

Medtech Talent & Employment Programme

Module	Technical Subjects	Duration (Days)
1	Medical Device Design Control	2
2	Process Validation for Medical Devices	5
3	Risk Management in Medical Device Manufacturing	2
4	Medical Device Sterilisation (EtO)	2
5	ISO 13485 Quality Management System	5
6	ISO 13485 Internal Auditing	2
7	CE Marking and EU Medical Device Directive	2
8	FDA Good Manufacturing Practice (21 CFR Part 820)	4
9	FDA Quality System Inspection Technique (QSIT)	2
10	Malaysian Good Distribution Practice for Medical Devices (GDPMD)	2
11	Medical Device Classification and Labelling	1
12	Post Market Surveillance, Vigilance and Adverse Event Investigation	1
13	Team Building	2
	Duration	32 days