Alceon
MONTHLY NEWSLETTER

July 2020

Dear Readers,

Welcome to the second edition of our monthly newsletters. This edition is divided into two sections.

In the first section, we discuss the process of usability engineering and providing you with a primer on US FDA regulations.
Use errors have been identified as one of the major causes of medical device adverse events. Use errors occur because manufacturers often design for themselves rather than the users of the device. The usability engineering process aims for designers to observe people, understand their psychology and behaviour and then design the product. In this section we touch upon how the usability engineering process works and what are the regulatory requirements for usability.

In the second section we provide you with a primer on how to place your device in the US market.

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USABILITY ENGINEERING & TESTING 01

The safety and performance of a medical device or a diagnostic device depends a lot on how the device is used. The process of design considering the aspects of human psychology, behaviour, cognitive ability physiology, age, anthropometry (obtaining systematic measurements of the human body) and environment of use, is called usability engineering. The term human factors engineering and usability engineering are used alternatively.

In its simplest terms, ‘human factors’ refers to how a person will interact with the systems surrounding them, including the technology they use.

Usability is however a component of User Experience (UX) Design. A product's usability depends upon how well its features accommodate user's needs and contexts. A usable design must have the following components:

Effectiveness	It supports users in completing actions accurately.
Efficiency	Users can perform tasks quickly through the easiest process.
Engagement	Users find it pleasant to use and appropriate for its industry/topic.
Error Tolerance	It supports a range of user actions and only shows an error in genuine erroneous situations. You achieve this by finding out the number, type and severity of common errors users make, as well as how easily users can recover from those errors.
Ease of Learning	New users can accomplish goals easily and even more easily on future visits.

Source: Interaction-Design.org

Regulations to Consider

Regulations around the world require designers to consider usability during the process of their design. Below are given requirements from the ISO13485 and the EU MDR on usability:

Usability engineering as per ISO13485:2016

Cl. 7.3.3 a: Functional, performance, usability and safety requirements according to the intended use shall be determined and recorded as an input for design and development
Cl. 7.3.9: Significance of the design change to usability for medical devices and its intended use shall be determined as part of control of design and development changes

Usability requirements in the EU MDR and IVDR

Chapter VII, Post Market Surveillance, Article 83, point f: Data gathered by the manufacturer's post-market surveillance system shall in particular be used for the identification of options to improve the usability, performance and safety of the device

Article II, Definitions, "Incident": Incident means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect

ANNEX I, Chapter I, General Requirements:
GR 5: In eliminating or reducing risks related to use error, the manufacturer shall:(a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety)
GR 14.2: Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features
GR 14.6: Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used

Similar provisions can be found in Annex I GR5; GR13.2; GR 13.7; of In Vitro Diagnostic Medical Device Regulations (EU) 2017/746.

International Standards

The international standard for usability engineering of medical devices is the IEC 62366 (its European version being the EN 62366). There are two parts to this standard. The part 1 published in 2015 is the main standard, whereas the part 2 published in 2016 is a more elaborate guidance of the part 1.

The usability engineering process as given in the IEC 62366-1:2015 consists of the following steps:

Prepare use specifications (clause 5.1)

In this stage identify the user profile, the environment in which the device will be used, the sequence of tasks that the user has to perform, any training that the user would receive before using the product and how frequently the user will use the product.

Identify use interface characteristics related to safety and potential use errors (clause 5.2)

Identify known or foreseeable hazards and hazardous situations (clause 5.3)

Identify & describe hazard related use scenarios (clause 5.4)

Select hazard related use scenarios for summative evaluation (clause 5.5)

Establish User Interface Specification (clause 5.6)

Collect information on use errors known and published in various internal and external resources.

Identify the high-level tasks and the user interfaces that can have an impact on safety of the medical device.

Establish User Interface Evaluation Plan (clause 5.7)

Perform user interface design, implementation & formative evaluation (clause 5.8)

Formative evaluation is conducted during the design stage. It is usually done by testing the device by users in a simulated environment. This is an iterative process. Usability problems identified during each test are followed by an iteration in the design.

Perform summative evaluation of the usability of the user interface (clause 5.9)

Summative evaluation is done at the end of the design process. Similar to formative evaluation, this is also done by testing the device by users who represent relevant characteristics of the intended users. Testing is done either in a lab under simulated setting or in an actual clinical setting. At this stage the user manual is validated with its intended users.

