



Training Course Agenda

615 – Injectable Combination Product Integrated Development

DAY 1

8:30 **Welcome and Introductions**

9:00 The Evolving Regulatory Landscape for Combination Products
Convergence of Quality by Design and Design Controls

10:30 **Coffee/Tea Break**

10:45 The Role of Human Factors and Patient Focused Design
Break Out Session: Hands-On Delivery System and Design Considerations from Phase 1 to Approval

12:00 **Lunch**

13:00 Taking a Risked based Approach to Combination Product Quality, Safety and Performance
Essential Performance Requirements and Established Conditions

14:30 **Coffee/Tea Break**

14:45 Compatibility of Primary Containers with Delivery Systems
Case Studies

16:00 **End of Training Course**