

Using Human Factors Evaluation Outputs to Drive Risk Analysis and Design Inputs

Forward:

MEDICEPT is very active in both assessing device usability and integrating the outputs of usability studies into other elements of manufacturers' Quality Management Systems (QMS), particularly design control and risk management. This article is intended to provide some background on the application of the human factors/usability engineering process, but the focus is on the linkages between that process and the other elements of your QMS.

Our team at MEDICEPT publishes these articles to capture best practices, to explore the more challenging aspects of maintaining risk management systems over the long term, and to elicit discussions among practitioners.

To this last point, if you have questions or comments on the issues discussed, or if you have recommendations for topics to consider in the future, please let us know: 508-231-8842.

The Case for Human Factors

As medical devices become more complex and the use of devices increasingly moves from hospitals to the patients' homes, manufacturers must focus more and more on ensuring the usability of their devices – i.e., can the intended user operate the device in a safe and effective manner.

Why is this important? Even back in 2000, researches looking at medical errors (i.e., all types of errors including drugs and devices) found that:

- Adverse events occurred in 2.9% of hospitalizations in Colorado/Utah – 6.6% of these led to death.
- In New York, adverse events occurred in 3.7% of hospitalizations – 13.6% of these led to death.
- Over half of these events resulted from medical errors and could have been prevented.
- Extrapolating . . . More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).¹

More recently, in 2010 the Health and Human Services Inspector General estimated that:

- 13.5% of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays.
- An additional 13.5% experienced events during their hospital stays that resulted in temporary harm.
- Physician reviewers determined that 44% of the adverse and temporary harm events were clearly or likely preventable.
- The annual cost to Medicare of these adverse and temporary harm events is 3.5% of inpatient care expenditures – or about \$137 billion.²

¹ Kohn, Linda; Corrigan, Janet, Donaldson, Molla; *To Err is Human: Building a Safer Health System*, Committee of Quality of Health Care in America – Institute of Medicine, 2000.

While many of these adverse events were not preventable, the studies suggest that close to half were. And a preventable event suggests that an error was made in the administration of a drug, or the use/misuse of a device.

When it comes to medical devices, the ECRI Institute does a nice job of tracking and communicating the most significant hazards. Here's their list of Top Health Technology Hazards for 2014³:

1. Alarm hazards
2. Infusion pump medication errors
3. CT radiation exposures in pediatric patients
4. Data integrity failures in EHRs and other health systems
5. Occupational radiation hazards in hybrid ORs
6. Inadequate reprocessing of endoscopes and surgical instruments
7. Neglecting change management for networked devices and systems
8. Risk to pediatric patients from "adult" technologies
9. Robotic surgery complications due to insufficient training
10. Retained devices and retrieved fragments

What do you notice about the ECRI list? Arguably, almost all of the hazards (excluding Data Integrity Failures) are associated with device usability. There's nothing on the list about a device breaking, electrical safety, or other items that you would likely address in a design FMEA. Almost all of the issues on ECRI's list involve use errors. By "use error" what we mean is that an error occurs as a result of "undesirable or unexpected events resulting from the interaction between a user and a device; use error accurately indicates error but does not attribute fault to the user. It should be noted that use error is not the same as abnormal use by a user who actually intends to use a device incorrectly" (ANSI/AAMI HE 75:2009, Section 5.1.4).

The list is full of misunderstood or ignored alarms, misapplication of technology, poor cleaning and failure to maintain/operate the device. And these are largely concerns when the devices are being used by professionals in a hospital setting. When the device is used in the home by in-home caregivers or the patients themselves, attention to usability is even more important.

The environment plays a large role in the overall usability of a device. Hospitals can be chaotic places to work, with multiple patients in a room, multiple devices alarming at any one time, and a myriad of connections to be maintained and monitored. Not only are there many different devices in operation, there are many similar devices being used. So, if a ward is using several infusion pumps or monitors that are produced by different manufacturers, the staff needs to keep in mind all of the sometimes subtle differences in how any one device must be set up and monitored.

² Levinson, Daniel, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, Department of Health & Human Services, November 2010, OEI-06-09-00090

³ www.ecri.org/2014hazards.

In the home, there are very different distractions, but the challenge is in the user's ability to use the device in a safe and effective manner. Whether the user is a home healthcare provider or the patient, the design of the device needs to consider the capabilities of the user so that the setup, monitoring, control, cleaning, and interpretation of device outputs can be performed effectively.

What to do?