No improvement necessary

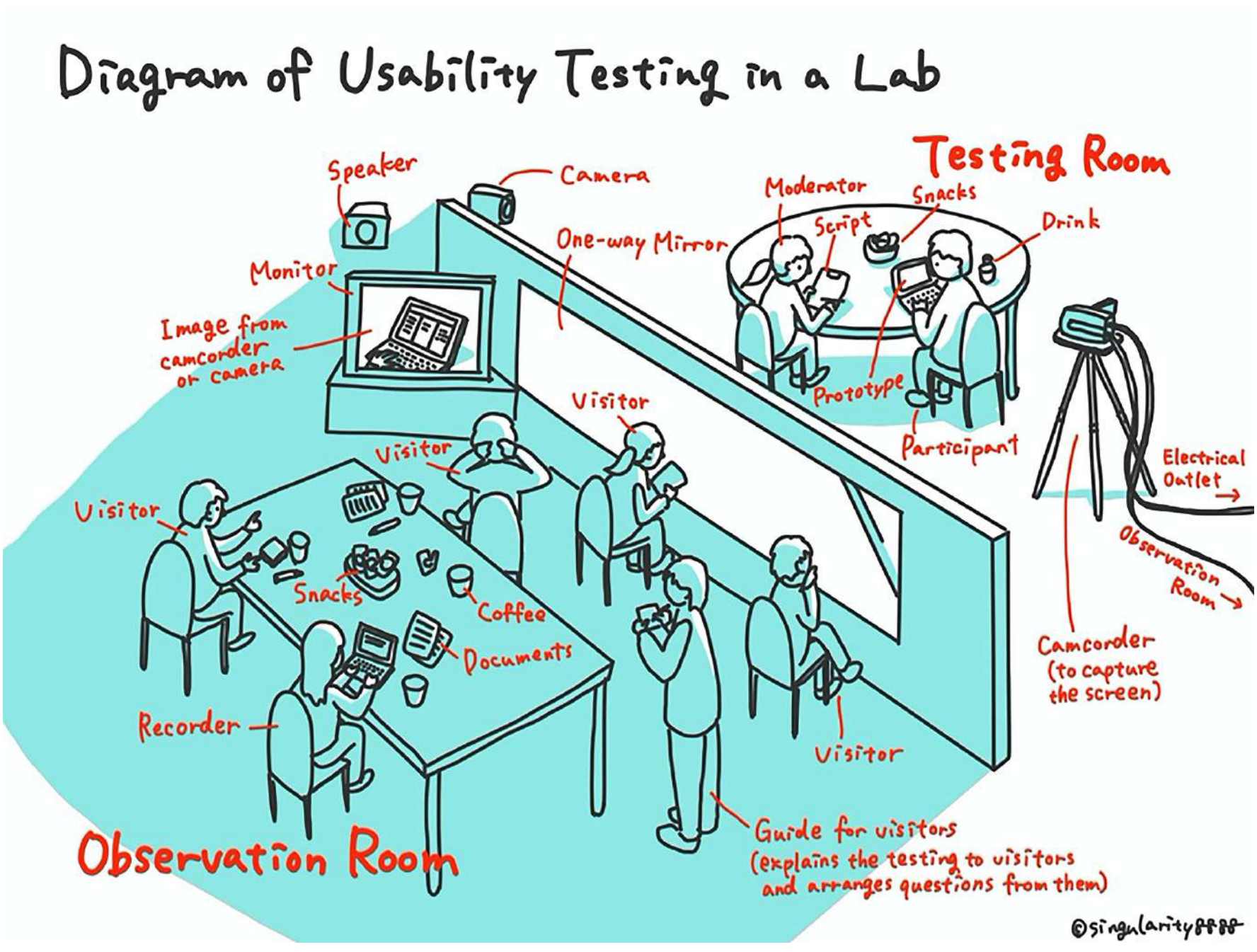
Evaluate residual risks (clause 6.4)

Legacy User Interface or User Interface of Unknown provenance (UOUP)

An annex has been added to the IEC 62366-1:2015 (Annex C) to address requirements of medical devices with User Interface of Unknown Provenance (UOUP) such as the interface of a previously designed medical device for which records of the user interface process are not available.

