第27回ICH即時報告会

Q7：原薬GMP Q&A

2012年12月14日

寶田　哲仁
日本製薬工業協会
Q7実施作業部会トピックリーダー

Q7 IWG開始までの経緯

- 2012年5月： Informal Quality Brainstorming Group（IQBG）にて、Q7 Q&A作成の必要性を結論 ⇒ SC
- 2012年6月福岡会議： Q7 Informal WGの立ち上げ承認 ⇒ Concept Paperのfinalise
- TC（9/4）を経てConcept Paperのfinalise
- San Diego（11/12～15）より対面会議開始

Q7 IWGメンバー

- Swissmedic (EFTA*:　Interim Rapporteur)
- Core: FDA, PhRMA, EU, EFPIA

  MHLW
  - TL:　　森末　政利（PMDA）
  - DTL:　　大野　勝人（PMDA）

  JPMA
  - TL:　　寶田　哲仁（持田）
  - DTL:　　仲川　知則（大塚）
  - Expert:　　松村　清利（原薬工:　大塚化学）
- Observer: Health Canada, WHO
- Interested Party: WSMI*, Biotech*, EDQM*, APIC*
- GCG*: Korea (KFDA), Singapore
- Pending: IGPA*, PIC/S

*参考
EFTA: European Free Trade Association
WSMI: World Self-Medication Industry / 世界大衆薬協会
Biotech: Biotechnology Industry Organization
EDQM: European Directorate for the Quality of Medicines / 欧州医薬品品質部門
APIC: Active Pharmaceutical Ingredients Committee
GCG: Global Cooperation Group
IGPA: International Generic Pharmaceutical Alliance / 世界ジェネリック医薬品協会

解決すべき課題（Concept Paperから）

1. Existing Q&As
   - IWG Q&Aとしての取り込み
     - PIC/S Expert Circle, Initial Regulatory/PDA training
2. Technical Issues
   - 解釈が不確実（uncertainties）になってきた部分への解説（Slide 5）
3. Impact of Q8/Q11, Q9 and Q10 on Q7
   - “Q-quartet”の概念（life-cycle approach）からの解説

     ⇒ New Concept

Technical Issues (Concept Paper)

- Supply chain control
- Contractor/supplier management (outsourcing)
- Monitoring of impurity profiles
- Quality systems
- Applicability to biologicals/biotech and relationship with Q5D
- GMP expectations in the development phase

San Diegoでの協議内容

Existing Q&As	・Q&Aの入手方法及びWorking Process（Issue共通） ・Existing Q&Asの評価基準（取捨選択のための） ・Existing Q&Asの範囲について
Technical Issues	・問題点のブレーンストーミング ・問題点の抽出方法
New Concept	・課題のブレーンストーミング

