

أجندة

ورشة عمل عن نظام الجودة الصيدلانية والحوكمة

Workshop on Pharmaceutical Quality System (PQS) & Governance

Topic	Speaker	Date	Duration
Day I: PQS Foundations			
GMP principles overview (WHO, PIC/S, EDA)	Dr. Mohamed Naiem Dr. Mahmoud Galal Dr. Samar Mamdouh	11/01/2026	Registration 09:30 to 10:00 a.m. 1st Session 10:00 -12:00 p.m.
PQS model & ICH Q10 alignment			
Change management in PQS			
Deviation management			
Root Cause Analysis techniques			
Supplier Management			
Internal and Quality Audit			
Day II: Risk & Knowledge Management			Break
Quality Risk Management (ICH Q9)	Dr. Mohamed Naiem	12/01/2026	12:00-12:30 p.m. 2nd Session
Knowledge Management			
Day III: Quality culture & Continuous Improvement			12:30-03:30 p.m.
Quality culture & leadership commitment	Dr. Reham Waheed Dr. Mohamed Naiem	13/01/2026	
CAPA effectiveness verification			
Quality Oversight			
Metrics & KPIs for PQS performance			



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Topic	Speaker	Date	Duration
Day IV: Documentation Systems			
Introduction to Data Integrity Foundations & Principles	Dr. Mohamed Fathy Dr. Mohamed Naiem	14/01/2026	Registration 09:30 to 10:00 a.m. 1st Session 10:00 -12:00 p.m. Break 12:00-12:30 p.m. 2nd Session 12:30-03:30 p.m.
Regulatory Expectations: Global Regulatory DI Trends			
Good documentation practices			
ALCOA+ Principles with examples			
Hybrid systems risks and mitigation controls			
Batch record review best practices			
Day V: Advanced Data Integrity			
Hands-On Group Work - Data Governance Framework & Policy Development	Dr. Mohamed Naiem	15/01/2026	
Case studies: DI from an Inspector's Lens (Common DI violations)			
Computer System Validation			
Audit trail review			