

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) <ul style="list-style-type: none">- 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 <ul style="list-style-type: none">- Usability- Risk Management- Safety classification- Lifecycle development model- SOUPS- Quality management system
	Short break
11.30 – 12.00	IEC 62304 and other standards <ul style="list-style-type: none">- 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 <ul style="list-style-type: none">- 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 – 15.50

Software and cybersecurity

- Impact of Cybersecurity on medical devices
- Typical threats to consider
- Typical mitigation measures to consider

15:50 – 16.00

End and conclusions

