

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA MEMORANDUM CIRCULAR No. 2018-003

113 JUL 2018

TO

All Drug Establishments and concerned Offices, Officers, and

Personnel within the Food and Drug Administration.

SUBJECT

Creation of Technical Working Group for the Effective

Implementation of the PIC/S GMP Guide for Medicinal

Products

The Pharmaceutical Inspection Cooperation Scheme (PIC/S) Good Manufacturing Practice Guide for Medicinal Products was officially adopted and implemented by virtue of the issuance of Administrative Order No. 2012-008 dated 25 June 2012. For capability building purposes, Paragraph 5, Item VI of the Administrative Order specifically authorizes the FDA and industry to provide trainings and workshops and may create technical working group/s for the effective implementation of the PIC/S Guide.

Hence, a Technical Working Group (TWG) is hereby established composed of the following:

1. FIELD REGULATORY OPERATIONS OFFICE, as Lead

2. CENTER FOR DRUG REGULATION AND RESEARCH, as Co-Lead

3. Two representatives from the industry representing local manufacturers and distributors (importers).

The TWG shall perform the following:

 Undertake impact analysis concerning the implementation of the PIC/S guides or requirements and recommend to FDA and the industry appropriate actions;

b. Coordinate with the FDA and industry for the provision of trainings, workshops, dissemination of information to stakeholders, and other appropriate action for the smooth implementation of the PIC/S guides or requirements including supplements or revisions thereto;

All materials, food, transportation, equipment, and other financial requirements that may be needed by the TWG during meetings shall be sourced out from available funds of the FDA, subject to the usual accounting and auditing rules and regulations.

This Order shall take effect immediately and shall be valid until revoked.

NELA CHARADE G. PUNO, RPh

Director-General



ISO 9001:2008 Management System

