Frequently Asked Questions

Intertek
Valued Quality. Delivered.

Human Factors for FDA Compliance

1. **Is there a standard test and acceptance criteria for determining if a system or product is "easy to use"?**
   It's very hard to define what ease of use means. A device might be easy to use yet can injure the users. Proper formative and summative testing will demonstrate if a device can be used effectively and safely.
2. **For usability/human factors, should risk and validation activities be covered separately?**
   No. Your validation activities will be based on the identified risks.
3. **What is the best book/reference where I can obtain the specifications for "normal" for human functions?**
   ANSI/AAMI HE-75: 2009/(R) 2013 is a good source of information.
4. **What are sample size requirements for usability studies for non-complex devices?**
   The sample size for formative studies is 5-8 per user group, for summative, a minimum of 15 per user group. Reference the FDA's Draft Guidance on Applying Human Factors and Usability Engineering to Optimize Medical Device Design Section 10.1.2.
5. **How far in advance should device training be provided to the users before the human factors validation test in order to be acceptable for a 510(k) submission?**
   An hour learning decay may be acceptable between the training and the validation testing, however, mirroring the real life setting would be preferred.
6. **How do you properly document human factors for FDA and IEC approvals?**
   In most cases, compliance to 62366 is sufficient.
7. **Define all 62366 regulatory and/or design control deliverables, including how it relates to IEC60601 testing requirements.**
   The regulatory and design controls requirements are outlined in IEC 62366. We recommend seeking expertise for specifics related to your device and IEC 60601 testing requirements.
8. **What is the status of the human factors standard? Will there be a new or revised version?**
   IEC 62366-1:2015 was recently released and IEC 62366-2:2015 will be released soon.
9. **Must compliance of IEC 62366 be verified by an accredited test lab, or may it be done by the manufacturer of the medical device?**
   Compliance to IEC 62366 can be accomplished by the medical device manufacturer or an outsourced vendor. Using an independent vendor with expertise in HFE helps mitigate liability and compliance with necessary standards earlier in the design process – a factor that tends to save manufacturers time and cost.
10. **What is the best way to address human factors for legacy irrigation devices?**
    Based on the changes, you may need to complete IEC 62366. Your regulatory consultant/group should be able to provide guidance.
11. **Can data from a product currently in a pivotal FDA clinical study for an unapproved FDA device be used in place of Human Factors Engineering (HFE)?**
    Clinical studies or HFE during clinical studies are not acceptable. Many times errors are introduced in the task to see how users would react to it. This type of task cannot be accomplished during a clinical trial.

Intertek

Valued Quality. Delivered.

