VICH GL61
Pharmaceutical Development

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VICH GL61-Pharmaceutical Development

Topics to be covered:

- How the Quality Subgroup was formed
- Subgroup Membership
- Concept Paper
- Timeline/Status
- Key Sections/Work Plan/Topics covered by VICH GL61
- Overview of VICH GL61
- Pharmaceutical Development
- Examples
- Discussion & Revision
- Next Step (s)
- Anticipated Benefits
- ICH vs VICH Quality Guidelines
- References

How the Subgroup was formed

- **Concept paper:**
  - Drafted by FDA/CVM and was presented to
    - VICH Steering Committee (SC)- 2020 for adoption of ICH Q8, Q9 and Q10
  - VICH SC endorsed moving forward in developing equivalent Guideline to ICH Q8 only
    - November 2021
- A new subgroup was formed within Quality Expert Working Group
    - q8qualsubg@vichsec.org
    - Topic Leader: FDA/CVM
    - Each region added additional members to the subgroup:
      - 1 lead member (Expert)
      - 1 advisor
- Work did not start until early 2022

Membership of the subgroup

Regulators

EU:

- Norbert Möller (Expert)
- Christopher Janich (New Expert)
- Pascale Macours (New Advisor)

JMAFF:

- Kaoru Eguchi (Expert)
- Yuko Hosoda (New Expert)

US FDA:

- Mai Huynh (Topic Leader)
- Stephanie Bowman (Advisor)

UK VMD:

- Gill Clarke (Expert)

APVMA:

- Rongwei Teng (Expert)

Health Canada:

- Joseph Benoliel (VDD/DMV)

South Africa

- D. Katerere (Expert)

