Clarifying the complexity of human factors engineering

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When preparing your medical device for the market, human factors engineering (HFE) can prove complex and challenging. Evaluating the probable use errors that could occur plays a vital role in designing a safe and effective medical device. Expectations among regulatory bodies are growing just as HFE methods become more and more complex. How will you meet the requirements involved with marketing a medical device?

Access to best practices can help guide major human factors engineering stages of a development effort.

These include:

- Use-related risk analysis
- User research
- Summative and formative usability testing
- Designing effective user interface (UI) medical device platforms
- Product design through task analysis
- Overall product validation testing

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Chapter I: How to conduct an effective use-related risk analysis

Conducting a use-related risk analysis plays an essential part in developing a medical device design that accounts for and addresses potential human use errors. A step-by-step approach can guide your process to include a careful examination of the human use errors you need to consider.

What steps should you take to develop a use-related risk analysis (URRA)? Below, we outline 10 steps for conducting an effective URRA.

Ten steps to conducting a use-related risk analysis as part of your human factors engineering process

Use-related risk analysis represents a cornerstone activity for a thorough human factors engineering process that meets the expectations set forth by the U.S. Food and Drug Administration (FDA) and international reviewers. A complete and well-considered URRA, such as a Use Failure Mode and Effects Analysis, helps ensure that manufacturers consider and mitigate use-related risks to an acceptable level throughout the development process. Further, URRA serves as the basis for the scope of tasks evaluated in an HF validation test, the culminating HFE activity that seeks to assess whether a product is effective and safe to use.

What steps should you take to develop a use-related risk analysis? Below, we outline 10 steps for conducting an effective URRA. We use a medication delivery device as an example throughout. However, these steps can also adapt to developing a URRA for more complex medical technology.

1 Conduct a task analysis

First, conduct a detailed task analysis, breaking down the use of the product into specific, discrete steps. Consider all of the device's touchpoints and how the user will interact with them. During this analysis, focus on the user's interaction with the device and consider how the user could make errors of perception, cognition and action.

For example:

- **Error of perception:** User does not realize the device is out of medication
- **Error of cognition:** User thinks they have delivered a dose of medication but haven't
- **Error of action:** User delivers twice the appropriate dose

The task analysis will result in a list of tasks. Tasks are individual actions the user will complete when interacting with the device. For example, tasks could include cleaning the injection site, inserting the needle into the skin, or discarding the needle after injecting.

2 Conduct a hazard analysis

A hazard is an object or event (e.g., physical item, chemical reaction) that causes harm to a user. A simple way to think about hazards is using the example of falling: When one falls, the tripping obstacle is the hazard. During the hazard analysis, identify all of the hazards associated with your device. Much of this analysis might focus on underdosing or overdosing for a medication delivery device. Identify a hazard for each task. Notably, each use scenario/task could have more than one hazard.

3 Identify use errors

Next, identify a use error for each task/hazard. We'll call this collection a "risk line item" because each use error is associated with one row in a URRA table. "Use error" refers to the action the user takes that does not meet the manufacturer's expectations. Examples of use errors could include the user withdrawing the incorrect volume of medication into the device, injecting into the incorrect location or injecting at the incorrect angle. Notably, you might identify several use errors for each task.

4 Identify hazardous situations

For each line item, identify a hazardous situation. Think of the hazardous situation as the link between the use error and the harm — it explains how the error could cause the user (or someone else) harm. For example, if a user withdrew the wrong volume of medication into the device (use error), the device would deliver the incorrect dose to the patient (hazardous situation), possibly leading to harm. Notably, you might identify several hazardous situations for each use error.

5 Identify the associated harm

The user (or someone else) could face harm if a use error and/or hazardous situation occur. In the example from No. 4, the harm could result in a short-term persistence of the patient's condition, or it could prove fatal.

6 Rate the severity and probability

For each risk line item resulting from the above steps, identify the risk's severity and probability. Most manufacturers have a quality system process explaining their approach to this rating.

7 Identify the risk rating

To identify the risk rating for each risk line item, multiply the severity and probability (No. 6) together. Many manufacturers have a quality system process explaining their approach to this rating — i.e., they often use it to identify which risks to mitigate.

8 Identify whether each risk line item is critical or non-critical

In general, you will identify a severity threshold. Any risk line item with a severity above that threshold will qualify as critical, and any risk with a rating below that threshold will be non-critical. The critical tasks serve as the basis for the use scenarios evaluated in the HF validation test.

