

Tentative

Day 1 – Monday, November 15, 2021

- 9:00 am - 9:15 am Introductions and overview of class
- 9:15 am - 9:25 am Keynote speaker
- 9:25 am – 10:30 am FDA Part 1: Overview of programs, breakthrough device, EUA
- 10:30 am – 10:45 am Break
- 10:45 am – 12:00 pm FDA Part 2: Humanitarian device, combination products, and other special programs.
- Q&A
- 12:00 am – 1:00 pm Lunch
- 1:00 am – 2:30 pm EU: Regulations and practices
- 2:30 pm - 2:45 pm Break
- 2:45 pm – 3:45 pm Canada and Australia: Overviews and special programs
- Q&A
- 3:45 pm – 4:15 pm Q&A and Panel discussion

Day 2 – Tuesday, November 16, 2021

- 8:30 am - 10:30 am S. Korea: Medical Device Regulations and special programs (speakers in Korea).
- Q&A
- 10:30 am - 11:00 am Break
- 11:00 am - 12:00 pm China: Innovative track, priority review, regional policies.
- Q&A
- 12:00 pm-1:00 pm Lunch

1:00 pm - 2:30 pm	Japan Part 1: Medical Device Regulations, HBD program, special committee review, recent developments
2:30 pm - 2:45 pm	Break
2:15 pm – 2:45 pm	Japan Part 2: Reimbursement, market access, strategy. Q&A
2:45 pm - 3:15 pm	Guest speaker: Global strategies
3:15 pm - 4:00 pm	Q&A and panel discussions
4:00 pm	End of Day 2 Workshop