NDA No.: 32591325659
Usarea is partnered with a Qualiopi-certified organisation

TRAINING CATALOGUE

Usability engineering training for medical devices

Design, evaluate and document safe use in accordance with IEC 62366-1, IEC 62366-2 and IEC 60601-1-6.

IEC 62366-1 | IEC 62366-2 | IEC 60601-1-6

1 day	The fundamentals of usability engineering	03
2 days	Mastering the usability engineering process	04
Half day	Workshop: preparing your summative evaluation	05

Training available in English and French

Usarea

Introduction

Usability engineering aims to identify and reduce use-related risks. It is an essential step for the safety of your medical device (MD) and a requirement for CE marking under the MDR and IVDR.

Usarea supports medical device manufacturers in implementing pragmatic usability engineering processes that comply with European and US regulatory requirements.

The Usarea approach

- **Strong practical experience**
- **In-depth knowledge of applicable standards**
- **An approach centred on real-world use**

Your trainer



Amandine Broussier

Founder - Senior Usability Consultant

A usability specialist with over 10 years of experience, Amandine supports medical device manufacturers with their CE and FDA processes, from strategy through evaluation.

She regularly works on:

- ✓ Structuring usability engineering files
- ✓ Formative and summative evaluations
- ✓ CE / FDA usability strategies

A teaching approach focused on practice

01
Practical
Based on real cases and field situations

02
Progressive
Understanding → application → consolidation

03
Participatory
Exercises, practical scenarios, educational games

04
Actionable
Deliverables, methods and best practices you can apply

> **The goal is not just to understand the standard, but to know how to apply it in your real projects.**

Training available in English and French

TRAINING - 1 DAY

The fundamentals of usability engineering

A course covering regulatory requirements, key process steps and the methods to use, with a hands-on approach (examples, exercises and quizzes) that you can apply directly to your projects.

DURATION	FORMAT	PRICE	PARTICIPANTS
1 day 7 hours	**In-house** on site or remote	**€1,200** excl. VAT, per session	**Up to 10** per session

Tailored to your device: examples, exercises and case studies built around your own product

Objectives

- Understand the applicable regulatory requirements
- Identify the key steps of the usability engineering process
- Initiate and structure a usability engineering process within your projects

At the end of the course, you will be able to:

- Identify the requirements applicable to your device
- Structure a usability engineering process suited to your project
- Choose appropriate evaluation methods
- Integrate usability engineering into your development and market access strategy

Programme

1. **Regulatory context**
   MDR, IVDR: the role of usability engineering
2. **Principles of usability engineering**
   Definitions, benefits and relationship with risk management
3. **Process according to IEC 62366-1**
   Use specification, use-related risks, user interface specification
4. **Formative and summative evaluations**
   Evaluation plan, methods and objectives of each evaluation
5. **Best practices and mistakes to avoid**
   Lessons learned, points to watch and common pitfalls
6. **Documentation**
   Structure, traceability and required content
7. **Questions and answers**
   Discussion of your projects

TRAINING - 2 DAYS

Mastering the usability engineering process

An in-depth course to understand and apply the entire process in accordance with IEC 62366-1, through practical scenarios, exercises, case studies and a final wrap-up exercise.

DURATION	FORMAT	PRICE	PARTICIPANTS
2 days 14 hours	**In-house** on site or remote	**€2,200** excl. VAT, per session	**Up to 10** per session

Tailored to your device: examples, exercises and case studies built around your own product

Objectives

- Gain a comprehensive understanding of the usability engineering process according to IEC 62366-1
- Know how to apply methods and tools in a project context
- Scope and manage a usability engineering project

At the end of the course, you will be able to:

- Structure a usability engineering process suited to your project
- Plan and conduct evaluations
- Integrate usability engineering into your development and market access strategy
- Produce the required documentation (MDR, IVDR)

Programme

1. **Regulatory context**
   MDR, IVDR: the role of usability engineering
2. **Principles of usability engineering**
   Definitions, benefits and relationship with risk management
3. **Process according to IEC 62366-1**
   From use specification to user interface design
4. **Formative evaluations**
   Methods, evaluation plan and use of results
5. **Summative evaluation**
   Preparing, conducting, analysing and documenting
6. **Hands-on practice: exercises and case studies**
   Applying methods and tools to real cases, final wrap-up exercise
7. **Documentation**
   Structure, traceability and required content
8. **Questions and answers**
   Discussion of your projects and challenges

HANDS-ON WORKSHOP - HALF DAY

Preparing your summative evaluation

A practical workshop to understand the stages of a summative evaluation and how to carry them out. You work on users, critical tasks, scenarios, testing and analysis of results, using your own device.

DURATION	FORMAT	PRICE	PARTICIPANTS
Half day 4 hours	**In-house** on site or remote	**€750** excl. VAT, per session	**Up to 6** per session

Tailored to your device: examples, exercises and case studies built around your own product

Objectives

- Understand the purpose and objectives of a summative evaluation
- Know how to select users, tasks and scenarios
- Know how to organise and conduct the study under representative conditions
- Know how to analyse results and produce the required documentation

At the end of the workshop, you will be able to:

- Build representative scenarios and test conditions
- Conduct user testing
- Analyse the results
- Identify the key elements to document

Programme

1. **Purpose and objectives of a summative evaluation**
   Regulatory considerations
2. **Users and samples**
   Representative user profiles and sample size
3. **Tasks, scenarios and test conditions**
   Link to use-related risks, realistic scenarios
4. **Practical organisation and study conduct**
   Preparation, conduct, data, logistics
5. **Analysis of results**
   Observations, events, root causes
6. **Documentation and next steps**
   Evaluation report and inclusion in the file
7. **Hands-on practice**
   Work on your device and simulated testing

A specific need?

The courses in this catalogue cover the main needs in usability engineering. If your need does not exactly match one of them, get in touch to discuss it: the format and content can be adjusted to your team and your schedule.

The courses at a glance

	DURATION	PRICE	PARTICIPANTS	BEST FOR
The fundamentals	1 day	€1,200 excl. VAT	Up to 10	Understanding the process and getting started
Mastering the process	2 days	€2,200 excl. VAT	Up to 10	Running the whole process and its documentation
Summative workshop	Half day	€750 excl. VAT	Up to 6	Preparing the summative evaluation of your device

4.9/5 ★★★★★

Average participant satisfaction across my training courses

Let's discuss your project

A question, a specific need, or a training session you would like to organise? Let's talk about how I can support you.



Amandine Broussier
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