*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
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
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<tbody>
<tr>
<td>1:00 pm - 2:30 pm</td>
<td>Japan Part 1: Medical Device Regulations, HBD program, special committee review, recent developments</td>
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<td>2:30 pm - 2:45 pm</td>
<td>Break</td>
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<tr>
<td>2:15 pm – 2:45 pm</td>
<td>Japan Part 2: Reimbursement, market access, strategy. Q&amp;A</td>
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<td>2:45 pm - 3:15 pm</td>
<td>Guest speaker: Global strategies</td>
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<td>3:15 pm - 4:00 pm</td>
<td>Q&amp;A and panel discussions</td>
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<td>4:00 pm</td>
<td>End of Day 2 Workshop</td>
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