and tactile feedback
- Do not require high dexterity
- Prevent operation if assembled incorrectly
- Provide great instructions for use (more later)
- Provide image of properly assembled device

An auto-injector viewing window turning yellow after administering the medication will show the user that all medication has been delivered and the device cannot be used again.

Device - Inspecting the medication

If users are required to inspect medication prior to administering, take the following into account:

- Make viewing windows large
- Change device appearance in conspicuous way if it has already been used or is almost empty
- Provide visual references in instructions for use (e.g., presence of particulate in solution)



Auto-injector with needle shield, cap, viewing window, and indication of where to hold it.

Device - Handling the device

Make device use self-evident by doing the following:

- Ensure intuitive and ergonomic gripping
- Apply rubberized surfaces to primary grip points
- Clearly differentiate moving parts and, in the case of injectors, the needle end
- Visually differentiate controls from other parts
- Label primary features and controls

An inhaler is connected to an app enabling users to see the number of puffs remaining and when last puff was administered.

Device - Adhering to treatment

For combination products it is often critical to track usage and compliance. This can be done by the following means:

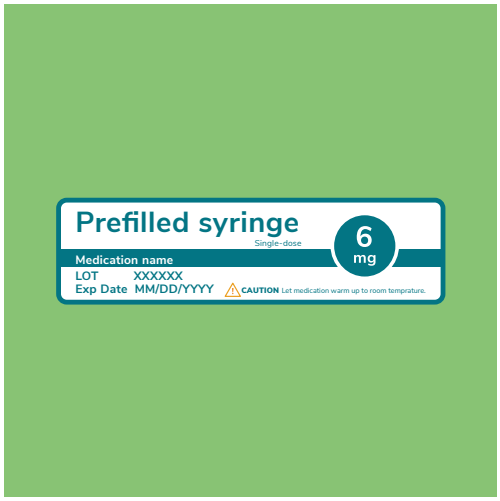
- Provide a manual log
- Make device “smart” with embedded sensor, counter, or tracker
- Connect device to tracking software (mobile app, application, patient portal/cloud)
- Implement reminders (integrated into device and/or companion mobile app, for example)

This packaging design presents the product name, dose strength and an image of the device. Additionally, it gives users clear instructions on where and how to open the package.

Packaging - Affording high-quality interactions

Consider the following to design packages that afford high-quality user interactions:

- Ensure users can open packages without damaging contents
- Clearly present product name and critical detail(s), such as dose strength
- Add an image of contents to package
- Add key steps to the packaging (e.g., a quick guide on the inner lid)
- Accommodate users with limited dexterity while also ensuring child resistance
- Dramatically vary appearance among various dose strengths to avoid substitution errors

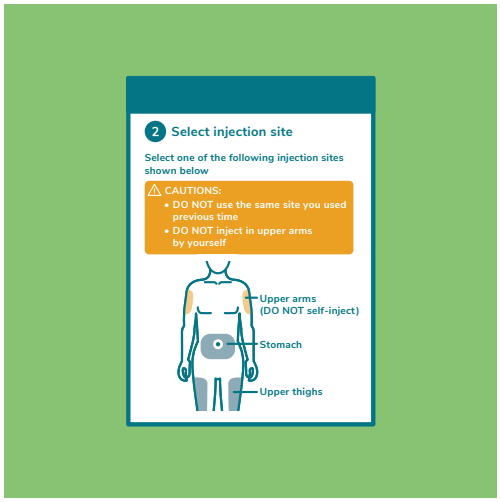


Injection device label with product name, medication name, dosage, lot number, expiration date, and a caution.

Label - Ensuring legibility and readability

Make on-product labels legible and readable by these means:

- Ensure content contrasts sharply with background
- Limit information density
- Make critical values very large; accommodate people with imperfect vision

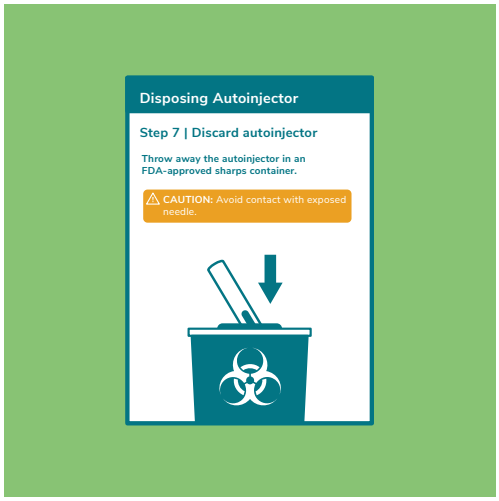


This IFU page shows a good balance between text, illustrations, and white space.

