ICH Q12 Update

4th, Dec., 2017
15:30 — 17:45

Session Chairs: Niklas Ekman, Finnish Medicines Agency
Toshiyuki Suzawa, Kyowa Hakko Kirin Co., Ltd.

Introduction
Current Status and Next Step for Q12

• ICH Meeting
  • May-June 2017  Step 1 in Montreal
  • November 2017 Step 2 in Geneva
  • TBD        Step 3, Public consultation expected

• Planned Activities in Japan
  • 15\textsuperscript{th}, March 2018  Briefing in Osaka
  • 29\textsuperscript{th}, March 2018  Briefing in Tokyo
Objective of The Session: Abstract

- There are some differences in data requirements, regulatory reporting categories as well as timeline for post-approval CMC changes among regions, which leads to the complex product lifecycle management and sometimes hinders innovation and continual improvement in the pharmaceutical and biotechnology sectors. To address this, the new ICH Quality topic, Q12, was proposed and has been discussed in the expert working group and the draft guideline is expected to be published for public consultation in the course of this year.

- This session will provide an update on ICH Q12 including the introduction of newly-defined KPP (key process parameter). In addition, the challenges and current thinking on implementation of ICH Q12 from the perspective of regulators and industry will be shared.
Points to Be Sheared and Discussed

• Q12 Update

• The challenges and current thinking on implementation of ICH Q12
  • Established Conditions in/outside Japan
  • KPP (key process parameter) newly-defined
  • PACMP in JAPAN

• Perspective from regulators and industry side
Contents

• Presentation
  • Frank Montgomery (Astra Zeneca)
    Does Japan Need ICH Q12?
  • Yasuhiro Kishioka (PMDA)
    How Will ICH Q12 Fly in Japan?

• Panel Discussion
  • Frank Montgomery (Astra Zeneca)
  • Yasuhiro Kishioka (PMDA)
  • Anthony Ridgeway (Health Canada)
  • Mats Welin (Medical Products Agency, Sweden)
  • Yamin Wang (Center for Drug Evaluation, China)
  • Wassim Nashabeh (F. Hoffmann-La Roche)