الاتحاد العربي لمنتجي الادوية والمستلزمات الطبية

(AUPAM)

First Announcement

بالتعاون مع غرفة صناعة الدواء والمستلزمات الطبية

ومستحضرات التجميل

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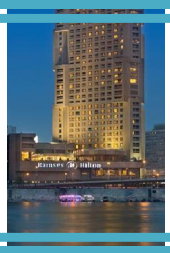
أمين عام مجلس الوحدة الإقتصادية العربية

ملتقى الصناعات الصيدلانية العربية العشرون



CAIRO – EGYPT
27-28 SEPTEMBER 2017 - HILTON RAMSES

دعم الصناعات الصيدلانية العربية

يعقد الاتحاد العربي لمنتجي الادوية والمستلزمات الطبية ملتقى الصناعات الدوائية العشرين تحت عنوان:

" مؤتمر دعم الصناعات الصيدلانية العربية"

في فندق هيتلون رمسيس القاهرة يومي الاربعاء والخميس

2017/9/28-27

Agon Academy

Agon Academy

Pharmaceutical manufacturing compliance challenges in the Arabic Region

Cairo – Egypt

27-28 September 2017

I. Conference Objective:

The conference aims to open the discussion panels regarding the challenges facing the pharmaceutical manufacturing companies and relevant regulations regarding cGMP compliance tackling the challenges of compliance in terms of optimizing cost and efforts.

The conference will have speeches by different experts in the region, and it will contain parallel workshops that will address the most needed topics for compliance in the pharmaceutical industry.

II. Session Topics

The conference will include morning and afternoon sessions where variety of topics will be presented covering different cGMP subjects, that will include compliance, Regulatory affairs, Total Quality System, operation and engineering also.

<u>The morning sessions will include but not limited to the following topics:</u>

1. Common pharmaceutical registration and manufacturing protocol legislation between Arabic countries
2. Highlight of the pharmaceutical manufactures production capacity and non-utilized production capacities
3. Introduction to accredited recently bioequivalence centers to conduct bioequivalence studies, clinical studies, and stability studies
4. Introduction to accredited centers for registration service including preparing registration files, and pharmacovigilance files preparation services
5. Introduction to Egyptian successful case study on tackling virus C and the effectiveness of (Tour and Cure) Program
6. The future provision and available opportunities for Bioindustry in the Arabic region (Joint Ventures)

Agon Academy

The workshops will include but not limited to:

1. **Introduction to Data Integrity: this workshop will tackle the following issues:**
   a. Why is Data Integrity Important?
   b. Role of Management in Data Integrity
   c. Data Integrity in Labs
   d. Principles of Data Integrity
   e. US 21 CFR 211 and EU GMP Chapter 4: Complete data v raw data
   f. Discussion

2. **Quality Culture and Enabling life cycle quality improvement: this workshop will tackle the following issues:**
   a. Introduction to product/ process and machine lifecycle concept
   b. Lifecycle concept in process validation
   c. Quality by Design concept
   d. Product quality review principles

3. **Quality Risk Management: this workshop will tackle the following issues**
   a. ICH Q9 guideline
   b. Creating risk management system from scratch
   c. Incorporating risk management concepts in handling of deviation and investigation techniques.
   d. Risk management team

4. **Compliance-in Requirements for facilities**
   a. FDA Requirements for Pharmaceutical facilities and Equipment
   b. Calibration Risk Assessment Workshop (Including Utility Calibration)
   c. Streamline approach for Q&V Requirements (EU Annex 15) workshop

5. **Streamline approach for successful cleaning Validation**
   a. New EU guideline for cleaning validation in shared manufacturing facility (ADE based limits)
   b. Creating a comprehensive cleaning validation system
   c. What limits to be used
   d. The concept of bracketing

III. Target group

1. Quality Managers
2. Clinical Drug Development
3. R&D Staff
4. Validation scientists manufacturing supervisors
5. Equipment Engineers
6. Engineering quality assurance specialists
7. Professionals from service organizations and vendors who serve pharmaceutical clients
8. Regulatory personnel involved in pharmaceutical industries.
9. Pharmaceutical/Healthcare Project Manager
10. Calibration Manager/Technician
11. Production/Planning Managers
12. Business Owners
13. IT Manager