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برنامج تدريبى عن القواعد المنظمة وإرشادات تقديم ملف الجودة الخاص بـ CTD للمستحضرات البشرية File

Overview on guidelines, submission guidance and evaluation process of Quality Module (Module 3) of the CTD File

Topic		Speaker	Date	Duration
DAY I				
Registration				**09:30-10:00 a.m.**
Welcome and opening		Prof.Dr.Hanan Amin Dr. Hamada Sherief	28/8/2022	10:00-10:30 a.m.
Introduction and brief about Technical Affairs Administration, its role and activities.		Dr.Mona Moussa		10:30 - 11:00 a.m.
Guidelines on submission of documentation for pharmaceutical products: Quality S- Part	3.2.S.1 General information 3.2.S.2 Manufacture 3.2.S.3 Characterization	Dr. Mohamed Mohsen		11:00 - 12:15 p.m.
	3.2.4 Control of Drug Substance 3.2.S.5 Reference Standards	Dr. Aya Osama		12:15 - 01:30 p.m.
	3.2.S.6 Container Closure System 3.2. S.7 Stability	Dr. Ahmed Abd El- Samie		01:30 - 02:30 p.m.
Break				**02:30 - 03:00 p.m.**
Certificate of Suitability of the European Pharmacopoeia (CEP)	How to read a CEP	Dr. Haitham Shaaban	28/8/2022	**03:00—04:00 p.m.**

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Overview on guidelines, submission guidance and evaluation process of Quality Module (Module 3) of the CTD File

Topic		Speaker	Date	Duration
DAY II				
Registration				**09:30-10:00 a.m.**
Guidelines on submission of documentation for pharmaceutical products: Quality P- Part	3.2.P.1 Description and Composition	Dr. Zeinab Hamdy	29/8/2022	10:00-10:30 a.m.
	3.2.P.2 Pharmaceutical Development	Dr.Mohamed Mofreh		10:30-11:30 a.m.
	3.2.P.3 Manufacture 3.2.P.4 Excipients	Dr. Ahmed Abdelrahman		11:30-12:15 p.m.
Break				**12:15 – 12:45 p.m.**
Guidelines on submission of documentation for pharmaceutical products: Quality P- Part	3.2.P.5 Control of Drug product 3.2.P.6Reference Standards	Dr. Youstina Fouad	29/8/2022	12:45 –01:45 p.m.
	3.2.P.7 Container Closure System 3.2. P.8 Stability	Dr. Ahmed Abd El - Samie		1:45-02:45 p.m.
Guidelines on submission of documentation for pharmaceutical products: 3.2.A Appendices 3.2.R Regional information		Dr. Haitham Shaaban		02:45-03:00 p.m.
Submission guidance for the preliminary evaluations & Emergency Use Authorization Products Evaluation		Dr. Mohamed Mohsen		03:30-03:30 p.m.