9 List any mitigations

For each risk, identify the mitigations in place to either reduce the likelihood that a user encounters the risk or reduce the risk's severity. Identifying mitigations provides an excellent opportunity to support your assertion to regulators that your device is safer for use. This activity might also provide a chance to identify which necessary mitigations are not currently in place in the device design.

10 Identify severity, probability and risk rating post-mitigation

Consider your device within the context of the mitigations you have in place and re-rate the severity and probability to generate post-mitigation risk assessment as described above.

Upon performing these 10 steps, you will have completed a thorough URRA, an important component of your HFE process. Bear in mind that you should treat the URRA as a living document; make sure to update it regularly throughout your development process.

Once you've conducted a use-related risk analysis, you're ready to lead a usability test for your medical device. However, before you do, it may prove helpful to study best practices for moderating usability tests.

Chapter II: How to best moderate usability tests

Ready to lead a usability test for your medical device? Great. First, be prepared to ask users the right questions to help thoroughly identify the potential pitfalls of using your medical device. You need to prepare yourself to moderate a productive usability test to gather useful product development data.

Usability test moderator's toolbox: The Five Whys

Anyone who has spent time with small children has probably heard them ask one question more than any other: "Why?" Sometimes, it seems like a child's curiosity (or stubbornness) leads to a never-ending stream of "why?" When a parent, grandparent or attentive adult answers the first "why," the child again asks "why," precociously implying that the first answer is not the truest, deepest answer to their question.

When interviewing usability test participants about device misuse (use errors, close calls, operational difficulties), employing the Five Whys method can prove effective as a strategy to encourage usability test participants to think more deeply about which elements of device design, negative transfer or study artifact might have caused them to misuse the device.

Applying the Five Whys method to usability testing

It turns out that children are on to something. When interviewing usability test participants about device misuse (use errors, close calls, operational difficulties), employing the Five Whys method can prove effective as a strategy to encourage usability test participants to think more deeply about which elements of device design, negative transfer or study artifact might have caused them to misuse the device.

Let's use a common example from daily life to examine the Five Whys in action: Norman doors. Imagine your friend walks up to the door shown in Figure 1 and tries to push it open. You wonder what caused your friend to push the door when the sign clearly says "Pull."

Figure 1

WHY NO. 1
Why did you push that door instead of pulling it?

ANSWER NO. 1
The door looks like it should be pushed.

WHY NO. 2
Why does it look like it should be pushed?

ANSWER NO. 2
The horizontal bar looks like a push bar.

WHY NO. 3
Why did the horizontal bar signify it should be pushed?

ANSWER NO. 3
The gap between the horizontal bar and the door makes it easier to push than pull.

WHY NO. 4
Why does the gap make the bar easier to push than pull?

ANSWER NO. 4
There's barely space for a hand between the bar and the door.

WHY NO. 5
Why does having a small space between the bar and the door make it seem like you should push the door?

ANSWER NO. 5
It's difficult to reach into the small space, grip, and pull. It seems like my hand should be on the outside of the bar, which would only allow me to push, not pull.

After five “whys,” you can clearly state your friend’s reported root cause as, “The friend pushed the door instead of pulling it because the small gap between the door and its horizontal crossbar left little space for them to insert their hand, grip the bar and pull the door. The door seemed easier to push, which caused them to think the door should be pushed.”

Of course, the Five Whys is just a framework; it might take only two whys to get to the deepest-level root cause. The key of the Five Whys is that continually asking “why” helps participants move past the symptoms of the problem that caused misuse and work toward the true cause.

Using the Five Whys as a framework, not a script

Usability test moderators can vary their questions to avoid asking seemingly repetitive questions while still leveraging the core tenets of the Five Whys. For example, if a participant states that they pressed X instead of Y because the button layout is unclear, the moderator can ask, “What about the button layout is unclear?” rather than asking, “Why is the button layout unclear?” The Five Whys framework is exactly that: a framework. Strong usability test moderators use the Five Whys as a lens through which to view and approach a findings debrief, not as a script.

Now that you’re ready to ask the right questions to effectively moderate usability testing for your medical device, it’s helpful to prepare effective use scenario prompts so you can gather good data.

Chapter III: The key to crafting use scenario prompts in usability tests

Moderating a productive usability test means crafting use scenario prompts that can elicit valuable insights into user behavior and prove invaluable in designing a medical device that is effective and as safe to use as possible.