Like all engineering challenges, addressing device usability starts with clearly defining the problem to be resolved. But before getting into the details of the usability engineering process, a few definitions are needed.

- **Usability:** IEC 62366 defines it as “characteristic of the user interface that establishes the effectiveness, efficiency, ease of user learning and user satisfaction”. So for a medical device, “good device usability” is the result of a design effort that has fully considered and effectively addressed the needs of the intended user.
- **Human Factors and Ergonomics:** There are a variety of ways that these terms are defined – most view them as synonyms. The Human Factors and Ergonomics Society provides this definition:
 - Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance. Ergonomists contribute to the design and evaluation of tasks, jobs, products, environments and systems in order to make them compatible with the needs, abilities and limitations of people.⁴

Note: The term “ergonomics” tends to be used in Europe and the term “human factors” tends to be used in North American.

We also worked with experts in the field who make a finer distinction, by using the following definitions:

- **Human Factors**, while applicable to all aspects of the user-device interaction, addresses the cognitive aspects of the interaction – the “above the neck” interactions. For example, is the set up of the device intuitive/mistake proof, do users understand how to respond to device alarms, can users interpret device outputs properly, etc.
- **Ergonomics**, while also broadly applicable, focuses on the bio-mechanical aspects of the user-device interaction – the “below the neck” interactions. For example, does the button require appropriate force to engage, does the device fit comfortably in the intended user's hand, will the wrap fit around the arms of the smallest and largest intended users, etc.

The key point is to understand that designing a usable device requires the consideration of both the cognitive and the biomechanical aspects of the device (and how each aspect affects the other). The greater the risk associated with the use of the device, the more attention that needs to be placed on building this understanding and implementing effective design solutions.

⁴ International Ergonomics Association (found at <http://www.iea.cc/ergonomics/>)

When designing a medical device for usability, several important, initial questions to ask are:

- Who are the intended users?
- How does the device fit with the user's expectations?
- What are the user's potential limitations?
- What decisions will the user need to make when using the device?
- How will the use environment influence operation of the device?

There are two important standards that have been published over the past few years that provide device manufacturers with processes that they can follow to ensure that these (and many other) questions are asked at the right point in the design and development process and that the effectiveness of the implemented solutions is tested and verified. These standards are:

- ANSI/AAMI HE 75:2009 – Human Factors Engineering – Design of Medical Devices
- IEC 62366:2007 – Medical Devices – Application of Usability Engineering to Medical Devices

HE 75 has a bit of a textbook feel to it and at 450 pages, it covers a lot of ground. It contains valuable background on human factors engineering (e.g., basic human skills and abilities, anthropometry and biomechanics, etc.); specific guidelines for designing key product elements (e.g., packaging, alarms, documentation, etc.); details on design elements (e.g., connections, controls, software-user interfaces, etc.); and integrated solutions (e.g., hand tool design, workstations, home health care, etc.).

IEC 62366 is a quicker read (running at about 100 pages) and like many IEC/ISO type standards focuses mostly on the process – i.e., more on “how” to integrate usability into the design rather than “what” specific design elements need to be considered. This standard is linked very closely to ISO 14971, *Medical Device – Application of Risk Management to Medical Devices*.

For anyone who has submitted an electronic medical device for IEC 60601 3rd edition testing – you are well aware of the emphasis being placed on both usability engineering and risk management. The balance of this paper focuses on the usability engineering process, as defined in IEC 62366, and how it relates to both risk management and design control.

Usability Engineering per IEC 62366

The usability engineering process described in IEC 62366 focuses on establishing a comprehensive understanding of:

- how the device under consideration is intended to be used,
- what risks are associated with its use, and
- how the device can best be designed to mitigate those risks.

Figure 1 illustrates the flow of activities identified in the standard. The usability engineering process begins with the “Application Specification” (i.e., the intended medical indication, the intended part of the body or type of tissue applied to or interacted with, the intended user profile, the intended conditions of use, and the operating principle of the device).

