

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

Date: 9 - 11 September 2024



**LOCATION:** TOPRA OFFICE, LONDON, UK / ONLINE

**Module Leader:** Rhydian Howells

**Date:** Monday 9<sup>th</sup> September 2024

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

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**Date:** Tuesday 10<sup>th</sup> September 2024

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

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



Date: 9 - 11 September 2024

**Date:** Wednesday 11<sup>th</sup> September 2024

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>09.00 – 10.15</b>	Lecture 8: Regulation of Biosimilars	<b>Cecil Nick,</b> Parexel
<b>10:15 – 10.30</b>	Refreshment Break	
<b>10.30 – 11.45</b>	Lecture 9: Regulation of Vaccines	<b>Andrew Deavin,</b> GSK Vaccines
<b>12.00 – 12.45</b>	Lunch	
<b>12.45 – 14.00</b>	Lecture 10: Regulation of Gene and Cell Therapy Products	<b>Sergio Fracchia,</b> Novartis
<b>14.00 – 14.30</b>	Refreshment Break	
<b>14.30 – 16.00</b>	Case Study 2	<b>All</b>
<b>16.00 – 16.30</b>	Review of Course and Close	All + TOPRA