Deree
School of Graduate and Professional Education

THE AMERICAN COLLEGE OF GREECE
Pierce Deree Alba
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REGULATORY AFFAIRS

7TH LEVEL AUDITORIUM / MAIN BUILDING, AGHIA PARASKEVI CAMPUS

DAY 1 – Friday, May 13, 2016			
09:00-9:30	Introduction Day 1: Welcome & Objectives	Nikos Moutzouris	Head of Regulatory Affairs, South East EU cluster, Pfizer
09:30-13:00	Competent Authorities (Greece, Cyprus & EMA), Regulatory Procedures in EU	Marianna Karafoulidou & Grigorios Akgyralidis	Marianna Karafoulidou: Head of QA & Regulatory Affairs, Mylan Grigorios Agkyralidis: Head of Regulatory Affairs, Boehringer Ingelheim Ellas AE
13:00-14:00	**LUNCH**		
14:00-14:45	Understanding & Implementing New EU Clinical Trial Regulation	Barbara Baroutsou	Chief Scientific Officer Novartis
14:45-15:30	Early Access Programs, Special Imports, Off label EOF procedures	Christine Hatzidakis	Regulatory Affairs Head Novartis
15:30-15:45	**BREAK**		
15:45-16:15	Commercial agreements (Co-marketing, Co-promotion)	Marianna Karafoulidou	Head of QA & Regulatory Affairs, Mylan
16:15-16:45	Regulatory Science, postgraduate studies and Continuous Professional Education in EU	Barbara Baroutsou	Chief Scientific Officer Novartis
16:45-17:00	Wrap up of the day		

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DAY 2 – Saturday, May 14, 2016			
09:00-09:30	Introduction	Nikos Moutzouris	Head of Regulatory Affairs, South East EU cluster, Pfizer
09:30-10:15	Good Distribution Practice	Marianna Karafoulidou	Head of QA & Regulatory Affairs
10:15-11:00	Marketing Exclusivity Rights / Patents / Regulatory Data Protection	Nikos Moutzouris	Head of Regulatory Affairs, South East EU cluster, Pfizer
11:00-11:15	**BREAK**		
11:15-13:00	Falsified Medicines Directive / Coding & Serialization	Nikos Moutzouris	Head of Regulatory Affairs, South East EU cluster, Pfizer
13:00-14:00	**LUNCH**		
14:00-14:45	Promotional Practices	Christine Hatzidakis	Regulatory Affairs Head Novartis
14:45-15:00	**BREAK**		
15:00-16:00	Biologics / Biosimilars / Advanced Therapies	Grigorios Akgyralidis	Head of Regulatory Affairs, Boehringer Ingelheim Ellas AE
16:00-16:45	Open discussion		
16:45-17:00	Wrap up		