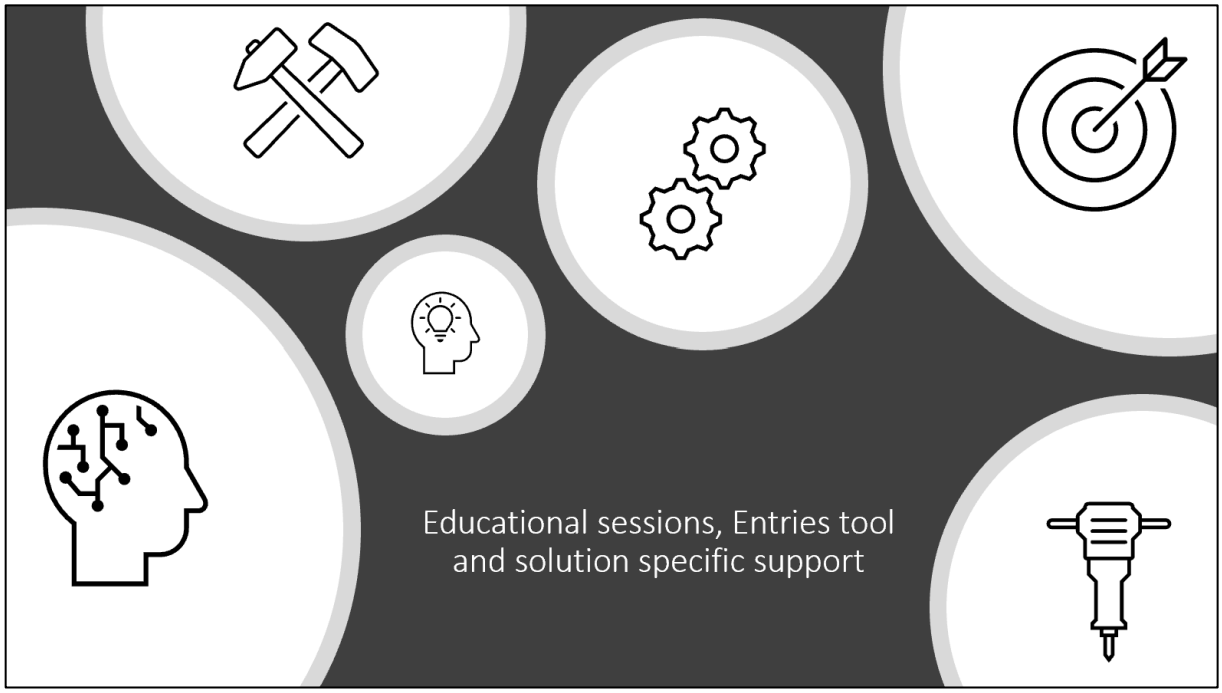


The regulatory navigation program – for increased tempo while minimizing risks and hurdles

by HealthTech Nordic in collaboration with Lean Entries

Regulatory compliance is an essential part of the journey when developing safe healthtech solutions for the European and global markets. It's a common struggle, entering this new line of business and which cause months and years of unnecessary delays in reaching the market.

Our **training sessions** combined with the **interactive online tool Entries** and **one-to-one sessions** with regulatory experts, serves to navigate faster, minimize risk and overcome some of the hurdles that you commonly face while developing safe healthtech solutions for the European and global market.

Overview

The **training sessions** covers the most important regulatory aspects and starts with session 1 that gives a global overview to all people involved in the introduction of new healthtech solutions and all stakeholders interested in saving months in time-to-market of healthtech innovations and to avoid typical dead-ends due to non-compliance. Founders, investors, advisors, market and salespeople, developers, researchers etc.

Session 2-4 mainly address business advisors and start-up founders, but other target groups may have interest and find these sessions very valuable. Session 5-10 contains more in-depth information, see list below.

With the **interactive online tool Entries** you can match your solution to the regulatory EU framework in a minute and get instant access to applicable documentation and improve your knowledge. This service is provided by Lean Entries in cooperation with HealthTech Nordic for the purpose of supporting the success of Nordic healthtech solutions and improving world health.

One-to-one sessions with regulatory experts and solution specific support is not included in this offer. Contact your HealthTech Nordic business advisor for information about tailored regulatory help for your company.

Training sessions

Please visit the Regulatory navigation program page at the HealthTech Nordic website to find links to the following training sessions:

Session 1 – Introduction to regulatory essentials

Session 2 – Early development and management

Session 3 – The core of regulatory requirements

Session 4 – Design control and the regulatory environment

Session 5 – Medical device software

Session 6 – Risk management in practice

Session 7 – Usability and labelling

Session 8 – Biological and electrical safety

Session 9 – Clinical evaluation in practice

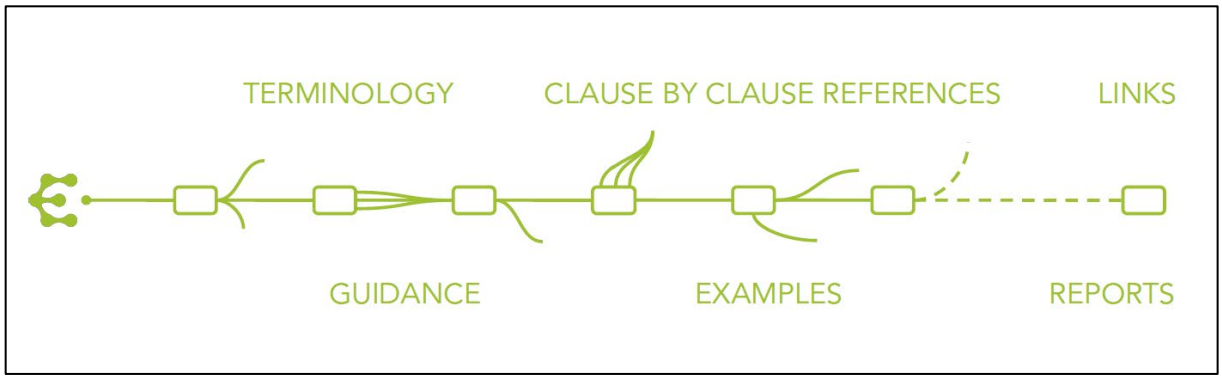
Session 10 – Post-market surveillance and post market clinical follow-up

Accessibility and Price

- HealthTech Nordic startup members (in the ÖKS region): Educational sessions + tool is free of charge
- HealthTech Nordic startup members (outside of the ÖKS region): Educational sessions free of charge and the tool is available at a reduced price
- Founding partners of HealthTech Nordic: Educational sessions + tool is free of charge for all personnel
- Associated partners to HealthTech Nordic (and other institutions and organizations): Please contact Markus Mårtensson at markus.martensson@innovationskane.com for more information

Entries – interactive regulatory navigation tool

Use the Entries tool for the minute and complete Qualification and Classification of medical devices according to the MDR and the IVDR and walkthrough the central regulatory consequences on the EU market. You can at all times go back and alter your answers to see what difference it makes to the regulatory framework.



To request access to the tool, please contact Susanne Hertzberg at susanne.hertzberg@innovationskane.com.

One-to-one sessions – solution specific support

Not included in this offer. Sessions are available on-demand to HealthTech Nordic startup members inside the ÖKS region. Contact your HealthTech Nordic's business advisors for more information.