

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

Module A	Morning	Morning	Midday	Afternoon	Evening
Day 1: 5 June 2024	Welcome & introduction to case studies	Global trends and challenges in holistic drug development	The regulatory framework, the when, the how, the why	Implications of the new Pharmaceutical Legislation: an industry perspective	Welcome diner and key note lecture with
Speaker(s)	Jens van Wijngaarden	Graziella Collu	Jens van Wijngaarden	Sini Eskola	Larissa de Lannoy
Time	09:30 – 10:00	10:15–12:15	13:30–14:30	15:00–16:30	18:00 – 21:00
Day 2: 6 June 2024	Other European registration procedures, why do they exist and how to deal with them	The European centralised procedure and the role of the EMA		Drug development and route to market: academic, startup and SME perspective	Time to work on case studies
Speaker(s)	Kora Doorduyn	Maud Dirken		Edwin Spaans	Jens van Wijngaarden & Hans van Bronswijk
Time	9:30–11:00	11:15–12:15 and 13:15–14:00		14:15–16:00	19:00 – 21:30
Day 3: 7 June 2024	Scientific evolution of medicines' regulation	The pending new Pharmaceutical Legislation; an overview of pending reforms.		The international context of medicines' regulation, convergence, reliance and collaboration	Wrap-up Module A and case studies (looking forward to Module B)
Speaker(s)	Bert Leufkens	Anna Wawrzyniak		Aimad Torqui	Jens van Wijngaarden & Hans van Bronswijk
Time	9:00–10:30	10:45–12:30		13:30–15:00	15:15 – 15:45