IEC 62366-1 Essentials:

Elevating User Safety in Medical Devices

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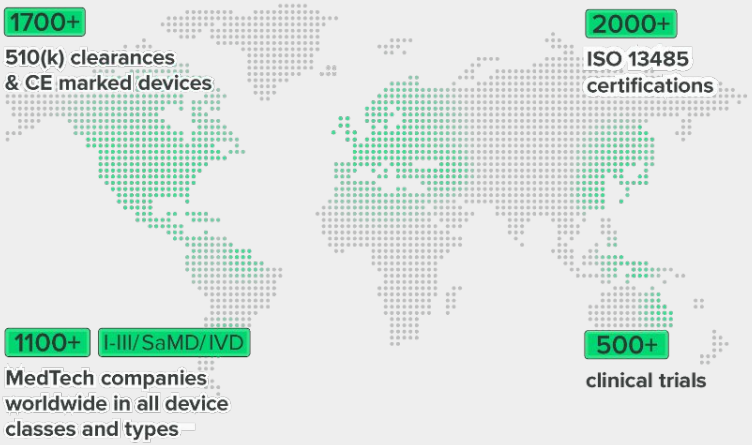

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IEC 62366-1 Essentials:

Elevating User Safety in Medical Devices

About CLEIO

Together, we design medical devices that shape our future

- → Innovation Strategy
- → Human Factors Research & UX
- → Medical Device Design & Engineering
- → Connected Devices (IoMT) & Cloud Platforms
- → Regulatory Compliance & Quality Assurance
- → Software as a Medical Device (SaMD)

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

Visit our new website experience on **cleio.com**

Session Agenda

- Let’s introduce ourselves!
- How Quality Assurance and Human Factors work hand in hand
  Regulatory framework | Overview of the IEC 62366-1 standard | Development | Risk
- Design and Human factors can’t be dissociated
  Use error | Formative evaluation | Iteration
- Conclusion and questions

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Section 1

Let’s introduce ourselves!

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Jean-Yves Pairet

Quality Assurance Director at CLEIO

I work in the Medical Device industry since my beginnings in 2009, supporting Quality Management Systems and Medical Device development projects. My background is in Mechanics and Risk Management. I am thrilled to improve the quality of life of patients through the development of innovative and safe Medical Devices.

Maude Leclerc-De Guire

Senior Human Factors Specialist at CLEIO

I'm a Human Factors specialist at CLEIO. My background is in Industrial Design. I love waking up every morning knowing that my work is helping people feel safe when using medical devices, and it allows me to combine two of my passions, design and human factors.

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Question #1

What Makes a Quality Medical Device?

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What Makes a Quality Medical Device?

- Clinical Effectiveness
- Performance

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What Makes a Quality Medical Device?

- Clinical Effectiveness
- Performance
- Safety & Security
- Regulatory Compliance

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What Makes a Quality Medical Device?

- Clinical Effectiveness
- Performance
- Safety & Security
- Regulatory Compliance
- Reliability
- Manufacturing Quality

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What Makes a Quality Medical Device?

- Clinical Effectiveness
- Performance
- Safety & Security
- Regulatory Compliance
- Reliability
- Manufacturing Quality
- **User Experience**
- **User Satisfaction**

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Section 1

What is Human Factors (HF)?

Definition

*The extent to which a product can be used by **specific users** to achieve **specific objectives**, effectively, efficiently and satisfactorily under **real-life conditions**.*

Human Factors standard Practice Document, February 28th, 2020

Division of Human Factors,
U.S. Consumer Product Safety,
Commission, Rockville, MD USA

Risk Assessment Division,
Consumer Product Safety and
Hazardous Product Safety,
Health Canada, Ottawa (Ontario)
Canada

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Section 2

How Quality Assurance and Human Factors Work Hand in Hand

Their **interrelation within the Development and Risk Management** processes

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The Regulatory Framework

- Rise of **new technologies**
- Integration of **Artificial Intelligence**
- More **complex user interfaces**
- Changes and emergence of **new use environment**
- Evolving **user considerations**
- New and **increasing risk related to Usability**:

“Medical Devices May Pose Usability Challenges for Home Users, Risking Misuse and Patient Harm”

ECRI’s Top 10 Health Technology Hazards for 2024

Applicable Standards

Design and Development Activites & Design Controls

ISO 13485:2016
Medical Devices -
Quality Management Systems -
Requirements for regulatory purposes

US FDA 21 CFR 820
Quality System Regulation
Section 30 Design controls

Risk Management

ISO 14971:2019
Medical Devices -
Application of Risk Management to Medical Devices

ISO/TR 24971:2019
Medical Devices -
Guidance on the Application of ISO 14971

IEC 60812:2018
Procedure for FMEA

Mechanical and Electrical

IEC 60601 (Series)
Medical electrical equipment –
General requirements for basic safety and essential performance

Other Specific Safety Standards

Usability

IEC 62366-1
Medical devices – Part 1: Application of Usability Eng. to Medical Devices

IEC/TR 62366-2
Guidance on the Application of Usability Eng. to Medical Devices

AAMI HE75
Human Factors Engineering Design Of Medical Devices

Applying Human Factors and Usability Engineering to Medical Devices

Content of Human Factors Information in Medical Device Marketing Submissions

Software

IEC 62304
Medical device software – SW life cycle processes

IEC/TR 80002-1
Guidance on the Application of ISO 14971 to Medical Device Software

Content of Premarket Submissions for Device Software Functions

Off-The-Shelf Software Use in Medical Devic

AAMI TIR45
Guidance on the use of AGILE practices in the development of medical device software

Cybersecurity

IEC 81001-5-1
Health SW: Security - Activities in the PLC

IEC/TR 60601-4-5
Safety-related Technical Security Specifications

UL 2900-2-1
SW Cybersecurity for Healthcare and Wellness Systems

Content of Premarket Submissions for Mgt. of Cybersecurity in Medical Devices

Postmarket Management of Cybersecurity in Medical Devices

Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Softw

Principles and Practices for Medical Device Cybersecurity

Biocompatibility

ISO 10993-1
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Use of International Standard ISO 10993-1

Performance

FDA Class II Special Controls Documents

Other Specific Performance Standards

Health Software, SaMD, MDDS, AI/ML

IEC 82304-1:2016
Health Software - Part 1: General Requirements for Product Safety

