

أجندة

البرنامج التدريبي عن كيفية اختيار الاختبارات المثلي لضمان تقديم ملف الـ CTD بنجاح طبقاً لـ ICH Q6 A ومتطلبات أحدث دساتير الأدوية العالمية.

Training Program on Test procedures & acceptance criteria (Specifications) for successful submission of CTD File according to ICH Q6 A & pharmacopeia requirements

Topic	Speaker	Date	Duration
DAY I			Registration : 9:30a.m - 10:00a.m. Session 1: 10:00 a.m.- 12:00p.m. Break: 12:00p.m- 12:30p.m. Session 2: 12:30p.m-2:30p.m. Break: 2:30p.m-3:00p.m. Session 3: 3:00p.m-5:00p.m.
Setting Specification: test procedures & acceptance criteria for new Solid drug product according to ICH Q6 A& pharmacopeia requirements (Part I)	Ass. Prof. Rania El Hosary	30-1-2022	
Setting Specification: test procedures & acceptance criteria for active pharmaceutical ingredients (API) according to ICH Q6 A & pharmacopeia requirements	Dr. Mohamed Badawi		
Setting Specification: test procedures & acceptance criteria for new Solid drug product according to ICH Q6 A& pharmacopeial requirements (Part II)	Ass. Prof. Rania El Hosary		
DAY II			
Setting Specification: test procedures & acceptance criteria for new Liquid drug product according to ICH Q6 A& pharmacopeial requirements	Ass. Prof. Rania El Hosayr	31-1-2022	
Setting Specification: test procedures & acceptance criteria for active pharmaceutical ingredients (API) according to ICH Q6 A & pharmacopeia requirements	Dr. Rafeek Fahmy		
Setting Specification: test procedures & acceptance criteria for new Topical & transdermal drug product according to ICH Q6 A& pharmacopeia requirements	Ass. Prof. Rania El Hosary		
DAY III			
Setting Specification: test procedures & acceptance criteria for new mucosal drug product according to ICH Q6 A & pharmacopeial requirements	Ass. Prof. Rania El Hosary	1-2-2022	
studies for procedures& acceptance criteria for new drug substance: universal tests	Dr. Mohamed		
Setting Specification: test procedures & acceptance criteria for new Inhalation & nasal drug products according to ICH Q6 A & pharmacopeial requirements	Dr. Rafeek Fahmy		