Biologicals EWG

Chairperson: Kota Sato (JMAFF)

Introduction

The Biologicals Expert Working Group (EWG) was established in 2020, succeeding the Biologicals Quality Monitoring (BQM) EWG established in 1999. Its objective is to establish comprehensive, scientifically correct, effective, proven and practical VICH guidelines (GLs) for harmonized quality assays of veterinary biologics and biological origin components thereof. As the EWG's scope continued to expand (e.g. Biotechnology-derived pharmaceuticals), several subgroups have been established for each topic, and three independent GLs are currently being developed by the respective subgroups.

Guidelines adopted

The Biologicals (previous BQM) EWG completed the following guidelines;

- Testing of residual formaldehyde (VICH GL25)
- Testing of residual moisture (VICH GL26)
- Test for the detection of Mycoplasma contamination (VICH GL34)
- Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use (VICH GL50R)
- Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use (VICH GL55)
- Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use (VICH GL59)

Guidelines under development

The Biologicals EWG continues work with three GLs:

1. General principles for detection of extraneous agent viruses in mammalian veterinary vaccines
2. Target animal safety evaluation for veterinary monoclonal antibody product
3. Principles for technical guidance for the transition to in-vitro methods for batch potency tests in veterinary immunologicals

New topics

1. How to reconstruct the common test groups of extraneous virus tests for vaccines into limited numbers according to the cell substrates and methods in mammalian species.
2. How to harmonize the safety guidelines for biotechnology-derived veterinary medicinal products.
3. How to adopt the in vitro procedures instead of in vivo animal-based batch potency tests for vaccines.

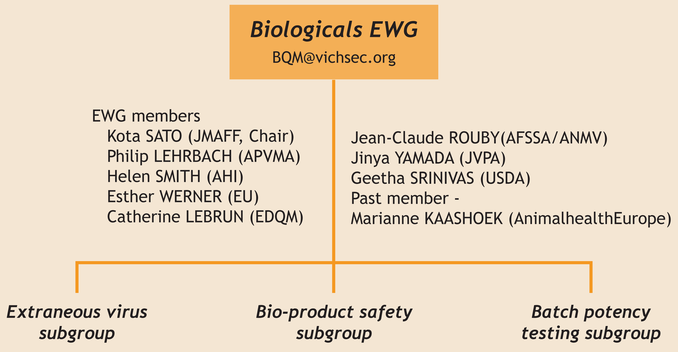
Key scientific issues resolved

- Procedures to waive batch safety testing have been established for target animals and laboratory animals.
- Common test groups for extraneous virus testing for vaccines in participant regions.
- Several quality measures for veterinary vaccines, such as Mycoplasma testing methods, formaldehyde, residual moisture (established according to collaborative studies by previous BQM EWG).

Key benefits of the harmonized guidelines

- To consumers, patients, users: Assurance of safe and pure veterinary vaccines, uniformly tested to global standards for extraneous deleterious biological and chemical agents. Improved product availability and food chain safety.
- To authorities: Standardized guidelines and references. Centralized reference material preparation and distribution.
- To industry: Elimination of duplicate testing for product release in other regions. Expedite new product registration and batch release. Participation in evaluation and validation of new guidelines and references.
- To animal welfare: Reduced in vivo procedures. Prevention of vaccine related epizootics.

EWG structure



Amsterdam
November 2024