

DAY 1: Tuesday, September 14

Time	Session
11:00 a.m. – 11:15 a.m.	Opening Plenary: Welcome & Opening Remarks
11:15 a.m. – 12:15 p.m.	Opening Plenary: Keynote – Promoting Culture of Quality
12:15 p.m. – 12:45 p.m.	<i>Break</i>
12:45 p.m. – 2:00 p.m.	What to Expect on a 503B Inspection - From Initiation to Closeout
2:00 p.m. – 2:15 p.m.	<i>Break</i>
2:15 p.m. – 3:15 p.m.	FDA Approvals: 505(b)(2) and ANDA Pathways
3:15 p.m. – 3:45 p.m.	<i>Break</i>
3:45 p.m. – 4:45 p.m.	Stability/BUDS: Science and Guidance Or Elevating SOPs and Work Aids
4:50 p.m. – 5:35 p.m.	Compounding Policy Updates

DAY 2: Wednesday, September 15

Time	Session
11:00 a.m. – 12:00 p.m.	Cross-Sector Panel: Outsourcing Facilities and Purchasers
12:00 p.m. – 12:30 p.m.	<i>Break</i>
12:30 p.m. – 1:30 p.m.	FDA Form 483, Responses and Beyond
1:30 p.m. – 2:00 p.m.	<i>Break</i>
2:00 p.m. – 3:00 p.m.	Quality Management Systems Or Analytical Testing for Compounded Drugs
3:00 p.m. – 3:30 p.m.	<i>Break</i>
3:30 p.m. – 4:45 p.m.	Closing Plenary: The Future of Outsourcing Facility Compounding

Pre-Conference Session: Monday, September 13

Time	Session
2:00 p.m. – 4:00 p.m.	Compounding Law and Policy