



## **CONCEPT PAPER**

# **For the adoption of ICH Q7: Good Manufacturing Practice for Active Pharmaceutical Ingredients**

### **Introduction:**

ICH Q7 provides guidance regarding good manufacturing practices (GMPs) for the manufacturing of active pharmaceutical ingredients (APIs) for use in human drug (medicinal) products. It allows manufacturers and regulators a framework to ensure that APIs meet the quality and purity characteristics that they are intended to possess.

ICH Q7 was adopted for implementation by ICH regions since 2001, and the United States (US) has since integrated the concepts described in this guideline to ensure the quality of APIs through GMP inspections of facilities that manufacture APIs for use in medicinal products for human use.

### **Current situation:**

The US have used the general concepts described in the ICH Q7 for GMP inspection of facilities that manufacture APIs for use in veterinary medicinal products, in particular those facilities that manufacture both human and veterinary APIs, although the guideline is specific for APIs for use in human medicinal products. Several APIs used in veterinary medicinal products are also used in human medicinal products, and therefore, it is not uncommon that the same GMP principles described in ICH Q7 are being used for those inspections.

Not having a VICH guideline with the same principles as those described in ICH Q7 results in a knowledge gap for those facilities that manufacture APIs for veterinary use only, which often leads to poor quality of the APIs and non-compliance with GMPs and the relevant legislation.

### **Impact for public health, animal health and animal welfare:**

Adopting ICH Q7 will facilitate harmonization of a single set of international standards for GMP inspections of APIs and starting materials. The guideline would allow regulators and manufacturers to work on the same framework that would ensure the quality and purity characteristics of APIs intended for use in human or veterinary medicinal products.

### **Anticipated Benefit:**

The guideline would harmonize expectations during GMP inspections of facilities that manufacture APIs. The ICH Q7 guideline has been referenced in The Pharmaceutical Inspection Cooperation Scheme (PIC/S) training program for APIs for the last several years. The goal of this training program is to raise awareness among global inspectorates in the

relation to API manufacture as well as their supply chain, especially for manufacturers located in countries subject to a Mutual Recognition Agreement (MRA) inspection review such as the US/EU MRA.

The harmonized guideline will also provide manufacturers a framework to establish an appropriate quality system to manage the production of their products, which helps ensure that APIs meet the quality and purity characteristics that they purport, or are represented, to possess.

#### **Anticipated Benefit to industry:**

The proposed guideline will:

1. Establish global guideline for inspection of APIs for use in veterinary medicinal products.
2. Provide clarity on the requirements and therefore, reduce regulatory uncertainty.
3. Enhance industry knowledge of establishing a quality management system to ensure consistency of the production of APIs.

#### **Anticipated Benefit to Regulators:**

The proposed guideline will:

1. Bring consistency in the inspection of APIs for use in veterinary medicinal products
2. Help align VICH guideline with ICH's
3. Facilitate implementation of global initiatives such as the MRA between the US and EU.

#### **Recommendations:**

For VICH to form a subgroup within the Quality Expert Working Group for the following steps:

- Review the information that currently exists in ICH Q7 regarding requirements or expectations for active pharmaceutical ingredients used in clinical trials. Propose alternative wording for further clarification, where needed.

Information from PIC/S GMP Guide: Part II: Basic Requirements for APIs (PE 009-14 (Part II), July 1, 2018) can also be used as additional source reference. Note that this Guide applies to the manufacture of APIs for medicinal products for both human and veterinary use (see Scope section of the Guide).

- Review and recommend adoption of all items, some items and recommend alternatives if changes are warranted for the remaining of the information in the current ICH Q7.

For VICH to adopt the concept and principles described in ICH Q7 and establish a similar VICH guideline to further assist in the global harmonization effort for the manufacture of APIs used in veterinary medicinal products.

#### **Timetable and Milestones (tentative):**

- November 2020: Revised concept paper to be reviewed by the VICH Steering Committee.  
Subgroup to be formed within Quality Expert Working Group (EWG)
- December 2020: Nomination of Topic Leader and members of the subgroup.
- Summer 2021: Subgroup to complete the review of the information that currently exists in ICH Q7 regarding requirements or expectations for active pharmaceutical ingredients (APIs) used in clinical trials. PIC/S Guide for APIs should be considered. Provide recommendation to Quality EWG.
- Fall 2021: Review and respond to comments received from Quality EWG.
- December 2021: Draft VICH Quality Guideline with principles aligned to ICH Q7 where possible.
- Summer 2022: Distribute proposed guideline to Quality EWG for review and comment.

**Impact Assessment:**

**Industry:**

- a. Provide clarity and global consistency of requirements.
- b. Reduce the number of non GMP compliance of facilities that manufacture APIs for use in veterinary medicinal products.
- c. Accelerate availability of new drugs, which potentially could reduce drug shortage.

**Regulators:**

- a. Increase in clarity of requirement (less uncertainty expressed by Industry).
- b. Enhance global consistency among inspectorates.

**References:**

ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients:  
[https://database.ich.org/sites/default/files/Q7\\_Guideline.pdf](https://database.ich.org/sites/default/files/Q7_Guideline.pdf)