ANSI/AAMI SW91
Classification of defects in health software

Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML) - Enabled Device Softw

Home Healthcare Environment

IEC 60601-1-11
Requirements for MEE & MES used in the home healthcare environment

Design Considerations for Devices Intended for Home Use

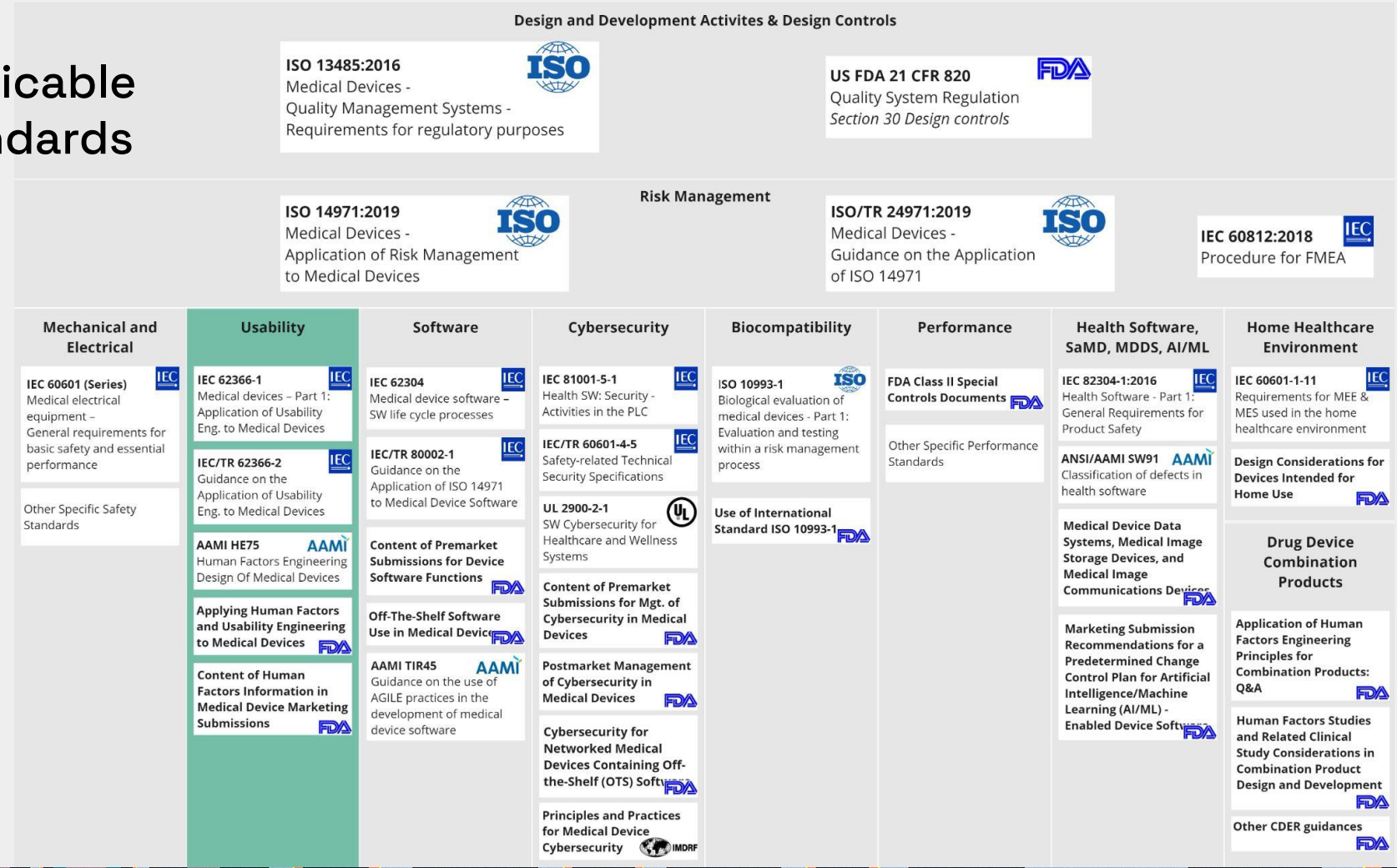
Drug Device Combination Products

Application of Human Factors Engineering Principles for Combination Products: Q&A

Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development

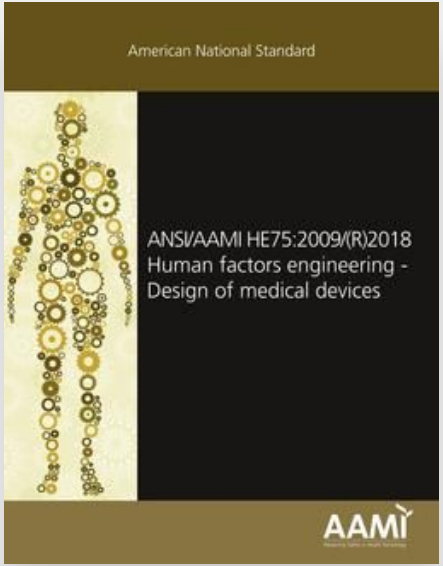
Other CDER guidances

Applicable Standards



Overview of Human Factors Standards & Guidelines

Medical Device



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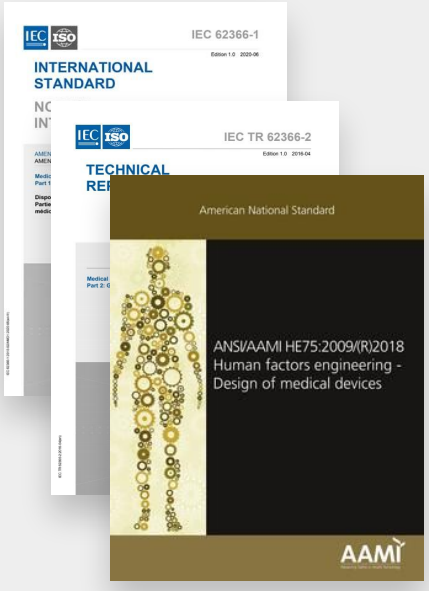
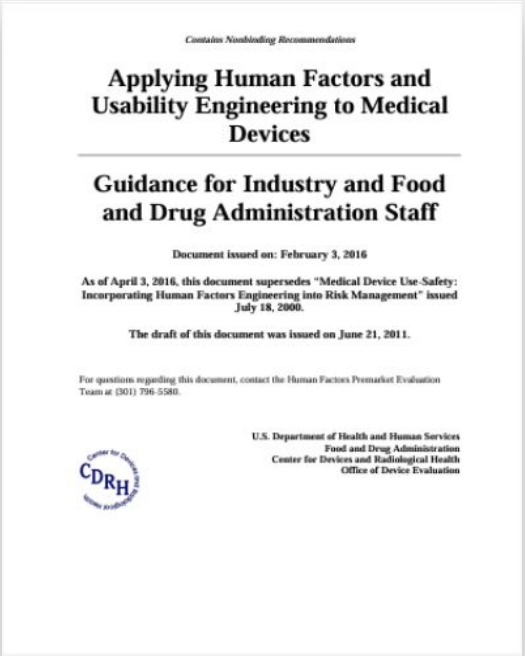
Overview of Human Factors Standards & Guidelines

Medical Device





Contains Nonbinding Recommendations

Applying Human Factors and Usability Engineering to Medical Devices

Guidance for Industry and Food and Drug Administration Staff

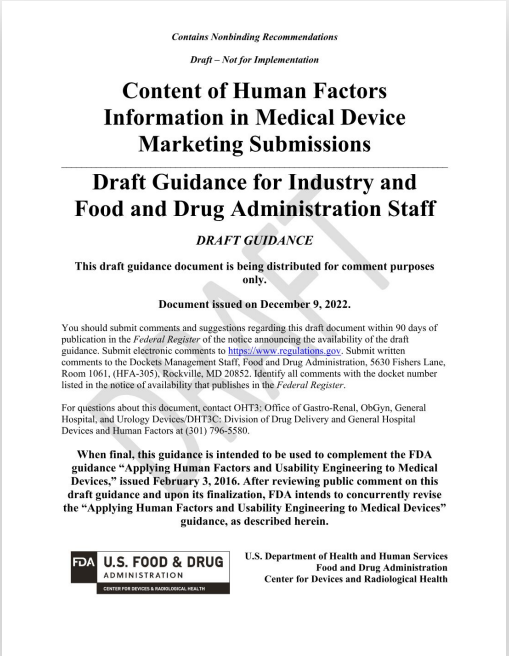
Document issued on: February 3, 2016

As of April 3, 2016, this document supersedes "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" issued July 18, 2000.

The draft of this document was issued on June 21, 2011.

For questions regarding this document, contact the Human Factors Premarket Evaluation Team at (301) 796-5580.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation



Contains Nonbinding Recommendations

Draft – Not for Implementation

Content of Human Factors Information in Medical Device Marketing Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on December 9, 2022.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact OHT3: Office of Gastro-Renal, ObGyn, General Hospital, and Urology Devices/DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors at (301) 796-5580.

When final, this guidance is intended to be used to complement the FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices," issued February 3, 2016. After reviewing public comment on this draft guidance and upon its finalization, FDA intends to concurrently revise the "Applying Human Factors and Usability Engineering to Medical Devices" guidance, as described herein.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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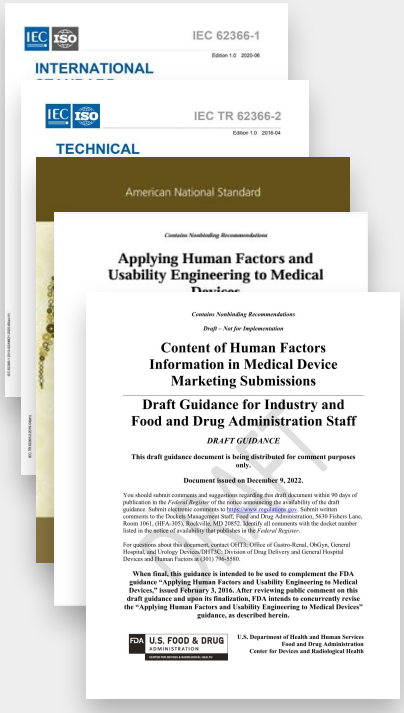
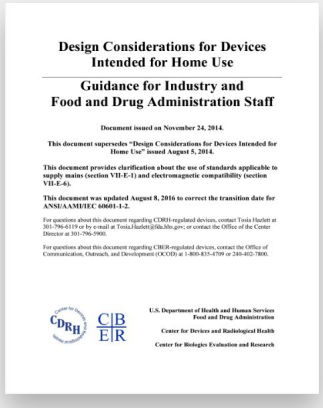
Overview of Human Factors Standards & Guidelines

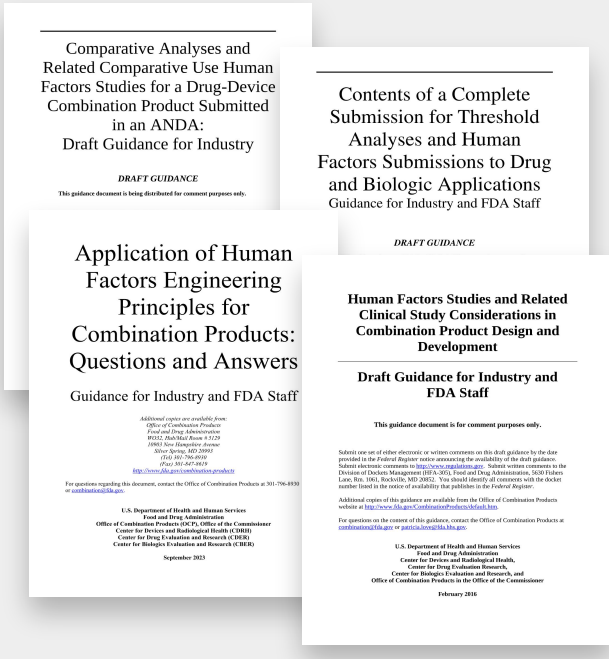
Medical Device



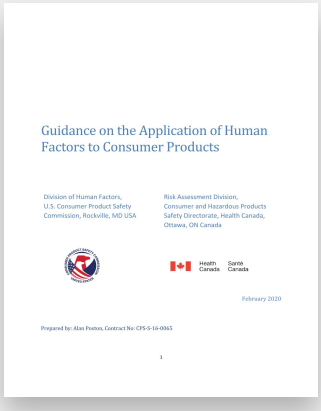
Home Use



Drug Device Combination Products



Consumer Products



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Question #2

When Should Human Factors Be Involved in the Product Lifecycle?

