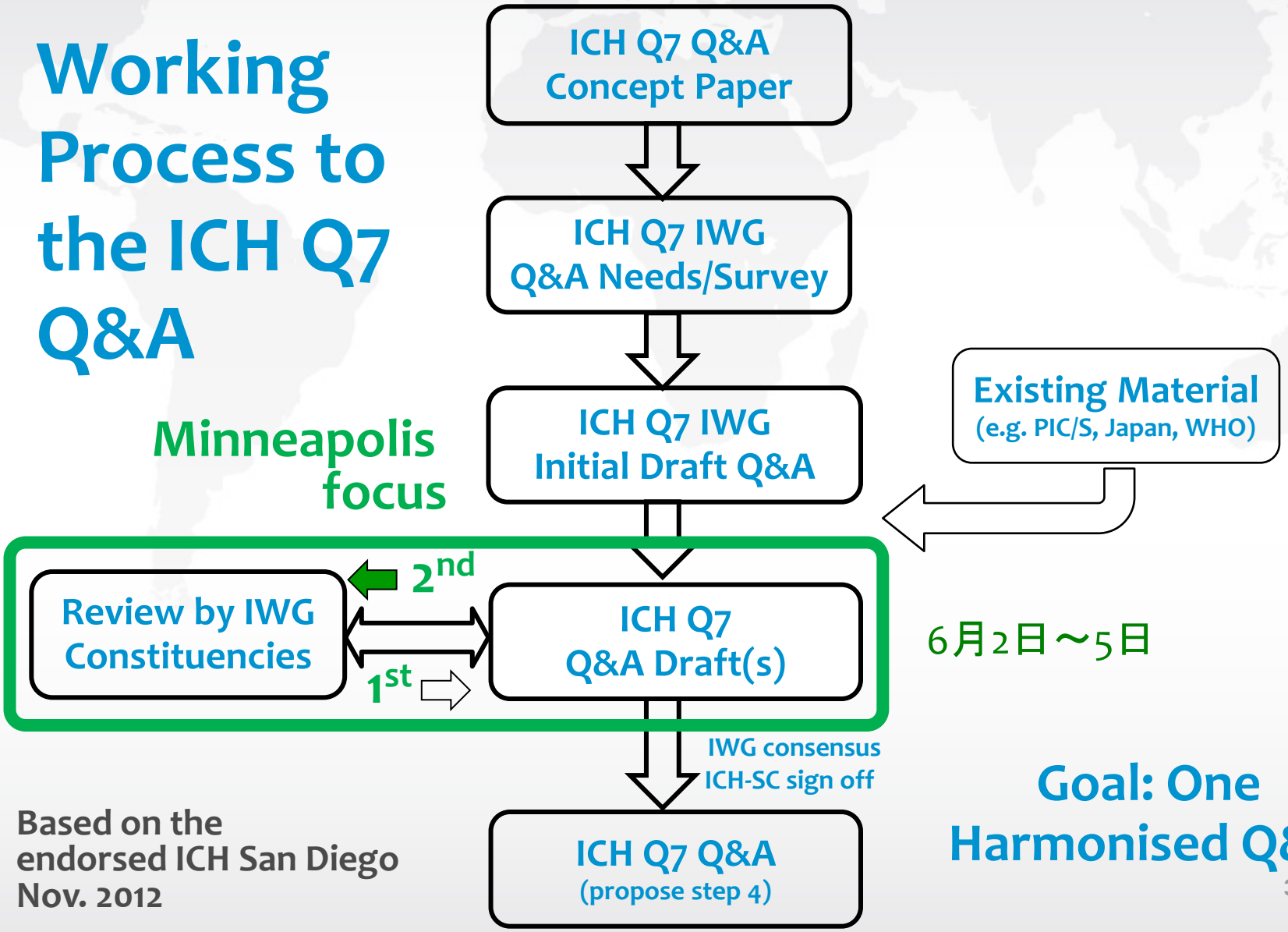
第30回ICH即時報告会

Q7：原薬GMP Q&A

Q7 IWG現在までの状況

- 第1回対面会議：San Diego（2012/11/12～15）
  - Working Process
  - Discrimination Criteria
  - Existing Q&As: PIC/S Expert Circle, WHO, 日本
  - Survey：実施の決定～様式　⇒　各極で実施
- 第2回対面会議： Brussels (2013/6/3～6)
  - 実施したSurvey結果のまとめ～Q&A候補絞り込み
  - 大阪会議までの課題確定（Scope; EU, Supply chain; US, Containment & Control; JP/Asia）
- 第3回目対面会議： 大阪 (2014/11/11～14)
  - 32件のQ&A合意　➡　EU, US, Asia teamで会議後レビュー: 1st Set
  - 会議後にPIC/SからQ&A提供　➡　大阪会議で合意しなかったものを含めて、各チームでレビュー: 2nd Set

