أجندة

ورشة عمل عن نظام التحقق و عملياته واستراتيجيات التحكم

Workshop on Validation System – Lifecycle Approach, Process Validation & Control Strategies

Topic	Speaker	Date	Duration
Day I : Validation System Fundamentals			
1. The Validation Lifecycle Approach • Regulatory basis (WHO TRS), Validation Master Plan (VMP) – structure, governance, and approval, Risk-based decision	Dr. Mohamed Naiem	30/03/2026	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.
2. Integration with PQS • Link between CAPA, change control, and validation • Inspection expectations and common pitfalls			
Day II: Process Validation			
• Stage 1 – Process Design, Stage 2 – Process Performance Qualification, Stage 3 – Continued Process Verification • Case studies: Critical vs. major validation deficiencies from inspections	Dr. Mohamed Naiem Dr. Nehal Ahmed	31/03/2026	
Day III: Annual Product Quality Review (APQR)			
1. Annual Product Quality Review (APQR) • Purpose and regulatory basis, Data collection, trending, and interpretation, APQR as a tool for continual improve-ment and validation requalification triggers	Dr. Mohamed Naiem	01/04/2026	
2. Validation of Support Systems (overview) • Integration with contamination control strategy (CCS)			
Day IV: Cleaning Validation & Control Strategies			
• Regulatory requirements, Setting acceptance criteria (MACO, PDE-based limits) • Sampling techniques (swab vs. rinse, recovery studies) • Visual inspection and its limitations, Worst-case product selection & changeover protocols	Dr. Mohamed Naiem Dr. Ahmed Gad	02/04/2026	