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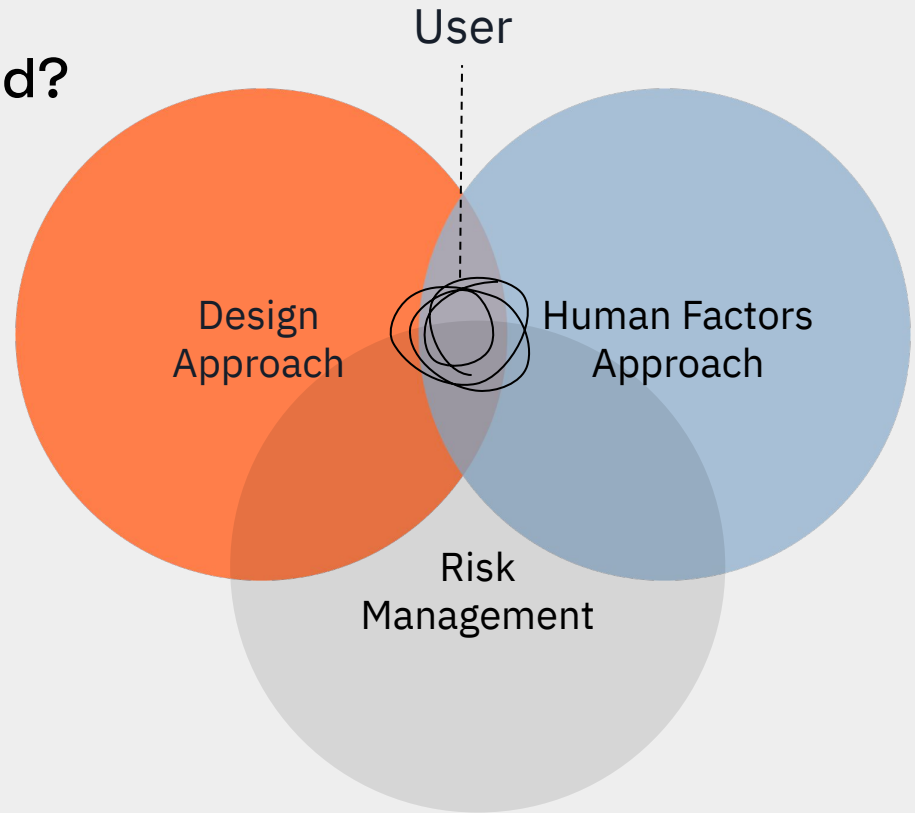
From the Very Beginning!

Why Human Factors and Design can't be dissociated?



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A Bird's-Eye View of Human Factors in the Development Process

1

Identify

Users and beneficiaries
Use environment
User interfaces
Known issues
Critical tasks

2

Research & Design

Define research questions
Conduct formative evaluations
Identify use-related errors
Iterate and improve

3

Validation testing

Complete report
Protocol
Critical tasks
Scenarios
Datas

Update Use-related risk analysis throughout the design process

https://medicaldeviceacademy.com/usability-procedure/

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Overview of Human Factors in the Development Process

Deliverable:

→ Usability plan

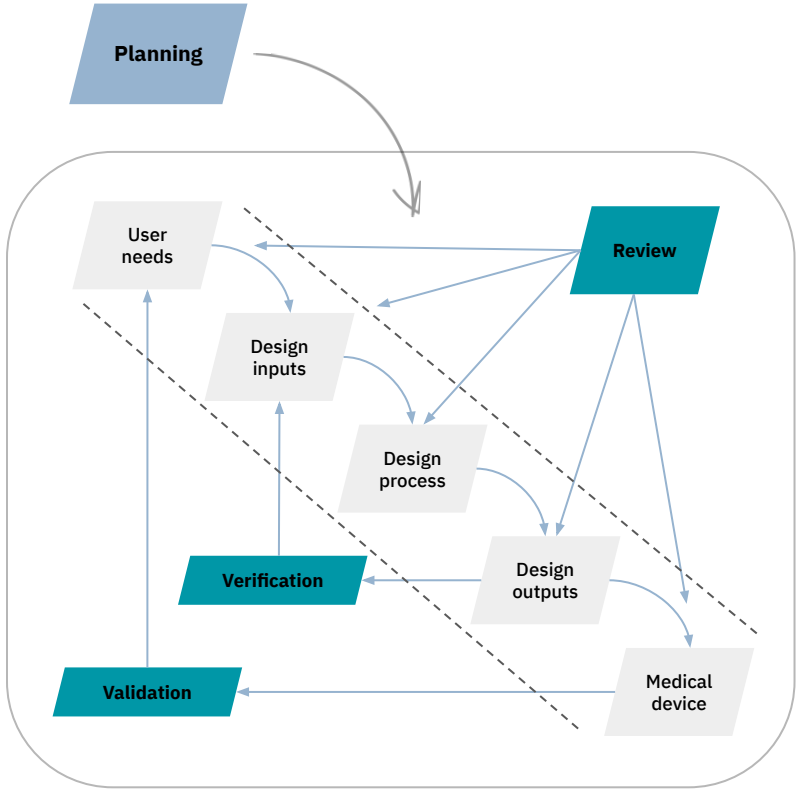
Activities:

→ Define the main HF activities
- → Use Specifications
- → Use-Related Risk Analysis
- → User Interface Specifications
- → Formative evaluations
- → Summative evaluations

→ Define Roles & Responsibilities (HF, UX/UI, Industrial Design)

Top Tips

Define your regulatory strategy early to have more accurate planning.



