MEDICO INDUSTRIEN
MEDTECH DENMARK

IEC 62304: Software Lifecycle

Day 1:

08.30 – 09.00	**Registration and breakfast**
09.00 – 09.10	**Welcome by Medicoindustrien**
09.10 – 10.10	**Regulatory considerations (EU and US rules and guidance)** - Software as a medical device (EU) - The role of IEC 62304 - Software in the upcoming EU Regulation - Software as a medical device (US) - Characteristic of a medical device - Practical case
10.10 – 10.30	**Coffee break**
10.30 – 11.30	**Key concept associated with IEC 62304** - Usability - Risk Management - Safety classification - Lifecycle development model - SOUPS - Quality management system
	Short break
11.30 – 12.00	**IEC 62304 and other standards** - IEC 62304 and other standards - System standard – ISO 13485, ISO 14971, IEC 62366 - Product standard – IEC 60601
12.00 – 13.00	**Lunch**
13.00 – 14.30	**IEC 62304 – Content of the standard** - Application of software classification - Overview of the standards - Review of Chapter 1 to 4

- Risk Management process
- Review of chapter 7
- Example of risk associated with software

14.30 – 14.50 **Coffee break**

14.50 – 15.50 **IEC 62304 – content of the standard**
- Software development
- The V Model
- Why requirements are so essential
- Chapter 5
- Practical case

15:50 – 16.00 **Wrap up and conclusions**

Day 2:

08.30 – 09.00 **Breakfast**

09.00 – 10.10 **IEC 62304 – Content of the standard**
- Verification and validation
- Verification approach
- Why requirements are so essential
- Software configuration management

10.10 – 10.30 **Coffee break**

10.30 – 12.00 **IEC 62304 – Content of the standard**
- Software maintenance
- Integration of software problem resolution in the improvement system
- Chapter 6, 8 and 9

12.00 – 13.00 **Lunch**

13.00 – 14.00 **IEC 62304 – content of the standard**
- Typical documentation architecture
- Key items of the software technical file
- Adjustment to QMS SOP's

14.00 – 14.20 **Coffee break**

14.20 – 15.20 **Software and cybersecurity**
- Impact of cybersecurity on medical devices
- Typical threats to consider
- Typical mitigation measures to consider

15:20 – 15.30 **End and conclusions**