Republic of the Philippines
DEPARTMENT OF HEALTH
Office of the Secretary

BAGONG PILIPINAS

May 20, 2025

DEPARTMENT CIRCULAR
No. 2025 - 0210

FOR: **ALL UNDERSECRETARIES, ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS, DOH-CENTERS FOR HEALTH DEVELOPMENT, SERVICES AND SPECIALTY HOSPITALS, CHIEFS OF DOH-HOSPITALS, MEDICAL CENTERS AND INSTITUTES, DIRECTORS OF TREATMENT AND REHABILITATION CENTERS, AND OTHERS CONCERNED**

SUBJECT: **Pharmacovigilance Capacity Building and Module Development on Model-Based Stability and Detection of Impurities in Pharmaceutical Products in the Distribution Supply Chain of the University of the Philippines Manila - Institute of Pharmaceutical Sciences under the National Institutes of Health, in collaboration with Disease Prevention and Control Bureau (DPCB) on June to August 2025 thru Online via zoom**

The University of the Philippines Manila - Institute of Pharmaceutical Sciences under the National Institutes of Health, in collaboration with Disease Prevention and Control Bureau (DPCB) is inviting participants (free-of-charge) for the "Pharmacovigilance Capacity Building and Module Development on Model-Based Stability and Detection of Impurities in Pharmaceutical Products in the Distribution Supply Chain" on the following dates thru Online platform via Zoom:

Area	Date of Training
1. National Capital Region	June 2-5, 2025
2. Luzon	June 16-19, 2025
3. Visayas	July 14-17, 2025
4. Mindanao	August 11-14, 2025

In accordance with the Department Order No. 2007-0053, attendance to this activity of concerned **DOH Pharmacists, Nurses, Physicians, Chemical Engineers, Chemists, and other DOH Personnel working on Pharmacovigilance** shall be on:

A. **Official Business**
   (1) When the DOH employee is a presenter/discussant, facilitator, moderator, or panelist. As such, the registration/enrolment fees, per diems, and traveling and other incidental expenses, shall be borne by the sending office; or

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B. **Official Time** when the DOH employee (whether presenter/discussant, facilitator, moderator, panelist, or participant) is duly funded through sponsorships by development partners or local partners in health. For participants, the activity should be relevant to the performance of job functions or related to the practice of his/her profession, and the LDI is identified in the employee's LDP.

Additionally, attendees must be authorized by their respective Directors or office heads, through an appropriate Personnel Order.

All other transactions shall be in accordance with the following issuances:

(1) Administrative Order (AO) No. 2021-0007, entitled "Guidelines on the Integrated Learning and Development Management System of the Department of Health (DOH)"; and

(2) Department Order (DO) No. 2014-0094, entitled "Guidelines on the Allowable Rates of Payment for Human Resource Development Activities."

Attached is the letter of invitation for your ready reference.

Dissemination of the information to all concerned is requested.

By Authority of the Secretary of Health:

ANNA MARIE CELINA G. GARFIN, MD, MM
Director IV and Officer-in-Charge
UHC Policy and Strategy Cluster

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Institute of Pharmaceutical Sciences
National Institutes of Health
University of the Philippines Manila
Room 212 NIH Bldg., 623 Pedro Gil St., Ermita, Manila
Tel. No.: 027-577-2001, 09178386327; Email address: ips_nih.upm@up.edu.ph
Office Hours: Mon – Fri 8:00 AM – 5:00 PM

29 April 2024

FIDES MARIA AILEEN V. BUENAFE, MD
Division Chief
Pharmaceutical Division Department of Health

Dear **Dr Buenafe**:

The Institute of Pharmaceutical Sciences under the National Institutes of Health, University of the Philippines Manila, has an ongoing collaborative project with the Department of Health through the Pharmaceutical Division (PD) and Disease Prevention and Control Bureau (DPCB). This project is entitled, ***"Pharmacovigilance Capacity Building and Module Development on Model-Based Stability and Detection of Impurities in Pharmaceutical Products In the Distribution Supply Chain."***

As our partner in this project, we would like to request your assistance in facilitating the invitation of the DOH's public health pharmacists, FDA pharmacists and chemists, pharmacists employed in the LGUs, as well as other pharmacovigilance professionals employed in the DOH hospitals, such as doctors, nurses, chemists and chemical engineers, if there are, for their official attendance and participation in the capacity-building sessions scheduled for the four (4) regions where they are employed. We have applied for accreditation of the training program comprising four (4) days for continuing professional development (CPD) units per discipline with the Professional Regulation Commission (PRC). Other details of the training program are herein attached.

The approved CPD units are in Table 1, though the units for pharmacists and chemists are under appeal for reconsideration on increase in the number of CPD units. However, only those who will complete the four (4) day training will be conferred CPD units and certificate of completion. No CPD units and certificates will be provided for incomplete days of attendance.

The schedule of the training sessions can be found in Table 2.

Table 1. PRC-approved CPD units for the training program per discipline

Professionals	No. of PRC-approved CPD units
Pharmacists	10
Nurses	27
Doctors	22
Chemists	6
Chemical Engineers	8

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Table 2. Schedule of training /capacity-building on PV and model-based stability and detection of impurities in pharmaceutical products

REGION	DATE OF TRAINING	PLATFORM
NCR	June 2, 3, 4 & 5, 2025	Zoom
Luzon	June 16, 17, 18 & 19, 2025	Zoom
Visayas	July 14, 15, 16 & 17, 2025	Zoom
Mindanao	August 11, 12, 13 & 14, 2025	Zoom

We believe that the PV professionals will greatly benefit from this training program in gaining valuable knowledge and practical skills that will enhance their professional development and contribute to the improvement of PV practices and regulation in the country. Given the significant learning experience and relevant applications in their workplace, we hope that your division will be able to provide support to the participants by granting them the opportunity to fully focus on the training program. May we request the cascade of the invitation to all the target PV professionals to allow them to participate in the **four (4) consecutive days for the training on official time**?

We look forward to the participation of DOH's and FDA's PV professionals in the aforecited training program for the overall realization of the capacity-building activities.

Thank you very much for your continuous and steadfast support for the success of our project.

Sincerely,

IMELDA G. PEÑA, RPh, DrPH
Professor and Project Leader

Favorably endorsed:

BRYAN PAUL BULATAO, PhD
Director
Institute of Pharmaceutical Sciences

EVA MARIA CUTIONGCO-DELA PAZ, MD, FPPS
Executive Director
National Institutes of Health, UP Manila

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Pharmacovigilance Capacity Building on Model-Based Stability and Detection of Impurities in Pharmaceutical Products in the Distribution Supply Chain

Overview of the program

Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse events or any drug-related problems. With the goal of safeguarding public health, PV involves continuous monitoring and mitigation of risks associated with pharmaceutical products at all levels of the complex drug distribution supply chain. To ensure the quality, safety, and efficacy of pharmaceutical products reaching patients and consumers and to address challenges of the pharmaceutical supply chain, there is an imperative need to enhance the technical capacities of regulators, clinical researchers, pharmaceutical scientists, product or quality control analysts, pharmacovigilance professionals, community pharmacists, as well as hospital pharmacists, nurses, and medical doctors. Thus, this program will incorporate training modules, live lectures, and hands-on exercises designed to build expertise on PV practices, develop practical skills in applying model-based stability, and equip professionals with knowledge on impurities that could compromise drug integrity and patient safety. Specifically, this program will focus on the impurities and stability of anti-HIV and anti-tuberculosis (TB) drugs. The program will span four (4) days, with one (1) day of asynchronous or self-paced learning, two (2) days of live lectures, and one (1) day of live case discussions.

Objectives of the program

The program generally aims to equip learners with relevant knowledge focusing on the following areas: *pharmacovigilance and stability testing of pharmaceutical products, including impurity assessment.* Specifically, the training program aims to:

a. Explain the concepts, legal frameworks, process of pharmacovigilance, and real-world PV practices, and apply these concepts in analyzing real-world PV cases.
b. Apply the principles of risk management plan (RMP) in the context of minimizing risks of antiHIV and anti-TB drugs and the methods of causality assessment to real-world PV cases.
c. Describe drug supply chain management in the context of stability.
d. Explain model-based stability testing and its application to developing stability profiles of anti-HIV and anti-TB drugs.
e. Explain types, sources, and impact of impurities in drugs and pharmaceutical products as well as the relationship of the presence of impurities and drug stability.
f. Explain the importance of drug impurity profiles in ensuring the safety, efficacy, and quality of drug products including the regulatory policies relevant to drug impurities.

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Target participants

This program aims to train regulators from the Department of Health (DOH) and the Food and Drug Administration (FDA), researchers, pharmaceutical scientists, product or quality control analysts, regulatory affairs pharmacists, clinical researchers in the pharmaceutical industry, as well as other PV professionals. Moreover, CPD units are granted for professionals, such as, nurses, *pharmacists, medical doctors, chemists, and chemical engineers*.

Benefits of participating in the program

Participation in this training program offers professionals the opportunity to strengthen their expertise in pharmacovigilance, stability testing, and impurity assessment, with a specific focus on HIVAIDS and TB drugs. Through a structured blend of self-paced learning, live lectures, and case-based discussion, participants will gain practical and regulatory-aligned knowledge and experience that are essential in safeguarding drug quality, safety, and efficacy. Moreover, this training may address critical issues in the pharmaceutical supply chain as it promotes interdisciplinary collaboration among healthcare providers, regulators, and pharmaceutical scientists. This training also supports professional development and potential career advancement in drug safety, regulatory affairs, and quality assurance.