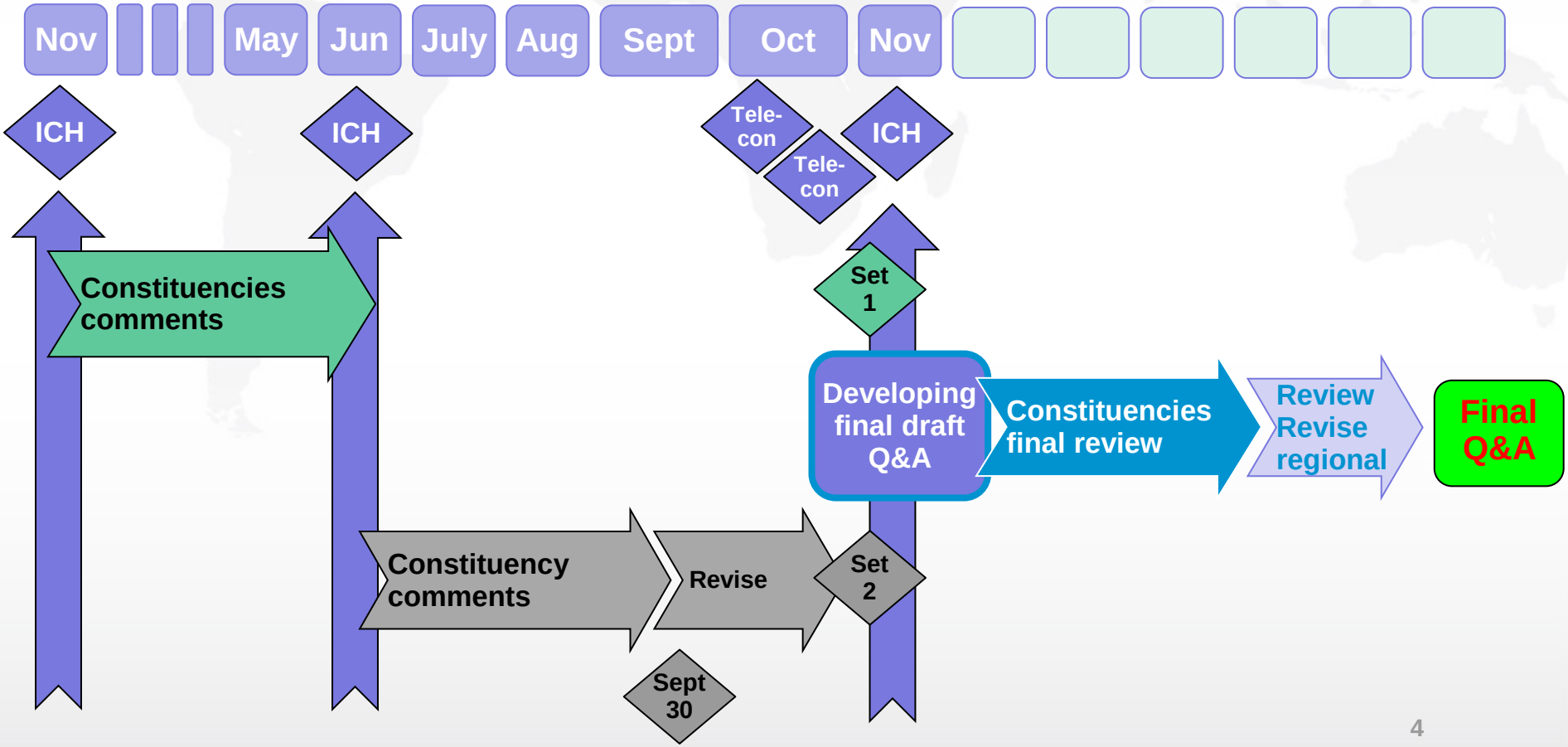
Working Process to the ICH Q7 Q&A



Based on the endorsed ICH San Diego Nov. 2012

Goal: One Harmonised Q&A

Work Plan Proposal (IWG最終日)