Development Process

The User Needs

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User Needs in the Development Process

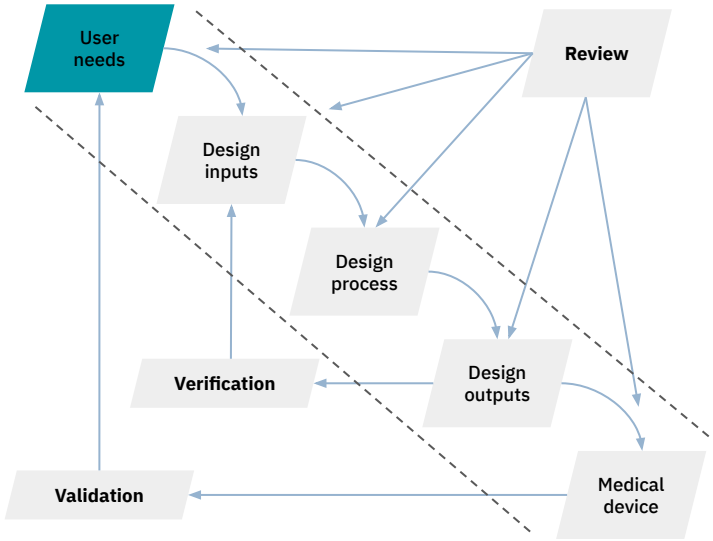
Deliverables:

→ Use Specifications & Intended Use

Activities:

→ Define User Profiles / Use Environment / Patient populations

→ Market & User Research
(Field Observation and SME Interviews)



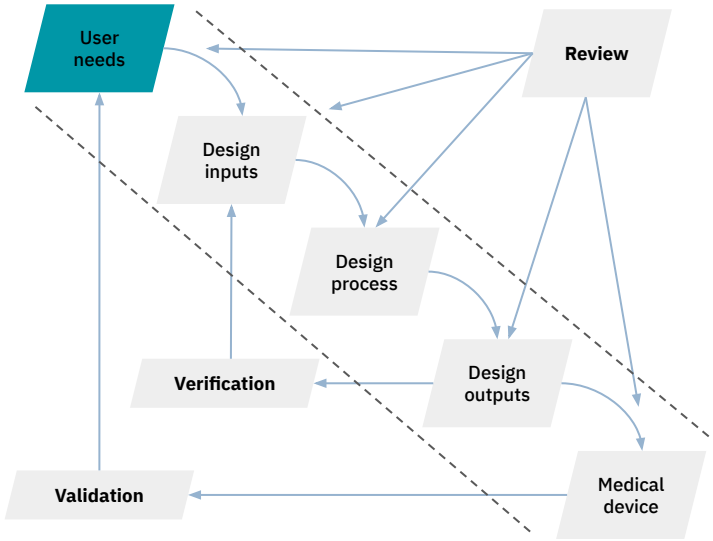
User Needs in the Development Process

Deliverables:

- Use Specifications & Intended Use
- Summary of known problems

Activities:

- Define User Profiles / Use Environment / Patient populations
- Market & User Research
  (Field Observation and SME Interviews)
- Identify known & foreseeable Use hazards



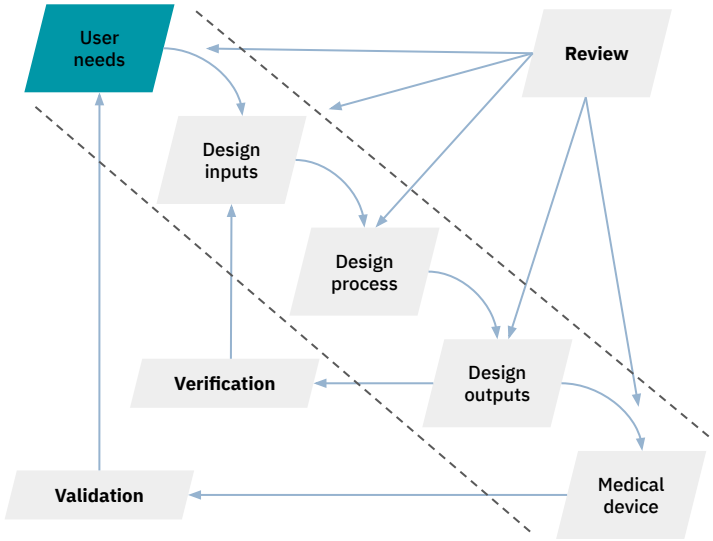
User Needs in the Development Process

Deliverables:

- Use Specifications & Intended Use
- Summary of known problems
- User Needs

Activities:

- Define User Profiles / Use Environment / Patient populations
- Market & User Research
  (Field Observation and SME Interviews)
- Identify known & foreseeable Use hazards
- Participate in User Needs Definition



User Needs in the Development Process

Top Tips

- **Share the Use Specifications with all stakeholders**. It will help them to have a good understanding of the product.
- **Bonify the Use specifications by conducting different kind of user research activities** (Interviews, Field Observations & Shadowing, Surveys).

Pitfalls

- **Do not start to define these specifications too late in the process** since the Use specifications have a key role in the product definition.
- **As a manufacturer, you cannot define alone the user needs**. The needs shall come from the users themselves.

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Development Process

The Design Inputs

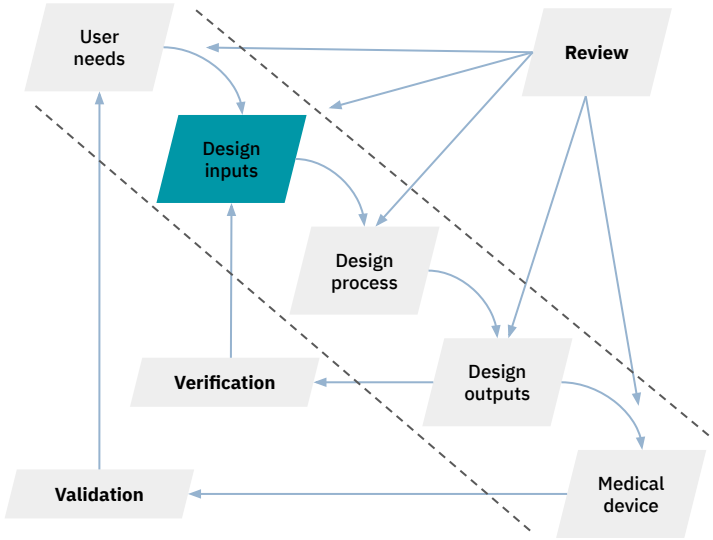
Design Inputs in the Development Process

Activities:

- Translate User Needs into Design Inputs (user interface)
- Task Analysis
- Analyze the Use-Related Hazards

Deliverables:

- Use Related Design Inputs
- User Interface Specifications
- Use-Related Risk Analysis (URRA)



Design Inputs in the Development Process

Top Tips

- **A Task analysis is a great way to identify the user interface characteristics related to safety**, as well as Annex A of ISO/TR 24971 (A.2.31).
- **Do not hesitate to involve designers or engineers in this activity.** It is valuable for them to have a clear understanding of the task analysis and the potential risks derived from it.

