



The GCC Biosimilar Medicinal Products Workshop

DAY ONE: Tuesday 19th April 2011

Opening Session:

Time	Lecture	Speaker
0800-0900	Registration and refreshments	
0900-0905	Opening Remarks	
0905-0910	Welcome speech	<i>Prof. Saleh A. Bawazir</i>
9010-9015	President speech	<i>Prof. Mohammed Al kanhal</i>
0915-0930	ICH GCC presentation	<i>Prof. Saleh A. Bawazir</i>

Session One: Quality of Similar Biological Medicinal Products GCC Workshop

Moderator: Dr. Mohammad Alahdal, KFSHRC, Riyadh, Saudi Arabia

Time	Lecture	Speaker
0930-1015	ICH and EU regulatory framework	<i>Dr. Falk Ehmann</i>
1015-1100	Quality of biologicals	<i>Dr. Kowid Ho</i>
1100-1115	Discussion	
1115-1145	Refreshment Break	
1145-1230	ICH and EU regulatory framework	<i>Dr. Kowid Ho</i>
1230-1245	Discussion	
1245-1330	Lunch & Prayer Break	

Session Two: Quality of Similar Biological Medicinal Products GCC Workshop

Moderator: Dr. Amal Fatani, KSU, Riyadh, Saudi Arabia

Time	Lecture	Speaker
1330-1415	Cell substrate / Genetic stability	<i>Dr. Kowid Ho</i>
1415-1430	Discussion	
1430-1515	Comparability	<i>Dr. Kowid Ho</i>
1515-1630	Discussion	



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority



The GCC Biosimilar Medicinal Products Workshop

DAY TWO: Wednesday 20th April 2011

Session Three: Specific Aspects of Similar Biological Medicinal Products Regulations

Moderator: Dr. Murad Alsaggaf, SPIMACO company, Saudi Arabia

Time	Lecture	Speaker
0900-0945	EU Biosimilar framework	<i>Dr. Falk Ehmann</i>
0945-1000	Discussion	
1000-1045	EU Biosimilar Quality aspects	<i>Dr. Kowid Ho</i>
1045-1100	Discussion	
1100-1130	Refreshment Break	
1130-1215	Biosimilar Non clinical and clinical aspects	<i>Dr. Falk Ehmann</i>
1215-1230	Discussion	
1230-1330	Lunch & Prayer Break	
1330-1630	<i>Close round table discussion with the Drug Evaluation and standards setting Department</i>	



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority