Q6(R1)
「医薬品の規格及び試験方法の設定」の改訂

2024年12月18日 第50回ICH即時報告会

日本製薬工業協会
Q6(R1) トピックリーダー
山口　貴宏

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

本日の内容

- トピックの概要
- モントリオール会合前の状況
- モントリオール会合での進捗
- Work Plan

本発表は演者の個人的見解を示したものであり、
所属団体からの公式見解ではないことにご留意ください。

トピックの概要

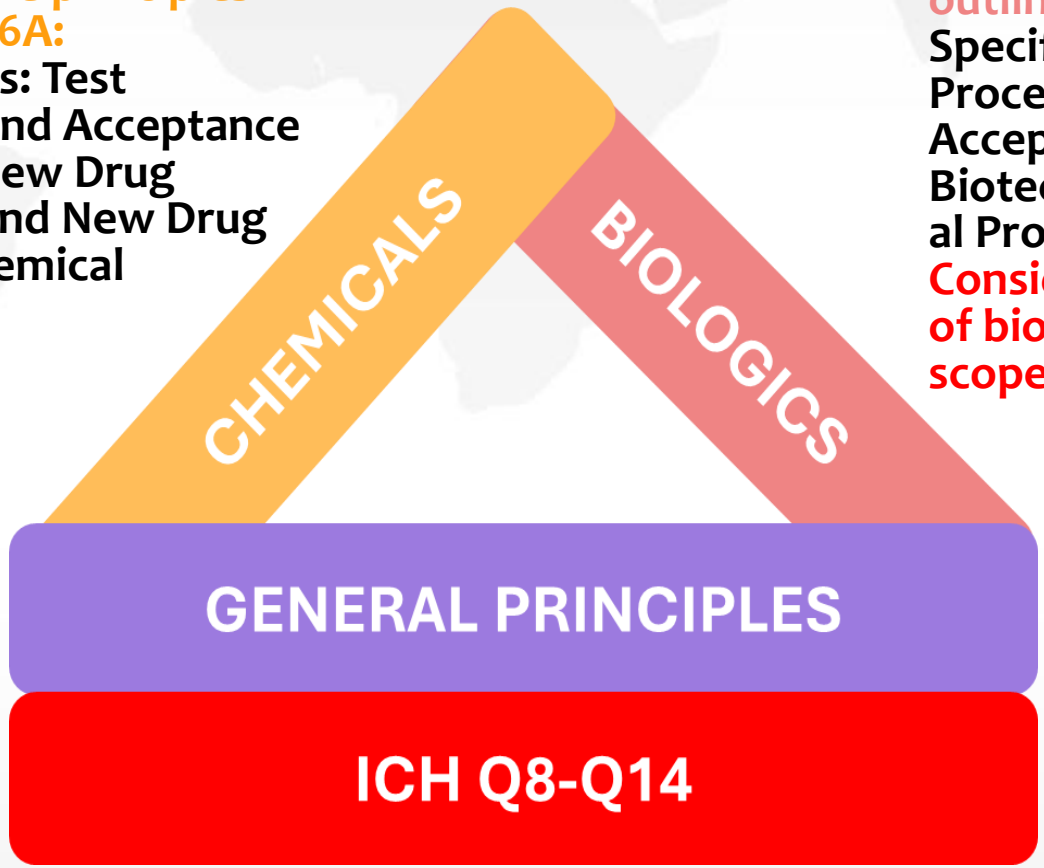
- **ICH Q6A and Q6B were finalized in 1999. These guidelines address setting specifications for chemicals and some specific biological products, respectively.**
- **Quality Discussion Group (QDG), as part of their purview, recommended revision of Q6A and Q6B to reflect current scientific advances and address the following:**
  - 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, Q2, Q8-Q14, M7, and others)
  - Include science and risk-based approaches and not only reliance on batch data
  - Clarify pharmacopeial role in setting specification
- **ICH Q6A/B Concept Paper Outline from QDG endorsed in December 2020.**

Q6(R1) 方針

Leveraging the principles outlined in Q6A:
Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances

Leveraging the principles outlined in Q6B:
Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products.
Considerable expansion of biological modalities in scope

Identifying common unifying principles applicable to all product types



Q6(R1) 構成案

1. INTRODUCTION
2. GENERAL PRINCIPLES
3. CONSIDERATIONS FOR CHEMICALS
4. CONSIDERATIONS FOR BIOLOGICALS
5. GLOSSARY
6. REFERENCES
7. APPENDIXES (if needed)

