SOFTWARE DEVELOPMENT FOR MEDICAL DEVICES

ACHIEVING BEST PRACTICE THROUGH IEC62304 TRAINING COURSE
SOFTWARE DEVELOPMENT FOR MEDICAL DEVICES

ACHIEVING BEST PRACTICE THROUGH IEC62304 | TRAINING COURSE

Unlike many other industries, developing software for medical devices is highly regulated, requiring manufacturers to understand risk management, controlled lifecycle management, validation and verification, configuration management and change control. The key, mandated software standard within the medical devices industry is IEC62304. However, many of IEC62304’s requirements are not defined prescriptively, leaving many medical device manufacturers with the challenge of how to best interpret the standard.

This training course will provide much needed clarification of IEC62304’s requirements and present a detailed examination of how they can be implemented by manufacturers looking to efficiently deliver safe, effective and secure medical devices whilst conforming to industry best practice. A step-by-step breakdown of IEC62304 will be accompanied by clear guidance on what each section means in practice, equipping attendees with the knowledge and confidence to apply their learnings within the industry.

The course will also provide a supplementary overview of the application of risk management to software development, as defined in ISO14971. Other topics will also include an exploration of the legal approval process required for the sale of medical devices, setting out the role that regulators and other organisations play, and examining the importance of obtaining approval for software embedded within medical devices.

The course is ideal for software developers, systems engineers and managers involved in the development of software for medical devices. The course will also be suitable for QA and RA professionals who are new to the area of software development for medical devices.

TWO-DAY COURSE CONTENT

Introduction:
- The legal process for the sale of medical devices and the importance of software approval
- The role of regulators, standards and other organisations

Software Lifecycle Processes:
- General requirements: Quality management systems, risk management and safety classification
- Software Development Process: Development planning, requirements analysis, architectural design, detailed design, implementation and verification, integration and integration testing, system testing and release
- Software Maintenance Process: Maintenance plans, problem & modification analysis, implementation
- Software Risk Management: Risk analysis, risk control, verification of risk control measures, change management
- Software Configuration Management
- Problem Resolution: Coding Standards, sub-setting in programming languages, MISRA C/C++

ATTENDEE COMMENTS

“I wanted to better understand IEC 62304 and how it dovetails into ISO 13485 and ISO 14971. The course was very helpful in achieving that objective.”

“Thoroughly enjoyed the course and found it really very useful indeed.”

WANT TO KNOW MORE?

For further information, email us at training@criticalsoftware.co.uk

CRITICAL SOFTWARE AROUND THE WORLD:

FOR MORE INFORMATION:
info@criticalsoftware.co.uk
www.criticalsoftware.co.uk