

**Cybersecurity Risk Management & Introduction to AAMI TIR57**

**Day 1:**

08.30 – 09.00 **Registration and breakfast**

09.00 – 09.10 **Welcome by Medicoindustrien**

09.10 – 10.10 **Introduction to Security Risk Analysis & Threat Modeling**

* Understanding Bad Actors (“The Hackers”) and how they work
* What are the real risks of cyber-attacks on healthcare systems
* How Security Threat Modeling is different from traditional safety risk analysis
* What are the key concepts, terms, and activities of Threat Modeling

10.10 – 10.30 **Coffee break**

10.30 – 11.00 **Introduction to Security Risk Analysis Process & Standards**

* Understanding Assets, Threats, and Vulnerabilities
* Overview of several standards useful to manufactures

11.00 – 12.00 **Introduction to AAMI TIR57**

* Overview of how AAMI TIR57 works together with ISO 14971
* The elements of a Security Risk Management Plan

12.00 – 13.00 **Lunch**

13.00 – 14.30 **Security Risk Analysis – Threat Surface**

* Introduction to Identifying Assets & the Threats Surface
* Case Study: What is a Threat Surface?
* Breakout Activity – Breakout session with teams to identify a system threat surface & assets

14.30 – 14.50 **Coffee break**

14.50 – 16.20 **Security Risk Analysis – Vulnerabilities & Weaknesses**

* Introduction to Software Weaknesses and Security Vulnerabilities
* Information Sources & Tools that support identification of common known weaknesses & threats
* Breakout Activity – Breakout session with teams to identify Common Vulnerabilities from the CVE database

16.20 – 16.30 **Wrap up**

**Day 2:**

08.30 – 09.00 **Breakfast**

09.00 – 10.10 **Security Risk Analysis – Exploitability**

* Introduction to security vulnerability exploitability
* Exploitability scoring systems
  + NIST
  + Common Vulnerability Scoring System (CVSS)
* Group Activity – Determining exploitability using CVSS and comparison to NIST method

10.10 – 10.30 **Coffee break**

10.30 – 12.00 **Security Risk Analysis – Criticality: The relationship between Security & Safety**

* Examination of the relationship between Security & Safety in Medical Devices
* Overview of AAMI TIR57 treatment of safety & security
* Breakout Activity – Completion of Security Risk Analysis to determine Criticality and need for security risk controls

12.00 – 13.00 **Lunch**

13.00 – 14.30 **Security Risk Analysis – Security Risk Controls**

* Introduction to Security Countermeasures (Security Risk Controls)
* FDA recommended Security Measures
* NIST SP 800-53 Standard for Security Controls
  + NIST Families
  + Controls for Low, Medium, & High Impact Risk
* Comparison between NIST CSF & FDA Premarket Guidance

14.30 – 14.50 **Coffee break**

14.50 – 15.50 **Security Risk Analysis – Completion of Sample Security Risk Analysis**

* Breakout into Groups
* Identify appropriate Risk Controls
* Class Presentation by Groups

15.50 – 16.00 **Wrap up and conclusions**