

Seminar on GCP Renovation -Recent Work of ICH and Overview of ICH E6(R3)-

<< Venue changed >>



September 7, 2020
Pharmaceuticals and Medical Devices Agency

Introduction

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is working to revise the ICH E6 Guideline on Good Clinical Practice, as a part of the council's "GCP Renovation" initiative. It will be accommodating current situation into the document and revised as the E6(R3) guideline. This timely seminar will focus on topics of revising the E6(R3) guideline.

Experts who are working on the E6(R3) guideline will give briefing on the potential revisions. Speakers representing the regulators, industry and academia will give presentations and a panel discussion on their expectations for the revised guideline. Presentation will also include the update of other E Guidelines and a panel discussion on the latest activities of ICH will also be given. Through this seminar, we expect to invite various stakeholder views for incorporation into the E6(R3) Guideline and help appropriate usage of the document after implementation.

Hosts

Ministry of Health, Labour and Welfare (MHLW)
Pharmaceuticals and Medical Devices Agency (PMDA)
Japan Pharmaceutical Manufacturers Association (JPMA)

1. Date and Time

Thursday, December 17, 2020, 10:00 - 16:45

2. Seminar Format

This seminar will be held in two formats: the in-person format and the online format

Venue:

Tokyo Conference Center Shinagawa
Area Shinagawa 5th Floor, 1-9-36 Konan, Minato-ku, Tokyo
(Directions)
2 minutes by foot from JR Shinagawa Station East Exit
<https://www.tokyo-cc.co.jp/eng/shinagawa/index.html>

Depending on the situation of COVID-19 infections, the seminar format may become online only.

3. Registration

Please register through the following website. (Available only in Japanese)

https://www.praise-net.jp/pn/m/member_signup.asp?path=semi/list.asp&PG=2

Capacity differs between the seminar formats; choice of in-person or online format needs to be made when registering.

There is no registration fee for this seminar.

4. Program

Time	Contents, Speakers
10:00 - 10:10	Opening Remarks Speakers: YAMAMOTO Fumi (MHLW), HIYOSHI Hironobu (JPMA)
<Session 1> Moderator: UEDA Mami (PMDA)	
10:10 - 10:40	Keynote Session: Measurement of COVID-19 in Japan –International Collaboration– Speaker: FUJIWARA Yasuhiro (PMDA)
10:40 - 11:50	Panel Discussion: Latest Work of ICH Chairs: NAKASHIMA Nobumasa (PMDA), HIYOSHI Hironobu (JPMA) Panelists: YASUDA Naoyuki (MHLW) SATO Junko (PMDA) YOKOTA Masafumi (JPMA) OKADA Mihoko (Institute of Health Data Infrastructure for All) WATANABE Hiroshi (Hamamatsu University School of Medicine)
11:50 - 13:00	Lunch Break
<Session 2> Moderator: YANAGISAWA Manabu (JPMA)	
13:00 - 13:30 (incl. Q&A)	Current Status of ICH E Topics Speaker: ANDO Yuki (PMDA)
13:30 - 14:00 (incl. Q&A)	E6(R3): Introduction Speaker: KITABAYASHI Aki (PMDA, EWG member)
14:00 - 14:30 (incl. Q&A)	E6(R3): Non-Traditional Interventional Clinical Trials Speaker: AOYAGI Mitsuki (JPMA, EWG member)
14:30 - 14:50 (incl. Q&A)	Academia Perspective on E6(R3) Speaker: NAKAMURA Kenichi (National Cancer Center Hospital, Principal Investigator of MHLW Special Research on ICH E6(R3))
14:50 - 15:10 (incl. Q&A)	Industry Perspective on E6(R3) Speaker: KAWAKATSU Eiji (JPMA, EWG member)
15:10 - 15:30	Coffee Break
<Session 3> Moderator: YANAGISAWA Manabu (JPMA)	
15:30 - 16:40	Panel Discussion Chairs: TAKEUCHI Satoshi (MHLW), YOKOTA Masafumi (JPMA) Panelists: ANDO Yuki (PMDA) KITABAYASHI Aki (PMDA) AOYAGI Mitsuki (JPMA) KAWAKATSU Eiji (JPMA) NAKAMURA Kenichi (National Cancer Center Hospital) MAJIMA Yoshiyuki (PanCAN Japan)
16:40 - 16:45	Closing Remarks Speaker: UZU Shinobu (PMDA)

5. Other Points to Note

- Participants for the in-person format will be asked to provide a print out of their registration confirmation email or their business card at the seminar venue. This will be use in counting the number of people in the audience.
- Social distancing will be observed at the seminar venue for the in-person format: no walk-ins will be allowed entry that day. Please make sure to register beforehand.
- In an effort towards a paperless briefing, printed materials will not be handed out at the venue. Briefing materials will be available on our website at least one day prior to the event, i.e., by Wednesday, December 16. Participants are asked to prepare beforehand by bringing their own copies (printed or downloaded on their mobile devices).