However since EN 62366-1:2015 considers usability engineering as part of the product development process, it should be noted that if the user interface or part of the user interface were not developed using the processes of this standard, they are considered as unknown provenance with respect to these processes. Requirements of Annex K (EN 62366/A1: 2015) and Annex C (EN 62366-1:2015) replace the requirements of clauses 5.1 to 5.9 to evaluate the UOUP mainly focusing on:

- Documentation of use specifications and main service functions
- Post-production information Review
- Risk management file review
- Review of accompanying documents



Conclusion

The usability engineering process is not a stand-alone process, but must be integrated to the design and development process. It is recommended for a medical device development team to have available adequate usability engineering expertise in the form of a trained usability specialist.
Usability engineering is an iterative process and doesn't end with the design of the process. Information on use errors must be collected even during the post-marketing phase.

Alceon can help you with your usability testing requirements. We collaborate with usability experts of a prestigious engineering institute and also have trained usability experts in-house.

US FDA REGULATIONS- A PRIMER

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In the USA, medical devices are regulated by the Food and Drug Administration (FDA) with an aim to ensure safety and effectiveness of the devices. The Center for Devices and Radiological Health (CDRH) is an FDA component and looks after this program.

There are various regulation applicable for the medical device as follows:

- Establishment Registration & Medical Device Listing – 21 CFR Part 807
- Premarket Notification 510(k) – 21 CFR Part 807 Subpart E
- Premarket Approval (PMA) – 21 CFR Part 814
- Quality System (QS) regulation 21 CFR Part 820
- Labeling requirements – 21 CFR Part 801
- Medical Device Reporting (MDR) – 21 CFR Part 803

Approval Process

The main steps to get a medical device approved and marketed in the USA are as follows:

Classification

Medical devices are classified in 3 classes based on the risk:

