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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	2/11/2025	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			1st Session 10:00—12:30 P.M
Re-registration of human pharmaceuticals according to EDA Chairman Decree No. (150) of 2022			
What's next regarding CTD & e-CTD platform	Dr. Radwa El-gamil		
Most Common deficiencies	Dr. Eman Hussien		Break 12:30—01:00 P.M
Day II: Module-3 of the CTD registration file			
Overview of different modules of CTD file	Dr. Menna El -gamil	3/11/2025	2nd Session 01:00—03:30 P.M
Different sections of module 3			
Overview of phase I review of module 3	Dr . Rana Magdy		
Introduction to S-Part of module 3	Dr. Shereen Alaa Eldeen		
General properties of drug substance and their impact on drug product	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	4/11/2025	
Basic principles of validation of analytical procedures	Dr. Ismail Mohamed		

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Topic	Speaker	Date	Duration
Day IV: Module-3 of the CTD registration file			Registration 09:30—10:00 A.M 1st Session 10:00—12:30 P.M Break 12:30—01:00 P.M 2nd Session 01:00—03:30 P.M
Introduction to P-Part of module 3	Dr. Menna El -gamil	5/11/2025	
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			
Introduction & Overview on Bioequivalence Guidelines	Dr. Basma Ismail	6/11/2025	
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		