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	25/1/2026	Registration 09:30—10:00 A.M
Registration of local human pharmaceuticals according to EDA Chairman Decree No. (450) of 2023	Dr. Reham Ali		
Registration of imported human pharmaceuticals according to EDA Chairman Decree No. (450) of 2023	Dr. Yasmin Hisham		
Re-registration of human pharmaceuticals according to EDA Chairman Decree No. (150) of 2022	Dr. Mohamed Rashad		1st Session 10:00—12:30 P.M
What's next regarding CTD & e-CTD platform	Dr. Radwa El-gamil		
Most Common deficiencies	Dr. Mohamed Rashad		
Q&A	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	26/01/2026	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	27/01/2026	
Basic principles of validation of analytical procedures	Dr. Ismail Mohamed		

الإدارة المركزية للمستحضرات الصيدلية

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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. Menna El -gamil	28/01/2026	Registration 09:30—10:00 A.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	Dr. Ghada Abo Zeid	01/02/2026	1st Session 10:00—12:30 P.M
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. Nihal Hassan		Break 12:30—01:00 P.M
Potency ,Uniformity of dosage unit & avoiding common errors			2nd Session 01:00—03:30 P.M
Dissolution test , similarity calculation & avoiding common errors			
Bioanalytical Method Validation	Dr. Noran Said Dr. Samhaa El-Saleh Abd Elhady		
Discussion	All speakers		