Guiding Principles for the ICH Q7 Q&A

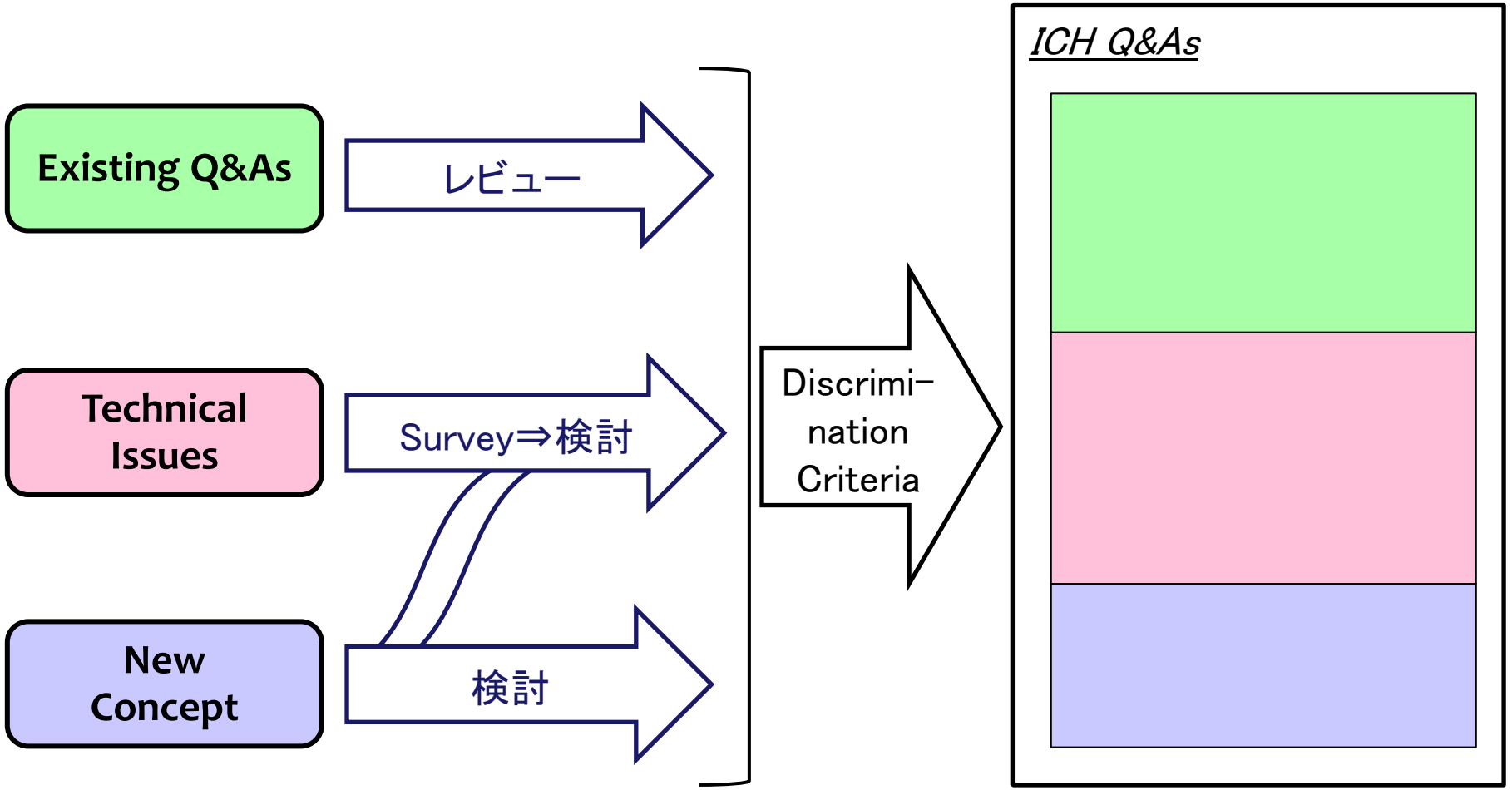
- **A 'What to do' document**
  - One harmonised Q&A document
  - Address current issues identified by the Q7-IWG
  - Address one issue at a time

- **Potential rules for the answers**
  - Clear and concise
  - Reference to the sections in ICH Q7 and/or other ICH documents, if appropriate

