Q7：原薬GMP Q&A

Q7 IWG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
- 2012年11月サンディエゴ会議より対面会議開始
- 2013年6月ブルッセル会議では前会議で作成したアンケートを各極で実施し、結果をレビュー
- 2013年11月大阪会議では前会議のレビュー結果を踏まえ、各極が作成したQ&Aをレビューし、24のQ&A案を作成

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)
  - Expert:　　長嶋　孝司(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(次のスライド)
   - 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

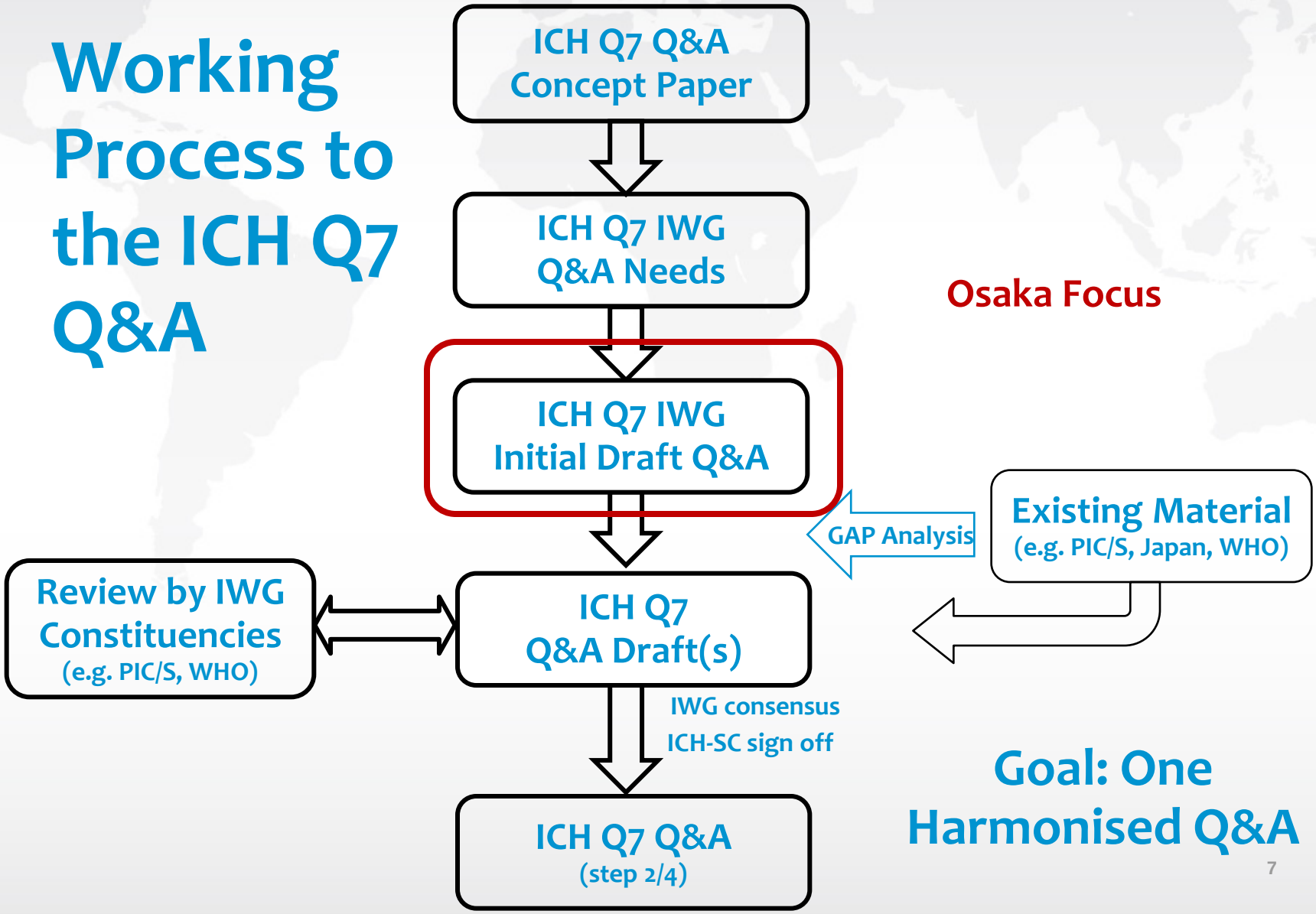
Technical Issues (Concept Paper)

- 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

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  - Be outdated, no longer relevant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