Schedule and Mode of Delivery of the program

The first of four (4) days of the training program will be held asynchronously for participants to accomplish the self-paced learning of modules. Modules will be accessed through a website provided a few weeks prior to the actual training schedule. The remaining three (3) days of the program will be delivered synchronously via Zoom webinar. The training will begin at 8:00 AM until 12:30 PM. Asynchronous answering of case activities will commence at 1:30 PM until 5:30 PM. Participants must submit their work by 5:30 PM to signify the completion of the day's learning activities and to ensure their attendance and participation are duly recorded. Table 3 displays the daily training schedule.

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Table 3. Daily schedule of training/capacity building on PV and model-based stability and detection of impurities in pharmaceutical products

DAY 1 *Asynchronous*	**DAY 2** *Synchronous*	**DAY 3** *Synchronous*	**DAY 4** *Synchronous*
Pre-test questionnaire; Studying of uploaded four (4) modules (8 hours)	Live lecture discussion on Modules 1 and 2, with case examples (4 hours) **Module 1** – Basic PV and PV Practices **Module 2** – Applied PV, Risk Management Plan, PV Plan & Causality Assessment	Live lecture discussion on Modules 3 and 4, with case examples (4 hours) **Module 3** – Model-based Stability Testing **Module 4** – Impurity Detection in Pharmaceutical Products	Discussion of answers to problem sets / cases (6 hours)
Participate in Discussion Forum (Virtual) *(in between modules)*	Answer individually problem sets and to be submitted in the website/LMS (4 hours)	Answer individually problem sets and to be submitted in the website/LMS (4 hours). Post-test questionnaire	Synthesis with feedback of performance and evaluation of the program (1 hour)

Registration mechanics

Detailed information on how and when to register to the training program will be provided soon.

SUMMARY OF PRC-CPD PROGRAM ACCREDITATION NO. AND CPD UNITS PER PROFESSION for the four (4) runs of the program, entitled, "*Training on Pharmacovigilance, Model-based Stability, and Detection of Impurities in Pharmaceutical Products in the Distribution Supply Chain*"

Title	Accrediting CPD Council	Dates	Application No.	Accreditation No.	CPD Units
Training on Pharmacovigilance, Model-based Stability, and Detection of Impurities in Pharmaceutical Products in the Distribution Supply Chain	**Pharmacy**	June 2 - 5, 2025	PROG-2025-102999	MED-2012-002-2079	10.00
		June 16 - 19, 2025	PROG-2025-103040	MED-2012-002-2081	10.00
		July 14 - 17, 2025	PROG-2025-103100	MED-2012-002-2082	10.00
		August 11 - 14, 2025	PROG-2025-103111	MED-2012-002-2087	10.00
Training on Pharmacovigilance, Model-based Stability, and Detection of Impurities in Pharmaceutical Products in the Distribution Supply Chain	**Nursing**	June 2 - 5, 2025	PROG-2025-102996	MED-2012-002-9155	27.00
		June 16 - 19, 2025	PROG-2025-103022	MED-2012-002-9107	27.00
		July 14 - 17, 2025	PROG-2025-103098	MED-2012-002-9117	27.00
		August 11 - 14, 2025	PROG-2025-103108	MED-2012-002-9119	25.00
Training on	**Medicine**	June 2 - 5, 2025	PROG-2025-102991	MED-2012-002-9005	22.00

Pharmacovigilance, Model-based Stability, and Detection of Impurities in Pharmaceutical Products in the Distribution Supply Chain		June 16 - 19, 2025	PROG-2025-103018	MED-2012-002-9009	22.00
		July 14 - 17, 2025	PROG-2025-103097	MED-2012-002-9014	22.00
		August 11 - 14, 2025	PROG-2025-103106	MED-2012-002-9015	22.00
Training on Pharmacovigilance, Model-based Stability, and Detection of Impurities in Pharmaceutical Products in the Distribution Supply Chain	**Chemical Engineering**	June 2 - 5, 2025	PROG-2025-102980	MED-2012-002-531	8.00
		June 16 - 19, 2025	PROG-2025-103005	MED-2012-002-532	8.00
		July 14 - 17, 2025	PROG-2025-103069	MED-2012-002-533	8.00
		August 11 - 14, 2025	PROG-2025-103102	MED-2012-002-534	8.00
Training on Pharmacovigilance, Model-based Stability, and Detection of Impurities in Pharmaceutical Products in the Distribution Supply Chain	**Chemistry**	June 2 - 5, 2025	PROG-2025-102996	MED-2012-002-9155	6.00
		June 16 - 19, 2025	PROG-2025-103090	MED-2012-002-573	6.00
		July 14 - 17, 2025	PROG-2025-103090	MED-2012-002-573	6.00
		August 11 - 14, 2025	PROG-2025-103103	MED-2012-002-574	6.00