Quality Expert Working Group

Chairperson: Tomoko Ogata (JMAFF)

Introduction

The Quality Expert Working Group (QEWG) was established in 1997. QEWG has developed guidelines for veterinary drugs based on various quality guidelines harmonized by ICH. To date, 15 guidelines have been adopted. The majority of discussions are conducted mainly by e-mail or written procedure. Currently, two active subgroups have been formed within QEWG, ICH Q7 subgroup and ICH Q8 subgroup.

Guidelines adopted

Analytical validation: 2
- GL1: Validation of analytical procedures : definition and terminology
- GL2: Validation of analytical procedures : methodology

Stability: 8
- GL3: Stability testing of new drug substances and products
- GL4: Stability testing for new dosage forms
- GL5: Stability testing : photostability testing of new drug substances and products
- GL8: Stability testing for medicated premixes
- GL17: Stability testing of new biotechnological/biological products
- GL45: Bracketing and Matrixing Designs for Stability Testing of new Veterinary Drug Substances and Medicinal Products
- GL51: Statistical evaluation of stability data
- GL58: Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV

Impurities: 3
- GL10: Impurities in new veterinary drug substances
- GL11: Impurities in new veterinary medicinal products
- GL18: Impurities: residual solvents in new veterinary medicinal products, active substances and excipients

Specifications: 2
- GL39: Test Procedures and Acceptance Criteria for new Veterinary Drug Substances and New medicinal Products: Chemical Substances
- GL40: Test Procedures and Acceptance Criteria for new Biotechnological/Biological Veterinary Medicinal Products

Guidelines under development

Two active subgroups are currently developing new guidelines.
GL60: Good Manufacturing Practice for Active Pharmaceutical Ingredients used in Veterinary Medicinal Products (based on ICH Q7)
GL61: Pharmaceutical Development (based on ICH Q8)

Key scientific issues resolved

GL58 provides guidance regarding the stability data package for a new veterinary drug substance and medicinal product to be included in a registration application submitted within the regions in climatic zones III and IV. In developing this guideline, additional members from non-VICH regions were included in the discussion.

Key benefits of the harmonized guidelines

The use of internationally harmonized guidelines reduces the cost of veterinary drug development and facilitates regulatory review.

EWG Composition


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