



FDA MEMORANDUM CIRCULAR
No. **2017-002**

19 JUL 2017

SUBJECT: 1st Food and Drug Administration (FDA) Regulatory Advocacy Fair and Back-to-back Qualified Person in the Industry Regulatory Affairs (QPIRA) Trainings

I. BACKGROUND

The Food and Drug Administration will hold the 1st FDA Regulatory Advocacy Fair coinciding its 54 years as health product regulator. Timely with the celebration, FDA will be holding activities which not only showcase the Agency's milestones but extend its services to valued stakeholders. One of the main activities is the Qualified Person in the Industry Regulatory Affairs (QPIRA) training. In this event, subject to rules and guidelines that will be strictly implemented, FDA will have an avenue to promote awareness and learning for its stakeholders, to showcase industry best practices, professional organization membership, regulatory affairs success stories; quality management programs, good manufacturing practices, product safety projects, and anti-counterfeit programs, and the like. With corresponding fees and charges, booths will be opened for Stakeholder Organizations strongly promoting the Agency's advocacies as mentioned as a way to enhance stakeholder engagement and learning.

II. OBJECTIVE

The Objectives are as follows:

1. To hold a back-to-back event that will promote awareness of FDA's mandates and the role of its stakeholders;
2. To conduct simultaneous QPIRA Trainings to promote good submission practice and good regulatory practices;
3. To supplement learning from QPIRA Lectures through the Regulatory Advocacy Fair and maximize learning of participants and provide up-to-date information with regard to health products regulated through a showcase of best practices, advocacy programs, good regulatory practices and the likes from industry stakeholders and partner government agencies; and
4. To provide training for trainers, i.e. for capacity building of technical trainers in the Regional Field Offices.

1. SCOPE AND PURPOSE



This Circular aims to provide the QPIRA training courses/seminar schedule to be held by the FDA Academy – PPS for August 2017, including the Regulatory Advocacy Fair, and the corresponding schedule of fees.

2. DETAILS

2.1.COURSE SCHEDULES AND FEES

The FDA Academy shall offer the following training courses for a fee on the dates specified:

Training Course	Date	Course Fee
Qualified Person in Industry Regulatory Affairs (QPIRA)		
Training Accreditation		
QPIRA for Center for Cosmetics Regulation and Research (2-day training with a minimum of 250 participants per session)	17-18 August 2017	Php 6,000.00 As per FDA MC 2013-004
QPIRA for Center for Devices Regulation, Radiation Health and Research (2-day training with a minimum of 250 participants per session)	17-18 August 2017	Php 6,000.00 As per FDA MC 2013-004
QPIRA for Center for Food Regulation and Research (2-day training with a minimum of 250 participants per session)	17-18 August 2017	Php 6,000.00 As per FDA MC 2013-004
QPIRA for Center for Drug Regulation and Research	17-18 August 2017	Php 6,000.00 As per FDA MC

(2-day training with a minimum of 250 participants per session)		2013-004
Booth Fees and Charges		
One (1) unit of of 2.0m (W) x 3.0m (L) x 2.5m(L) x 2.5m(H) booth shell	17-18 August 2017	Php 25, 000.00

2.2 QPIRA REGISTRATION PROCEDURES AND PAYMENT

Registration is on a first-come, first-served basis. The registration procedure may be found at www.fda.gov.ph (Industry Corner – Downloadables - FDA Academy Forms). Payment can be made **over-the-counter (FDA Cashier Room 106)** or thru **Development Bank of the Philippines (DBP) Branches, Account name: FDA Special Fund and Account number: 0430-013669-030.**

2.3 BOOTH RENTALS PROCEDURES AND PAYMENT

1. Availing of booths is open to all FDA stakeholders/agency partner organizations;
2. Booth rentals and other incidental costs are payable only at FDA Cashier;
3. No fees shall be required for government partners that will participate on the subject event provided that the intent to join be made known or communicated with FDA on/or before 28 July 2017;
4. The activities that the participants will be carrying out during the subject event for which booth rentals have been secured shall only be limited to advocacy activities (e.g. those relating to industry best practices, professional organization membership, regulatory affairs success stories; quality management programs, good manufacturing practices, product safety, anti-counterfeit programs, etc.) and shall not in any way promote or endorse any FDA-regulated establishment or health product; and
5. Booth rentals is on a first-come, first-served basis only due to limited available booths.


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