Crafting effective use scenario prompts: A key to medical device usability test success

One of the most important steps in planning a usability test is to carefully select the participant tasks and use scenarios. That said, no matter how meticulously you have selected use scenarios, when it's time to conduct testing, it all comes down to how you communicate your chosen use scenarios to test participants. This is where use scenario prompts come into play, which the moderator might present to participants verbally or in written form.

While crafting clear and specific prompts without being too verbose or direct can turn into a tricky balancing act, putting in the thought and effort to do so is key to a successful usability test. To help navigate the process of writing and refining prompts, keep the following tips in mind.

Set the scene concisely

Using a prompt can help transport the participant out of the test room and into the mindset of actual product use. As such, it is important to set up the scenario with contextual details. You might present a setting ("You are at work..."), previous actions ("You just picked up your medication from the pharmacy..."), or the time of day ("It's time for lunch...") to add realism to a simulated use scenario.

That said, an overly elaborate prompt can make it hard for participants to stay attentive, remember the details presented and identify the information on which they should take action to perform the use scenario. A one- to three-sentence prompt usually suffices to provide the necessary context and guidance for most use scenarios.

Furthermore, details that are too specific can distract participants from the use scenario's intent. Consider the following prompt, intended to evaluate an insulin pump's "extended bolus" function: "You are about to eat pizza. Use your pump to deliver 10 units of insulin over two hours." Mentioning pizza might help put participants in an actual pump use mindset. However, some participants might focus more on pizza than on the guidance provided in the prompt's second sentence. As a result, these participants might apply their usual insulin delivery approach for eating pizza (which might not include delivering an extended bolus) rather than following the prompt's guidance. Opening the prompt with more general context, such as "You are about to eat dinner," would encourage participants to focus on the rest of the prompt for more specific guidance.

While crafting clear and specific prompts without being too verbose or direct can turn into a tricky balancing act, putting in the thought and effort to do so is key to a successful usability test.

Describe what to do, not how to do it

To elicit participants' natural and unbiased interactions with a product, a prompt should present a goal or objective without describing how to get there. In most cases, a prompt should not directly point participants to any particular user interface features, nor should it list the steps or subtasks involved in a use scenario.

Returning to the extended bolus example above, imagine that the prompt instead stated, "Use your pump to deliver an extended bolus of 10 units of insulin over two hours." In this case, because the prompt uses the exact language used on the device itself ("extended bolus"), the use scenario would fail to evaluate whether participants can identify the appropriate function for the insulin bolus specifications provided. In contrast, by excluding the function's name, the original prompt focuses on the use scenario's objective of delivering a specified amount of insulin over a specified time rather than directly identifying a key step to achieving that objective for them.

Speak participants' language

It's important to consider who your participants are and select use scenario prompt language accordingly. For layperson participants, avoid using technical jargon, and if your study includes children, seek opportunities to further simplify prompt wording. Doing so helps make participants feel comfortable while simultaneously ensuring that you effectively communicate the prompt's intent.

On the other hand, when working with clinicians or other technical professionals, you should ensure that prompts include the appropriate technical terminology and syntax. Using language that matches how participants converse in their professional environments helps them feel more like they're completing tasks at work rather than within a simulated scenario, thereby adding realism to the test.

Facilitating a productive and fulfilling usability test

A usability test's success hinges on effective communication between the test team and the participants, and for this reason, strong use scenario prompts play a key role. Taking the time to craft and refine clear and concise prompts that convey realistic scenarios tailored to participants' backgrounds will help facilitate a productive and fulfilling usability test.

Once you've prepared to conduct use-related risk analysis and usability testing, it's time to look at best practices for designing an electronic medical device platform.

Chapter IV: Critical concepts for designing electronic medical device platforms

Electronic medical record (EMR) design

How do you utilize human factors engineering to design an intuitive and effective electronic medical record (EMR)?

Medical records have always served as a foundation for tracking patient care. Healthcare workers must collect and consolidate patients' medical histories, reported symptoms and laboratory results to paint a comprehensive picture of their health. Nowadays, most of these records are electronic, referred to as EMRs.