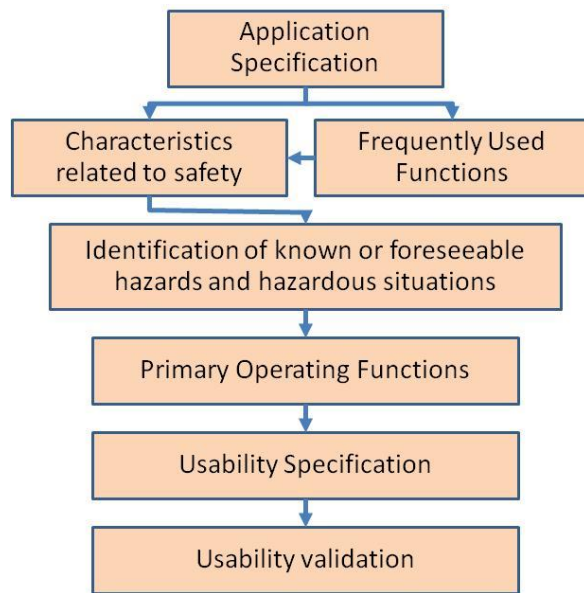


Figure 1: Usability Engineering Process

The application specification sets the stage for range of usability issues to be considered. If your device is to be used by trained surgeon in an OR, the range of usability issues is fairly limited. If, however, your device is intended to be used by anyone over the age of eight, is portable and needs to operate indoors and outdoors 24 hours a day, and there are a variety of outputs (text screens, alarms, etc.) that the user needs to interpret, you will have a good number of usability issues to consider.

The standard then calls for the consideration of frequently used functions that involve user interaction and the identification of characteristics of the use of the device that could affect safety. Here it is often valuable to create a process flow chart that illustrates the sequences of tasks that the user follows when using the device in order to identify where in the process use errors can affect patient safety.

In the next step, there is an explicit link to the risk management process as defined in ISO 14971. The hazards identified in the usability engineering process become inputs to the risk management process (more on that later).

Primary Operating Functions are defined as those functions that involve user interaction and are either frequently used or related to the safety of the medical device. These functions, along with the understanding of the hazards associated with those functions, serve as inputs to the Usability Specification. Just like your product design specification, the Usability Specification establishes design input requirements for your device.

The Usability Specification is a critical document. It establishes the requirements against which you will need to conduct tests to assess the usability of your device. Important elements of the Usability Specification are the description of use scenarios related to the primary operating functions. The intent of these scenarios is to describe the use of the device under both typical and worst case conditions. The

standard, therefore, is looking for device designers to consider not only how a typical adult user will use the device; but also, for example, how the device would be used by an elderly user with arthritis or poor hearing – if such a person fits within the group of intended users as defined in the Application Specification.

The testing of your device against the Usability Specification will involve both verifications (e.g., expert reviews, design audits, formative usability tests, etc.) and usability validation (i.e., summative usability testing typically in simulated clinical environments and field testing). The general rule here – like all other aspects of your design effort – is that the better job you do with verifications the more likely you will be to conduct efficient validation studies that are successful the first time through. You don't want to be identifying design problems during validation – it's too late in the game and the fix may be very expensive.

The results of your Usability Validation studies provide feed back to your risk management process - providing evidence that risk controls put in place to address use-related hazards are effective. The Usability Verifications and Validations also provide evidence that use-related design input requirements (that may not be directly related to safety) have been adequately addressed.

Linkages to Risk Management (ISO 14971)

The linkages to the risk management process described in ISO 14971 are alluded to above. ISO 62366 includes a very detailed description of these linkages – including a pretty complex flow chart (see Figure A.1 in ISO 62366:2007-10). Figure 2 provides a much simplified description of these linkages.

