





Presented by **Management Forum** 

# **Cyber Security for Medical Devices**

11-12 September 2025

This seminar will provide you with an understanding of cybersecurity and its increasing regulatory focus, and how to embed and apply state-of-the-art security in your existing processes to deliver safe and secure products and solutions.



Format:

Live online



CPD:

12 hours for your records



Certificate of completion

## **Course overview**

The impact of Cyber Security incidents on society is high, and in critical infrastructures such as healthcare it impacts the ability for hospitals to provide care. Cybersecurity for medical devices is not just about safety, it should also protect the confidentiality, integrity and availability of systems and data. This seminar will provide you with an understanding of cybersecurity and its increasing regulatory focus and how to embed and apply state-of-the-art security in your existing processes to deliver safe and secure products and solutions.

## **Benefits in attending**

- Gain a comprehensive overview of the EU, US and global regulations
- **Introduction** to the various healthcare security standards and their application
- Best practices on how to embed security by design in existing processes
- Receive practical advice on threat modelling
- Better understand security risk management and its linkage to safety management
- Understand shared responsibility and the information needs

## 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

## Cybersecurity regulatory overview

- For the manufacturer (both medical and non-medical)
- For the user (hospital)
- US focus (FDA, Biden's Executive Order on Improving the Nation's Cybersecurity)
- EU focus (MDR, MDCG Guidance and upcoming NIS2)
- Global focus (IMDRF and guidance's around the world)

## Security by design

- 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
- Supply chain
- Secure coding
- Testing
- Monitoring
- Coordinated vulnerability disclosure
- Obsolescence/security updates

## Security risk management

- Methodologies
- Introduction to threat modeling
- Relation to safety risk management

## Day 2

#### Threat modeling

- Introduction to threat modeling
- Threat modeling exercise

## Shared responsibility and the hospital view

## Security standards

- For processes
- For products (MD and SaMD)
- For health and wellness apps
- For services and cloud
- For hospitals
- Security certifications

## **Further security considerations**

- Security in the development, manufacturing and service environments
- Shared responsibility
- Security information, e.g., MDS2



## **Presenter**



## Ben Kokx

Ben Kokx joined Philips in 2001 as a software designer. He quickly moved into a new role as a product security and privacy officer and worked as such in several business and market positions. As Director Product Security within the central Philips Product Security Office, he is responsible for security related standards and regulations next for the Philips Product Security Policy and Process Framework since 2013. Ben is a healthcare and IoT security expert who leads and participates in several industry associations and standard development organizations like ISO/IEC JTC 1/SC 27, IEC ACSEC, IEC TC62/ISO TC 215, IEC TC65, ETSI TC-CYBER and others. He is the convenor of CEN/CENELEC JTC 13/WG 6 on product security. Ben is an ENISA eHealth cybersecurity expert, chairs the COCIR Cybersecurity focus group and through DITTA, participates in several public-private organizations such as the IMDRF cybersecurity workgroup.

## **Course date**

11-12 September 2025 Live online

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

Course code 15006

GBP **1,299** <del>1,499</del>

EUR 1,819 2,099

USD 2,087 2,399

Until 07 Aug

## How to book



## Online:

ipi.academy/2200

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



## Email:

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+44 (0)20 7749 4749

## **Discounts**

- Booking more than one delegate on any one date qualifies for a 15% 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**

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

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## **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

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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 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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