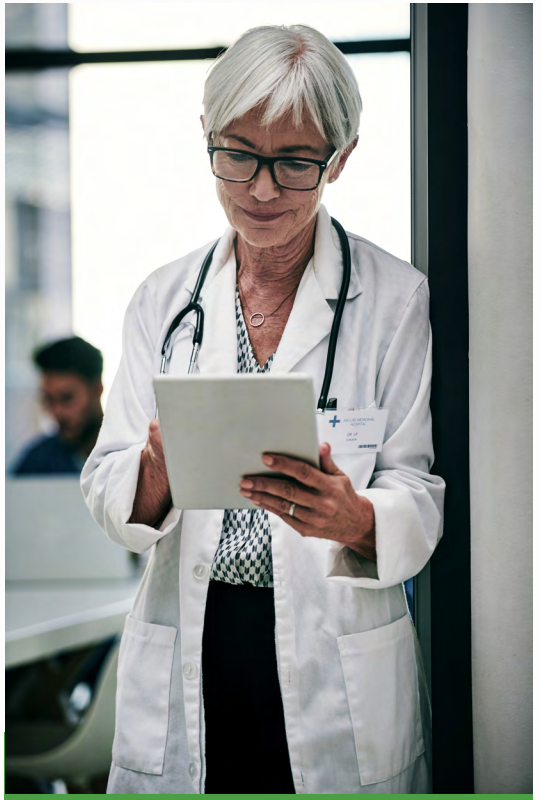
When designing an electronic medical record system, it's important to consider how design can facilitate safe and effective use. Poor usability could lead to unintended consequences and patient harm.

Consider the following five concepts when developing an EMR platform:

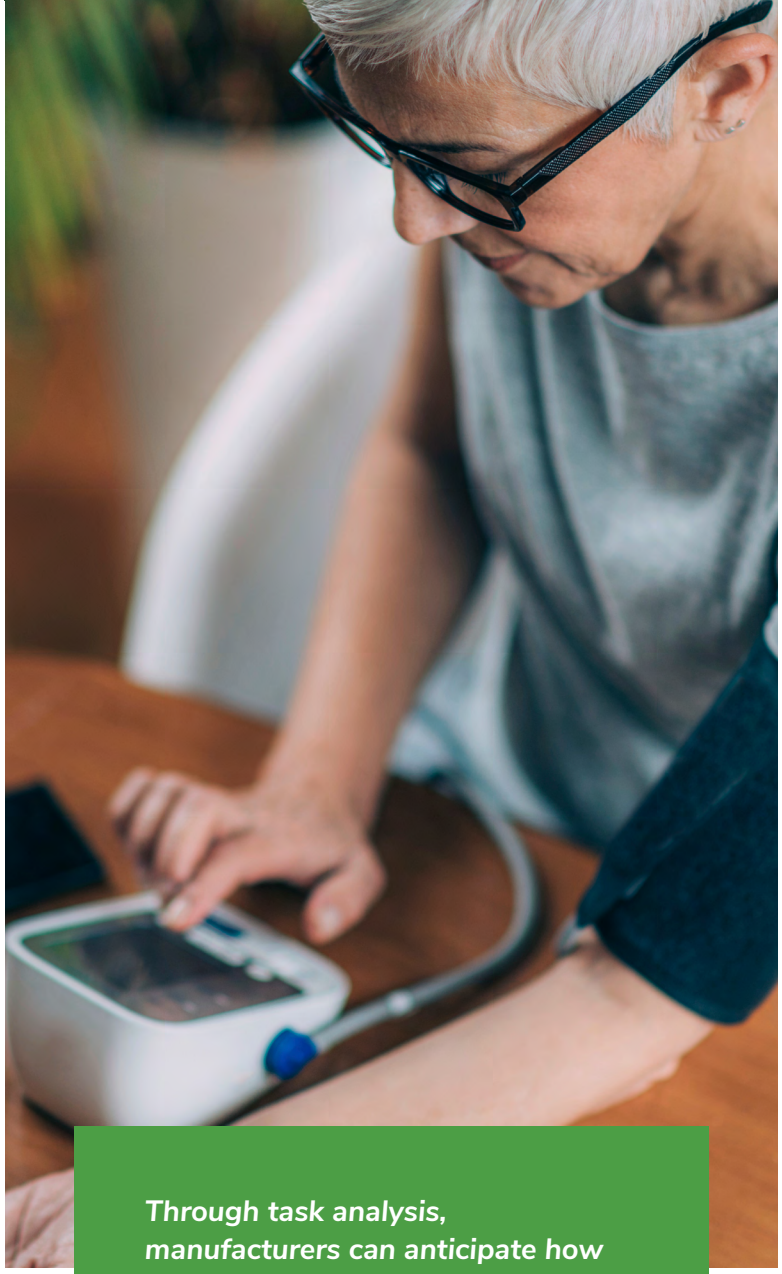
- **Implement accurate and sufficient labeling.** For example, labels and icons should describe a button's functionality and minimize reliance on users to intuit its purpose. Alerts and error messages should also provide sufficient feedback for users to understand how to proceed.
- **Limit multifunctional words and controls.** Controls should perform a single action, and terms should have a single meaning within the system. Consistency will build user understanding of and confidence in the system.
- **Differentiate default settings and custom inputs.** Many EMR systems allow users to import templated settings and/or notes. When changing default settings, users might overlook templated items, assuming their accuracy. Calling users' attention to these items can limit errors.
- **Apply universal symbols and colors.** Consider how colors signal urgency, importance or differentiability. For example, the color green and checkmark symbols typically indicate completeness or success. Alternatively, the color red and exclamation mark symbols usually indicate alerts or calls to action.
- **Enable customized data presentation.** Depending on the clinical context, healthcare providers might prefer an abbreviated or expanded view of relevant patient data. EMR systems should consider effective ways to utilize trend and summary tools to display information with an appropriate density.