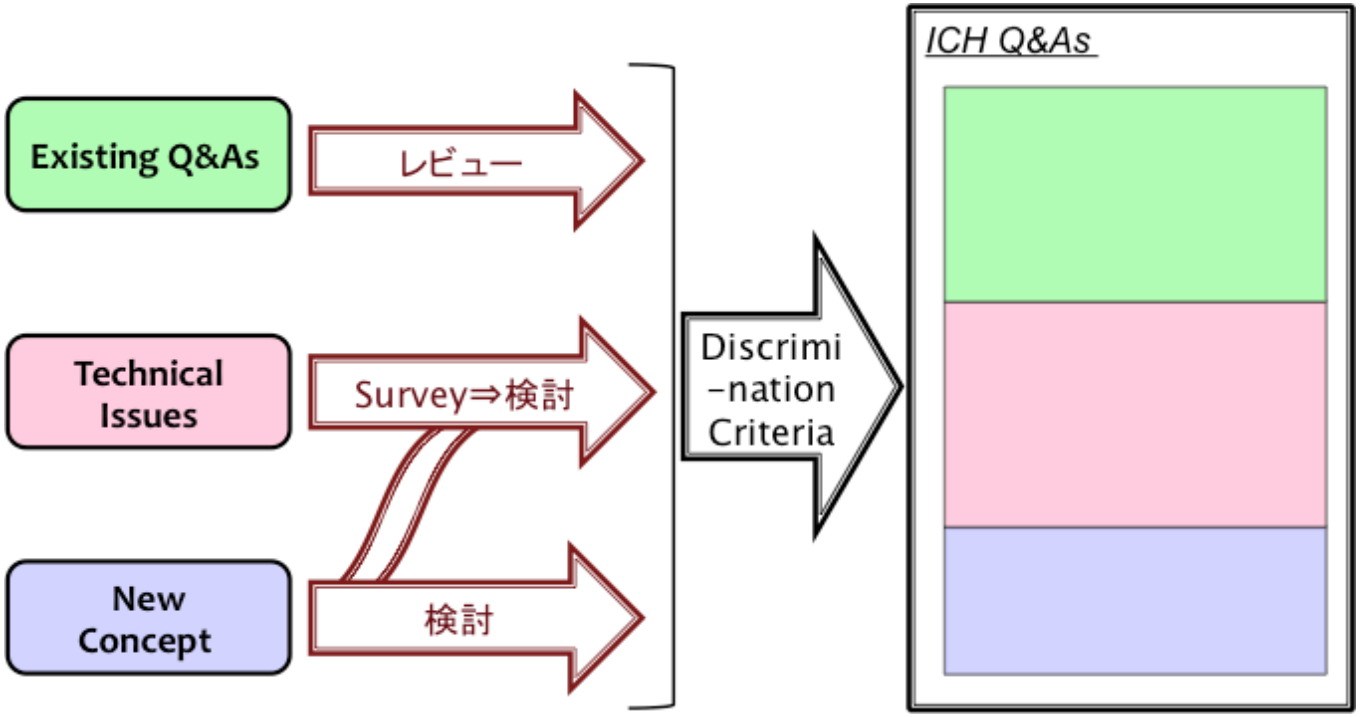


ミネアポリス会議結果

- Q&A
  - 1st Set Q&A（23件）：レビュー完了せず　➡　リスボンで継続
  - 2nd Set Q&A（34件）：ミネアポリス後チームで評価
- Public consultation　➡　実施しない
  - Q7ガイドラインの規定の範囲を越えていない（＝新たな要件を作成していない）
  - スケジュールに影響
- リスボン対面会議を実施
  - 11月10日～13日
- リスボン会議以降継続の可能性

