BS EN 62366 Usability Engineering for Medical Devices

Gain an understanding of usability engineering and how it should be applied to medical devices by attending this BS EN 62366 Usability Engineering training course.

The 1-day usability engineering workshop explores the usability engineering methodology detailed in BS EN 62366, from analysing and specifying the design, through identifying potential risks, to verifying and validating the user interface. The tutor will use a combination of teaching, interactive workshops and group discussions around the development of a real product to explore the application of usability engineering.

Delegates will learn how to expand their current risk management activities to ensuring the user interface of their medical devices is safe and effective, in line with the expectations of the EU and FDA in the US.

COURSE DURATION
1 day

CPD
Equivalent to 8 hours

COURSE PRICE
TBC

IN-COMPANY TRAINING
Check availability

CERTIFICATES
All delegates will receive a certificate on completion.

Course details >

Who should attend?

This course provides valuable information for those involved in the design and development of medical devices, including:

- R&D managers/engineers
- RA/QA managers/engineers
- management representatives
- members of multi-discipline design teams
- members of design review teams
- ergonomic designers
- usability engineers
- product, project, and programme managers
- Internal auditors

The course complements Bywater's range of courses applicable to the medical device industry.

Key topics

Topics covered on the course include:

- expectations of the FDA and the EU in applying usability analysis to medical devices
- applying the usability management standard BS EN 62366 to medical devices
- the relationship between ISO 14971 and the EU directive and the implications the changes represent
- usability and use errors and examples of risks associated with user interfaces
- the stages of the Usability Engineering Process
- application of usability analysis methodologies, such as FMEA, to medical devices
- principles of usability management planning in developing procedures and practices to analyse, evaluate and control usability
- sources of information and further development

Skills gained

By the end of this training course, delegates will be able to:

- apply the Usability Engineering Process in BS EN 62366 to medical devices and to conduct usability analysis to identify hazards and possible use errors
- understand how to prepare the documents for the key stages of the Usability Engineering Process: application specification, primary operating functions, characteristics relating to safety, hazard identification, usability specification, usability validation plan

A certificate of completion will be awarded to delegates who attend and fully participate in the course, which recognises their new understanding of the Usability Engineering Process.

Course agenda >

Course agenda

Our training courses are designed to optimise the learning experience for delegates both in face-to-face settings and in our Virtual Classroom.

Under the guidance of our expert tutors, attendees will follow an agenda which is briefly outlined below:

- Welcome and Introductions
- Module 1 Background and Changes to the new Medical Device Regulation
- Module 2 Description of the EN 62366 Standard
- Module 3 FDA Requirements
- Module 4 Use specification
- Module 5 Workshop 1: Using a real product – Defining the use specification
- Module 6 User Interface Characteristics
- Module 7 Workshop 2: Using a real product – Identify User Interface Characteristics
- Module 8 Identify known or foreseeable hazards and hazardous situations
- Module 9 Workshop 3: Using a real product – Identify known or foreseeable hazards and hazardous situations
- Module 10 User Interface Specification
- Module 11 Workshop 4: Using a real product – User Interface Specification
- Module 12 Establish User Interface Evaluation Plan
- Module 13 Workshop 5: Using a real product – Evaluation Planning
- Module 14 Perform User Interface design implementation and formative evaluation
- Module 15 Summative Evaluation
- Module 16 User Interface of Unknown Origin
- Summary and Course Evaluation

In-company training

Receive this course exclusively for your organisation, either in-person at your chosen venue or online in our user-friendly Virtual Classroom.

Enjoy cost-effective flexibility and personalised learning with tailored messaging designed to address your unique business challenges.
Contact us for a quote.

Reviews & Booking >

The tutor was excellent at breaking down and explaining a complex subject for all candidates to understand.

2gether Support Solutions

The content was excellent to now apply what I've learnt. I found the tutor to be very thorough and used practical tasks extremely well. I really enjoyed the team tasks and content.

Wardray Premise Limited

Our tutor was very knowledgeable and helpful. They had an incredible ability to break down complex topics into easy-to-understand concepts. Their patience and engaging teaching style made learning enjoyable.

Dartford And Gravesham NHS Trust

Read our Medical Devices course reviews

Why train with Bywater?

Bywater is the leading independent provider of professional management systems training in the UK.

Our expert training offers practical understanding of how to realise the benefits and assess the success of implementing and operating successful management systems.

Bywater delegates know they can rely on proven training delivered by experts at times and locations to suit their needs.

40 years established

100+ course titles

15 UK locations

1000+ courses annually

Global Virtual Classroom

CQI & IRCA, ISEP, RSS and IOSH approved training provider.

CHECK AVAILABILITY

Booking is easy

Simply select a course date and venue and fill in the online form. View our full range of courses at **www.bywater.co.uk**

If you have any questions please call us on 0333 123 9001, use our online chat or email **contact@bywater.co.uk**

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