MEDICO INDUSTRIEN
MEDTECH DENMARK

Person Responsible for Regulatory Compliance according to MDR and IVDR

08.30 – 09.00	**Registration and breakfast**
09.00 – 09.10	**Welcome by Medicoindustrien**
09.10 – 10.10	**Basic Authority Requirements** - Authority Requirements - Role & Responsibility - Required competences
10.10 – 10.30	**Coffee break**
10.30 – 12.00	**Personal Responsibility** - Quality Management System Content (ISO 13485:2016)
12.00 – 13.00	**Lunch**
13.00 – 14.30	**Associated Tasks** - Technical documentation - Post Market Surveillance extent
14.30 – 14.50	**Coffee break**
14.50 – 15.45	**How to implement the requirements** - Independency - Authority Reporting - How to implement in the organization
15.45 – 16.00	**Wrap up and conclusions**