أجندة

ورشة عمل عن كيفية تطوير المستحضرات الصيدلية الجنيسة طبقا لإرشادات منظمة الصحة العالمية و إرشادات المجلس التنسيقي الدولي وضمان الحصول علي الاعتماد الدولي ملف الprequalification من قبل منظمة الصحة العالمية/ أو اعتماد EMA or FDA

Workshop on Pharmaceutical Development of Generic Drug Products according to ICH & WHO guidelines for successful Prequalification dossier submission

Topic	Speaker	Date	Duration
DAY I			Registration 09:30-10:00 a.m. 1st Session 10:00-12:00 p.m. Break 12:00-12:30 p.m. 2nd Session 12:30-03:00 p.m.
Welcome address	Prof. Hanan Amin	19/11/2023	
Quality Risk Management according to ICH Q9 & WHO requirements	Ass. Prof. Rania El Hosary		
Pharmaceutical development of Generic Finished drug Product according to ICH Q8 & WHO requirements			
DAY II			
Pharmaceutical Process development of Generic Finished drug Product according to ICH Q8 & WHO requirements	Ass. Prof. Rania El Hosary	26/11/2023	
Microbiological attributes & Compatibility	Dr. Rafeek fahmy		
DAY III			
Characterization & Limits of Impurities according to Reference drug product Profile & International Guidelines	Dr. Rafeek fahmy	03/12/2023	
Container Closure System Studies	Ass. Prof. Rania El Hosary		
DAY IV			
Setting Leachables & Extractables limits	Dr. Rafeek fahmy	10/12/2023	
Application of Quality by Design (QbD) in Pharmaceutical Development & case studies	Ass. Prof. Rania El Hosary		
DAY V			
Formulation Development & Process Development case Studies	Ass. Prof. Rania El Hosary	17/12/2023	
Compatibility & impurities Case Studies	Dr. Rafeek fahmy		