Pitfalls

- **During your Task analysis, try to maintain a reasonable level of detail.** Do not fall into the trap of over-branching your tasks.
- **Don't try to be creative here!** Known or foreseeable hazards should come from analytical and factual sources: Use specifications, adverse events from similar devices and use errors.

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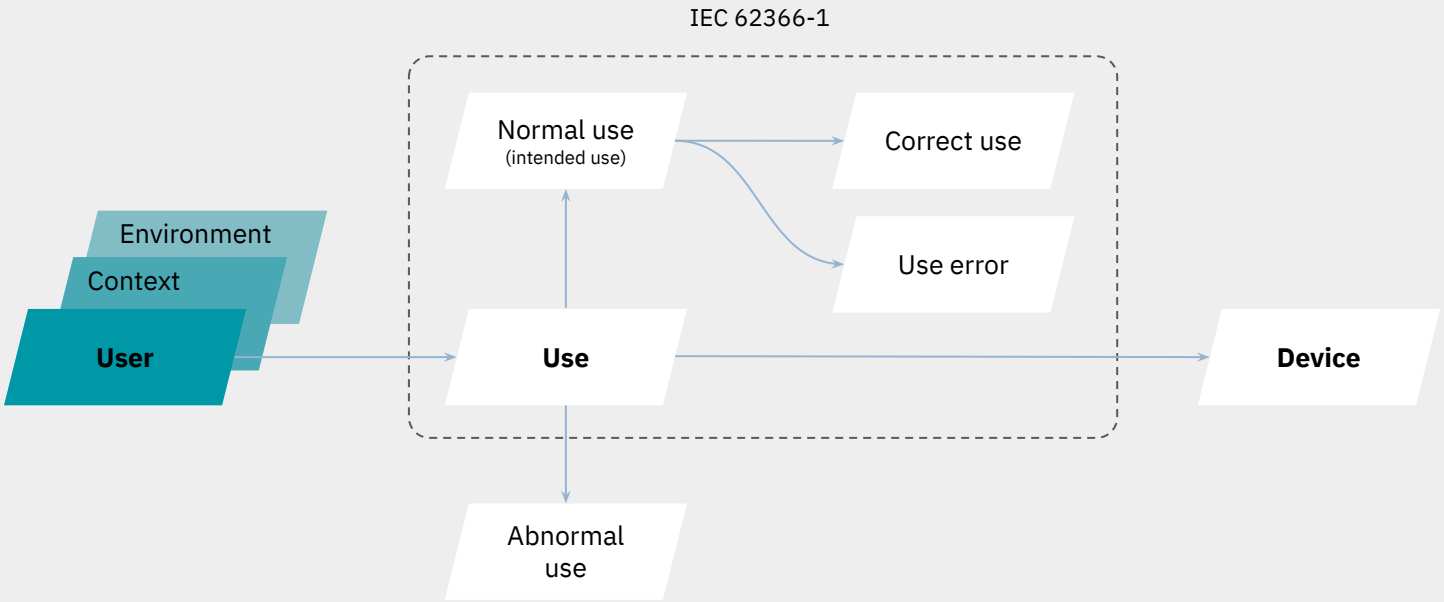
Meticulous Attention to Risks that Arise During Use



Medical devices - Part 1: Application of Usability Engineering to Medical Devices (IEC 62366-1:2015 + IEC 62366-1:2015/AI;2020)

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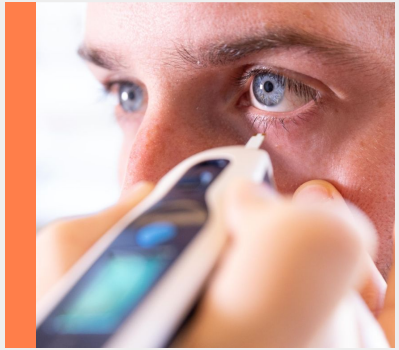
Definition

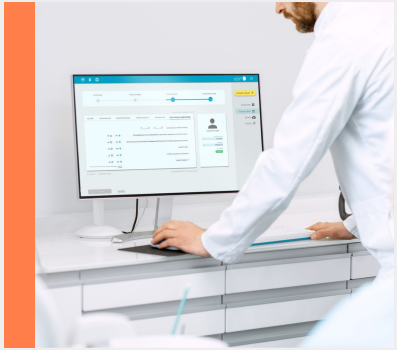
What is a Use Error?

*It is an **incorrect or omitted action** by the user that results in a different outcome than the **manufacturer's intent** or the **user's expectation**.*

The types of Use Errors



Perception
Difficulty to see visual information or hear auditory information.



Cognition
Failure to remember, incorrect application of a rule, or error due to lack of knowledge (improvisation or misinterpretation).

Action (Manipulation)
Inability to reach a command, contact with the wrong element, inappropriate force applied, failure to activate a monitor.

