

2023 SCH APEC Medical Device CoE Training Lecture List

November 7th & 8th 2023 | Special Session (In-person Hands-on Workshop)

November 1st – 24th 2023 | Online Training (SCH Website)

(Version updated on August 9th, 2023)

| Lectures for 2023 SCH APEC CoE Training (Only Available on SCH Website) | | | |
|--|--|--|--|
| Method | Time | Topic | Speaker |
| Subject 1: Medical Devices | | | |
| <u>Objective:</u> 1) To understand the requirement of clinical evaluation for medical devices based on IMDRF guidance 2) To share the best practices in the clinical investigation of medical devices | | | |
| <u>Core Curriculums:</u> 1) Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N047: 2018) 2) Clinical Investigation (IMDRF MDCE WG/N57FINAL:2019) 3) Clinical Evaluation (IMDRF MDCE WG/N56FINAL:2019) 4) Clinical Evidence (IMDRF MDCE WG/N55 FINAL:2019) 5) IMDRF terminologies for categorized Adverse Events (IMDRF AE WG/N43 FINAL:2022) | | | |
| VOD Lectures | 40 mins | Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices | Frances Richmond, Univ. of Southern California |
| | 40 mins | Understanding the Clinical Evidence and Clinical Evaluation, an overview of IMDRF MDCE WG/N55 & N56 document | TBD |
| | 40 mins | Best practice for clinical evaluation, systematic approach to synthesize clinical experiences | Eric Woo, ECRI |
| | 40 mins | IMDRF principles and best practices for Clinical Investigation of medical devices | Jaesoon Choi, Ulsan Univ. |
| | 40 mins | Best practice for clinical evaluation, practical scientific approach for data generated through a literature review of IMDRF N56 | You Kyoung Lee, SCH Univ. |
| | 40 mins | IMDRF terminologies for medical device adverse event | Ishikawa Hiroshi, Univ. of Yamanashi |
| Online Activity (Hands-on 1) | IMDRF terminologies for medical device adverse event | | |
| Subject 2: IVD Medical Devices | | | |
| <u>Objective:</u> 1) To understand harmonized approach to the classification of IVD medical devices | | | |
| <u>Core Curriculums:</u> 1) Principles of IVD Medical Devices Classification (IMDRF/IVD WG/ N64 Final: 2021 formerly GHTF/SG1/N045:2008) | | | |
| VOD Lectures | 40 mins | Classification of IVD medical devices | Jin-ah Kim, MFDS |
| Online Activity (Hands-on 2) | Classification of IVD medical devices | | |

*There is a Special Session (In-person Hands-on Workshop) to practice Hands-on 1 & 2 on 7th – 8th November 2023 at Grand Hyatt Hotel Incheon, Rep. of Korea. Limited seats are available for the Special Session (In-person Hands-on Workshop). We will provide travel support for a limited number of regulators from travel-eligible economies. Interested candidates can apply for the Special Session during the registration process.

*The special session (In-person Hands-on Workshop) will only focus on the group work of hands-on 1 & 2. So, all participants need to watch the lecture videos online at the SCH website <https://ebdiagnostics.org/schmc/index.do> to complete the training.

**2023 SCH APEC Medical Device CoE Training
Agenda for Special Session (In-person Hands-on Workshop)**

November 7th & 8th 2023 | Special Session (In-person Hands-on Workshop)
November 1st – 24th 2023 | Online Training (SCH Website)
(Version updated on August 9th, 2023)

| Venue – Grand Hyatt Hotel Incheon, Republic of Korea | | |
|---|---|--|
| 7 th November 2023 (Day 1) | | |
| Time | Topic | Speakers |
| 09:00 – 09:30 | Offline Registration | Participants |
| 09:30 – 09:50 | Intro and Welcome Message | SCH APEC CoE |
| 09:50 – 10:00 | Photo session | Participants |
| 10:00 – 10:15 | Coffee Break | |
| 10:15 – 10:45 | Hands-on 1 - IMDRF Terminologies for medical device adverse event • How to practice virtual hands-on cases on the SCH website | Kichang Nam, Dongguk Univ. |
| 11:00 – 12:00 | Group activity for Hands-on 1 using virtual cases | SCH APEC CoE team and participants |
| 12:00 – 13:00 | Lunch | |
| 13:00 – 14:00 | Continue Group activity for Hands-on 1 using virtual cases | SCH APEC CoE team and participants |
| 14:00 – 14:30 | PowerPoint preparation for Group Presentation | |
| 14:30 – 16:00 | Group Presentation by Participants | Kichang Nam, Dongguk Univ. Soo Jeong Choi, SCH Univ. |
| 8 th November 2023 (Day 2) | | |
| Time | Topic | Speakers |
| 09:00 – 09:15 | Offline Registration | Participants |
| 09:15 – 09:45 | Hands-on 2 – Classification of IVD medical devices • How to practice virtual hands-on cases on the SCH website • Explanation of Group work and Group Allocation | Soe Ye Yint Tun, SCH Univ. |
| 09:45 – 10:00 | Coffee Break | |
| 10:00 – 11:00 | Group activity for Hands-on 2 using virtual cases | Participants |
| 11:00 – 11:30 | PowerPoint preparation for Group Presentation | |
| 11:30 – 12:30 | Group Presentation for Hands-on 2 | Hwansub Lim, Seoul Clinical Lab. Soe Ye Yint Tun, SCH Univ. |
| 12:30 – 12:45 | Closing Day 2 and Lunch | SCH APEC CoE |
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