Er du bekymret for pasientsikkerheten ved bruk av KI verktøy for helse og medisin?
Trenger du å forstå regelverket for medisinsk utstyr?
Lurer du på hva QMS er for noe?

Vi har laget kurset for deg!

Nørs har utviklet en app for kvinnehelse med over 50.000 ukentlige brukere, og ser nå behov for opplæring innen regelverk, kvalitet og kvalitetssystem. SurViva og Pedro Consulting vil i samråd med Nørs invitere også andre interesserte til det planlagte kurset:

8. mai, 10:00-12:00:	Introduction to Regulatory and Quality requirements, and ISO13485
16. mai , 10:00-12:00:	Introduction to Design and Development of medical device, including software
23. mai , 10:00-12:00:	Introduction to the Medical Device Regulation (MDR)

Kurset holdes i Nørs' lokaler Edvard Storms gate 2, 0166 Oslo

Pedro Consulting
Quality is science - Service is art

SURVIVA
SCIENCE FOR LIFE

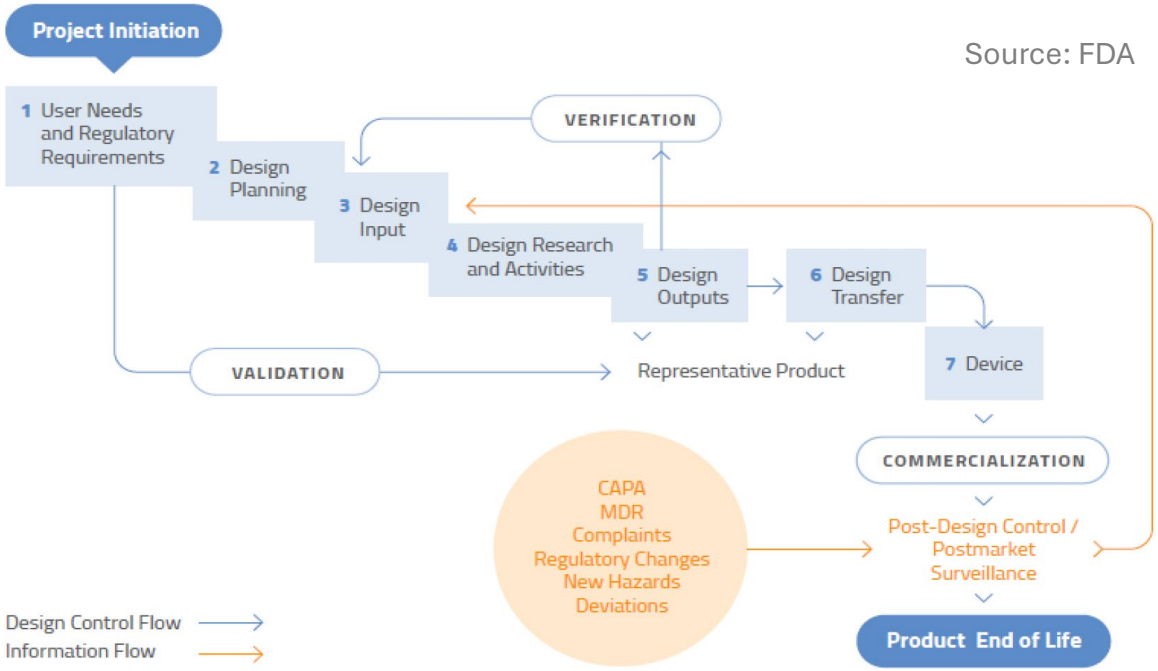
May 8th, 10:00-12:00
1: Introduction to regulatory and quality requirements.
2: ISO13485 for medical devices

- Part 1: You will be introduced to the terminology of the regulatory space and become familiar with regulatory standards within the life science. We will discuss why such standards have been developed, and how they add value to the end users and to society. Topics will include product classification, and how this affects the product development process.
- Part 2: The content of the ISO13485 standard will be presented, and implications of a quality management system (QMS) according to ISO13485 will be discussed.

May 16th, 10:00-12:00:
Introduction to the design and development process of medical device, including software as a medical device

- The design and development process with steps and acitvities as described in ISO13485 will be presented.
- Integration of software development according to ISO62304 as part of this process will be described, and topics related to the development and CE marking of machine learning software will be discussed.

Source: FDA



May 23rd, 10:00-12:00:
Introduction to the Medical Device Regulations (MDR and IVDR)

- MDR and IVDR – what is it, and for whom do these regulations apply?
- How does MDR / IVDR relate to ISO13485 and other standards?
- Major chapters and annexes of MDR will be highlighted, with a focus on topics relevant for companies
  - designing
  - developing
  - manufacturing

  medical devices and other devices covered by the regulations

Interessert?

- NB: Begrenset antall plasser!
- Påmelding vi QR-koden

Pris per kursdag: NOK 5.000

Redusert pakkepris for hele kurset: NOK 10.000 til dere som er medlem av / har tilhørighet til

- Norway Healthtech
- Aleap
- Veksthuset UiO
- OsloMet
- NMBU
- Wild Norway