Programme

Design Control for Medical Devices

Location: Medicoindustrien, Agern Allé 13, 2970 Hørsholm

Instructor: Peter Sebelius

Start and finish	**09:00 – 16:30**
Breakfast	**08:30 – 09:00**
Lunch	**11:45 – 12:30**

Day 1	**Day 2**
Introduction to Design control and key terms Project process The medical device files The regulatory framework Classification and product approval Essential requirements, standards and guidelines Using standards in medical device product development Design and development inputs and traceability How to manage requirements	Risk management and ISO 14971 Usability engineering Design planning Design review Design phase and design output Design transfer Design verification and validation What is enough? Change control Documentation pitfalls

Please note that minor changes to the program may occur.