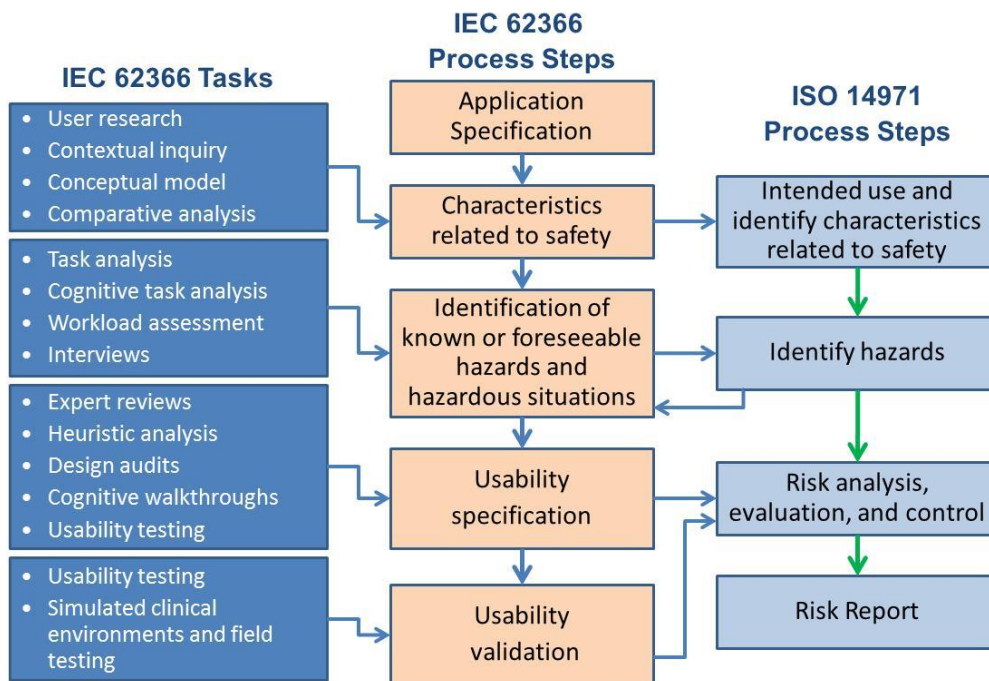


Figure 2: Linkages Between Usability Engineering and Risk Management

As you can see from the flow chart, Usability Engineering informs, and is informed by, risk management. The Application Specification is a very valuable starting point that is often skipped over by the risk management team. Often risk management teams tend to focus on the typical user and the typical (if not the ideal) operating environment. By considering hazards associated with the full range of intended users across the intended use environments, risk management teams are in a better position to assess the comprehensive set of risks that will need to be addressed. Again, it's far better to identify these issues early in the design and development process than at, or near, the end of the process when the cost of a change is high and will likely affect time to market.

So, just as Usability Engineering informs risk management by describing users, the use environment, and related hazards; risk management informs Usability Engineering by feeding back an assessment of the risks associated with those hazards. Since the risk management process is set up to consider all device-related risks in a consistent manner, this feedback provides direction to Usability Engineering on where risk controls need to be implemented.

Finally, as described previously, Usability Engineering provides risk management with the evidence required by ISO 14971 that risk controls have been verified and are effective.

What about Design Control?

While the linkages between Usability Engineering and risk management are important, they are not the only important linkages to consider. Remember that these activities are all taking place as part of the design and development of a device, so they both must be integrated into your design control process.

Figure 3 illustrates a high-level process flow for the three elements of a medical device development effort: Usability Engineering, risk management, and the overall design control process. In practice, this process will not be as neat and linear as depicted in this graphic (there's a lot of back and forth that needs to take place), but it should provide a good feel for the proper flow of activity.

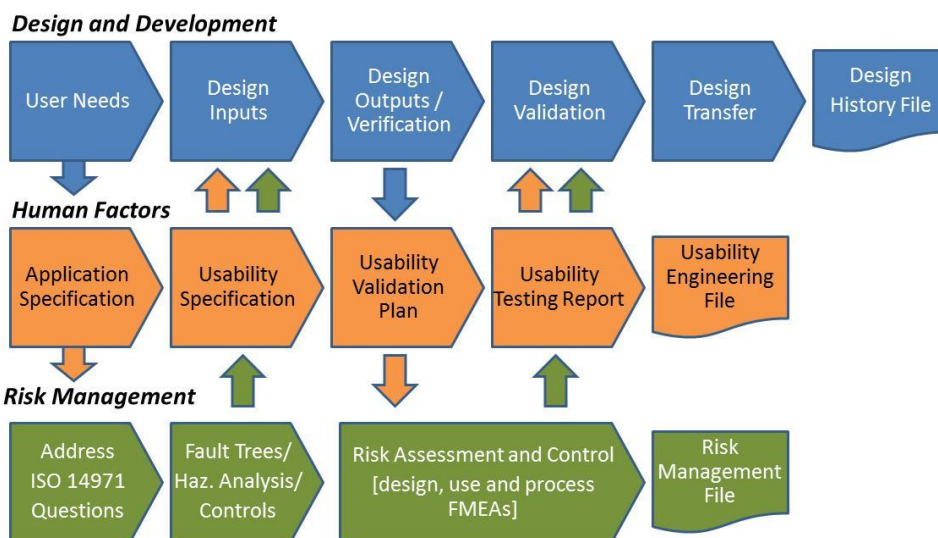


Figure 3: An Integrated Medical Device Design Control Process

This process flow highlights the large amount of Usability Engineering and risk management work that is intended to take place in the earliest stages of the design control process. As you can see, when your

Design Inputs are finalized, the Application Specification, initial hazard analysis, and Usability Specification are all also complete. It may seem demanding, but it's also very logical. Until you understand the hazards that you need to control, and you've established the Usability Specification, there's no way to finalize the Design Inputs. Granted, you may still have some Design Input "TBDs" to resolve, but the requirements for the device should be complete and be based on a clear understanding of usability challenges and identified risks.

