MEDICO INDUSTRIEN
MEDTECH DENMARK

Program

FDA Regulation of Medical Devices: Recent FDA Guidance Documents (FDA New Medical Device Guidance Documents)

Instructor: H. Semih Oktay, PhD President CardioMed Device Consultants, LLC	
Day 1:	
08.30 - 09.00	Registration & Breakfast
09:00 - 09:10	Introduction – Course Goals
09:10 - 10:00	FDA and CDRH Overview
10:00 - 12:00 (Coffee/tea break where appropriate)	• Presubmission Process • Communication During FDA Review • Evaluating Substantial Equivalence for 510(k)
12.00 - 13.00	Lunch
13:00 - 15:00	• De Novo 510(k)s • Breakthrough Devices Program • FDA Regulation of Mobile Applications
15:00 - 15:15	Coffee Break
15:15 - 16:30	• Updated Sterility Guidance for 510(k)s • FDA IDE Decisions and Procedures

*All times approximate

Day 2:	
08:30 - 09:00	Breakfast
09:00 - 11:00	• Early Feasibility Studies • Design of Pivotal Clinical Studies
11:00 - 11:15	Coffee break
11:15 - 12:00	Clinical Trials Outside the US
12:00 - 13:00	Lunch
13:00 - 14:00	Leveraging Existing Clinical Data for Pediatric Indications
14:00 - 14:15	Coffee break
14:15 - 15:30	• Live Case Presentations • Emergency Research
15:30 - 16:00	Open discussion, Question & Answers, Adjourn

*All times approximate