AI IN MEDICAL DEVICES

Modular Training Programme

Tailored for an organisation developing AI-enabled medical imaging

This menu sets out a series of focused training sessions on the regulation, standards and quality management of AI-enabled medical devices, with an emphasis on imaging applications. 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 (typically 2 hours each – *see Delivery & next steps for detail*)	Select
1	**Regulations & Standards Overview and Trustworthy AI in Healthcare** ★ RECOMMENDED FOUNDATION The full regulatory landscape for AI-enabled medical devices and the principles of trustworthy AI — the essential grounding for every other session. *Key standards & frameworks:* EU MDR 2017/745 · EU AI Act (Reg. 2024/1689) · FDA SaMD · IEC 62304 · ISO 14971 · ISO 13485 · ISO/IEC 42001	☐
2	**Introduction to AI — Overview of AI Model Types** Core AI/ML concepts for regulatory, quality and engineering teams, with emphasis on the model types most relevant to medical imaging (convolutional and vision models, and pre-trained/foundation models). *Key standards & frameworks:* Foundational — no single standard	☐
3	**AI Management System (e.g. ISO/IEC 42001)** Establishing an AI management system and integrating it with an existing ISO 13485 quality system rather than running it in parallel. *Key standards & frameworks:* ISO/IEC 42001 · ISO 13485	☐
4	**Pre-Trained Models and Evaluation** Evaluating externally sourced and pre-trained models — common in imaging pipelines — for safety, bias and regulatory acceptability. Drawn directly from peer-reviewed published research. *Key standards & frameworks:* ISO 14971 · EU AI Act · supporting evaluation frameworks	☐
5	**Deep Dive into an Example Imaging Device** A worked walkthrough of an example AI imaging device from concept through to evidence — connecting the regulatory theory to a concrete development case (optionally using a modelling tool such as Neural Designer). *Key standards & frameworks:* Applied — integrates IEC 62304 / ISO 14971	☐
6	**AI Risk Management** AI-specific hazard identification and risk control across the device lifecycle, including data, model and performance-drift hazards particular to imaging AI. *Key standards & frameworks:* ISO 14971 · ISO/TR 24971 (AI risk guidance)	☐
7	**Software Functions for AI — FDA** The FDA approach to AI/ML software functions and Software as a Medical Device, and how it differs from the EU route. *Key standards & frameworks:* FDA SaMD guidance · 21 CFR Part 820 / QMSR	☐
8	**Software Development Lifecycle & Agentic AI** Applying the software lifecycle to AI/ML components, including IEC 62304 Edition 2 developments and considerations for agentic AI. *Key standards & frameworks:* IEC 62304 (incl. Ed.2 developments)	☐

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9	**Predetermined Change Control Plans / Monitoring Plans** Designing PCCPs and monitoring plans so adaptive or updatable imaging models can be maintained without re-triggering full conformity assessment. *Key standards & frameworks:* FDA PCCP guidance · EU change-management expectations	☐
10	**EU AI Act 2024/1689 (as amended) + MDCGs** High-risk AI system obligations, the interplay with EU MDR, and emerging MDCG guidance, reflecting the latest amendments and the EC Simplification Digital Package. *Key standards & frameworks:* EU AI Act (Reg. 2024/1689) · EU MDR · MDCG guidance	☐
11	**AI Data Management** Dataset governance, quality, representativeness and bias — with specific attention to imaging datasets, annotation and labelling provenance. *Key standards & frameworks:* IEC PAS 63621 · ISO/IEC 42001	☐
12	**AI Data Management — PAS, Example Plan & Report** A practical, worked example of a data management plan and the corresponding report, using the structure of the data-management PAS. *Key standards & frameworks:* IEC PAS 63621 (worked example)	☐
13	**AI Test Methods & Metrics** Verification and validation methods and metrics for AI, including cross-validation and the test-method approaches now emerging in standards. *Key standards & frameworks:* IEC 63450 (in development) · V&V methods	☐
14	**AI Security Risks and Mitigations** Cybersecurity for AI-enabled medical devices — threat modelling, SBOM, and mitigation across the lifecycle. *Key standards & frameworks:* IEC 81001-5-1 · EU MDR security requirements	☐
15	**AI in PEMS — IEC 60601-4-1** AI within programmable electrical medical systems and the concept of degree of autonomy, where the imaging device is also electrical medical equipment. *Key standards & frameworks:* IEC 60601-4-1 · IEC 60601-1	☐
16	**AI Usability & Human Factors** Usability engineering for AI-enabled devices, including how clinicians interpret and act on imaging-AI output. *Key standards & frameworks:* IEC 62366-1 · IEC 62366-2 · emerging IEC 62366-3 (AI)	☐
17	**Performance Evaluation** Analytical and clinical performance evaluation for imaging AI — sensitivity, specificity and AUROC, and standalone versus reader-study designs. *Key standards & frameworks:* Performance evidence aligned to EU MDR / FDA expectations	☐
18	**Post-Market AI Requirements, Maintenance & Change Management** Post-market surveillance obligations specific to AI/ML, ongoing maintenance, and managing change in deployed models. *Key standards & frameworks:* EU MDR PMS · EU AI Act · post-market ML surveillance	☐

Delivery & next steps

Each session is two hours, delivered live online or on-site, and combines regulatory and standards content with practical, worked examples. Sessions are informed by active participation in IEC TC62, NSAI/ETC/TC10 and CEN-CENELEC AI Task Groups, and by ongoing doctoral research into AI-enabled medical device regulation. The material reflects where the standards are going, not only where they are today. To build a programme, mark the sessions of interest above and return this sheet, or get in touch to discuss a tailored sequence and scheduling. Since these sessions can be tailored to company-specific needs, with focus in on a precise device-type, the sessions can be reduced to 1 hour each as required and completed over 9-10 sessions.