How does all this work?

To illustrate how the Usability Engineering process links to risk management and design control in practice, the authors of ISO 62366 describe the process from the initial identification of user needs to design inputs using an Electronic Thermometer as an example (the full example is in Annex H of the standard).

Figure 4 summarizes the basic user needs and types of information that would feed into the Application Specification.

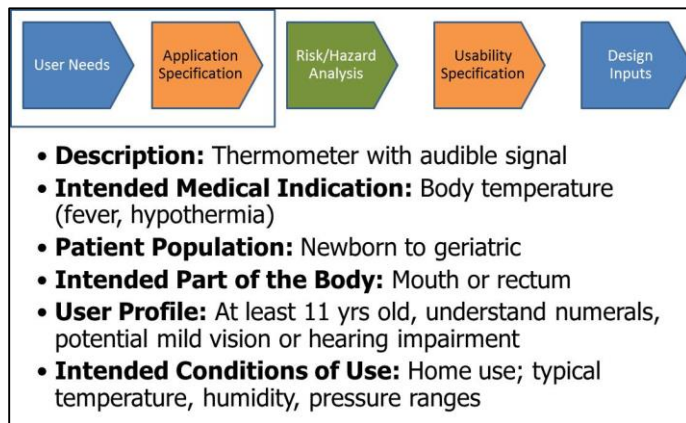


Figure 4: User Needs and Application Specification

Based on this understanding of the likely users and the intended conditions for use, potential hazards can be identified, as illustrated in Figure 5. Once the hazards are identified, an initial risk assessment can be completed to identify needed controls.

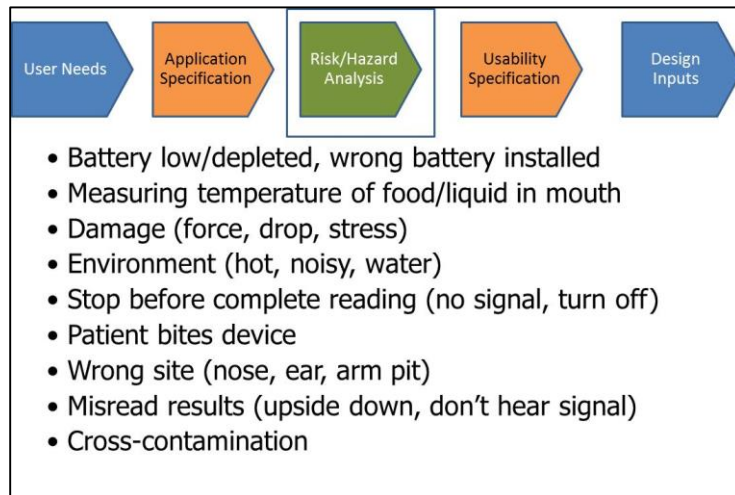


Figure 5: Risk/Hazard Analysis

The Usability Specification is the tool that you use to capture the requirements that designers and engineers must satisfy to reduce the risks associated with the identified hazards. The Usability Specification can be stand-alone document, but typically manufacturers will integrate use-related requirements into their product requirements document, which captures all the design input requirements that must be met during the development process.

To ensure that the Usability Specifications are comprehensive, it's best to identify use-related design requirements for each step in the use process. Figure 6 identifies key steps in the use of a thermometer from preparing for use ("Remove Cover"), through use, and ending with returning the device to storage ("Store"). This is the same approach that you should be using when you set up your use-FMEA.

It is also valuable (and required by the standard) to describe both "frequent use scenarios" and "reasonably foreseeable worst case use scenarios" in the Usability Specification. The example in Annex H of the standard presents a pretty extreme worst case scenario for the use of the thermometer (Figure 6). The value in writing down these scenarios is that it provides you with context for establishing requirements: If the device might be used in the dark, the display may need to be lit; if it will be used in a noisy environment, an alarm loud and distinct enough to be heard may be needed; etc. Ultimately, the performance of the device in these scenarios will need to be assessed as part of the Usability Validation.