This list serves as a starting point for developing a user-friendly EMR system. Different clinical environments call for different user needs and considerations to deliver safe and effective medical care.

Now that you're versed in developing a user-friendly EMR system, let's look at how the right approach to task analysis can help you gather insights so you can improve product design.



When designing an electronic medical record system, it's important to consider how design can facilitate safe and effective use.



Chapter V: How to improve product design through task analysis

Task analysis, if executed properly, can help you gather insights for improving product design.

Improving product design through task analysis

For medical device manufacturers, discovering use errors is perhaps the most alarming outcome of human factors research. As a result, many companies focus intensely on designing user-friendly products to minimize use error. To give credit where credit is due, good design practice plays a critical role in creating a great medical device. So how can you know what a good design is until you put it in front of users?

The answer, of course, is task analysis. The FDA's human factors guidance and IEC 62366-2 emphasize the importance of using task analysis to analyze human–system interactions and understand the many factors that can impact use error. For example, the FDA asks manufacturers to identify the perceptual inputs, cognitive processes and user actions that must occur for intended users to utilize a medical device safely and effectively for its intended purpose. Through task analysis, manufacturers can anticipate how users might perceive and interact with a device within a given context, allowing design teams to predict where use errors could occur and most importantly, what harms might occur as a result.

However, regulatory guidelines fail to provide critical details on creating a task analysis. What does the identification of user perception, cognition and action entail? How can manufacturers have confidence that their analysis represents actual device use?

Through task analysis, manufacturers can anticipate how users might perceive and interact with a device within a given context, allowing design teams to predict where use errors could occur and most importantly, what harms might result.

Medical device task analysis in four simple steps

Fundamentally, task analysis involves investigating how humans operate within their environment. For manufacturers, this procedure requires you to consider humans' underlying cognitive mechanisms to provide an effective analysis for use error prediction. Fortunately, you don't need a human factors degree to analyze human cognition. Here is a procedure you can use to improve any task analysis effort:

1 Identify the task to be analyzed.

Limit the scope of your task analysis to a use scenario, critical task or element of the user workflow that has important design implications.

2 Break down the high-level task into its discrete steps.

Deconstructing the task into a finite set of sub-steps helps ensure that the analysis doesn't become too broad as you proceed.

3 Describe the user's goals or motivations within each sub-step.

Think about what users must accomplish to achieve each sub-step:

- What do users need to know?
- What do users need to decide?
- What do users need to do?
- What do users need to perceive — e.g., hear, smell, see, taste, touch?

By describing user goals instead of simply focusing on rote user actions, manufacturers can more accurately depict the role of human cognition within their task analysis model. It is important to note that you should also seek to clearly define rules for successfully completing a sub-step.

