

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

Date: 15 - 17 May 2023



LOCATION: TOPRA OFFICE, LONDON, UK / ONLINE

Module Leader: Rhydian Howells

Date: Monday 15th May 2023

Time	Activity	Speaker
09.15 – 09.30	Welcome & Introduction to the Module	TOPRA & Rhydian
09.30 – 10.30	Lecture 1: Development of Regulation of Biologicals	Rhydian Howells, KPMG
10.30 – 11.00	Refreshment Break	
11.00 – 12.00	Lecture 2: Module 3 Guideline Requirements	Richard Keane, Biogen Idec
12.00 – 13.00	Lunch	
13.00 – 14.00	Lecture 3: Implications and Regulations of Changes during Process Development	Zabin Younes, Scendea
14.00 – 14.30	Refreshment Break	
14.30 – 15.30	Lecture 4: Clinical Development of Biopharmaceuticals	Tara Hutton, Biogen Idec
15.30 – 16.30	Lecture 5: Viral Safety and TSEs	Zabin Younes, Scendea

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Date: 15 - 17 May 2023

Date: Tuesday 16th May 2023

Time	Activity	Speaker
09.00 – 10.00	Lecture 6: Bioassays	Paula Urquhart, Labcorp Drug Development
10.00 – 10.30	Refreshment Break	
10.30 – 12.30	Case Study	Richard Keane & Rhydian Howells
12.30 – 13.30	Lunch	
13.30 – 14.30	Lecture 7: Regulation of Biosimilars	Cecil Nick, Parexel
14.30 – 15.00	Refreshment Break	
15.00 – 16.00	Lecture 8: Immunogenicity Issues	Isabelle Cludts, MHRA

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Date: 15 - 17 May 2023

Date: Wednesday 17th May 2023

Time	Activity	Speaker
09.00 – 10.00	Lecture 9: Preclinical Testing of Biologicals	Alison Wolfreys, UCB Celltech
10.00 – 10.30	Refreshment Break	
10.30 – 11.30	Lecture 10: Regulation of Vaccines	Andrew Deavin, GSK Vaccines
11.30 – 12.30	Lecture 11: Regulation of Gene and Cell Therapy Products	Sergio Fracchia, Novartis
12.30 – 13.30	Lunch	
13.30 – 15.15	Case Study 2	Sergio Fracchia, Novartis
