
GHC
Global
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Center
Global Harmonization Center
International Workshop 2026
2026년 글로벌 규제조화센터 국제워크숍
30 NOVEMBER (MON) - 1 DECEMBER (TUE), 2026
SEOUL, REPUBLIC OF KOREA
MINISTRY OF FOOD AND DRUG SAFETY
National Institute
of Food and Drug Safety Evaluation

2026 Global Harmonization Center International Workshop: PV and MSC

※ **The workshop series covers key regulatory areas relevant to WLA designation. In 2026, the program will focus on Pharmacovigilance and Market Surveillance and Control.**

Date: November 30 - December 1 (Mon, Tue)
Venue: Floating Island Convention, Some Chavit
Theme: Strengthening National Regulatory Systems toward WHO Listed Authority (WLA) Designation: Pharmacovigilance, Market Surveillance and Control

1. Background

Strong and well-functioning national regulatory systems are essential to ensuring the quality, safety, and efficacy of medical products throughout their lifecycle. As countries work toward strengthening regulatory capacity and achieving or maintaining recognition as a WHO Listed Authority (WLA), effective pharmacovigilance, market surveillance and control, and interoperable regulatory information systems have become increasingly important.

The WHO Global Benchmarking Tool (GBT) provides a structured framework for assessing national regulatory systems and identifying areas for institutional development. Within this framework pharmacovigilance and market surveillance represent key regulatory functions that require not only appropriate policies and procedures, but also sustainable operational capacity, risk-based decision-making, effective communication, and international collaboration.

At the same time, regulatory systems are undergoing rapid transformation. Increasing volumes of safety information, globalization of pharmaceutical supply chains, emerging risks related to substandard and falsified medical products, and the growing need for standardized and interoperable regulatory data are reshaping the way national regulatory authorities operate.

Against this background, the Global Harmonization Center (GHC) will convene an international workshop bringing together representatives from WHO, national regulatory authorities, international organizations, and regulatory experts to share practical experiences and discuss approaches for strengthening national regulatory systems.

The workshop will also provide an opportunity to mark GHC's designation as a WHO Collaborating Centre and to explore the role of WHO Collaborating Centres in supporting regulatory capacity building, knowledge sharing, and international cooperation in an era of global transformation.

2. Workshop Objectives

The workshop aims to:

- **Enhance understanding of WHO expectations and international approaches relevant to WLA designation and regulatory system strengthening;**
- **Share practical national experiences in establishing and strengthening functional pharmacovigilance systems;**
- **Explore risk-based approaches to safety signal detection, risk management, and risk communication;**
- **Strengthen understanding of effective national market surveillance systems, including approaches to substandard and falsified medical products, product defects, and recalls;**
- **Discuss how ISO IDMP and standardized regulatory information can support regulatory efficacy, interoperability and digital transformation; and**
- **Promote collaboration and knowledge exchange among WHO, national regulatory authorities, WHO Collaborating Centres, and other regulatory partners.**

3. Expected Outcomes

By the end of the workshop, participants are expected to have:

- **A clearer understanding of the role of pharmacovigilance and market surveillance in strengthening national regulatory surveillance in strengthening national regulatory systems toward WLA designation;**
- **Greater awareness of practical approaches and international experiences that can be adapted to different national contexts;**
- **Improved understanding of risk-based pharmacovigilance and market surveillance practices;**
- **Strengthened networks for future regulatory cooperation, capacity building, and information exchange.**

Day 1 (November 30) : Building National Pharmacovigilance Systems

Time		Subject / Topic	Speaker
WHO Vision for WLA and Pharmacovigilance **Learning Objective:** To understand WHO's expectations for pharmacovigilance as a regulatory function and identify key elements for strengthening national PV systems toward WHO Listed Authority (WLA).			
12:55-13:00	5 min	Day 1 Opening and Speaker Introductions	MC
13:00-13:30	30 min	Building Pharmacovigilance as a Regulatory Function toward WLA Designation	Dr. Christine Guillard (WHO)
13:30-14:00	30 min	Korea's experience with WLA Designation	Mr. Kyung-jin Cho (MFDS)
Building a Functional Pharmacovigilance System within the WHO GBT Framework **Learning Objective:** To understand the practical requirements for a functional pharmacovigilance system within WHO GBT framework and explore how countries can establish, operate and continuously strengthen their PV systems through international collaboration			
14:00-14:05	5 min	Speaker Introductions	MC
14:05-14:35	30 min	WHO Programme for International Drug Monitoring (PIDM)	Ms. Anna Baumgarten (UMC)
14:35-15:05	30 min	Building a National Pharmacovigilance System in Korea	Ms. Ji-ae Kim (MFDS)
15:05-15:25	20 min	From Signal Detection to Risk Management : Medical Device Vigilance System in Korea	Mr. Do-yeop Kim (NIDS)
15:25-15:55	30 min	Building a National Pharmacovigilance Centre under Resources Limited Settings	Dr. Hadir Rostom (ISoP)

