

MEDICAL DEVICE & IN VITRO DIAGNOSTIC SOFTWARE

Modular Training Programme

Tailored for organisations developing SaMD, SiMD, CDSS and IVD Software

This menu sets out a series of focused training sessions on the regulation, standards and quality management of Software as a Medical Device (SaMD) and in-vitro diagnostic (IVD) software. Each session runs for two hours and can be delivered online or on-site. Sessions are modular: your team can select the topics most relevant to where you are in development, in any combination.

Session 1 is the recommended foundation and is included as a minimum, as it provides the regulatory and standards grounding that the other sessions build on. The remaining sessions can then be chosen freely.

#	Training session (2 hours each)	Select
1	<p>Regulations & Standards Overview for Medical Device & IVD Software ★</p> <p>RECOMMENDED FOUNDATION</p> <p>The regulatory landscape and core standards for software that is, or is part of, a medical device or IVD — the essential grounding for every other session.</p> <p><i>Key standards & frameworks:</i> EU MDR 2017/745 · EU IVDR 2017/746 · FDA SaMD · IEC 62304 · ISO 14971 · ISO 13485</p>	<input type="checkbox"/>
2	<p>What is SaMD? Qualification & Classification</p> <p>Determining whether software qualifies as a medical device and how it is classified across the EU and FDA frameworks.</p> <p><i>Key standards & frameworks:</i> IMDRF SaMD framework · MDCG 2019-11 · MDR Rule 11 · FDA SaMD categories</p>	<input type="checkbox"/>
3	<p>IVD Software — Qualification, Classification & Specifics</p> <p>How software is qualified and classified under the IVDR, including software that drives or influences an IVD, companion diagnostics and accompanying software.</p> <p><i>Key standards & frameworks:</i> EU IVDR 2017/746 · MDCG 2019-11 · IVDR classification rules</p>	<input type="checkbox"/>
4	<p>Clinical Decision Support Systems (CDSS)</p> <p>When clinical decision support qualifies as a medical device and when it does not — the criteria that distinguish device CDS from exempt decision support, and the obligations that follow under the EU and FDA frameworks.</p> <p><i>Key standards & frameworks:</i> FDA CDS guidance (2022) · MDR Rule 11 · MDCG 2019-11 · IMDRF SaMD</p>	<input type="checkbox"/>
5	<p>Software Development Lifecycle — IEC 62304</p> <p>The software lifecycle processes and software safety classification (Class A/B/C), and how they shape your development plan.</p> <p><i>Key standards & frameworks:</i> IEC 62304 · IEC 82304-1</p>	<input type="checkbox"/>
6	<p>Software in a Medical Device (SiMD) & Medical Electrical Equipment</p> <p>Where software is embedded in medical electrical equipment (SiMD rather than SaMD): how IEC 62304 interfaces with the IEC 60601 series, including programmable electrical medical systems (PEMS) and the related risk and usability collateral standards.</p> <p><i>Key standards & frameworks:</i> IEC 60601-1 (Clause 14, PEMS) · IEC 60601-1-x collaterals · IEC 62304</p>	<input type="checkbox"/>
7	<p>Software Risk Management</p> <p>Applying ISO 14971 to software — identifying how software can contribute to hazardous situations and designing effective risk controls.</p> <p><i>Key standards & frameworks:</i> ISO 14971 · ISO/TR 24971 · IEC 62304 (risk)</p>	<input type="checkbox"/>
8	<p>Software Requirements & Architecture</p> <p>Eliciting and managing software requirements and defining architecture and detailed design with traceability through the lifecycle.</p> <p><i>Key standards & frameworks:</i> IEC 62304 · requirements & architecture practice</p>	<input type="checkbox"/>
9	<p>Verification & Validation of Software</p> <p>Building a V&V strategy — unit, integration and system testing, test management and traceability to requirements and risk.</p> <p><i>Key standards & frameworks:</i> IEC 62304 · FDA software validation / CSA</p>	<input type="checkbox"/>

#	Training session (2 hours each)	Select
10	SOUP, Off-the-Shelf & Open-Source Software Managing software of unknown provenance, third-party and open-source components, including the software bill of materials (SBOM). <i>Key standards & frameworks:</i> IEC 62304 (SOUP) · SBOM · FDA OTS guidance	<input type="checkbox"/>
11	Software Configuration & Change Management Version control, configuration items, change control and problem resolution across the software lifecycle. <i>Key standards & frameworks:</i> IEC 62304 §§6-9 · ISO 13485	<input type="checkbox"/>
12	Cybersecurity for Medical Device & IVD Software Pre- and post-market security across the lifecycle — threat modelling, secure development and vulnerability management. <i>Key standards & frameworks:</i> IEC 81001-5-1 · MDCG 2019-16 · FDA premarket cybersecurity	<input type="checkbox"/>
13	Usability & Human Factors Engineering Usability engineering and use-related risk for software interfaces, including formative and summative evaluation. <i>Key standards & frameworks:</i> IEC 62366-1 · IEC 62366-2 · FDA HFE guidance	<input type="checkbox"/>
14	Health Software & Health IT Standalone health software, mobile and cloud/SaaS delivery, and product-level safety considerations beyond the device itself. <i>Key standards & frameworks:</i> IEC 82304-1 · IEC 80001-1 (health IT networks)	<input type="checkbox"/>
15	Interoperability & Data Exchange Connecting software safely — clinical and laboratory data exchange, and the standards that underpin interoperability. <i>Key standards & frameworks:</i> HL7 FHIR · DICOM · IEC 80001-1 · LIS/LIMS connectivity	<input type="checkbox"/>
16	Clinical Evaluation & Performance Evaluation for Software Generating the clinical and performance evidence expected for software, and how the requirements differ between the MDR and IVDR. <i>Key standards & frameworks:</i> MDR clinical evaluation · IVDR performance evaluation · MDCG guidance	<input type="checkbox"/>
17	IVD Performance Evaluation Scientific validity, analytical performance and clinical performance for IVD software, and structuring the performance evaluation plan and report. <i>Key standards & frameworks:</i> IVDR Annex XIII · ISO 15189 context · CLSI guidance	<input type="checkbox"/>
18	Quality Management System for Software Teams Applying ISO 13485 and design controls to software development, including how agile fits within a compliant QMS. <i>Key standards & frameworks:</i> ISO 13485 · FDA design controls (QMSR) · AAMI TIR45 (agile)	<input type="checkbox"/>
19	Technical Documentation & Conformity Assessment Compiling MDR/IVDR technical documentation for software and what to expect from Notified Body review. <i>Key standards & frameworks:</i> MDR Annex II/III · IVDR Annex II/III · Notified Body review	<input type="checkbox"/>
20	Post-Market Surveillance, Maintenance & Vigilance for Software Post-market obligations for software — surveillance, maintenance, updates and patches, and incident reporting. <i>Key standards & frameworks:</i> MDR/IVDR PMS · PMCF/PMPF · software maintenance & vigilance	<input type="checkbox"/>

Delivery & next steps

Each session is two hours, delivered live online or on-site, combining standards content with practical, worked examples. The material is grounded in active participation in IEC TC62, NSAI/ETC/TC10 and CEN-CENELEC committees and in Notified Body and industry QA/RA experience. AI-specific modules are available separately and be selected from the AI-specific menu as required. To build a programme, mark the sessions of interest above and return this sheet, or get in touch to discuss scheduling.