

أجندة

البرنامج التدريبي الخاص بتحضير الملف الخاص بالمادة الفعالة للمستحضرات الصيدلانية وفقًا لإرشادات ICH وإرشادات منظمة الصحة العالمية لضمان تقديم ملف CTD بنجاح

Filing of active pharmaceutical ingredient (API) DMF for according to ICH & WHO guidelines for successful submission of CTD file training program

Agenda

DAY I

Topic	Speaker	Date	Duration
Registration			09:30 a.m.– 10:15 a.m.
*Drug Master File: Types and general structure.	Dr. Mohamed Badawi	26/09/2021	10:15 a.m.- 12:15 p.m.
The certificate of Suitability of the European Pharmacopeia (CEP) option for submission of API information by the applicant /FPP manufacturer in the CTD file.	Dr.Rafeek Fahmy		
Break			12:15p.m.-12:45p.m.
Manufacturing of API according to ICHQ7&Q11	Dr.Rafeek Fahmy	26/09/2021	12:45 p.m.– 02:45 p.m.
Break			02:45 p.m.– 03:15 p.m.
Characterization & Structure Elucidation of API	Dr. Mohamed Badawi	26/09/2021	03:15 p.m.– 05:15 p.m.

DAY II

Topic	Speaker	Date	Duration
Registration			09:30 a.m.– 10:15 a.m.
Setting Specification: test procedures & acceptance criteria for active pharmaceutical ingredients (API) according to ICH Q6 A & Pharmacopeia requirements	Dr.Rafeek Fahmy	27/09/2021	10:15 a.m.-12:15 p.m.
Break			12:15 p.m.-12:45p.m.
Analytical validation information, including experimental data for the analytical procedures used for testing the API	Dr. Mohamed Badawi	27/09/2021	12:45 p.m.– 02:45 p.m.
Break			02:45 p.m.– 03:15 p.m.
Container closure &Stability according to ICH and WHO requirements	Asso.Prof. Rania El Hosary	27/09/2021	03:15 p.m.– 05:15a.m.
Closing session	All the trainers		05:15p.m.-05:45p.m.

الإدارة المركزية للمستحضرات الصيدلانية