Instructional materials - Designing clear and complete instructions

Provide well-designed instructions for use (IFUs) by following these principles:

- Use graphics extensively and consistently
- Use simple language
- Limit information density; use white space to differentiate key content
- Number procedural steps
- Make important information stand out
- Embed important warnings
- Use legible text
- Use color to emphasize important details
- Consider the matrix created by paper folds that implies groupings

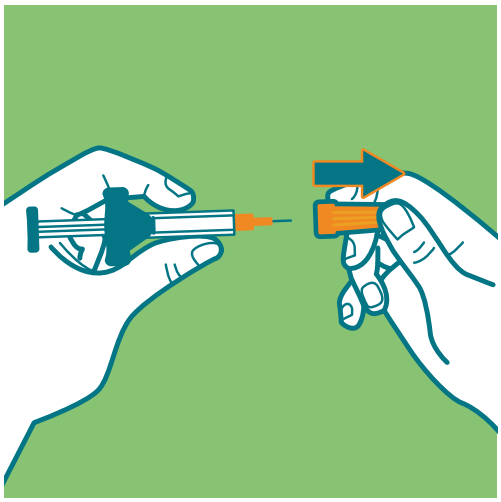


The IFU page shows that a caution should stand out from other information and that it should be placed near instructions to which it applies.

Instructional materials - Highlighting critical information

Make critical information conspicuous by means of these design efforts:

- Ensure information is visible while performing primary operating steps
- Use simple font
- Make text sufficiently large
- Ensure good figure-ground contrast
- Account for color blindness
- Avoid unfamiliar and confusing abbreviations



This illustration is from the “first-person view” and highlights the component with which users should interact. It also provides an arrow to indicate direction of motion.

Instructional materials - Using graphics

Utilize graphic design to clarify instructions with these practices:

- Eliminate unnecessary detail by using simple drawings (instead of photos)
- Clearly indicate direction of motion
- Provide a “first-person view” where appropriate
- Emphasize salient details
- Use color consistently
- Avoid confusion between color coding and actual device appearance

Training - Facilitating complex and critical tasks

Facilitate complex and critical tasks by the following actions:

- Provide training by a company representative and/or healthcare professional (using training protocol/checklist)
- Develop training animation/video and/or checklist
- Provide a practice device (i.e., trainer)
- Provide guidance via a display and/or voice

After implementing these design solutions, re-evaluate your design to ensure the mitigations are effective – that they are actually solving the known interaction problems and do not introduce any new ones. For example, by highlighting certain information in the IFU, you might draw the users’ attention away from other important information. Because you simply cannot highlight every bit of information, there is an obvious need to focus on what is most critical. Finally, you will need to conduct an HF validation test with a production-equivalent prototype to validate that the product is safe and effective.

Good HFE/UX process is key

To avoid use errors properly, implementing a good HFE process is key. You will need to apply HFE to all components of your product, going beyond the device itself to also include accessories, instructional materials, packaging, device labeling, and training. This process should be iterative, so you evaluate your design, identify strengths and opportunities for improvement, implement design solutions, and then evaluate those again. This process will continue until you see few, if any, interaction issues during the formative tests. Once you are confident the product is reasonably safe and effective, you will go into HF validation testing to validate that the device is indeed safe and effective to use.

Competitive Advantage

As a final thought, we know that products that are easy to use are more satisfying for users. Patients are more likely to comply with a treatment regimen, and prescribers are more likely to prescribe the product, based on positive feedback from users. Therefore, there is not only a strong regulatory imperative, but also a strong commercial imperative, to make combination products safe, effective, and satisfying to use.

For more information about Human Factors Research & Design, visit us at HumanFactors.EmergobyUL.com.

End Notes

1. Applying Human Factors and Usability Engineering to Medical Devices. FDA Guidance February 3, 2016.
2. European Medical Devices Regulation 2017 Annex I; chapter I.
3. IEC 62366-1:2015 Application of usability engineering to medical devices. Section 3.2.1.
4. EN ISO 14971:2019, Medical devices – Application of risk management to medical devices. Section 7.1.
5. Applying Human Factors and Usability Engineering to Medical Devices. FDA Guidance February 3, 2016. Chapter 7.
6. IEC 62366-1:2015 Application of usability engineering to medical devices. Section 4.1.2.
7. Medical Device Use Error: Root Cause Analysis, by Michael Wiklund, Andrea Dwyer, Erin Davis. CRC Press. 2016.

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About the authors

Richard Featherstone leads the Human Factors Research & Design team based in Europe. He is an experienced human factors and usability practitioner and the founder of Medical Device Usability Ltd. Richard helps clients develop their Human Factors / Usability engineering strategy and identify activities needed to ensure usability work complies with the MDR, as well as other regulatory imperatives for applying human factors engineering during product development.

Linda Giesselink is a Managing Human Factors Specialist and has been with the HFR&D team since 2015. She has experience delivering HFE services to the medical device and pharmaceutical industries. Linda leads and oversees research and design activities such as conducting usability tests and design of user interfaces and user documentation.

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