MEDDEV SOLUTIONS
A Trinzo Company

Connected Health Skillnet

SOFTWARE AS A MEDICAL DEVICE (SaMD)

INDUSTRY-LEADING TRAINING SOLUTIONS

FOR THE MEDICAL DEVICE AND PHARMACEUTICAL INDUSTRY

About **This Course**

22 Hour Course

Our Industry leading experts have created a 22-hour course to help you understand the requirements of IEC 62304 and the importance for medical device manufacturers.

This course explores the IEC 62304 standard clause by clause to ensure a thorough understanding of the requirements. During this course, you will be provided with an understanding of how IEC 62304 aligns with Design Control and Risk Management towards meeting the new European MDR and IVDR and the US requirements of FDA 21 CFR 820, QMSR.

LEARNING OBJECTIVES

- Understand the purpose and structure of IEC 62304
- Understand the key terms and definitions used through IEC 62304 (incl. SaMD, Software as a component or accessory, embedded software)
- Describe and understand all elements of IEC 62304 and the deliverables required based on Software Risk Classification
- Understand the interconnection between Software Development, Design Control and Risk Management and Human Factors/Usability Engineering
- Explain with working examples the key deliverables required from IEC 62304
- Understand when IEC 60601 is required
- Identify Label Requirements for Software including UDI

WHO WILL BENEFIT FROM ATTENDING?

- Software Engineers
- Software Managers
- Quality Managers
- Design Assurance Managers
- Software Quality Engineers
- Quality Engineers
- Regulatory Affairs Professionals
- Marketing
- Internal Auditors

Course **Content**

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Day 1 - Regulatory Overview

- ISO 13485 Software Requirements
- MDR 2017/745 / IVDR 2017/746 Software Requirements
- MDR (UK) 2002 Software Requirements
- FDA 21 CFR Part 820
- MDCG Guidance / Consensus Guidance
- Software Definitions
- Software Development Life Cycle (SDLC)
- Software Classification
- Security & Data Protection

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Day 2 - Practical

- Software Development Planning
- Intended Use & User Needs
- Software Requirements Specification
- Integration with ISO 13485/QMSR Change Control and Design Control
- Integration with ISO 14971 Risk Management
- SBOM & OTS & SOUP
- Tools for Software Risk Analysis
- Integration with IEC 60601 & PEMS
- Integration with IEC 62366
- Software Design

Ready to Go?

Reserve My Place

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Day 3 - Verification & Validation

- Software V&V Protocols
- Unit Testing
- Integration Testing
- System Acceptance Testing
- Regression Testing
- Problem resolution & residual anomalies
- Software Development Report
- Post Market Surveillance
- Software Maintenance Plan
- Configuration Management
- Traceability
- Residual Risk & Labelling
- Predicate Devices & State of the Art

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Day 4 - Cybersecurity

- Security Regulatory Requirements & Guidance
- Security & Data Protection Risk Assessments
- Threat Identification & Modelling
- Penetration Testing
- Security Frameworks
- Vulnerability Management Plan

Meet the **Industry Expert**

Niamh

Niamh brings 30-years' global quality & regulatory experience and knowledge spanning Software Engineering, Database Technologies and Artificial Intelligence. Niamh started work in the UK as a Systems Engineer following completion of BSc (Hons) Cognitive Science (Artificial Intelligence) implementing SAP R/3 ERP Software System to multinational companies across Europe, before going to Basil, Switzerland to live and work with Novartis Pharmaceutical.

On returning to Galway, Niamh's native county, she moved into the medical devices, pharmaceutical, combination and active devices including in vitro diagnostic systems/software providing with responsibility for automated software systems under GAMP4 and GAMP5.

Niamh has amassed extensive knowledge & experience over 20+ years' in the life sciences, leading Design Control, Risk Management and Computer System Validation and Regulatory Teams to successful regulatory acceptance for companies such as Boston Scientific, Merit Medical, Johnson & Johnson, Mylan and Olympus. Her experience spans greenfield sites, start-ups, medium and multi-national organisations before moving to Regulatory Body.

Niamh became a leading risk and software trainer as a lead technical CE mark reviewer for NSAI Medical Device Notified Body specialising in MDR, Risk Management, Software & New Technologies, including Active Devices under IEC 60601 & IEC 62304. Niamh supported the 1st generation guidance for SaMD developed by the MDCG New Technology Group set-up by the EU Commission for identification of software requirements related to healthcare applications and new emerging technologies (AI).

Niamh is a certified Lead QMS Auditor with extensive knowledge of state of the art, risk management, product development and regulatory requirements with regulatory submissions in US, EU/UK, CA and Japan including MDSAP Certification. Niamh is a member of Engineering Ireland and holds a Master's in Software Engineering and Database Technologies, MScSED (1:1).

Niamh is currently the Director of Regulatory Affairs and Quality for active medical device with embedded software and software accessory/component application.