Biologicals EWG: Subgroups

Extraneous Viruses Subgroup

Extraneous agent testing is important to assure constant quality of veterinary vaccines in terms of biosafety during the entire production process, from starting materials to the final product products. it is necessary to demonstrate that materials of animal origin including seed materials, substrates for production (e.g. cell substrates, embryonated eggs, primary cells, animals) and other materials or substrates of animal origin are not contaminated by viral extraneous agents when used in the manufacture of vaccines.
This guideline will provide recommendations for generalized cell-based test methods to evaluate viral contamination of materials of animal origin, within the limits of the fit for purpose test system. Currently, swine extraneous agent testing is being evaluated with additional species to be evaluated in the future.

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Bio-products Safety Subgroup

Currently, no VICH guidelines specifically support marketing applications for Veterinary Monoclonal Antibody Products (VMAP). The VICH guidelines available for Target Animal Safety (VICH 43 for pharmaceuticals and VICH 44 for vaccines) do not fully address the TAS evaluation needed for VMAPs.
This guidance will provide recommendations regarding the TAS evaluation, a comprehensive risk assessment for the target animals, and development programs for regulatory approval of VMAPs. The recommendations are in accordance with the principle that TAS evaluations should reflect the different modes of action of the target molecules and the properties of the VMAP.

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Batch Potency Testing Subgroup

Despite historical use of in vivo methods for vaccine batch potency testing, in vitro methods are encouraged and desired to minimize the use of animals in recognition of the 3Rs principle.
In vitro tests also have numerous advantages such as removing inherent animal variability, rapidity of the technique,...
However, many challenges exist in the development of in vitro methods. These challenges include time, technologies, correlation to existing methods and set up of specifications, but also recognition, acceptance and implementation in the global regulatory setting.
This guideline will provide a general concept on technical aspects and points to consider for government regulatory bodies and the Animal Health Industry to support a path forward in the pursuit of in vivo method replacement while still upholding potency tests being able to demonstrate production of potent batches.

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