MEDICO INDUSTRIEN

Programme

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

14 – 16 December 2020 - Online Course

Instructors: H. Semih Oktay, PhD, President CardioMed Device Consultants, LLC
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Day 1: Monday, December 14, 2020	
13.00 - 13.10	Introduction – Course Goals
13:10 - 14:00	FDA and CDRH Overview
14:00 - 15:45 (Coffee/tea break where appropriate)	• Presubmission Process • Communication During FDA Review • FDA's Role in Device Innovation
15:45 - 16.00	Open discussion, Question & Answers, Adjourn

*All times approximate

Day 2: Tuesday, December 15, 2020	
13:00 - 13:30	• Evaluating Substantial Equivalence for 510(k)
13:30 - 14:00	• De Novo 510(k)s
14:00 - 14:30	• Balancing Premarket and Post-market Data for Premarket Approval (PMA) Applications
14:30 - 14:45	Coffee/tea break
14:45 - 15:15	• Breakthrough Devices Program
15:15 - 15:45	• FDA IDE Decisions and Procedures
15:45 - 16:00	Open discussion, Question & Answers, Adjourn

*All times approximate

Day 3: Wednesday, December 16, 2018	
13:00 - 13:30	• Early Feasibility Studies
13:30 - 14:00	• Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions
14:00 – 14:20	• The Special 510(k) Program
14:20 - 14:30	Coffee/tea break
14:30 – 14:45	• Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices

14:45 - 15:45	• Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
15:45 - 16:00	Open discussion, Question & Answers, Adjourn