MEDICO INDUSTRIEN
MEDTECH DENMARK

# Corrective & Preventive Actions (CAPA)

| | |
|---|---|
| 08.30 – 09.00 | **Registration and breakfast** |
| 09.00 – 09.10 | **Welcome by Medicoindustrien** |
| 09.10 – 10.10 | **Regulatory requirements CAPA**<br>- 21CFR820<br>- ISO 13485<br>- Wording / definitions<br>- Purpose of CAPA<br>- Logical quality system links |
| 10.10 – 10.30 | **Coffee break** |
| 10.30 – 11.30 | **The CAPA process**<br>- Inputs / triggers for CAPA<br>- Process sequence step by step<br>- Root cause analysis |
| 11.30 – 12.00 | **Case study + documentation**<br>- Description of the non-conformity encountered |
| 12.00 – 13.00 | **Lunch** |
| 13.00 – 14.45 | **Case study + documentation**<br>- Curative measures / immediate action<br>- Root Cause Analysis<br>- Determining CAPA related to identified root causes / CAPA plan |
| 14.45 – 15.00 | **Coffee break** |
| 15.00 – 16.30 | **Case study + documentation**<br>- Implementing CAPA<br>- Verification of effectiveness<br>- Closure of CAPA |
| 16.30 – 16.40 | **Q+A and conclusions** |