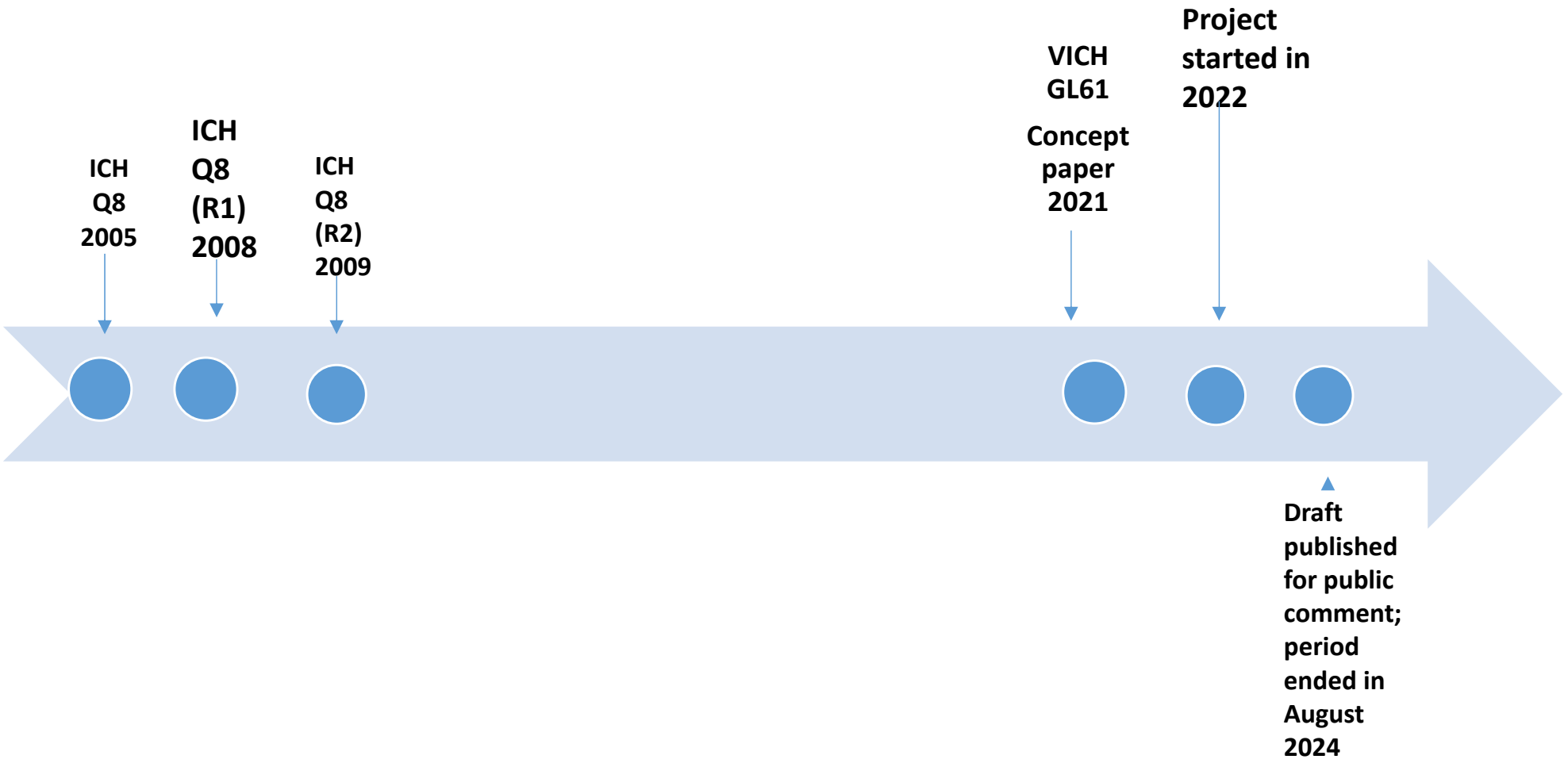
Industry Representatives

- AHE:
  -Viviane Neron De Surgy (Expert)
  - Martin Folger (Advisor)
- AHI:
  - Darryl Blum (Expert)-Zoetis
- JVPA:
  - Mamoru Ohashi (Expert)

Concept Paper-VICH GL61

- To establish equivalent VICH guideline to further assist innovation, continual improvement, and global harmonization efforts for the manufacture of new veterinary medicinal products, generics, or currently marketed veterinary medicinal products or active substances.
- Allow introduction of new concepts in development

Timeline


ICH Q8 2005
ICH Q8 (R1) 2008
ICH Q8 (R2) 2009
VICH GL61 Concept paper 2021
Project started in 2022
Draft published for public comment; period ended in August 2024

Key Sections-VICH GL61

Before the work started, a survey was sent to members of the subgroup:

To solicit feedback:

- How to work around ICH Q9/Q10 principles referenced in ICH Q8 guideline
- How to remove reference to CTD format
- Whether to work on the entire guideline or one section at a time since the current ICH guideline contains 2 portions:
  - The core guideline
  - Part II: Annex :
    - further clarification of the core guideline
    - Illustrative examples

VICH GL61-Work Plan

Survey:

To keep all in one document

-Main Guideline (Part I + Part II)

-Appendix 1

-Appendix 2

Key Sections-VICH GL61

Part 1: Pharmaceutical Development

1. Introduction
2. Pharmaceutical Development:
   - Drug Substances
   - Excipients
   - Drug Product
3. Glossary
4. References

Part 2: Annex to Pharmaceutical Development

1. Introduction
2. Elements of Pharmaceutical Development
3. Submission of Pharmaceutical Development and Related Information in Veterinary Drug Applications
4. Glossary

Key Sections-VICH GL61

Appendix 1

- Differing Approaches to Pharmaceutical Development
  - Minimal Approaches
  - Enhanced, Quality by Design Approaches

Appendix 2

- Illustrative Examples
  - Use of a Risk Assessment Tool
  - Depiction of Interactions
  - Presentation of Design Space

Overview of VICH GL61

Concepts and principles covered by GL61:

- Recommends content of the Pharmaceutical Development Report to share knowledge gained throughout the development stage of the product with regulators
- Introduces a new concept: Design Space-Quality by Design (QbD)
- Provides examples of QbD development approaches and design space
- Describes science and risk-based approaches for pharmaceutical product and manufacturing process development
- Recommends flexible regulatory approaches upon successful integration of QbD approach

What is Pharmaceutical Development?

