SESSION PLAN – NFS Pharma. Legislation and Guidance

Day 1 Monday 18 May 2026

Time	Sess #	Session Name
08.30 – 09.00		Course Registration
09.00 – 09.15	1	Course Overview and Objectives
09.15 – 09.45	2	TW: What Do We Want Medicines to Do?
09.45 – 10.00		Refreshment Break
10.00 – 10.45	3	Medicines Law – An Introduction
10.45 – 11.15	4	Role of Pharmacopoeias
11.15 – 11.45	5	EU Clinical Trials Legislation
11.30 – 12.30		Lunch Break
12.30 – 12.45		EU Clinical Trials Legislation continued
12.45 – 13.30	6	EU Laws for Commercial Medicines
13:30 – 14.00	7	Quiz: The EMA – Role and Activities What Do You Know About the EMA?
14:00 - 14.30	8	EU Marketing Authorisations & Dossiers
14.30 – 14.45		Refreshment Break
14.45 – 15.15	9	Post Approval Changes & Variations
15.15 – 15.45	10	Manufacturing and Wholesale Dealers Authorisations
15.45 – 16.15	11	TW: Manufacturing/Import Authorisations
16.15 – 16.45	12	TW: GDP Guidelines

Day 2: Tuesday 19 May 2026

Time	Sess #	Session Name
08.30 – 09.00		Day 1 Review
09.00 – 09.45	13	The Legal Duties and Role of the Qualified Person (QP)
09.45 – 10.15	14	TW: Qualified Person Scenarios
10.15 – 10.30		Refreshment Break
10.30 – 11.00		TW: Qualified Person Scenarios: Feedback
11.00 – 11.30	15	Regulatory Control of Starting Materials
11.30 – 12.30		Lunch
12.30 – 13.00	16	TW: API QP Declaration scenario
13.00 - 13.45	17	International Council for Harmonisation (ICH & VICH)
13.45 – 14.45	18	TW: Complaint Scenario
14.45 – 15.00		Refreshment Break
15.00 – 15.30	19	Recalls
15.30 - 16.00	20	TW: Recall Responsibilities
16.00 – 16.30	21	Mutual Recognition Agreements of Inspection

Day 3: Wednesday 20 May 2026

Time	Sess #	Session Name
08.30 – 09.00	**22**	**Review of Day 2**
09.00 – 09.45	**23**	**TW: EU Legislation and Guidance internet hunt**
09.45 - 10.00		**Refreshment Break**
10.00 – 10.30	**24**	**Decentralised Manufacturing**
10.30 – 11.00	**25**	**Medical Devices and Combination Products**
11.00 – 11.30	**26**	**Final course review, with summary of legislation.** **Close of NSF part of course**
11.30 – 12.30		**Lunch Break**
12.30 – 17.00		**Norwegian Medicines Agency briefing**