SIR Institute for Pharmacy Practice and Policy

Module B	Morning	Midday/afternoon	Afternoon	Afternoon/Evening
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) Time	**Anja Slikkerveer** 9:30 – 10:00	**Femke Jacobs** 10:00 – 12:30	**Tom Govaerts (GLPG)** 14.00 – 16.00	**Marlies Kubbinga (CBG)** 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) Time	**Walter Krauwinkel (UCB)** 09:00 – 11:00	**Vicki Venizelos** 11.00 – 12.30 13:30 – 15:00	**Karin Hoogendoorn** 15.00 – 17.00	**Anja Slikkerveer** 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) Time	**Ann Lampo (Janssen)** 9:00 – 11:30	**Kris Siezen (CBG)** 11:30 – 12:30 & 13:30 – 14:30	**Annelieke Peters (D2team)** 14:30 – 16:45	**Anja Slikkerveer** 16:45 – 17:00