Working Process to the ICH Q7 Q&A

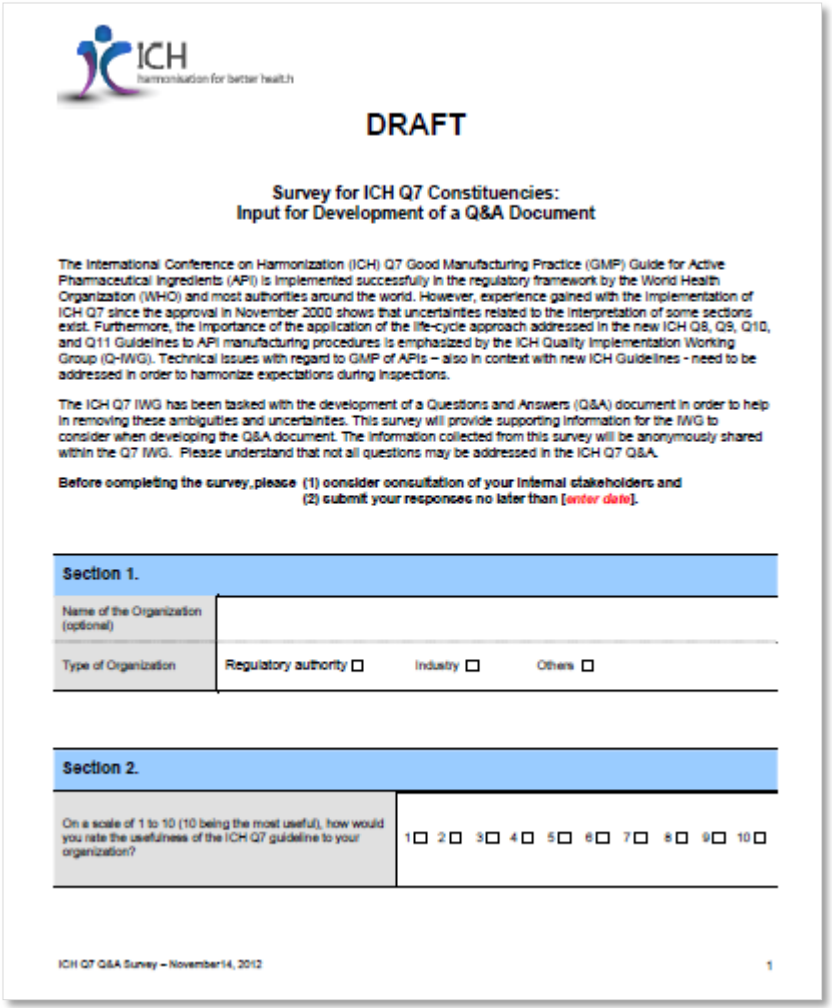


Osaka Focus

Goal: One Harmonised Q&A

Q&A Needs

- Survey用紙(和訳版)の配布(1月)～意見収集



ICH
harmonisation for better health

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☐

ICH Q7 Q&A Survey – November14, 2012 1

Survey Overview

- Survey to constituencies conducted over 4 weeks in February / March 2013
- 206 questions received from IWG constituencies
  - Questions received for all ICH Q7 chapters
  - Current issues for clarification
  - Number of complex technical issues
- Questions were evaluated against discrimination criteria resulting in 114 questions for further evaluation (Brussels)

Activities between Brussels and Osaka

- **The 114 questions divided amongst 3 regions**
  - **Scope (EU)**
    - Scope/API-starting material, WCB, Process Validation
  - **Supply Chain (US)**
    - Supply Chain , Supplier, Contract Mgmt
  - **Containment and Control (Jpn)**
    - Dedicated facility, high potent, Samples , re-test/re-use
- **Q7-IWG teleconferences held to check progress and align, where needed**
- **Regional meetings: All questions were evaluated resulting in about 39 questions and draft answers**

Osaka Accomplishments

- Reviewed regionally drafted Q&As by the ICH Q7-IWG
  - Brainstorming by ICH Q7-IWG
  - Worked in two cross regional sub-teams to discuss and revise Q&As
  - Reviewed drafted Q&As by the ICH Q7-IWG
- As of today 24 Q&As drafted

Between Now and Minneapolis

- Discuss and revise outstanding drafted Q&As
  - 32 Q&A within regional groups (incl. assessed existing Q&A from Japan and WHO)
    - Scope and Definitions / Quality Management, Quality System, and Quality Unit / Production and Materials Management (EU)
    - Training / Process and Cleaning Validation / Contractor and Supplier Management / Supply Chain Control (US)
    - Containment / Control: Sampling and Testing / Documentation / Clinical Trials (Jpn)
- Next level of review
  - Share 24 draft Q&As from Osaka with the constituencies
- Continue GAP analysis
  - Align against existing material e.g. 28 PIC/S Q&As
- IWG tele-conference to check status and progress

Next Step

- Reviewed regionally drafted Q&As by the ICH Q7-IWG
- Review and incorporate Q&As from GAP analysis
- Develop order and organisational structure of the Q&As
- Obtain consensus on the Q&As

  - *Early notification: based upon the number of questions, we may anticipate potential delay according to timeline in the concept paper*

ご静聴ありがとうございました