12. **How do you use human factors methodologies to validate the content of user manuals?**
    The process indicated in IEC 62366 applies to user manuals.
13. **It's possible to integrate the human factors process into the risk management process?**
    As with software or design, usability FMEA or any risk assessment methods that will evaluate and rank the potential risk human factors should be integrated into your process.
14. **What is the rigor necessary to meet FDA's expectations for documentation of human factors?**
    You should meet the IEC 62366 process and the draft guidance on usability proposed by FDA.
15. **What is the best way to integrate human factors in the early stages of a project (including hazard analysis, design requirements and checklist)?**
    There are many ways to integrate human factors in the early stages of a project. If you lack in-house expertise, seeking a vendor with expertise in HFE early in the design process can help mitigate liability and speed the process – a factor that tends to save manufacturers time and cost.
16. **Is there a timeline to comply with FDA human factors guidelines?**
    The human factors activities should be completed before your FDA submission. The HFE process should follow your product development process.
17. **Are human factors applied to dental devices?**
    If your device is classified as a medical device, human factors applies in the same way as any medical device.
18. **From a risk management perspective, how do the requirements in IEC 62366 differ from those in HE75?**
    HE75 is not a standard but a reference document.
19. **If a safety risk is found during a human factors evaluation what documentation can be used to show that a design change addresses the risk?**
    Conducting a follow up evaluation (formative or summative) will show that the risk was mitigated.
20. **Is there a guideline on when to conduct a Human Factors Engineering study and when not to?**
    Your human factors specialist should be able to guide you in relation to your device. Ideally considering HFE early and often so you are not slowing down the development yet input is gathered to aid in proper risk management and decision-making will save manufacturers time and cost.
21. **What criteria do you use to identify critical tasks from your risk assessment?**
    When the Risk Priority Number (RPN) of your severity and occurrence is medium or high, it indicates that the task is critical.
22. **Can employees be used for formative usability testing?**
    Employees can be used for some types of assessments (cognitive walkthrough, expert reviews, exploratory testing) but when a test is conducted based on a risk assessment/protocol and report, use of employees is not recommended.
23. **How is "frequently used" defined? Where is the tradeoff: 10 times a day or at least once for every diagnostic? Should we limit the type of functions to the ones that are related to diagnostic (measurements, image manipulation, information regarding patient and images, election of patients, etc.) and exclude other functions (user management, user preferences, etc.)?**
    It depends on the device, but as a rule of thumb it should be the ones that are used during normal operations.
24. **If a device expert group is located in Canada, can these participants be included in the summative testing?**
    Only if the participants are US residents.
25. **Is HFE required for Class II, but 510k exempt devices?**
    This requires review by a regulatory specialist.
26. **What are the various grade level reading requirements for Instruction for Use (IFU)?**
    We often hear "8th grade level" but if your IFU is used during testing and you are successful, then you have the right level. Illustrations and proper organization of the information might also be critical, not just the level.
27. **Cost is a factor for a summative test in our field. Fifteen users for a summative test is nearly impossible due to cost. Is there a way to rationalize a lower number?**
    Please contact 800-967-5352 or iCenter@intertek.com for review and advice.

Intertek

Valued Quality. Delivered.

28. **Can user groups that are expected to be worst case based on risk assessment (children, for example) be considered or all user groups (even low risk users, adults, for example) need to be considered in human factors?**
    Looking at the worst case user groups is recommended as they are the groups most likely to be negatively impacted by your device. However, you cannot ignore other groups, all user groups need to be represented in your testing results.
29. **You mentioned that not everything needs to be tested during summative testing. However we are required to validate all of our user needs. How do you explain this disconnect?**
    As far as FDA is concerned, the identified risks need to be tested during summative. A user need might not have an associated risk. If you want to test it for other reasons it is okay, but it is not a requirement.
30. **Is there a checklist to help facilitate completing these various sections from standards documents?**
    A checklist can be created from IEC 62366.
31. **Do human factors practitioners help with design concepts/prototypes? Or just deliver user research and risk analysis to the engineers/ designs?**
    Some do, some don't, Intertek Consulting offers design/concepts/prototypes in addition to Human Factors.
32. **Is the US resident requirement an absolute must for a FDA pre-market notification? Any reference where this requirement can be found?**
    Please reference the FDA Medical Device Regulation Guidance Document Section 10.1.2 and Appendix B.
33. **If you are confident in the results obtained through formative testing, is summative testing still required?**
    If a formative test with 15 users per user group was conducted, it should be sufficient. If this is not the case a summative test following the requirements is required.
34. **Is there a requirement for HF/use testing to be complete prior to filing a FDA 510k, or can it completed after submission as an amendment?**
    Please contact 800-967-5352 or iCenter@intertek.com for review and advice.
35. **When estimating the probability of occurrence in the user FMEA, should it be based on probability of the occurrence of the harm or the occurrence of the cause? There may be multiple harms associated with a single cause, or vice versa. How is this handled?**
    We usually focus on the occurrence of the harm. How you mitigate the root cause might reduce, keep or augment the occurrence of each harm.
36. **Does the FDA have any guidance or recommendations about having engineers who contributed to the design participating in usability studies? How does that apply to formative and summative testing?**
    The participants in the studies should have the qualification described in your user group. The participants need to be unfamiliar with the device so that you are replicating the real world device use scenario.
37. **Our product currently has an Investigational Device Exception (IDE) from the FDA but was launched in Europe many years ago. The product was designed prior to the requirement for IEC 60601-1-6, but will need IEC 60601-1-6 for FDA approval. Will a cumulative study be enough?**
    Much of the existing documentation can be used in the Usability Engineering file. If your device is working well in Europe, summative testing should be easy and quick to perform to be compliant with 60601-1-6.
38. **There wasn't any mention of the role of the benefit analysis in the human factors analysis. If the improvement reduces risk from a hazard, but reduces treatment because of fear of the newness of the usability, how should that be addressed?**
    Most device development should have a benefit/risk assessment. A scalpel will create a lesion but will also remove a tumor that can kill, therefore, the benefit outweighs the risk. In all cases, residual risks may exist after all the testing and revisions, but demonstrating risk mitigation as much as reasonably possible (ALARP principle) is necessary. It's possible to introduce an innovative solution for a treatment and do it in a safe way.

