

“Modeling and Simulation to Support Drug Development Decisions”

Day 2: Friday, 18th April 2014

8:00-9:00	Registration/ Breakfast	
9:00-10:00	Inauguration	
10:00-11:00	Introduction to Drug Development and Decision Making Introduction to Pharmacometrics	Dr. Pravin Jadhav
11:00-12:00	Modeling applications in early drug development <ul style="list-style-type: none">• FIM dose• Phase I clinical plan	Dr. Girish Bende
11:30-12:30	Modeling applications in late drug development <ul style="list-style-type: none">• Phase II/III dose selection• Clinical Trial design and simulations	Dr. Pravin Jadhav
12:30-13:30	Lunch	
13:30-14:30	Modeling applications in late drug development <ul style="list-style-type: none">• Pediatric Drug Development• Regulatory applications	Dr. Pravin Jadhav
14:30-16:00	Faculty led exercise for participants <ul style="list-style-type: none">• 2 Case studies for audience to experience problem solving in clinical drug development Group Discussion	All (Lead- Dr. Shariq Sayed)
16:00-16:15	Tea	
16:15-17:45	Introduction to generic drug development and modeling applications	Dr. Girish Bende
17:45-18:00	Wrap up	Dr. Pravin Jadhav