Symposium for the draft revision on the ICH E8 “General Considerations for Clinical Trials”: Update on the ICH and Overview of the ICH E8(R1) Draft Guideline

ICH Recognised Training Programme

May 17, 2019
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 E8 Guideline “General Considerations for Clinical Trials”, and work is underway for public consultation on the draft document in Japan. This symposium will be delivered during this public consultation of the draft revision on the ICH E8 Guideline “General Considerations for Clinical Trials”.

This symposium will cover the briefing on how the ICH E8 Guideline came to need revision, various work of ICH, and the latest international projects. Experts who have worked on the ICH E8 revision will brief on the draft document, and representatives from the regulators, the industries, and the academia will brief their expectations for the revised ICH E8 Guideline. Through these briefing, we aim to facilitate understanding of the draft revision and help in developing the best ICH E8 (R1) Guideline.

Hosts

The Ministry of Health, Labour and Welfare
Pharmaceuticals and Medical Devices Agency
The Japan Pharmaceutical Manufacturers Association

1. Date and Time

Thursday, July 25, 2019 10: 00-16: 50 (Reception desk to open at 9:30)

2. Location and Access

Yurakucho Yomiuri Hall
7th floor, Yomiuri-kaikan, 1-11-1 Yurakucho, Chiyoda-ku, Tokyo

(URL) http://yomi-h.jp/access
Just outside the International Forum Exit of Yurakucho Station (JR Yamanote Line or Keihin-Tohoku Line)
Exits D4 and D6 of Yurakucho Station (Yurakucho Line)
3-minute walk from Exit A2 of Hibiya Station (Hibiya Line or Chiyoda Line)
5-minute walk from Exit C9 of Ginza Station (Marunouchi Line or Ginza Line)
Exits D4 and D6 of Hibiya Station (Toei Mita Line)

3. Registraion

There is no registration fee for this seminar. Please register through the following website. (Available only in Japanese)
https://www.praise-net.jp/pn/m/semi/top.asp?seminar_id=MTI4Mg==&mode=3

4. Interpretation

Simultaneous interpretation languages: Japanese and English
Japanese/English simultaneous interpretation will be provided for the Opening Remarks up to the presentation "E8(R1) (Draft): Background, Concept of revised guideline (draft), Regulatory perspective."
The presentations will be in Japanese, with English simultaneous interpretation, except for “ICH Updates including GCP Renovation” given at 10:00-10:45, which will be in English.

5. Program

Time	Contents, Speakers
10:00 - 10:10 (5 min/each)	Opening Remarks Speakers: Kazuhiko Mori (MHLW), Akira Kawahara (JPMA)
<Session 1> Moderator: Junko Sato (PMDA)	
10:10 - 10:45 (35 min incl. Q&A)	ICH Updates including GCP Renovation Speaker: Theresa Mullin (US FDA, ICH MC Chair)
10:45 - 11:20 (35 min incl. Q&A)	Updates on MHLW/PMDA international activities Speaker: Nobumasa Nakashima (PMDA, ICH MC Vice-Chair)
11:20 - 11:55 (35 min incl. Q&A)	Current status of ICH E topics Speaker: Masafumi Yokota (JPMA)
11:55 - 13:00	Lunch Break
<Session 2> Moderator: Hironobu Hiyoshi (JPMA)	
13:00 - 15:00 (120 min incl. Q&A)	E8(R1) (Draft): Background, Concept of revised guideline (draft), Regulatory perspective Speakers: Mutsuhiro Ikuma, Yuki Ando (PMDA, EWG members)
15:00 - 15:15	Coffee Break
15:15 - 15:35 (20 min incl. Q&A)	Academia perspective on E8(R1) Speaker: Hiroshi Watanabe (Hamamatsu University School of Medicine)
15:35 - 15:55 (20 min incl. Q&A)	Industry perspective on E8(R1) Speaker: Mitsuhiro Kondo (JPMA, EWG member)
15:55 - 16:40 (45 min)	Q&A, panel discussion
16:40 - 16:50 (10 min)	Closing Remarks Speaker: Yoshikazu Hayashi (PMDA)

6. Other Points to Note

In an effort toward a paperless briefing, no printed materials will 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, July 24.
Participants are asked to prepare beforehand and bring their own copies by such means as:
◇ Downloading the materials onto their own portable devices to view at the venue
◇ Printing out their own copies to bring to the venue
We apologize for the inconvenience and thank you for your understanding on the effort for the paperless briefing.