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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	14/04/2025	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
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. Mohamed Rashad		
Requirements of Module 1 submission			
Most Common deficiencies			
Day II: Module-3 of the CTD registration file			
Overview of different modules of CTD file	Dr. Mohamed Badawi	15/04/2025	
Different sections of module 3			
Overview of phase I review of module 3	Dr . Zeinab Hamdy		
Introduction to S-Part of module 3	Dr. Mohamed Badawi		
General properties of drug substance and their impact on drug product			
Day III: Module-3 of the CTD registration file			
Overview of different types of impurities in drug substance & drug products	Dr. Mohamed Badawi	16/04/2025	
Basic principles of validation of analytical procedures			

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Topic	Speaker	Date	Duration
Day IV: Module-3 of the CTD registration file			
Introduction to P-Part of module 3	Dr. Mohamed Badawi	23/04/2025	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
Composition of finished product in module 3			
Overview on specifications of finished product in module 3			
Day V: Module-5 of the CTD registration file			
Introduction, Overview on Bioequivalence Guidelines & Selection Criteria of reference listed product	Dr. Asmaa Mohamed	24/04/2025	
Overview on comparative dissolution study & vivo vitro correlation Submission Guidance	Dr. Noran Saaid Dr. sara Fouad		
Overview on submission of In– vivo bioequivalence study according to ICH E3 format	Dr. Engy Nasef		
Selection of study design & sampling time Brief on pharmacokinetic parameters	Dr. Dalia Hussien		
Criteria for study acceptance based on statistical calculation			
Discussion	Dr. Dalia Hussien Dr. Engy Nasef		