



IPI
Academy



Presented by
Management Forum

Medical Device Cybersecurity and Regulatory Compliance

15-16 October 2026

Gain the skills to design medical devices with cybersecurity in mind, addressing today's rapidly evolving regulatory landscape and customer demand. This course provides a practical understanding of cybersecurity requirements and shows you how to integrate state-of-the-art security practices into your existing development processes to deliver safe, compliant, resilient, and trusted products and solutions.



Format:
Live online



CPD:
12 hours for your records



Certificate of completion

Course overview

As cyber threats against healthcare systems continue to rise, securing medical devices has become critical to protecting patient care and maintaining trust in healthcare services. Effective cybersecurity goes beyond safety alone, it also ensures the confidentiality, integrity, and availability of systems and sensitive data.

This course equips you with a practical understanding of medical device cybersecurity, the growing regulatory expectations, and the latest industry best practices. Learn how to embed state-of-the-art security into your existing development processes to deliver compliant, resilient, and secure products and solutions with confidence.

Benefits in attending

- **Gain** a clear overview of EU, US, and global cybersecurity regulations
- **Recognise** the regulatory expectations of the manufacturer's due diligence
- **Understand** key healthcare cybersecurity standards and how to apply them effectively
- **Learn** best practices for embedding security by design into existing processes
- **Receive** practical guidance on effective threat modelling techniques
- **Grasp** the link between cybersecurity risk management and patient safety
- **Discuss** shared responsibility and critical cybersecurity information requirements

Who should attend

- Security and privacy specialists
- Risk managers and architects
- R&D, product and project managers
- Regulatory and quality managers
- Software engineers
- Healthcare IT consultants and auditors

Programme

Day 1

Introduction to cybersecurity

- Impact of cybercrime
- Definitions
- Different perspectives

Cybersecurity regulatory overview

- For the manufacturer (both medical and non-medical)
- For the user (hospital)
- US focus (FDA)
- EU focus (MDR/IVDR, MDCG Cybersecurity Guidance, NIS2 and CRA)
- Global focus (IMDRF and guidance's around the world)

Security by design

- Introduction
- Security by design process standards (An introduction to IEC 81001-5-1:2021 Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle)
- Secure design, coding and testing
- Monitoring and Incident handling
- Documentation (Technical file and submission)
- Obsolescence/security updates
- Supply chain

Security risk management

- Dealing with risk
- Security versus Safety
- Methodologies
- Introduction to threat modelling

Day 2

Threat modeling

- Threat modelling exercise
- Relation to safety risk management

Organisational requirements, shared responsibility & user documentation

- Organisational requirements
- Shared responsibility
- User documentation (e.g., IFUs and MDS2)

Security standards

- For processes (Manufacturer, suppliers)
- For products (MD, SaMD and Health & Wellness apps)
- For services and cloud
- For hospitals
- Security certifications

Further considerations

- Products, services, apps (and a little bit on AI)
- Development models
- Coordinated vulnerability disclosure
- Information sharing and analysis centers
- Accountability and oversight

Presenter



Ben Kokx

Ben Kokx joined Philips in 2001 as a software designer before transitioning into product security and privacy leadership roles across multiple businesses and markets. Since 2013, as Director Product Security within the central Philips Product Security Office, he has been responsible for the global Philips Product Security Policy and Process Framework and has played a key role in cybersecurity-related standards and regulations. In 2023, he moved to the Regulatory Affairs department to focus more extensively on his external roles as a healthcare and IoT cybersecurity expert, contributing to public-private partnerships, industry associations, and standards development organisations.

Ben leads and actively contributes to several industry associations and standards organisations, including ISO, IEC, CEN-CENELEC, and ETSI. He is deeply involved in the development of the ISO/IEC 80001 series and ISO/IEC 81001 series healthcare cybersecurity standards.

He serves as convenor of CEN/CENELEC JTC 13 Working Groups 6, 8, and 9, focusing on the development of European harmonized cybersecurity standards supporting the RED Delegated Act and the Cyber Resilience Act. Ben is also an eHealth cybersecurity expert for ENISA and a member of the ENISA Advisory Group. In addition, he holds leadership positions within the cybersecurity working groups of MedTech Europe and COCIR, and through DITTA participates in international public-private initiatives such as the IMDRF Cybersecurity Working Group.

Course date

15-16 October 2026

Live online

09:00-17:00 **UK (London)** (UTC+01)

Course code 16308

GBP **1,299** ~~1,499~~

EUR **1,819** ~~2,099~~

USD **2,087** ~~2,399~~

Until 10 Sep

How to book

 **Online:**
ipi.academy/2200

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

 **Email:**
info@ipiacademy.com

 **Phone:**
[+44 \(0\)20 7749 4749](tel:+442077494749)

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

Reviews



Excellent, it was very interesting and I find the speaker very knowledgeable.



Kolbrun E Ottosdottir

Nox Medical

Jan 30 2024



Very knowledgeable, up to date on things in this field even parts you usually do not get a glimpse in. An excellent program.



Harpa Arnardóttir

Chief Quality Officer

Nox Medical

Jan 30 2024



Very passionate and answered questions clearly



Genn Kamei

Nox Medical

Jan 30 2024



I was looking for the exact standards what we could apply for our Device Cyber Security Perspective and how we could document Cybersecurity in Regulatory Documents (Risk Assessment, GSPR etc.) Training was helpful, now we could conclude which standard and how we could comply in our documents.



Meenakshi Kamboj

Senior Regulatory Specialist - Development •

Regulatory

Flexicare Ltd

Oct 10 2023

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

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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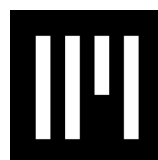


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IPI Academy

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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