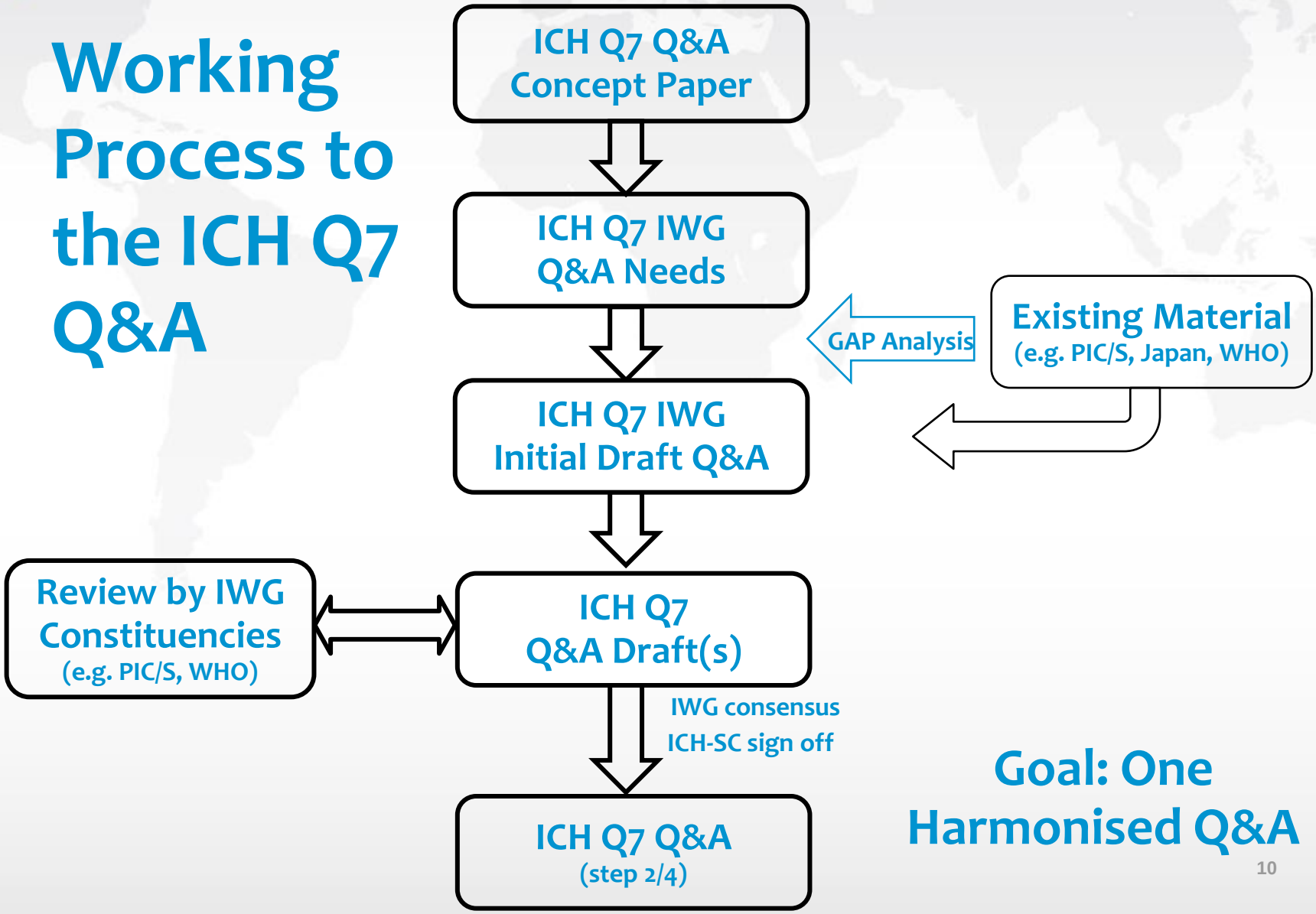
San Diego結論

Existing Q&As	・Working Process（Issue共通）作成 (Slide 10) ・Existing Q&Asの評価基準作成 （Discrimination Criteria: Slide 11） ・日本からQ7のQ&A提供（提供検討中） ・WHOから資料の提供（提供検討中）
Technical Issues	・Survey（3極等の規制当局・企業対象: Slide 15） ・問題点のブレーンストーミング
New Concept	・課題のブレーンストーミング

Working Process： ゴールのイメージ



Working Process to the ICH Q7 Q&A



Goal: One Harmonised Q&A

Guiding Principles for the ICH Q7 Q&A

- **Potential discrimination criteria for Q&As**
  The Q&A should NOT:
  - Explain ‘How to do’
  - Restate the text from ICH Q7
  - Enlarge scope of ICH Q7
  - Address too specific questions
  - Establish new requirement
  - Address regional matters
  - Be outdated, no longer relevant
  - Be included, if better handled in a training environment

Reviewed Existing Materials

- ICH Q7 EWG training 2001-2003
- PIC/S training - PIC/S Expert Circle Q&As on ICH Q7
- ICH Q7: Key Messages as part of the PIC/S Training
- PIC/S Aide Memoire on inspections of APIs (PI-030)
- WHO Technical Report Series 957, Annex 2, 2010
- CEFIC / APIC ‘How to do’ document
- ICH Q11: Specific considerations to ICH Q7
- ICH Q-IWG: Q&A and PtC & Impact of the implementation of ICH Q8/Q11,Q9,and Q10 on Q7
- ICH Q7: Implementation experience in Japan, US and EU

ブレーンストーミングの例

- Difference between GMP and GDP (Supply Chain)
- Glossaries in Q10: ‘outsourced activities’ vs. Q7: ‘manufacturing’ (Outsourcing)
- Responsibility to check in the registration dossier (Monitoring of impurities profiles)
- Management review/product quality reviews (Quality Systems)
- Where does Q7 start for Biotech? (Bio., *Ch. 18*)
- Level of Cleaning (Development phase, *Ch. 19*)
- Process Validation: reference to Q-IWG Q&A, PtC (Impact of Q8-Q11)