15:55-16:25	**30 min**	***Coffee Break***	
Strengthening Pharmacovigilance: From Smart Strategy to Risk Management and Communication **Learning Objective: To understand WHO's smart and risk-based approach to pharmacovigilance and explore how safety signals can be translated into effective risk management and risk communication to strengthen national pharmacovigilance systems.**			
16:25-16:30	**5 min**	**Speaker Introductions**	**MC**
16:30-17:00	**30 min**	**WHO Smart Pharmacovigilance Strategy: From Vision to Practice**	**Ms. Eunmi Kim (WHO)**
17:00-17:30	**30 min**	**From Signal Detection to Risk Management: A Risk-Based Regulatory Approach**	**Ms. Ji Yoon Park (KIDS)**
17:30-18:00	**30 min**	**Risk Communication and Stakeholder Engagement in Pharmacovigilance**	**Dr. Priya Bahri (EMA)**
18:00		**Closing**	

Day 2 (December 1) : Market Surveillance and Digital Regulatory Systems

Time		Subject / Topic	Speaker
Building Market Surveillance Systems **Learning Objective: To understand the key functions of a national market surveillance system and explore risk-based approaches for prioritizing surveillance activities, allocating resources and supporting regulatory decision-making.**			
09:25-09:30	**5 min**	**Day 2 Opening and Speaker Introductions**	**MC**
09:30-10:00	**30 min**	**WHO Market Surveillance Framework**	**Mr. Rutendo Kuwana (WHO)**
10:00-10:30	**30 min**	**Risk-based Market Surveillance**	**Mr. Wapapha Nthomiwa (BoMRA)**
10:30-11:00	**30 min**	**Building a Functional Market Surveillance System: Experience from an LMIC**	**Dr. Geraldine Hill (WPRO)**
11:00-12:30	**90 min**	***Lunch Break***	
Substandard and Falsified Medicines **Learning Objective: To strengthen understanding of systems for detecting, assessing and responding to substandard and falsified medicines, including product defect reporting, recall management and international information sharing.**			
12:30-12:35	**5 min**	**Speaker Introductions**	**MC**
12:35-13:05	**30 min**	**Substandard and Falsified Medicines: Regulatory Perspectives**	**Ms. Anita Sands (WHO)**

13:05-13:35	**30 min**	**Product Defects Reporting and Recall Management**	**Dr. Paulina Valuskova & Dr. Natalia Kalousova (ivigee)**
13:35-14:05	**30 min**	**National Regulatory Experience in Detecting and Responding to Substandard and Falsified Medicines**	**Dr. Manal Younus Al-Dabbagh (Iraqi MOH)**
14:05-14:35	**30 min**	***Coffee Break***	

ISO IDMP and Regulatory Systems

Learning Objective: To understand the role of ISO IDMP in standardizing medicinal product information and explore how interoperable regulatory data can support efficient regulatory processes, international collaboration and digital transformation.

14:35-14:40	**5 min**	**Speaker Introductions**	**MC**
14:40-15:10	**30 min**	**ISO IDMP Standards Overview: Structure and Content**	**Dr. Joerg Stueben (Boehringer Ingelheim)**
15:10-15:40	**30 min**	**ISO IDMP in Practice: Regulatory Use Cases & Benefits**	**Mr. David Filipovic (EMA)**
15:40-16:10	**30 min**	***Coffee Break***	

Closing Panel Discussion. Future of Market Surveillance and Digital Transformation toward WHO Listed Authority

Learning Objective: To understand the key elements and strategic priorities for strengthening market surveillance systems toward WLA designation.
To Explore the application of international data standards and digital transformation in market surveillance.
To Strengthen international information sharing and regulatory collaboration for pharmaceutical quality and falsified medicinal products.

16:10-16:40	**30 min**	**Future of Market Surveillance and Digital Transformation toward WHO Listed Authority** • Market Surveillance and Digital Transformation International Data Standardization	five of the participants Facilitator: Dr. Heesung Kim

		Enhancing Cooperation among Regulatory Authorities Strategies for Achieving WHO Listed Authority (WLA) Status Future Directions for International Cooperation and Development 1) What do you consider to be the most important elements to strengthen as a priority when establishing a market surveillance system? 2) How do you expect international data standards, such as ISO IDMP, to transform market surveillance activities conducted by national regulatory authorities? 3) What kind of collaborative framework should WHO and national regulatory authorities establish to facilitate more effective international information sharing on quality defects and substandard and falsified medical products?	Panels; WHO, UMC, ADB, EMA, NPRA
16:40-16:45	**5 min**	**Closing**	

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