

Module 9: Registering Biological Biotech & Advanced Therapy Products

Date: 8-10 September 2026



Location: TOPRA Office: 3rd Floor, City Reach 5, Greenwich View Place, London, E14 9NN

Module Leaders: Rhydian Howells

Day 1: Tuesday 8th September 2026

Time	Activity	Speaker
10.30 – 10.45	Welcome & Introduction to the Module	TOPRA & Rhydian Howells
10.45 – 12.00	Lecture 1: Overview of Regulation of Biologicals	Rhydian Howells, ProPharma Group
12.00 – 13.00	Lunch	
13.00 – 14.15	Lecture 2: Preclinical Testing of Biologicals	Alison Wolfreys, UCB Celltech
14.15 – 15.30	Lecture 3: Clinical Development of Biopharmaceuticals	Tara Hutton, Biogen Idec
15.30 – 15.45	Refreshment Break	
15.45 – 16.45	Lecture 4: Immunogenicity Issues	Kirsty Harper, UCB Celltech
16:45 – 17:00	Review of Day 1	All
	Close	

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Day 2: Wednesday 9th September 2026

Time	Activity	Speaker
09.00 – 11.00	Lecture 5: Quality/CMC Considerations	Zabin Younes, Granata Bio
11.00 – 11.15	Refreshment Break	
11.15 – 12.30	Lecture 6: Module 3 Guideline Requirements	Richard Keane, Biogen
12.30 – 13.30	Lunch	
13.30 – 15.00	Case Study 1 – Specification Setting and Comparability	Module Leader + Speakers
15.00 – 15.30	Refreshment Break	
15.30 – 16.30	Lecture 7: Bioassays	Paula Urquhart Lab Corp
16.30 – 17.00	Review of Day 2	All
Close		

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Day 3: Thursday 10th September 2026

Time	Activity	Speaker
09.00 – 10.15	Lecture 8: Regulation of Biosimilars	Cecil Nick, Parexel
10.15 – 10.30	Refreshment Break	
10.30 – 11.45	Lecture 9: Regulation of Vaccines	Andrew Deavin, GSK Vaccines
11.45 – 12.45	Lunch	
12.45 – 14.00	Lecture 10: Regulation of Advanced Therapies	Rhydian Howells, ProPharma
14.00 – 14.30	Refreshment Break	
14.30 – 16.00	Case Study 2	All
16.00 – 16.30	Review of Course	All + TOPRA
	Close	