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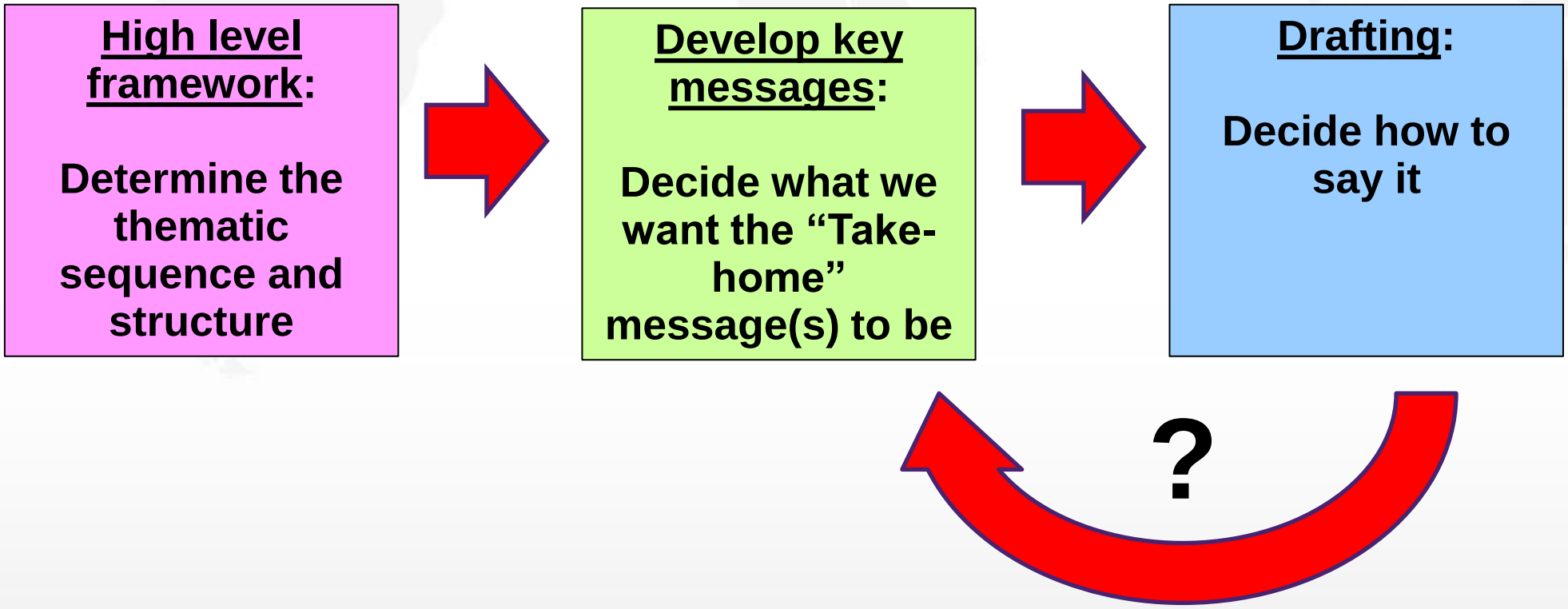
8. ANNEXES (if needed)

