

Event: ISPE 2009 Annual Meeting
 103 - Combination Products: Considerations for Entering a
Session: New Market
Session Leader: Rebecca Waterbury
Dates: Sunday, 8 November (13.00-17.00)
Location: San Diego, CA



Sunday, 8 November

Start

| Time | End Time | Presentation Title | Speaker |
|-------|----------|---|--------------|
| 13:00 | 13:10 | Course Introduction and Audience Survey | Waterbury |
| 13:10 | 13:50 | Product Development Challenges | Russ |
| 13:50 | 14:30 | Regulatory Submission Considerations for Combination Products (CP) | Koepke |
| 14:30 | 15:00 | CP Development Case Study: Business Strategy for Drug Eluting Stent (DES) | Slane |
| 15:00 | 15:30 | Networking Break | |
| 15:30 | 16:15 | US FDA Office of Combination Products | Lauritsen |
| 16:15 | 17:00 | Panel Q&A Discussion | All Speakers |
| 17:00 | | Session Adjourns | |

***Please Note Agendas are Subject to Change**