Programme

Quality management for medical devices and ISO 13485

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 The regulatory framework Standards Product approval process Introduction to ISO 13485 Introduction to risk The Quality Management System Audits and compliance Document and record control Medical device files Management responsibility Resource management	Product realization - Design Product realization - Purchasing Product realization - Manufacturing Traceability Design changes Internal audits CAPA Complaints

Please note that minor changes to the program may occur.