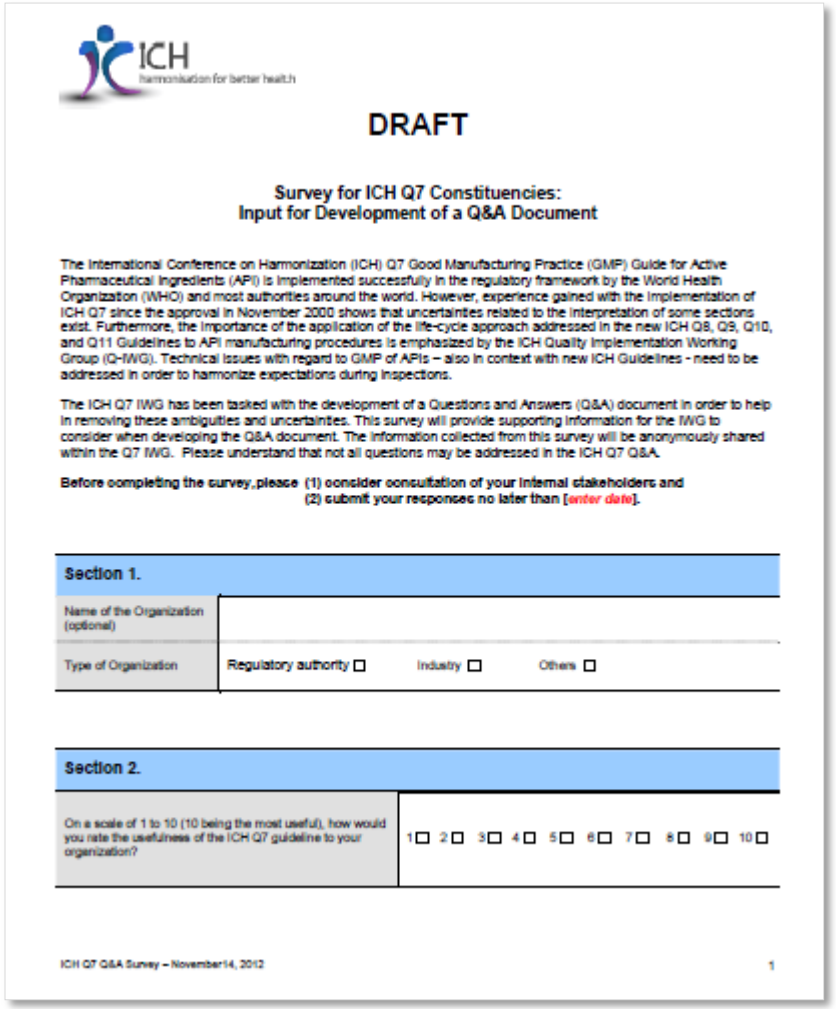
Brussels対面会議に向けた準備

- Existing Q&As
  - PIC/S Expert CircleからのQ&A ⇒ Discrimination Criteriaに準じた取捨選択(検討)
  - 日本からのQ&Aの提供 ⇒ Discrimination Criteriaに準じて取捨選択した後に英訳～提供(予定)
  - WHO Annex2(WHO検討中)
- Technical Issues
  - Surveyの実施(1月～:具体的な時期検討中)及び集計
- Telecon: 2013年2月及び4月
- Brussels: 2013年6月3日～6日(予定)

今後の国内対応

- Survey用紙（和訳版）の配布（1月）～意見収集

皆様のご協力を
お願い申し上げます。



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DRAFT

Survey for ICH Q7 Constituencies:
Input for Development of a Q&A Document

The International Conference on Harmonization (ICH) Q7 Good Manufacturing Practice (GMP) Guide for Active Pharmaceutical Ingredients (API) is implemented successfully in the regulatory framework by the World Health Organization (WHO) and most authorities around the world. However, experience gained with the implementation of ICH Q7 since the approval in November 2000 shows that uncertainties related to the interpretation of some sections exist. Furthermore, the importance of the application of the life-cycle approach addressed in the new ICH Q8, Q9, Q10, and Q11 Guidelines to API manufacturing procedures is emphasized by the ICH Quality Implementation Working Group (Q-IWG). Technical issues with regard to GMP of APIs – also in context with new ICH Guidelines - need to be addressed in order to harmonize expectations during inspections.

The ICH Q7 IWG has been tasked with the development of a Questions and Answers (Q&A) document in order to help in removing these ambiguities and uncertainties. This survey will provide supporting information for the IWG to consider when developing the Q&A document. The information collected from this survey will be anonymously shared within the Q7 IWG. Please understand that not all questions may be addressed in the ICH Q7 Q&A.

Before completing the survey, please (1) consider consultation of your internal stakeholders and (2) submit your responses no later than [*enter date*].

Section 1.	
Name of the Organization (optional)	
Type of Organization	Regulatory authority ☐ Industry ☐ Others ☐

Section 2.	
On a scale of 1 to 10 (10 being the most useful), how would you rate the usefulness of the ICH Q7 guideline to your organization?	1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

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