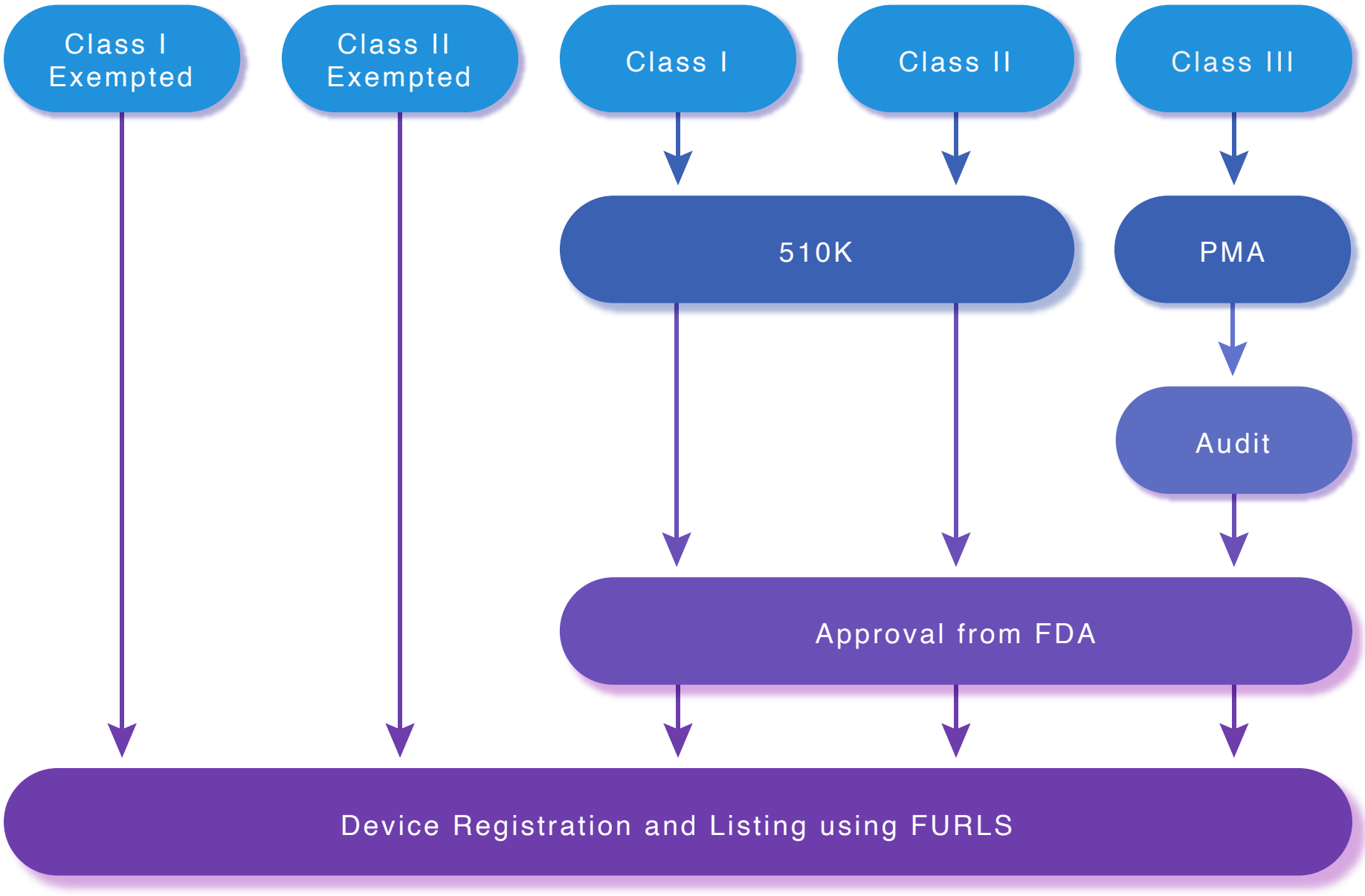
- Class I
- Class II
- Class III

Class I devices are generally categorised as low-risk devices, and many are exempted from the regulatory process.

Class II devices require remarkable controls for “labelling, guidance, tracking, plan, performance standards, and post-market observation”, and most require premarket notification 510(k) approval.

Class III devices generally continue or support life, are implanted, or present a remarkable risk of illness or injury. The majority of class III devices need premarket approval (PMA), which investigate a variety of factors in weighing the potential health benefits from the intentional use of a device versus the possible risks.

The easy understanding for this is depicted in the flow below:



Timelines & Review Process

Pre-market notification 510(k):

- Within 7 calendar days after a 510(k) application is received by the FDA, Document Control Center (DCC) emails an Acknowledgment Letter to the contact person identified in the 510(k) submission.
- The acceptance review is initiated and within 15 days of the receipt of the submission, the submitter will receive an electronic notification of the Acceptance Review result.
- Once accepted, a 510(k) proceeds to the Substantive Review.
- The Lead Reviewer has 60 calendar days for substantive review. This review does not mean clearance. During the process, the reviewer may request for additional information (AI) at which time the “clock” is stopped and after that continued upon the FDA’s receipt of the solution to their inquiries.
- The submitter has 180 calendar days from the date of the AI Request to submit a complete response.
- If a product is cleared, within 90 calendar days the FDA will mail a decision letter with an assigned 510(k) number to the submitter.

Pre-market approval PMA:

- Within 45 days after a PMA is received by FDA, the agency notifies the applicant whether the application has been filed via a letter. The letter will include the PMA reference number and the date FDA filed the PMA. The date of filing is the date that a PMA accepted for filing was received by the agency.
- FDA will begin substantive review of the PMA after it is accepted for filing. The 180-day period for review of a PMA starts on the date of filing. During the review process, FDA will notify the PMA applicant via major/minor deficiency letters of any information needed by FDA to complete the review of the application.
- The applicant may request a meeting (100-Day Meeting) to discuss the review status of the application.
- An FDA manufacturing facility inspection may be conducted for all original PMAs.
- Within 180 days of the date of filing of the PMA, FDA will complete its review of the PMA and issue an approval order, if the application substantially meets the requirements of the FD&C Act.

Application Fee:

Application Fee	Standard Fee	Small Business Fee
510(k)	$11,594	$2,899
PMA	$340,995	$85,249

We will be discussing the FDA Quality Management System requirements, generally known as 21CFR820 in one of our future issues.

Alceon can provide support to handle your 510(K) submissions. We have worked in several projects where we had done a gap analysis, prepared the documents and responded to FDA queries, all in record time.

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