

1st MOPI Bioequivalence Workshop

BE Report Module Program 11 - 12 August 2009



Day 1 – 11 August 2009		
Time	Topic	Description
8:30 – 9:00 am	Defining the basic requirements of GCP	<ul style="list-style-type: none"> - Overview of ICH/GCP requirements - Understanding the role of DCA/NPCB and EC - Understanding the roles and responsibilities of the clinical research teams and the sponsor
9:00 – 9:30 am	Contents of a Clinical Study Report	<ul style="list-style-type: none"> - The ICH E3: Structure and Content of a Clinical Study Report. - Understanding the requirements and expectations of each section of the ICH E3
9:30 – 10:30 am	The Appendices	<ul style="list-style-type: none"> - Protocol Compliance - CRF & ICF Compliance - Signature Sheet & Task Delegation - Ethics Approval & Composition
10:30 – 11:00 am	Tea Break	
11:00 – 11:30 am	The Appendices (cont.)	<ul style="list-style-type: none"> - Analytical Report
11:30 – 12:00 pm	Protocol Deviations	<ul style="list-style-type: none"> - Understand the impact of protocol deviations to the study - Case Studies
12:00 – 12:30 pm	BE Audits & Monitoring	<ul style="list-style-type: none"> - Ensure compliance of your BE report
12:30 – 1:30 pm	Lunch	
1:30 – 2:30 pm	BE Report	<ul style="list-style-type: none"> - Title Page - Synopsis - Administrative Structure - Investigational Plan
2:30 – 3:30 pm	Exercise 1	<ul style="list-style-type: none"> - Meeting ICH E3 requirements. Data extraction.
3:30 – 4:00 pm	Tea Break	
4:00 – 5:30 pm	Exercise 2	<ul style="list-style-type: none"> - BE Report - Investigational Plan
Day 2 – 12 August 2009		
8:30 – 10:00 am	Pharmacokinetics, Safety Reporting & Quality Assurance	<ul style="list-style-type: none"> - Pharmacokinetics & the 90% CI - AE listings - Quality aspects of a BE study
10:00 – 10:30 am	Tea Break	
10:30 – 11:30 am	Tables	<ul style="list-style-type: none"> - Table Listing
11:30 – 12:00 pm	Figures	<ul style="list-style-type: none"> - Figure Listing
12:00 – 1:00 pm	Lunch	
1:00 – 3:00 pm	Exercise 3	<ul style="list-style-type: none"> - Statistics - Result and Discussion
3:30 – 3:30 pm	Tea Break	
3:30 – 4:30 pm	EMA Draft BE Guidance 2009	<ul style="list-style-type: none"> - What to Expect - Preparing for Change
4:30 – 5:00 pm	End of Day & Summary	