

04 February 2013

**FDA MEMORANDUM CIRCULAR**  
No.: 2013-004

SUBJECT: **QUALIFIED PERSON IN INDUSTRY (FOOD, DRUG, COSMETIC AND DEVICE) REGULATORY AFFAIRS (QPIRA) TRAINING-ACCREDITATION GUIDELINES**

**I. INTRODUCTION**

On February 4, 1991, the Bureau of Food and Drugs, now the FDA, issued Memorandum Circular No. 5, series of 1991, which encouraged the companies to *designate an official liaison officer to register* with the FDA Drug Information Unit (now the Policy and Planning Office) so that *official recognition* could be accorded to him or her. On 22 January 2013, the FDA issued FDA Memorandum Circular No. 2013-003 to inform the industry that the FDA has scheduled training-accreditation for liaison officers and regulatory affairs officers to be Qualified Persons in Industry Regulatory Affairs (QPIRA), with unprejudiced objective that only that person who completed the training-accreditation shall have the accorded authority to transact business at the FDA.

The training and accreditation of liaison officers and regulatory affairs officers have been designed by FDA to ensure that the QPIRAs demonstrate competence and professionalism in preparing and submitting the correct and complete applications and dossiers. Correct and complete submission of requirements for market authorization applications ensures evaluation and approval without undue delay.

**II. OBJECTIVES**

The objectives of these guidelines are as follows:

1. To ensure that the company liaison officer or regulatory affairs officer is reasonably educated, qualified, trained and accredited by the FDA to represent the companies and transact business;
2. To ensure that the QPIRAs and the companies perform their duties and responsibilities to assure unhampered delivery of QPIRAs services to the companies they represent; and
3. To ensure that the FDA sustains QPIRA training and accreditation through updates and advance training.

### **III. QUALIFICATION**

The FDA role is to facilitate the QPIRA training-accreditation in order to ensure that the competency, communication gaps and variability among the companies, company representatives and FDA are bridged. Thus, the appropriate qualifications of the liaison officers or regulatory affairs officers authorized to attend the FDA training-accreditation shall be left to the full discretion of the companies. However, any allied healthcare professional is preferred.

### **IV. SCHEDULE OF FEES**

1. As per FDA Memorandum Circular No. 2013-002 dated 02 January 2013, a Php 6,000.00 for the two-day training-accreditation shall be imposed per registrant. The Php 6,000.00 shall cover meals and snacks, training materials, ID card, certificate of completion, posting of QPIRA in the FDA website, use of the training room, equipment and facilities.
2. A Php 6,000.00 is imposed for each additional company the QPIRA is authorized to represent.
3. A Php 6,000.00 is imposed for QPIRA ID card data update.
4. A Php 2,000.00 is imposed for replacement of lost QPIRA ID card.

### **V. ROLES AND RESPONSIBILITIES**

#### **A. FDA**

1. Provides training to liaison officers and regulatory affairs, through the FDA Academy, for all the Centers (Food, Drug, Cosmetic and Device);
2. Issues a certificate as QPIRA to participants after completion of the training-accreditation;
3. Issues ID card after the completion of training-accreditation, indicating the name of the QPIRA, and the name of the company or companies represented; and
4. Posts at the FDA website the list of names of QPIRA and the company they represent.

#### **B. Company**

1. Issues certification to FDA that the QPIRA applicant/s is/are authorized to represent the company; and
2. Promptly notifies the FDA when the service of the QPIRA as the company representative has ceased or has been terminated.

#### **C. Applicant/QPIRA**

1. Complies with all the FDA requirements prior to training-accreditation;

2. Attends all sessions of the training-accreditation;
3. Submits Letter/s of no Objection from a company or companies already represented by the QPIRA when applying for additional companies to represent;
4. Promptly notifies the FDA when he/she has ceased to represent a particularly company for whatever reason; and
5. Attends meetings and updates for QPIRA organized by the FDA.

## **VI. GUIDELINES**

1. Only one ID card per QPIRA shall be issued. The ID card shall be encoded with the name of the company or companies the QPIRA is authorized to represent.
2. Failure of the QPIRA to promptly inform the FDA one week after termination of his/her service as authorized company representative shall compel FDA to impose suspension on the QPIRA to represent any company.
3. A liaison officer or regulatory affairs officer seeking to be accredited as QPIRA for Food, Drug, Cosmetic and Device must attend all the training-accreditation to be conducted by all four (4) Centers.
4. The QPIRA ID card is non-transferrable.
5. There is no limit to the number of companies that the QPIRA will represent. Two or more registrants to the training-accreditation may be sent by the companies, provided that all requirements are completed.
6. For QPIRA who is serving only one company, the QPIRA ID shall be surrendered to the FDA upon termination of his/her service. For multiple companies served, the QPIRA shall submit the ID to FDA for updating purposes.
7. QPIRA who goes on leave from the company or companies does not need to notify or inform the FDA.
8. The FDA shall entertain experts and other representatives of a company, provided they are accompanied by the QPIRA.
9. The FDA shall entertain new applications transacted by non-QPIRA until June 2014, provided that all renewal of CPRs and LTOs after December 2013 shall be filed, handled or transacted by QPIRAs.
10. Guidelines on the point system for the QPIRA will be issued after full implementation of these guidelines.

## **VII. REQUIREMENTS**

1. Fully completed QPIRA Data Form (downloadable at FDA website).
2. Recent two (2) pieces 2x2 photo with white background
3. Certification from the company authorizing the person as the company liaison officer or regulatory affairs officer.
4. Letter of no Objection from all the companies, only for registrants representing more than one company.
5. Payment of the quoted fees.

## **VIII. REGISTRATION**

1. Download the QPIRA Data Form at [www.fda.gov.ph](http://www.fda.gov.ph).
2. Bring the completed QPIRA Data Form together with all the requirements to the Policy and Planning Office (PPO) (Rm. AB-313, 3<sup>rd</sup> floor annex building). The assigned staff at PPO shall hand the Assessment and Registration Form (ARF) upon determination of the completeness of the QPIRA Data Form and all the requirements. Incomplete QPIRA Data Form and requirements will not be processed.
3. Present the ARF to the Accounting Office at Rm. 113 (ground floor, main building) to get Order of Payment.
4. Present the Order of Payment to the Cashier at Rm. 112 (ground floor, main building) and pay the quoted fee.
5. Submit the ARF with the printed Official Receipt number back to PPO (Rm AB-313, 3<sup>rd</sup> floor annex building).

## **IX. EFFECTIVITY**

These guidelines shall take effect immediately.



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