MEDICO INDUSTRIEN
MEDTECH DENMARK

MDSAP Fundamentals and Readiness Training

Day 1:

08.30 – 09.00 **Registration and breakfast**

09.00 – 09.10 **Welcome by Medicoindustrien**

12.00 – 13.00 **Lunch**

Time	Topic
9:10 – 17:00	Benefits to you, welcome and introductions
	Course aim, learning objectives and course structure
	Fundamentals of MDSAP • Origin and objectives • Key terms and definitions • Manufacturer benefits • Structure, requirements and outputs
	Structure and scope of the MDSAP audit program • Process, sequence and duration • Regulatory audit approach and requirements • Stage 1 and Stage 2 audits • Nonconformity grading • Considerations for MDSAP participation • Relationship with other QMS standards
	MDSAP and other QMS audits • MDSAP and auditing in the medical device industry • Differences between ISO 13485 and ISO 14971
	MDSAP documents
	Management process • Purpose and outcomes of process • Top management focus in MDSAP • QMS requirements and planning • Development of audit scope • Jurisdictional additions (to ISO 13485) • Distribution controls
	Measurement, analysis and improvement process

	• Purpose and outcomes of process • Analysis of data • Control of nonconforming product • Internal audits • Jurisdictional additions (to ISO 13485)
	End of day 1

Day 2

08.30 – 09.00 **Breakfast**

12.00 – 13.00 **Lunch**

Time	Topic
9:00 – 17:00	Refresh quiz
	Design and development process • Purpose and outcomes of process • Design control and device classification • Risk management focus • Jurisdictional additions (to ISO 13485)
	Production and service controls process • Purpose and outcomes of process • Jurisdictional additions (to ISO 13485) • Control interactions
	Purchasing process • Purpose and outcomes of process • Purchasing control considerations • Jurisdictional additions (to ISO 13485)
	Device marketing authorization and facility registration process • Purpose and outcome of process • Jurisdiction specific definitions • Device market authorization • Facility registration • Change Notification considerations
	Medical device adverse events and advisory notices process • Purpose and outcomes of process • Jurisdictional additions (to ISO 13485)
	Course review and final questions
	End of course

Two short breaks will be taken at suitably convenient times in the morning and afternoon.
Additional breaks may be taken as long as agreed by delegates and tutor and all learning objectives are met.