

2025 Global Harmonization Center International Workshop

<Pharmacovigilance>

Date: November 3-4, 2025 (Mon-Tue)

Place: Sky31 Convention, Lotte World Tower, Seoul, Korea

Theme: Evaluation of WLA Vigilance and Strengthening Global Regulatory Cooperation

Day 1 (3 November)

Subject	Learning Objective	Speaker	Time	
Registration			09:00-09:30	
Opening				
<i>Opening remarks, Introduction of Key Attendees, Welcome Speech, Group Photo Session (09:30-09:50)</i>				
1. Overview of WHO GBT and WLA (1st day)				
Assessment of WLA and GBT for RSS	- Overview of the WLA Evaluation and Designation Process and Current Status - Understanding of WHO's approach to evaluating the maturity level of regulatory authorities and the Global Benchmarking Tool	Dr. Rogerio Gaspar (WHO) <i>in-person</i>	50min (09:50-10:40)	
2. Sharing of WLA Designation Case				
Sharing Korea's experience with WLA designation: Building a PV system	- Korea's strategy as the first WLA-listed country, inter-agency cooperation, introduction of major achievements	Dr. Juhyun Baek (MFDS) <i>in-person</i>	40min (10:40-11:20)	
Lunch (11:30-13:10)				
3. Practical Approaches to GBT Evaluation for WLA Designation				
WLA Evaluator's perspective: International Standard Methods of Evaluating PV System	- Understanding of Evaluation Method of "Regulatory function-Vigilance" following WHO GBT * Indicator, Sub-indicator and Expert Review Questionnaire	Hiiti Sillo (WHO) <i>virtual</i>	1hr (13:10-14:00)	
WLA Candidate's Perspective: Preparation and Response Strategies for WHO Listed Authority Designation	GBT Pharmacovigilance PE case study	- National PV regulatory system and management - GBT Vigilance evaluation preparedness and cases	Jiae Kim (MFDS) <i>in-person</i>	30min (14:00-14:30)
		- (Medicinal products) Introduction of adverse event collection, reporting, management, investigation/analysis etc., PE response cases	Dr. Hyunju Chung (KIDS, Korea) <i>in-person</i>	30min (14:30-15:00)
		-(Vaccine) Introduction of national immunization safety system, AEFI management and risk assessment & national compensation and PE response cases	Hyuna Bae (KDCA) <i>in-person</i>	30min (15:00-15:30)
Health Break (15:30-16:00)				
4. <Special Session> Future Pharmacovigilance				
Pharmacovigilance through AI and Digital Transformation	- Current Trends and Future Outlook in the Efficient Management of Pharmacovigilance through Emerging Digital Technologies	Dr. Min-kyung Shin (Seltasquare, Korea) <i>in-person</i>	40min (16:00-16:40)	

Day 2 (4 November, A.M.)

5. WLA Vision and Global Cooperation (2nd day)			
WLA Key Focus- Desired Objective	- Outlook, Expectations, and Future Plans for WHO Listed Authority (WLA) Designation	Dr. Rogerio Gaspar (WHO) <i>in-person</i>	2h (09:30-11:30)
WLA Projected Impacts	- Industry Perspective on WLA Listing: Changes in the Global Regulatory Landscape and Impacts on the Domestic Industry, Including Industry Expectations	Youngjin Choi (Eubiologics, Korea), <i>in-person</i> others	
Panel Discussion: Discussion on WLA and Global Collaboration	- Suggestions on WLA and Collaboration *Future Collaboration Directions, Including Training and Joint Initiatives *Impact of WLA Designation on Regulatory Trust and International Cooperation * Plans for Future Collaboration to Support RSS	Participants	

* The speakers and topic are subject to change.

2025 Global Harmonization Center International Workshop

<Medical Device Vigilance>

Date: November 4 p.m., 2025 (Tue)

Place: Sky31 Convention, Lotte World Tower, Seoul, Korea

Theme: Evaluation of Medical Device Vigilance and Strengthening Global Regulatory Cooperation

Day 2 (4 November, P.M.)

Subject	Learning Objective	Speaker	Time
Opening			
<i>Opening remarks, Introduction of Key Attendees, Welcome Speech, Group Photo Session (13:00-13:20)</i>			
(Singapore) Medical Device Vigilance in Singapore's HSA	Introduction to the Medical Device Adverse Event Management Systems (MD) by HSA	Siaw Kai Lun (HSA, Singapore) <i>in-person</i>	30 min (13:20-13:50)
(EC) Medical Device PV Management System	Introduction to the Medical Device Adverse Event Management Systems (MD and IVD) by European Regulatory Authorities (EC MDCG) and case studies	Jeppe Larsen (Danish Medicines Agency, Denmark) <i>virtual</i>	30 min (13:50-14:10)
(TGA) Medical Device PV Management System	Introduction to the Medical Device Adverse Event Management Systems (MD and IVD) by Australian Regulatory Authorities (TGA) and case studies	Dr. Marcelle Noja (TGA, Australia) <i>virtual</i>	30 min (14:10-14:50)
Health Break (14:50-15:10)			
(South Korea) Medical Device PV Management System	Collection, Reporting, Management, Case Investigation, and Analysis of Adverse Events for Medical Devices in Korea	Dr. Yoonsook Kim (NIDS, Korea) <i>in-person</i>	30 min (15:10-15:40)
(South Korea) Case Studies of Global Medical Device Regulatory Guidelines Application	Active Analysis of Medical Device Adverse Events Using Real-World Data(RWD)	Dr. SengChan You (Yonsei Univ., Korea) <i>in-person</i>	30 min (15:40-16:10)
(South Korea) Experience Sharing on Global Medical Device Market Entry & MDV	Case Studies of Domestic Companies' Experiences with Medical Device Regulatory and MDV Management Plans for Overseas Expansion	Domestic Companies <i>in-person</i>	30 min (16:10-16:40)
(Panel Discussion) Global RSS Solutions in the Medical Device Field	- Moderator: Senior Manager of Pre-Submission Consultation - Panelists (Proposed): Above speakers + Academia +Medical Device Management Department - Specific Topics TBD	Participants	30 min (16:40-17:10)

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