IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Developing and Managing Software as a Medical Device (SaMD) and Medical Device Software (MDSW)

13 November 2025

Gain essential knowledge in developing and managing Software as a Medical Device (SaMD) and Medical Device Software (MDSW), focusing on regulatory compliance, risk management, and lifecycle management to ensure safety and effectiveness.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Master best practices in regulated software development so that you can balance flexibility and control, enabling innovation early on while ensuring rigorous oversight and regulatory compliance as projects progress.

Best practices for the development and management of regulated software are straightforward, but the challenge lies in effectively implementing them without stifling creativity. This skill is essential for delivering a final build that is reliable, safe, and compliant with regulatory requirements. Early on, allow your team to explore and experiment—later, tighten the reins, meticulously assess code impacts, and conduct targeted testing to maintain system integrity without incurring exorbitant costs or risking regulatory implications. This nuanced balance is best learned through practical experience and informed guidance, which this course offers in abundance.

From studying different software development models and managing design activities to understanding state-of-the-art standards and effective outsourcing strategies, you will gain insights to avoid the pitfalls of poor software development. Practical case studies will illuminate real-world challenges and solutions, guiding you through the complexities of regulatory compliance and optimal project management. Led by an expert with extensive hands-on experience, this course provides the strategies and knowledge to transform your development process, ensuring your products meet the highest standards of quality and safety.

This course covers crucial topics such as:

- managing software suppliers
- designing and evaluating the product's user experience
- managing safety risks
- state-of-the-art standards like IEC 62304 and IEC 82304-1
- techniques for effective risk control and communication

Through hands-on case studies and expert-led discussions, you'll learn to navigate the complex regulatory landscape and apply proven strategies to ensure your software's success. Whether tackling system usability or evaluating risks throughout the product lifecycle, this course provides the tools and knowledge you need.

Benefits of attending

By attending this course you will:

- **Learn** best practices for compliant software development and management while keeping the administrative burden at bay
- **Examine** essential techniques to improve product quality and ensure business continuity given employee turnover and continuously changing IT environments
- **Consider** the advantages of automating documentation practices
- **Identify** real-world stories to help you motivate your team to follow best practices rather than threatening them with looming regulatory findings
- **Get up to date** with how state-of-the-art standards are evolving
- **Master** user experience evaluation techniques
- **Get to grips** with risk management terminology, techniques and strategies
- **Understand** how to communicate in times of crises

Who should attend?

Professionals involved in software development and regulatory compliance withing the medical device industry, including:

- Software developers
- Project managers
- Product managers
- System analysts
- Biomedical engineers
- Risk management moderators
- Clinical validation specialists
- Usability engineers
- Technical writers
- Regulatory affairs specialists
- Quality assurance engineers
- Clinical informatics managers of hospitals

Programme

Software development models

- Symptoms and root causes of poor design control
- Waterfall vs agile, iterative, and spiral development
- Principles of good design control
- Stage-gated models

Best practices to manage design activities

- Project management
- Development planning
- Change management
- Requirements management
- Architecture and design
- Development
- Configuration management
- Verification and validation
- Defect management
- Design reviews

State-of-the-art standards for regulatory compliance

- Software development standards for regulatory compliance
  - IEC 62304 software lifecycle management
  - IEC 82304-1 General requirements for product safety

Managing software suppliers and subcontractors

- Managing software suppliers
- Outsourcing design activities
- Identifying critical suppliers
- Managing software platforms and plugins
- Using open-source software
- Using legacy software

Software usability

- Managing the human element of risk
- Designing for happiness
- Terminology, roles and responsibilities
- Human factors engineering
- User Experience Design (UXD)
- Process

User experience evaluation techniques

- Formative evaluation
  - User observations
  - Walkthroughs
  - Heuristic review
  - Key-stroke level model
- Summative evaluation
  - Product reaction cards / word association
  - Single Ease Question (SEQ)
  - System Usability Score (SUS)
  - Interface with risk management
- Regulatory requirements and standards
  - EU MDR/IVDR requirements
  - US FDA requirements
  - IEC 62366-1, etc.
  - Usability guides

Safety risk management

- Process, terminology, roles
- Risk identification methodologies
  - Checklists
  - Grey box
  - Hazard and Operability Analysis (HAZOP)
  - Failure Mode and Effects Analysis (FMEA)
  - Fault Tree Analysis (FTE)

Programme

Risk control

- Risk reduction paradigms
- Risk reduction under single fault condition
- Inherently safe design
- Preventive measures
- Corrective measures
- Mitigations
- Safety notices
- Disclosures of residual risk
- Risk control strategies

Case study on risk identification

Risk assessment and evaluation

- IMDRF terminology
- Determining severity and probability of harm
- Determining if a risk is acceptable
- Benefit-risk assessment
- Risk management deliverables

Risk management throughout the product lifecycle

- Risk management throughout the product lifecycle
- Risk management of External Software Component (ESCs), Software of Unknown Provenance (SOUPs), Commercial Off-The-Shelf (COTS) and platforms

Risk perception and communication

- Involving external stakeholders in assessing risk
- Communication in times of crisis

Presenter

Koen Cobbaert

Koen Cobbaert works for Philips as a quality, regulatory, and standards expert. Through trade associations COCIR and DITTA, he represents the industry at the European Commission and the IMDRF on matters related to software and artificial intelligence. He also contributes to various standardisation organizations focusing on software and artificial intelligence.

In the legislative domain, Koen chairs COCIR's and DITTA's software focus groups, representing its members at respectively the European Commission MDCG workgroups on Borderline and Classification and New Technologies and at the international level at the International Medical Device Regulators Forum (IMDRF) workgroup on artificial intelligence. Koen is also an advisor in the SaMD workgroup at the Global Harmonization Working Party (GHWP). Currently, Koen is engaged in various proposed EU legislation relating to artificial intelligence and data (AI Act, Machinery Regulation, General Product Safety Directive, Data Act, European Health Data Space…). Aside from various publications through trade associations, Koen also edited the book Software as a Medical Device, published through the Regulatory Affairs Professionals Society (RAPS).

In the standardization domain, Koen is a member of CEN-CENELEC's Industry Advisory Forum, and he is delegated as a Belgian expert to IEC JTC 1 SC 42 on artificial intelligence, CEN-CENELEC JTC21 on artificial intelligence, ISO TC215 JWG7 on health informatics, and to the IEC SC62A Advisory group on Software, Networks, and Artificial Intelligence (SNAIG).

Koen has a Master of Science in electrical engineering and safety risk management. He has over 15 years of hands-on experience establishing regulatory and market-access strategies for medical device software, performing worldwide regulatory submissions, and moderating risk management and clinical evaluation for software applications for general radiology, oncology, neurology, cardiology, orthopaedics, and clinical pathology. He has worked on software applications for pattern recognition, computer-aided detection, reasoning engines, clinical pathways, and other clinical decision support systems, including mobile apps, embedded software, and software operating in the cloud.

Course date

13 November 2025

Live online
09:00-17:00 **UK (London)** (UTC+00)
Course code 15444

GBP **649** ~~749~~
EUR **909** ~~1,049~~
USD **1,043** ~~1,199~~
Until 09 Oct

How to book

Online:
ipi.academy/3095

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

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+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Run this programme in-house for your whole team

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With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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