Suggested contents:

- Formulation and Process knowledge gained through product development
- Quality Risk Management to the development of a product and its process:
    - At initial
    - Throughout the life cycle of the product
- Information to be shared with reviewers and inspectors
    - Design space

Pharmaceutical Development Report is **“optional”**

What is Pharmaceutical Development? Cont.

Section 2 of the Guideline:

- The aim of pharmaceutical development is to design a quality product and its manufacturing process to consistently deliver the intended performance of the product. The information and knowledge gained from pharmaceutical development studies and manufacturing experience provide scientific understanding to support the establishment of the design space, specifications, and manufacturing controls.
- The Pharmaceutical Development section should describe the knowledge, based on which the type of dosage form is selected, and the formulation proposed are suitable for the intended use.

What is Pharmaceutical Development? Cont.

- At a minimum, those aspects of drug substances, excipients, drug product (formulation, container closure systems, manufacturing processes, etc.) that are critical to product quality should be determined and control strategies justified. Critical formulation attributes and process parameters are generally identified through an assessment of the extent to which their variation can have impact on the quality of the drug product.
- Quality cannot be tested in products

(Section 2, cont.-Information excerpted from VICH GL61)

Examples of Pharmaceutical Development

Some examples of Pharmaceutical Development Report included in US applications for Veterinary Medicinal Products:

- Drug substance
- Excipients
- Drug Product development:
  - Formulation
  - Properties/ specifications

Examples of Pharmaceutical Development-cont.

- Manufacturing processes
- Container closure system
- Compatibility (e.g. in-use shelf life, recommended storage temperature, supportive information for the labeling, etc.)

Discussion & Revision

Most of the suggestions/comments received were minor in nature. In summary:

- Replaced ICH reference to VICH equivalent Guideline if one exists;
- Kept the reference to ICH Q9 and Q10 as is since there is no VICH equivalent
- Removed reference to CTD format
- Provided examples of common type of products for veterinary use
- Added definition of Risk Assessment, Quality Risk Management and Risk Reduction to the Glossary section
- Minor editing throughout the document for clarity

Next Step(s)

- Public comment ended –August 16, 2024
  - Minor suggested revisions were received
  - Newly revised draft currently under review by the subcommittee
- VICH Quality can organize a workshop on GL61 once the guideline has been adopted for implementation to aid in the interpretation of concepts and principles of Pharmaceutical Development or Quality by Design. The workshop can be done virtually to encourage attendance.

Anticipated Benefits

Information from pharmaceutical development studies can be a basis for quality risk management. This information can be used to support:

- risk-based regulatory decisions (reviews and inspections);
  - manufacturing process improvements, within the approved design space described in the dossier (or application), without further regulatory review;
  - reduction of post-approval submissions;
  - real-time quality control, leading to a reduction of end-product release testing.

ICH vs. VICH Quality Guidelines

- **ICH Quality Guidelines**
- Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
- Q8 Pharmaceutical Development
- Q9 Quality Risk Management
- Q10 Pharmaceutical Quality System
- Q11 Development and Manufacture of Drug Substance
- Q12 Life Cycle Management
- Q13 Continuous Manufacturing of Drug Substances and Drug Products
- Q14 Analytical Procedure Development

- **VICH Quality Guidelines**
- GL 60 (Q7 equivalent)-Draft
- GL 61 (Q8 equivalent)- Draft

There is no VICH GL equivalent to ICH Q9 – Q14

REFERENCES

- ICH Q8 (R2):

  Pharmaceutical Development

- ICH Q9(R1)

  Quality Risk Management

- ICH Q10:

  Pharmaceutical Quality System

- VICH GL39:

  Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Veterinary Medicinal Products

- VICH GL40:

  Specifications: Test Procedures and Acceptance Criteria for Biotechnology/Biological Veterinary Medicinal Products

Thank You

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