INVITATION

Medical device software development

Presenters:
Árpád Zsolt Bús head of the medical division
Csaba Sántics consultant

Date
11. 03. 2025.

Location
Online (MS Teams)

Training fee
- 390 EUR + VAT/person for SAASCO clients and Mediklaszter members (Discount code: SA/MK)
- 490 EUR + VAT/person

Registration
Click HERE to access the application form!

About the training
Software is playing an increasingly important role in the control of medical devices and more and more software and applications are appearing on the market that are medical devices (SaMD) in their own right.
The design and implementation of the software is very different from the methods used for tangible tools. There is little opportunity for detailed post-production testing of the software, so detailed documentation of the software development process is the only way to demonstrate that the software is fit for its intended purpose.

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Registration number for adult education: B/2020/004232

SAASCO Consulting & Engineering Ltd.

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PROGRAM

Medical device software development

- Regulatory requirements (MDR/IVDR)
- Classification of healthcare software and related standards
- design process of medical device software
  - Software design strategies
  - The general process of medical device design and development (ISO 13485)
  - Medical device (SaMD) and embedded software development processes (IEC 62304, IEC 82304-1)
  - The place of software verification and validation in the software design process
  - Classification of software (IEC 62304)
- Software requirements and validation (IEC 82304-1)
  - Definition of intended use
  - Preliminary risk assessment
  - Definition of use requirements
  - Definition of system requirements
  - Requirements of accompanying documentation
  - Post-market activities
- Software lifecycle processes (IEC 62304)
  - Development process
  - Maintenance process
  - Risk management process (ISO 14971, IEC/TR 80002-1)
  - Configuration management process
  - Problem solving process

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ABOUT THE TRAINING

Certificate of participation

Training participants will receive a certificate of participation.

Basic knowledge needed

No basic knowledge is required, but the presentation will be easier to understand for those who are familiar with the requirements of the Medical Device Regulation (EU) 2017/745 (MDR) or the In Vitro Diagnostic Device Regulation (EU) 2017/746 (IVDR).

For whom we recommend

- medical device manufacturer
- software design and development engineers
- person responsible for regulatory compliance (PRRC)
- for quality professionals and auditors

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Under the Hungarian Adult Education Act, adult educators are obliged to provide information (including statistical information) on adult education activities that can be carried out under a declaration and licence, through the Adult Education Data Reporting System (FAR). Consequently, participants in the training are required to provide information by completing an online form, the link to which will be sent out prior to the training.

Application deadline
07. 03. 2025. 16:00

Duration of training
11. 03. 2025. 9,30 • 16,30

Cancellation conditions
Participation can be cancelled up to 5 calendar days prior to the training, otherwise the organiser is entitled to charge the full participation fee.

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