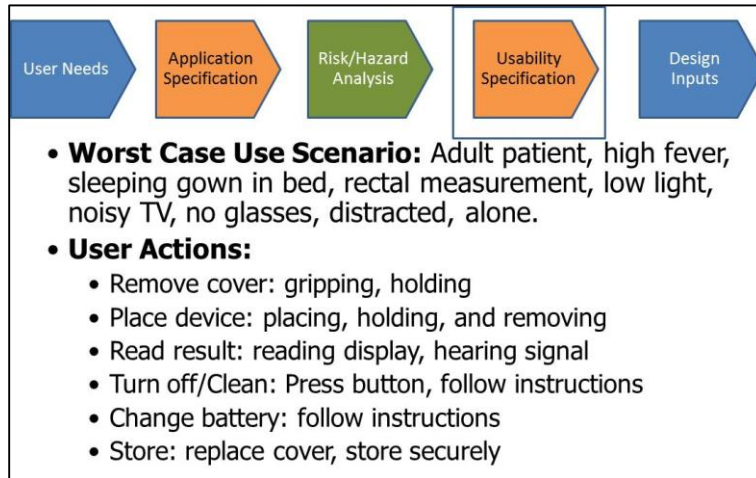


Figure 6: Usability Specification

Like other design input requirements, the requirements that you include in the Usability Specification will need to be measurable, but should not specify a particular solution. For example, to address hazards associated with gripping/holding the device, the Usability Specification can include requirements such as:

- Thickness: 8mm to 10mm
- Height: 13 mm to 15mm
- Length: 60mm to 65mm
- Surface Finish: textured to provide a secure hold on the gripping surface

(Figure 7 provides additional examples of likely requirements and Annex H of the standard has even more.)

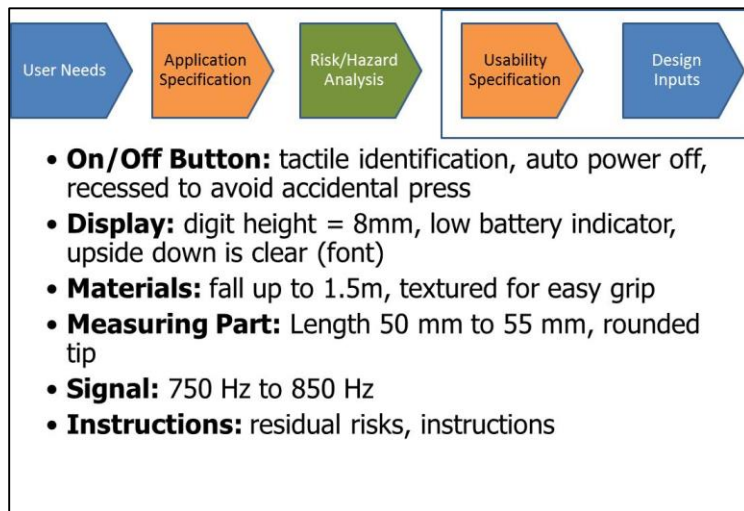


Figure 7: Usability Specification

Conclusion

As mentioned earlier, this approach requires that you do a lot of thinking about the use of the device during the earlier stages of product development and it can be challenging to rein in your design team when they are pushing to “start working”. However, putting a lot of thought into what the device needs to achieve is not just a good idea, it’s what the regulations now require.

By drafting the Application Specification as a first step in the design process, you will capture a lot of information about what the device is (and what it is not) in a format that everyone on the team can understand. The Application Specification provides the foundation on which all future development based. The product concept may evolve a bit during development (at least in the early stages). As it does, the Application Specification needs to be updated so that it accurately reflects the product that the team is developing.

From the Application Specification, you should have enough information to identify the types of hazards that will need to be mitigated in the design. The Risk Management process provides you with a common format to identify usage risks and assess them relative to the other product design risks. Some usage risks may be addressed through device design and others may be addressed through protective measures. Regardless, those risk reduction measures feed into your Usability Specification providing designers and engineers with the guidance that they need to develop the product.

Finally, the analysis of usability and assessment of risks provide key inputs into your design input requirements. By translating usability needs and into measurable requirements you will provide your design team with the direction they need to effectively develop the device and to test the device to verify that those requirements have been met. Considering usability early in the development process will help to ensure that your team has the right information to do their jobs and that the final product will meet user needs in all intended use conditions.

Next Steps

MEDicept is a medical device consulting firm dedicated to helping pre-revenue and established medical device manufactures with the complexity of international regulatory requirements. Let MEDicept help you develop your human factors evaluation and walk you through the process.

If you have questions or comments on the issues discussed, or if you have recommendations for topics to consider in the future, please let us know. 508-231-8842.

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