影響

- Q&A作成のコンセプト
  - Q7 IWGの目的
  - Discrimination Criteria



Guiding Principles for the ICH Q7 Q&A

- **Potential discrimination criteria for Q&As**

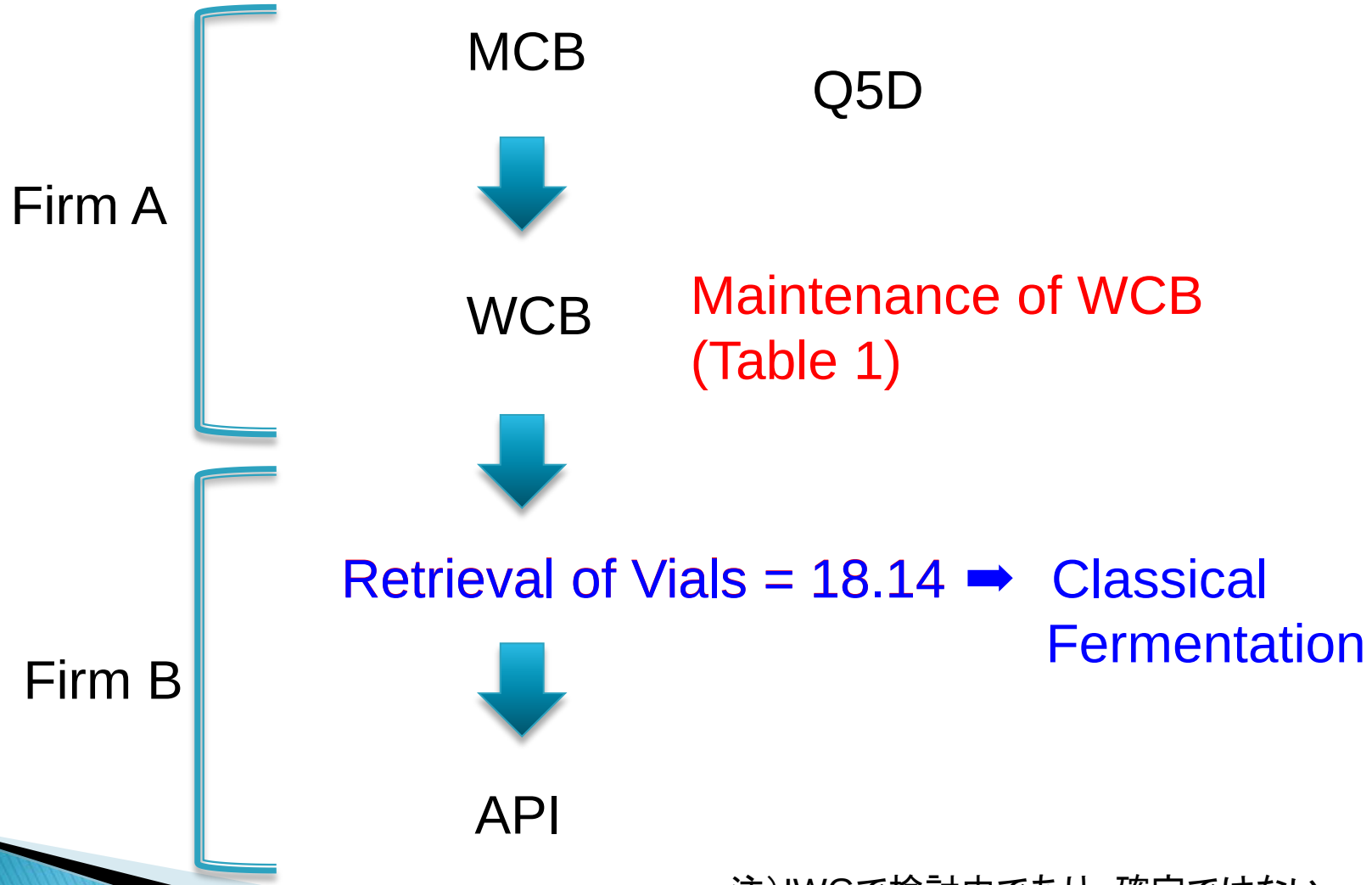
  The Q&A should NOT:

  - 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  - Be outdated, no longer relevant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

Items	Keywords
Scope	– Steps before defined SM, – Classical fermentation and biotech. (後述), – Replacing original labels
Quality Management	– QU independent from production, – PQR vs. trend analysis, – Quality defect vs. complaint, – Recalls
Training	– Periodic assessment of training
Containment	– Risk based approach (後述)
Validation	– Lifecycle approach of PV, – Source change, – Dedicated equipment vs. visually clean, – Equipment cleaning time limits vs. cleaning validation
Materials Management	– Appropriate spec. before blending, – Evaluation of suppliers
Laboratory Controls	– Extend API's retest date, – Use of more protective packaging system, – Impurity profiles for APIs from herbal or animal tissue origin
Supplier Management	– Responsibility of consultants, – Subcontracting, – Outsource activities
Supply Chain Management	– Transferring to another unit under the company's control

注）抜粋：IWGで検討中であり、確定ではない。

Applicability to Biologicals/biotech and relationship with Q5D



注）IWGで検討中であり、確定ではない。

Containment Q&A (Draft)

The principles of QRM [ICH Q9, Annex II.4] should be applied for control of and during design of buildings and facilities for the purpose of containment, taking into consideration the pharmacological / toxicological / chemical / biological properties of the API, intermediate and/or raw material to be handled or manufactured.

Appropriate containment measures and controls [ICH Q7, 4.42] include but are not limited to the following:

- Technical controls - e.g., dedicated production areas, closed / dedicated HVAC system, closed manufacturing systems, use of disposable technologies, design of facility and equipment for containment and ease of cleaning
- Procedural (organizational) controls – e.g., cleaning, personnel flow, environmental monitoring, training

Monitoring systems are important to check the effectiveness of the containment controls.

注）IWGで検討中であり、確定ではない。