



أجندة

Training program on comprehensive overview of CTD modules with preparation submission criteria of the dossier

البرنامج التدريبي الخاص بنظرة عامة شاملة على وحدات الملف الفني الموحد مع معايير إعداد و تقديم الملف

Topic	Speaker	Date	Duration
Day I: Regulatory updates for Registration of Human Pharmaceuticals			
Workshop Introduction & Overview on registration process according to EDA Chairman decree 450/2023	Dr. Eman Hussien	27/07/2025	Registration 09:30—10:00 A.M
Registration of local human pharmaceuticals according to EDA Chairman Decree No. (450) of 2023			
Registration of imported human pharmaceuticals according to EDA Chairman Decree No. (450) of 2023			
Re-registration of human pharmaceuticals according to EDA Chairman Decree No. (150) of 2022	Dr. Radwa El-gamil		1st Session 10:00—12:30 P.M
What's next regarding CTD & e-CTD platform			
Most Common deficiencies	Dr. Eman Hussien		
Day II: Module-3 of the CTD registration file			Break
Overview of different modules of CTD file	Dr. Menna El -gamil		12:30—01:00 P.M
Different sections of module 3			
Overview of phase I review of module 3	Dr . Rana Magdy	28/07/2025	2nd Session 01:00—03:30 P.M
Introduction to S-Part of module 3			
General properties of drug substance and their impact on drug product	Dr. Shereen Alaa Eldeen		
	Dr. Ismail Mohamed		
Day III: Module-3 of the CTD registration file			
Overview of different types of impurities in drug substance & drug products	Dr. Shereen Alaa Eldeen	29/07/2025	
Basic principles of validation of analytical procedures			
	Dr. Ismail Mohamed		

الإدارة المركزية للمستحضرات الصيدلانية



أجندة

Training program on comprehensive overview of CTD modules with preparation submission criteria of the dossier

البرنامج التدريبي الخاص بنظرة عامة شاملة على وحدات الملف الفني الموحد مع معايير إعداد و تقديم الملف

Topic	Speaker	Date	Duration
Day IV: Module-3 of the CTD registration file			Registration 09:30—10:00 A.M
Introduction to P-Part of module 3	Dr. Menna El -gamil	30/07/2025	
Composition of finished product in module 3	Dr. Ahmed Mahmoud		
Overview on specifications of finished product in module 3	Dr. Menna El -gamil		
Day V: Module-5 of the CTD registration file			1st Session 10:00—12:30 P.M Break 12:30—01:00 P.M 2nd Session 01:00—03:30 P.M
Introduction & Overview on Bioequivalence Guidelines	Dr. Basma Ismail	31/07/2025	
Selection Criteria of Innovator Product			
-Overview on In- vitro study (Required documents , Application form & Study summary) -Focus on points that accelerate evaluation of the study	Dr. Samah Hegazy		
Potency ,Uniformity of dosage unit & avoiding common errors			
Dissolution test , similarity calculation & avoiding common errors			
Bioanalytical Method Validation	Dr. Noran Saaid		
Discussion	All speakers		