MEDICO INDUSTRIEN
MEDTECH DENMARK

Training of internal auditors in relation to country specific requirements within the MDSAP program

Day 1

08.30 – 09.00	**Registration and breakfast**
09.00 – 09.10	**Welcome by Medicoindustrien**
09.10 – 10.10	**The Medical Device Single Audit Program** - Policies, coverage - MDSAP Audit approach - Prepare for hosting a MDSAP audit
10.10 – 10.30	**Coffee break**
10.30 – 12.00	**Management Subsystem incl. Device Marketing Authorization and Facility Registration** - Overview - Auditing the management subsystem and logical links - Auditing QMS processes for market authorization and facility registration - Coverage and comparison of specific requirements of MDSAP jurisdictions: Ord.169, 21CFR820, RDC 16/2013, SOR 98-282, TGA MDR 2002
11.30 – 12.00	**Measurement, Analysis and Improvement Subsystem incl. Adverse Event Reporting** - Overview - Auditing the CAPA subsystem and logical links - Auditing QMS processes for adverse event and advisory notices reporting - Coverage and comparison of specific requirements of MDSAP jurisdictions: Ord.169, 21CFR820, RDC 16/2013, SOR 98-282, TGA MDR 2002
12.00 – 13.00	**Lunch**
13.00 – 14.30	**Production & Service Controls incl. Purchasing Subsystem** - Overview - Auditing the Production & Service controls subsystem and logical links - Auditing QMS processes for Supplier qualification and evaluation and logical links to Production & Service Controls and Management Subsystem, CAPA Subsystem

	- Coverage and comparison of specific requirements of MDSAP jurisdictions: Ord.169, 21CFR820, RDC 16/2013, SOR 98-282, TGA MDR 2002
14.30 – 14.50	**Coffee break**
14.50 – 15.50	**Design & Development Subsystem** - Overview - Auditing the D&D subsystem processes with their logical links - Coverage and comparison of specific requirements of MDSAP jurisdictions: Ord.169, 21CFR820, RDC 16/2013, SOR 98-282, TGA MDR 2002
15:50 – 16.00	**Conclusions and wrap up**