ドラフト作業の進め方

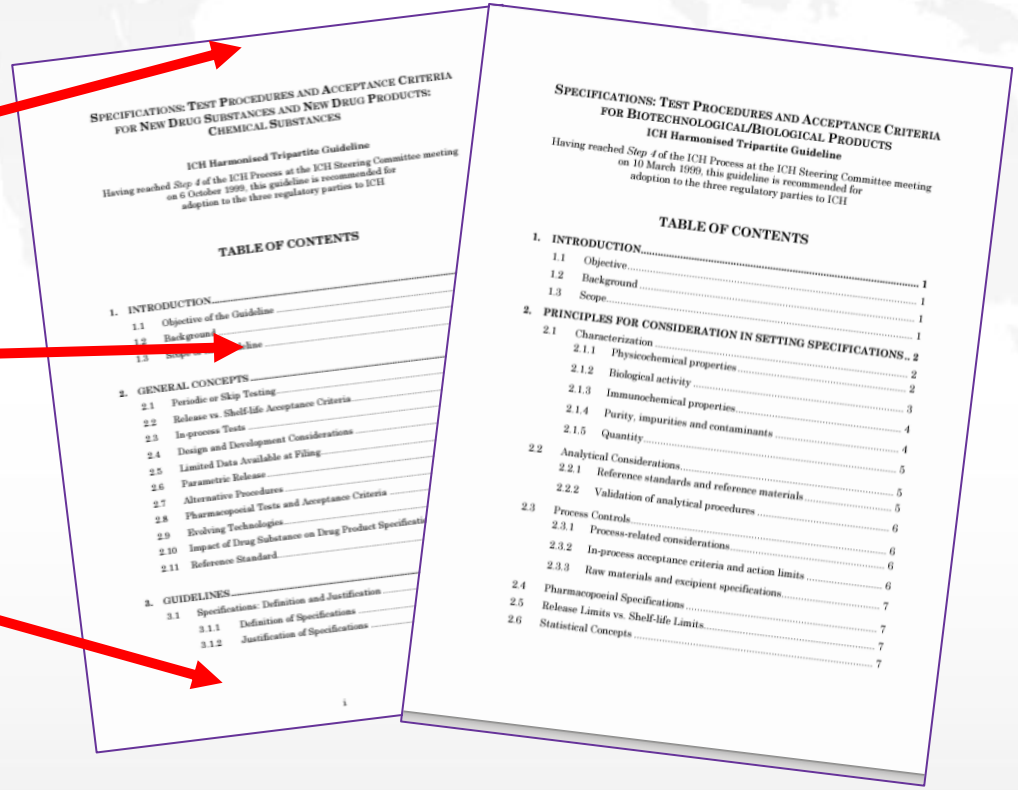

High level framework:
Determine the thematic sequence and structure
Develop key messages:
Decide what we want the "Take-home" message(s) to be
Drafting:
Decide how to say it
?

ドラフト作業の進め方

QDG Gap Analysis

ICH QDG's Recommendations	Problems/Gaps Affecting Q6A & Q6B	Additional P
1. Clarify ICH Quality Guideline Linkages:		
i) Link applicable guiding principles from Q6A to Q6B. This includes clarifying the applicability of existing and to-be-updated content in Q6A to products within the Q6B scope. The QDG recommends including either: cross-references to the applicable Q6A sections/ text and/or adding Points to Consider (PTCs) in appropriate sections of Q6B.	Many of the key concepts and terminologies that need updating and aligning to other guidances are present in the introduction of Q6A and not repeated in Q6B (EPFIA). This link is currently missing.	
ii) Include an explanatory note in Q6A and Q6B that guiding principles from other ICH guidelines (e.g., Q2, Q3C, Q3D and M7, Q8, Q9, Q10, Q12, Q13 and Q14) are applicable in the	• Q6A and Q6B work together and in conjunction with other ICH guidelines as always (EPFIA). This link is currently missing; • Q6A and Q6B are 20 years old, and the contents are not up to date with	

Q6A and Q6B



モントリオール会合前の状況

- Concept paper endorsed by the MC in July 2024
- ToC and General principles section (Section 1) draft developed and shared with EWG for review
- ToC and key messages developed for Chemicals and Biologics

モントリオール会合での進捗1

Is there any needs to introduce new terminologies for ICH Q6(R1)?

Consensus by EWG:

- Not to introduce new terminologies in ICH Q6(R1) unless it is necessary
- Support use of science- and risk-based concept/tools developed in Q8-Q14

Rationale

- New terminology could mislead readers and increase complexity. Both “traditional” and “enhanced” approaches are patient centric and relevant to patients.
- Science- and risk-based approaches used in Q-guidelines, e.g.,Q8-14 already covered patient relevant concept
- One of the objectives for Q6(R1) is to modernize in line other Q-guidelines.

モントリオール会合での進捗2

- **Key comments on the initial draft of General Principles section (Section 1):**
  - EWG acknowledges that the application of science and risk-based principles and a continuum of process and product knowledge are essential elements for modernization of specification setting.
    - Examples illustrating these ideas were developed and discussed in Montreal
    - These concepts require further discussion and refinement by EWG

モントリオール会合での進捗3

- **Role of Pharmacopoeias in Setting Specifications:**
  - Acknowledge the legal requirements where applicable
  - Defer to existing pharmacopoeial recommendations

- **ToC and key messages proposed for the Chemicals (Section 2) and Biologics (Section 3) discussed and generally agreed upon by EWG**

モントリオール会合での進捗4

他ICHグループとのミーティング

- **CGTDG:**
  - Initial contact with CGTDG and Q6 leadership after Fukuoka meeting
  - Montreal meeting - A formal in-person meeting with broader membership for alignment on expectations and ways of working together
- **ICH Q1/Q5C:**
  - Meeting with Q1/Q5C members to align on expectations for shelf-life/stability specifications

Work plan: Expected future Key Milestones

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

当初予定から変更なし

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Thank you!

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