



أجندة

برنامج تدريي عن كيفية تصميم و تطوير المستحضرات الصيدلية الجنيسة وفقًا لإرشادات منظمة الصحة العالمية للحصول على الاعتمادات الدولية

Training Program on Design and Development of Generic Pharmaceutical Product According to WHO guidelines

Торіс	Speaker	Date	Duration
DAYI			
Welcome address	Prof. Hanan Amin		
Quality Risk Management	Ass.Prof.Rania El Ho- sary	15/01/2023	
Pharmaceutical development of Generic Finished drug Product according to WHO requirements (Part 1)			Registration
DAY II			09:30-10:00 a.m.
Pharmaceutical Process development of Generic Finished drug Product according to ICH Q8 & WHO requirements (Part 2)	Ass.Prof.Rania El Ho- sary	16/01/2023	First Session
Microbiological attributes & Comptability	Dr. Rafeek fahmy		10:00-12:30 p.m.
DAY III			Break
Characterization & Limits of Impurities accord- ing to Reference drug product Profile & Inter- national Guidelines	Dr. Rafeek fahmy	18/01/2023	12:30 - 01:00 p.m.
Container Closure system Studies	Ass.Prof.Rania El Ho- sary		Second Session 01:00 - 03:00 p.m.
DAY IV			
Setting Leachables & Extractables limits	Dr. Rafeek fahmy		
Application of (quality by design) QbD in Pharmaceutical Development & case studies	Ass. Prof.Rania El Ho- sary	22/01/2023	