Development Process

The Design Process

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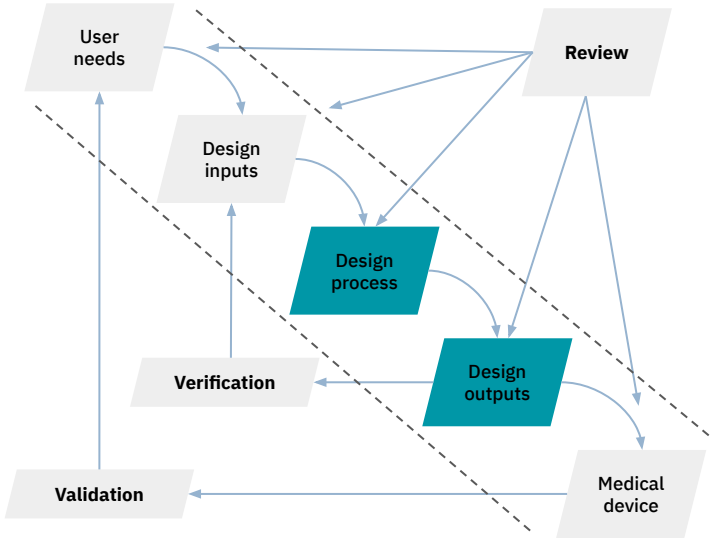
Design process in the Development

Activities:

- Design the user interface
- Iterative & collaborative process
  - Perform formative evaluations
  - Generate concepts and prototypes

Deliverables:

- Formative evaluation protocols and reports
- Refined Design Inputs
- User Interface Specifications (incl. labeling and IFU)
- Updated URRA (Use-Related Risk Analysis)

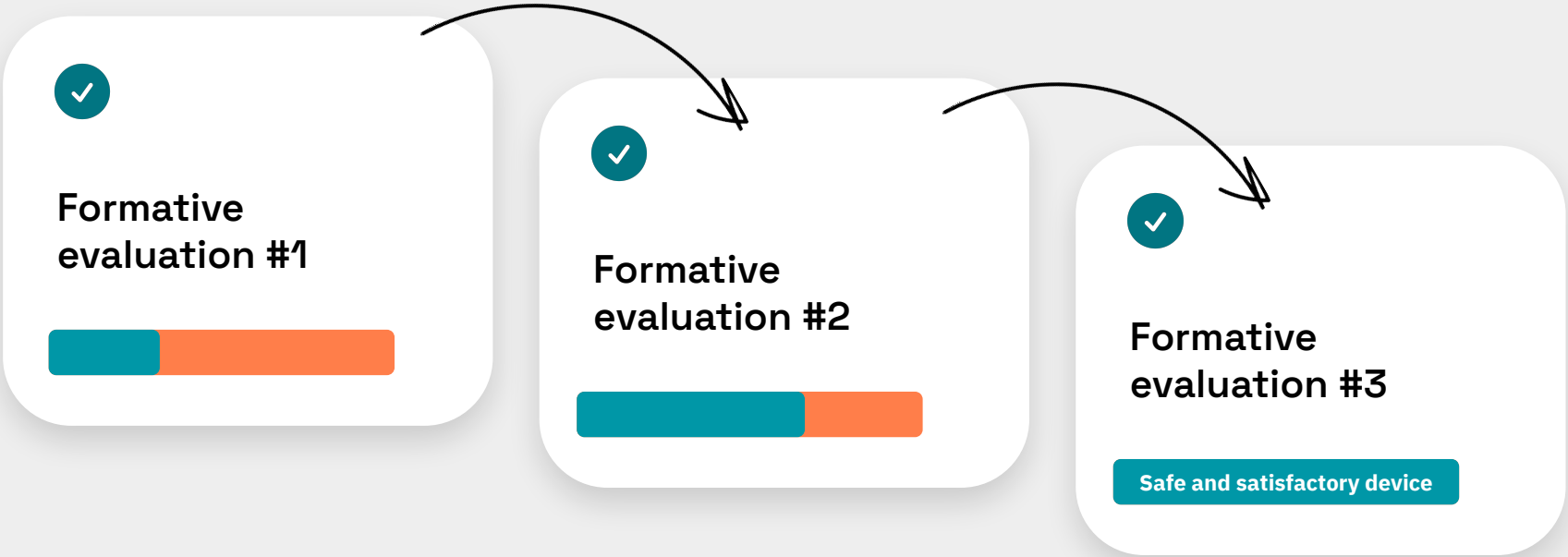


Definition

What is a Formative Evaluation?

The aim of a formative evaluation is to ***iteratively improve a product's user interface****.*

Reducing Use Risks with Formative Evaluations



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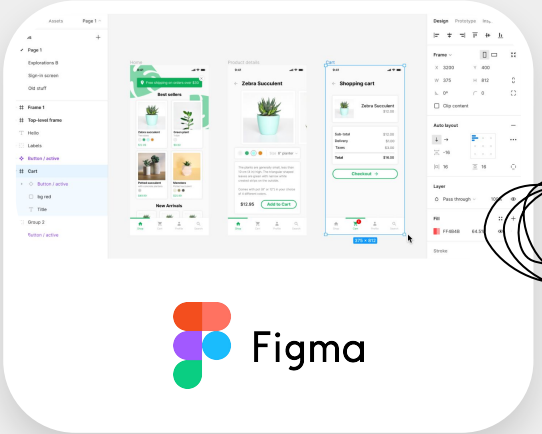
Collaborative Tools in the Development Process

User interface specifications



Figma

miro

https://help.figma.com/hc/en-us/articles/360041064814-Explore-the-canvas

https://miro.com/about/

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Behind the Scenes

Example of a Real Formative Evaluation

of an Innovative Console for
Calcified Artery Disease Treatment

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Design/Formative Evaluations

Final Result

Discover the Full Case Study on

cleio.com

The 3 Golden Rules of Formative Evaluations

1

One formative evaluation is not enough, iterate!

2

Include **people with a user centered approach** during test

3

Even if use risk identification is crucial, **take a broader approach by testing the user experience as a whole**

Top Tips

Sweet spot sample size: approximately 5-8 participants per evaluation.

