

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

22 - 24 March 2021 Online



**Module Leader:** Rhydian Howells

**Date:** Monday 22<sup>nd</sup> March 2021

**Chair:**

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>09.15 – 09.30</b>	Welcome & Introduction to the Module	
<b>09.30 – 10.30</b>	Lecture 1: Development of Regulation of Biologicals	<b>Mark Richardson</b> Richardson Associates
<b>10.30 – 11.00</b>	Refreshment Break	
<b>11.00 – 12.00</b>	Lecture 2: Module 3 Guideline Requirements	<b>Richard Keane</b> Biogen Idec
<b>12.00 – 13.00</b>	Lunch	
<b>13.00 – 14.00</b>	Lecture 3: Clinical Development of Biopharmaceuticals	<b>Tara Hutton</b> Biogen Idec
<b>14.00 – 14.30</b>	Refreshment Break	
<b>14.30 – 15.00</b>	Lecture 4: Preclinical Testing of Biologicals	<b>Alison Wolfreys</b> UCB Celltech
<b>15.00 – 16.00</b>	Lecture 5: Viral safety and TSEs	<b>Anne Stokes</b> GlaxoSmithKline

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**Date:** Tuesday 23<sup>rd</sup> March 2021

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<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>09.00– 10.00</b>	Lecture 6: Implications and Regulations of Changes during Process Development	<b>Rhydian Howells</b> <b>Diamond Pharma Services</b>
<b>10.00 – 10.30</b>	<b>Refreshment Break</b>	
<b>10.30 – 12.30</b>	<b>Case study</b>	<b>Richard Keane</b>
<b>12.30 – 13.30</b>	<b>Lunch</b>	
<b>13.30 – 14.30</b>	Lecture 7: Regulation of Biosimilars	<b>Cecil Nick</b> Parexel
<b>14.30 – 15.00</b>	<b>Refreshment Break</b>	
<b>15.00 – 16.00</b>	Lecture 8: Immunogenicity issues	<b>Isabelle Cludts</b> NIBSC

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**Date:** Wednesday 24<sup>th</sup> March 2021

**Chair:**

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<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>09.00 – 10.00</b>	Lecture 9: Bioassays	<b>Paula Urquhart</b> <b>Covance</b>
<b>10.00 – 10.30</b>	<b>Refreshment Break</b>	
<b>10.30 – 11.30</b>	Lecture 10: Regulation of Vaccines	<b>Andrew Deavin</b> <b>GSK Vaccines</b>
<b>11.30 – 12.30</b>	Lecture 11: Regulation of Gene and Cell Therapy Products	<b>Sergio Fracchia</b> Novartis
<b>12.30 – 13.30</b>	Lunch	
<b>13.30 – 15.15</b>	<b>Case Study 2</b>	<b>Sergio Fracchia</b> <b>(Lead)</b>

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