Module 9: Registration of Biological, Biotechnology and Advanced Therapy Products

3rd – 5th April 2019

Location: De Vere Latimer Estate, Chesham, UK

Module Leader: **Alexis Cockroft**

Date: Wednesday 4th April 2019

Time	Activity	Speaker
16.00	Registration	
16.30 – 17.00	Welcome & Introduction to the Module	**Alexis Cockroft**
17.00 – 18.00	Lecture 1: Development of Regulation of Biologicals	**Mark Richardson** Regulatory Affairs Ltd
18.00 – 19.00	Lecture 2: Module 3 Guideline Requirements	**Richard Keane** Biogen Idec
19.00 – 19.30	New Student Tutorial	**Dr Laura Brown** Course Director
19.30	**Dinner**	

Module 9: Registration of Biological, Biotechnology and Advanced Therapy Products

3rd – 5th April 2019

Date: Thursday 4th April 2019

Time	Activity	Speaker
09.00 – 10.00	Lecture 3: Clinical Development of Biopharmaceuticals	**Tara Hutton** Biogen Idec
10.00– 11.00	Lecture 4: Preclinical Testing of Biologicals	**Alison Wolfreys** UCB Celltech
11.00 – 11.20	**Refreshment Break**	
11.20 – 12.20	Lecture 5: Regulation of Gene and Cell Therapy Products	**Sergio Fracchia** Novartis
12.20 – 13.20	**LUNCH**	
13.20 – 14.10	Lecture 6: Implications and Regulations of Changes during Process Development	**Mairead Duke** BioMarin Europe Limited
14.10 – 14.30	**Refreshment Break**	
14.30 – 16.30	Case study 1	Module Leaders
16.30 -17.30	Lecture 7: Regulation of Biosimilars	**Cecil Nick** Parexel
19.00	Dinner	

Module 9: Registration of Biological, Biotechnology and Advanced Therapy Products

3rd – 5th April 2019

Date: Friday 5th April 2019		
09.00 – 10.00	Lecture 8: Immunogenicity issues	**Isabelle Cludts** NIBSC
10:00 – 10.30	**Refreshment Break and Check Out**	
10.30 – 11.30	Lecture 9: Bioassays	**Jane Robinson** BEBPA
11:30 – 12.30	Lecture 10: Regulation of Vaccines	**Andrew Deavin** GSK Vaccines
12.30 – 13.30	Lunch	
13.30 – 14.30	Lecture 11: Viral safety and TSEs	**Ann Stokes** GlaxoSmithKline
14.30 – 16.15	**Refreshment Break And Case Study 2**	**Sergio Fracchia**
16.15 – 16.30	Close	