

Get a glimpse of **Module B**  
of the SIR ERA Course  
**2024-2025**

<b>Module B</b>	<b>Morning</b>	<b>Midday/afternoon</b>	<b>Afternoon</b>	<b>Afternoon/Evening</b>
Day 1: 25 September 2024	Welcome & introduction to Quality	Pharmaceutical development and life cycle management	Quality of new biologic entities (NBE): Oligonucleotides and antibodies	Case study: regulatory aspects of Quality
Speaker(s)	<b>Anja Slikkerveer</b>	<b>Femke Jacobs</b>	<b>Tom Govaerts (GLPG)</b>	<b>Marlies Kubbinga (CBG)</b>
Time	9:30 – 10:00	10:00 – 12:30	14.00 – 16.00	16.00 – 17.00 19:30 – 21:00
Day 2: 26 September 2024	Bioavailability as link between pharmaceutical quality and drug safety and efficacy	The quality section of the regulatory dossier: -Drug substance -Drug Product	Quality aspects of new biologic entities (NBE):  Advanced therapy medicinal products (ATMP)	Essentials of pharmacology, pharmacokinetic and toxicology
Speaker(s)	<b>Walter Krauwinkel (UCB)</b>	<b>Vicki Venizelos</b>	<b>Karin Hoogendoorn</b>	<b>Anja Slikkerveer</b>
Time	09:00 – 11:00	11.00 – 12.30 13:30 – 15:00	15.00 – 17.00	19:30 – 22:00
Day 3: 27 September 2024	Timing of toxicology studies within the framework of the clinical investigation program	Pre-clinical regulatory affairs	Case study: Regulatory aspects of Preclinical	Closure of Module B, looking forward to Module C
Speaker(s)	<b>Ann Lampo (Janssen)</b>	<b>Kris Siezen (CBG)</b>	<b>Annelieke Peters (D2team)</b>	<b>Anja Slikkerveer</b>
Time	9:00 – 11:30	11:30 – 12:30 & 13:30 – 14:30	14:30 – 16:45	16:45 – 17:00