APPENDIX 1

Programme for 3-day Pharmaceutical Legislation & Guidance course

Session	Time	`Topic
DAY 1	**9 May 2022**	
	08.30 – 09.00	Registration
1	09.00 – 09.15	Welcome and Objectives
2	09.15 – 09.30	**Teamwork 1: What do we want medicines to do?**
3	09.30 – 10.10	Introduction to Medicines Law
	10:10 – 10:30	***Refreshment Break***
4	10.30 – 11.15	EU Law – An Overview
5	11.15 – 12.00	Marketing Authorisations and Dossiers: EU and USA
	12.00 – 13.00	***Lunch Break***
6	13.00 – 13.30	**Teamwork 2: Role and Activities of the EMA**
7	13.30 – 14.00	Regulatory Framework for Investigational Medicinal Products (IMPs) EU and UK
8	14.00 – 14.30	Post Approval Changes and Variations
8a	14.30 – 15.00	**Teamwork 3: EU MA Variations**
	15.00 – 15.15	***Refreshment Break***
8b	15.15 – 15.45	**Teamwork 3: EU MA Variations; Feedback**
9	15.45 – 16.15	Manufacturing and Wholesale Dealers Authorisations
10	16.15 – 17.00	**Teamwork 4: EU GDP Guidelines**

Session	Time	Topic
DAY 2	**10 May 2022**	
	08.30 – 09.00	Feedback – Key Learning Points from Day 1
11	09.00 – 10.00	The Legal Duties and Role of the Qualified Person (QP)
	10.00 – 10.15	***Refreshment Break***
12	10.15 – 11.15	**Teamwork 5: Qualified Person Scenarios**
13	11.15 – 12.15	Regulatory Control of Starting Materials
	12.15– 13.15	***Lunch Break***
14	13.15 – 14.00	**Teamwork 6: API QP Declaration scenarios**
15	14.00 – 14.45	International Council for Harmonisation (ICH) – Organisation, Role and Recent Quality Guidance
	14.45 – 15.00	***Refreshment Break***
16	15.00 – 15.30	**Teamwork 7: Complaint Scenario**
17	15.30 – 16.00	Recalls – EU and US Laws
18	16.00 – 16.30	**Teamwork 8: Product Recalls**
19	16.30 – 17.00	Mutual Recognition Agreements of Inspection

Session	Time	Topic
DAY 3	**11 May 2022**	
	08.30 – 09.00	Feedback – Key Learnings from Day 2
20	09.00 – 10.00	Data Integrity
	10.00 – 10.15	***Refreshment Break***
21	10.15 – 11.00	**Teamwork 9: Data Integrity Scenarios**
23	11.00 – 11.45	EU Legislation for Medical Devices and Combination Products
24	11.45 – 12.00	Q&A and Close of NSF portion of course
	12.00 – 1300	***Lunch***
	13:00 – 17.00	**Norwegian Medicines Agency briefing**