Q6(R1)「医薬品の規格及び試験方法の設定」の改訂

6月2日-5日　2024年福岡会合

医薬品医療機器総合機構　新薬審査第五部
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International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

本日の発表内容

- トピックの概要
- 会合前の状況
- 会合での進捗状況
- Work Plan

なお、本公演は演者の個人的見解を示しており、
所属する組織の公式な見解でないことをご留意ください。

トピックの概要

- ICH Q6A and Q6B were finalized in 1999. These guidelines address setting specifications for chemicals and some specific biological products, respectively.
- Quality Discussion Group (QDG), as part of their purview, recommended revision of Q6A and Q6B to reflect current scientific advances.
- ICH Q6A/B Concept Paper Outline from QDG endorsed in December 2020.
- ICH Q6(R1) Concept Paper discussed in Fukuoka in June 2024.

トピックの概要

- **QDGにより指摘された論点**
  - Cover contemporary modalities and complex biological products – considerable scope increase
  - Expand scope to cover marketing authorization and commercial phase of product lifecycle
  - Align with relevant ICH guidelines (Q1, Q8-Q11, Q12, M7, Q2, Q14, Q13 and others)
  - Include science and risk-based approaches and not only reliance on batch data
  - Clarify pharmacopeial role in setting specification

Informal WGの構成

IGBA
MFDS, Republic of Korea
USP
Health Canada, Canada
EDA, Egypt
SAHPRA, South Africa
PhRMA
APIC
SFDA, Saudi Arabia
EAC
TFDA, Chinese Taipei
Swissmedic, Switzerland
IFPMA

MHLW/PMDA, Japan
PhRMA
ANPP, Algeria
JFDA, Jordan
BIO
MHRA, UK
FDA, United States
COFEPRIS, Mexico
EDQM
EFPIA
ANVISA, Brazil
NMPA, China
JPMA
EC, Europe

ICH会合前の進捗

- ICH Informal Working Group (iWG) membership identified by the end of February 2024
- Q6 Leadership engagement
  - With QDG Leadership – Background and alignment on expectations and points of contacts for future interactions
  - With Q4B/Pharmacopeial Discussion Group (PDG)
- Q6 iWG Initial discussion and engagement on concept paper outline
  - Decision to have concept paper outline reviewed by constituents
  - Survey created to identify priority areas for harmonization activities

ICH会合前の進捗

- Concept paper outline constituents review and survey outcomes
  - ~230 comments from 26 organizations
  - Identification of key topics for discussion
    - Scope
    - Format of guideline
    - Patient centric approach
    - Interchangeability of monographs

福岡会合の成果

- Key topics
  - Scope – Agreement
  - Format of guideline: under discussion
  - Patient centricity/Clinical relevance – Agreement to discuss principles in guideline
  - Interchangeability of pharmacopeial monographs – PDG/Q4B has efforts underway to address

- Concept Paper and Work Plan Finalized awaiting final concurrence from iWG

福岡会合の成果

- **Proposed Scope for Q6 Guideline**
  - This guideline applies to pharmaceutical drug substances and products both chemicals and biologicals that require a marketing authorization, including but not limited to vaccines, advanced therapeutic modalities (e.g. cell and gene therapies, oligonucleotides, antibody-drug conjugates (ADCs), etc.); and drug-device combination products that meet the definition of a pharmaceutical or biological product. This guideline applies to new marketing authorizations and throughout the lifecycle of the already approved products. The scientific principles described in this guideline may be applied in a phase- appropriate manner during development.

Work plan

Expected Completion date	Deliverable
Jun. 2026	• Step 1 and 2a/b Sign-off • Step 2 presentation • Initiate work on training material
Jun. 2028	• Step 3 and 4 Sign-off • Step 4 presentation

＊11月のモントリオール会合にて5日間の会議を予定

Work plan

- **Justification for work plan proposal**
  - Modernize 25 years old guidelines on specifications
    - Aligning with relevant ICH guidelines
    - Expanding the use of clinically relevant/risk based approaches
    - Covering advanced tools (e.g. predictive modelling)
    - Covering expedited development considerations for setting specifications
  - Update and expand the scope of the guidelines (additional modalities and considerations for lifecycle management)
  - Develop unifying principles that apply to all modalities
  - Develop annexes to address unique considerations

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ご清聴ありがとうございました

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