HE75:2009 (R2018) Human Factors Engineering - Design Of Medical Devices

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Development Process

Verification

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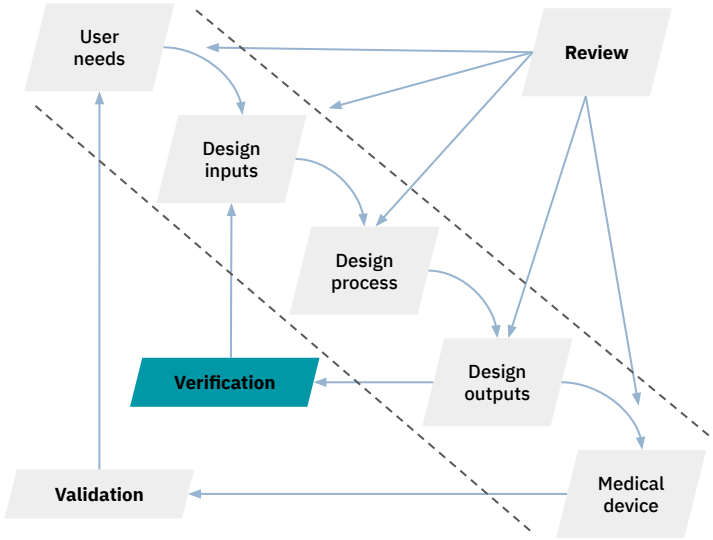
Verification in the Development Process

Activities:

- Verify User Interface and Use-related DI & Risk controls
- Verification test cases based on Use Scenarios
- Methods: Expert review, cognitive walkthrough and inquiries

Deliverables:

- Usability test protocols & reports



Verification in the Development Process

Top Tips

→ **Think about verification early in the development process.** Establish Design Inputs to ease their verification.

Pitfalls

→ **Formative evaluations are not used for verification** but way earlier in the development process.

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Development Process

Validation

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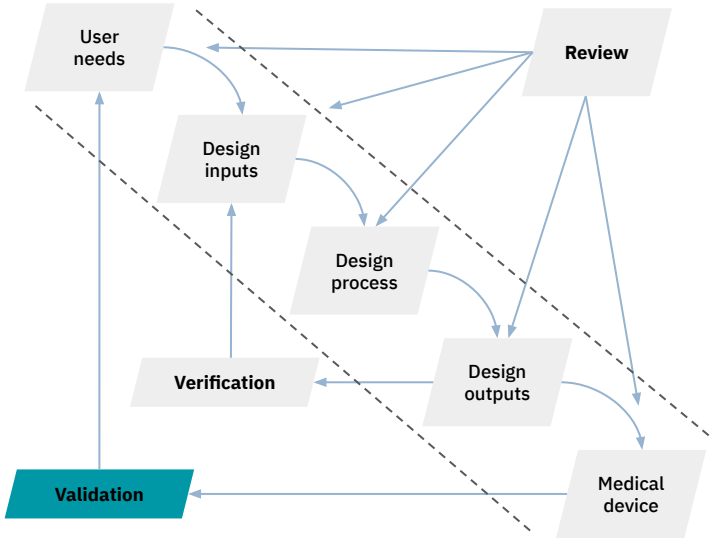
Validation in the Development Process

Activities:

- Summative evaluation
- Define critical tasks and select use scenarios
- Establish training requirements

Deliverables:

- List of critical tasks (URRA)
- Summative evaluation plan and report



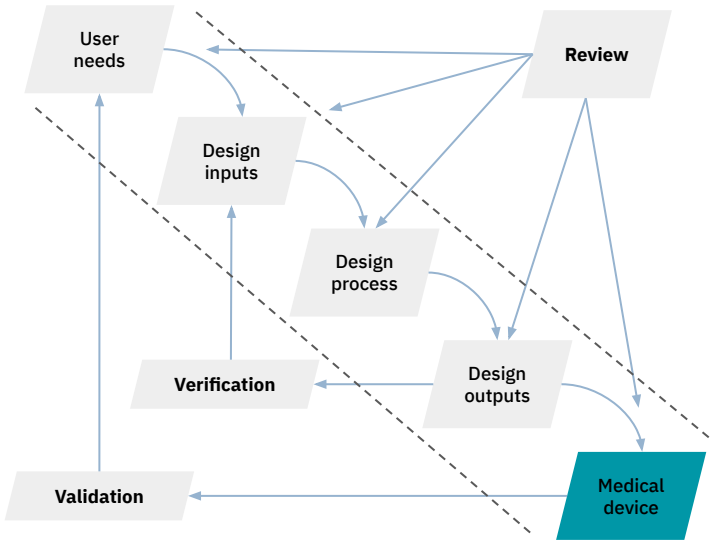
Summative Evaluation Guidelines

- Focus your attention on the **critical tasks**
- If possible, carry out the test in the **actual use environment**
- Sample size: a minimum of **15 users per user group**
- If training is part of the protocol, include a **waiting period between the training session and the summative evaluation** to allow for representative learning decay

Medical Device in the Development Process

Deliverables:

- Use specifications
- URRA & Critical tasks
- User interface specifications
- User interface evaluation plan
- Formative evaluation report(s)
- HF validation report
- HFE report
- IFU & Training



Top Tips

Involve Human Factors in design reviews to bring the user perspective and maintain a user-centered approach.

Why is Usability Important?

*A medical product that is safe to use is important... but, a product that is **safe and pleasant** to use is even more important!*

Definition

*"Characteristics of the user interface that facilitates use and thereby establishes **effectiveness**, **efficiency** and **user satisfaction** in the intended use environment."*

Top Tips

All aspects of usability can either increase or decrease safety.

Medical devices - Part 1: Application of Usability Engineering to Medical Devices (IEC 62366-1:2015 + IEC 62366-1:2015/AI;2020)

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Conclusion

- Human Factors brings value to risk controls by **reducing** use-related errors
- Incorporating Human Factors **early in the design** of medical devices is crucial for achieving inherent safety by design
- The benefits are above and beyond **user safety**

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Additional Benefits of Human Factors

- Better **Cost & Time Management**
- **Easier, Faster & Safer Onboarding**
- Reduced Needs for **Technical Support**
- Higher **Utilization Rates**
- Increased **Sales & Revenues**
- Stronger **Regulatory Records**


Achieving Together.
cleio.com

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10 things you need to know about IEC 62366-1

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Questions & Comments?

ISO 13485 Quality Management for Medical Devices CERTIFIED

TOP 5 greenlight guru TOP 5 Medical Device Product Design Companies

Learn more about CLEIO

CLEIO combines **strategy, design, engineering, and quality assurance** to deliver exceptional results with an **ISO 13485-certified** approach to medical device development.

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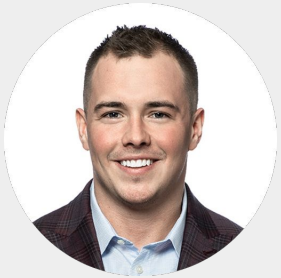

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