4 Continue to decompose subtasks into additional subtasks until you reach the desired level of detail.

Visualizing the task analysis process

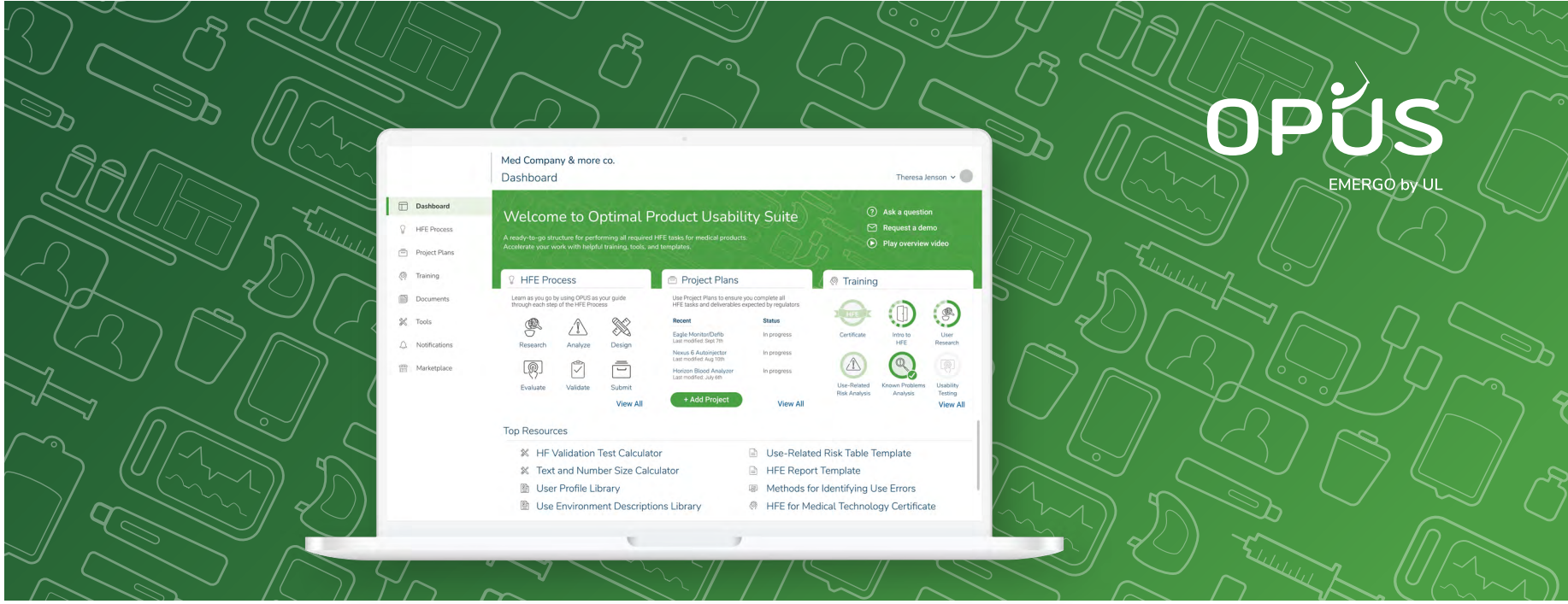
Let's consider a quick example. Imagine we are designing an insulin injection pen for diabetic patients and we are particularly focused on understanding how a use error might occur while administering the medication. To understand the potential incidence of use errors with the pen's current design, we can perform a task analysis using the procedure outlined above.

Task	Step	What do users need to perceive?	What do users need to know?	What do users need to decide?	What do users need to do?
Administer the medication	Remove the needle cap	See the needle cap located on the device	Recognize and identify the needle cap	How to remove the needle cap	Grasp and pull the needle cap
	Locate the injection site	See the exposed injection site	Know the appropriate injection site locations	Determine the consequences of their injection site choice	Choose an injection site
	Insert the needle at an appropriate injection angle	Angle of the injection pen relative to the injection site	Appropriate injection angle	Determine the appropriateness of the injection angle	Check the injection angle
	Press the injection button to administer the medication	See the injection button	How the injection button functions	How and when to press the button	Press the injection button
	Confirm that the medication was fully administered	See that all medication has been administered	How an injection device should look when empty	Decide whether all medication has been administered	Check to see whether medication was administered

Applying task analysis findings in the design process

Using our task analysis, we have identified several steps users must take to successfully administer the medication. More importantly, we have also identified each step's critical perceptual, cognitive and action-based components, which we can use to better understand where intended users might make mistakes when using the device.

Understanding the many factors that can influence users' task performance can help manufacturers identify potential use-related risks and direct product design efforts accordingly. Once potential use error sources are clear, manufacturers can create design mitigations to manage a device's use-related risk through user-centered design. When used correctly, task analysis is a powerful tool for creating safer and more effective products.



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