Intertek

Valued Quality. Delivered.

39. **Can clinical tests and summative tests be combined? What can small companies do to reduce evaluation costs? If this is correct, what is the rationale and what can small companies do to reduce evaluation cost.**
    Designing your testing in parallel to clinical testing is an option but if infrequent but dangerous tasks are introduced (as identified in your risk assessment), conducting these tasks during your clinical testing isn't recommended.
40. **If a user is defined by the person who will administer a vaccination (not the recipient of the vaccination), would a syringe for an infant need to be less long than for an adult? Might the same syringe model be used where everyone is of a different age group? If so, how is the recipient defined in the UFMEA?**
    A syringe for IM injection will be used the same way that is 7/8" or 1 ½". Your question is in relation to a clinical outcome, not to human factors.
41. **Where did the minimum number of users come from? Is that a recommendation from the FDA, or from Intertek, or a general rule of thumb?**
    The minimum number of users is from FDA Guidance. Please reference Section 10.1.2 and Appendix B.
42. **Can we self-certify ourselves to IEC 62366 requirements?**
    By self–certify, it's assumed that completing all the 62366 requirements internally, without consultant is desired. The response is, yes, and many large medical device manufacturers have internal HFE teams.
43. **Which function within the organization is best suited to do the functionality testing? It was mentioned that engineers should watch, should your clinical team conduct the testing?**
    The functional team isn't usually the issue but proper mindset and training of the team that is important for proper testing.
44. **If a device will be sold in the U.S. and Europe, is it okay to test with U.S. and European users? Or does the FDA still want to see a minimum of 15 U.S. users?**
    To adequately represent users in the United States population, the participants in the validation test should reside in the United States. English fluency or first-language abilities should only be used as a test participant inclusion criterion if this requirement is also stated in the device labeling. Reference Section 10.1.2 last paragraph in the link.
45. **It was mentioned that a user cannot be re-used for testing. Is this only related to a specific development project or can they never be re-used?**
    Users cannot be used in the course of a specific device development.
46. **What is training decay?**
    Training should represent the actual user training experience taking into account the environment in which training occurs and the fact that retention of training decays over time. For this reason, prior to testing, a period of time should elapse following training to provide an opportunity for training decay to occur. Please reference Section 10.1.3 last paragraph in the link.
47. **What is the difference between Use Specification and Usability specification?**
    Use Specification and Usability specification are one in the same.
48. **What is the impact to a completed human factor study if one user group is not accounted for? For example, adults are considered but not caregivers?**
    If one user group is not accounted for, your documentation is not complete. If your device is for home use, a caregiver should always be considered as an user unless it can be proved that isn't the case.
49. **Does FDA require compliance to 62366 as part of FDA approvals of medical device?**
    Not all devices require 62366, please confirm with your regulatory expert. In most cases, your device must meet the definition of a medical device, is Class II or III. It will then need to comply with ISO60601-1-6 or ISO14971.

Learn how to integrate human factors in the development process for FDA Compliance by downloading the recorded webinar at:

www.intertek.com/medical/integrate-human-fators-in-development-process-for-fda-compliance-webinar/