أجندة

البرنامج التدريبي عن الدليل الإرشادي لتنظيم المتغييرات للمستحضرات الحيوية المسجلة في مصر

Training Program on Guideline of the regulation of Post-approval Changes to a registered biological product in Egypt

Topic	Speaker	Date	Duration
DAY I			Registration
Opening Session	Dr. Asmaa Fouad	28/04/2024	09:30 to10:00 a.m.
Introductory session	Dr. Hbatallah		
Updates on procedures and data requirement's for	Dr. Reem Mahmoud		
Variation file essential requirements	Dr. Amira Gamal		1st Session
PACs evaluation	Dr. Amira Gamal Dr. Rana Maher Dr. Heba Mohamed		10:00-11:30 a.m.
Pharmacovigilance Requirements within the frame-	Dr. Walaa Ebrahim Dr. Mohamed Sayed		2nd Session
DAY II			11:30-12:30 p.m.
Stability considerations and data evaluation for PACs	Dr. Doaa Ali	29/04/2024	Break
Introductory session	Dr. Mohamed El		12:30-01:00 p.m.
Manufacturing Process of different	Dr. Marwa Fayez		
Common technical evaluation considerations for PACs	Dr. Amira El Sayed		3rd Session
Inspection Consideration for PACs	Dr. Donia Samir		01:00 -02:15 p.m.
PACs Evaluation Outcomes	Dr. Rana Maher		
Impact of PACs on lot release process and decision	Dr. Doaa Hassan		4th Session
DAY III			02:15 -03:30 p.m.
Introduction about Reliance practice in PAC &General	Dr. Reem Mahmoud	30/04/2024	
Procedures and data requirements for PAC handling through Reliance Track	Dr. Reem Mahmoud Dr. Amira Gamal		
Case Study / open discussion (Q&A)	All Trainers		