



The European Partnership  
for Alternative Approaches to Animal Testing

## ECVAM/EPAA Workshop on The Consistency Approach for Quality Control of Vaccines – a 3Rs opportunity 11-12 January, Centre Borschette, Brussels

### Background

- Due to the nature of biological products regulators require that quality control is performed on each batch of a vaccine (by manufacturers and if there is a need by Official Medicines Control Laboratories) before it can be placed on the market.
- Safety and potency testing (as part of QC) often involve animal tests. In particular, for conventional inactivated, vaccines such as tetanus, pertussis, diphtheria and clostridials large numbers of animals are used.

## Consistency Approach

- **As underlining principle: the quality of a vaccine is the consequence of the strict application of a quality system and of a consistent production of batches.**
- **Consistency approach is already implemented for some novel human vaccines, i.e. agreed product characteristics can be tested in vitro during the manufacturing process of a batch and shown to be similar to those of batches demonstrated to be safe and effective in clinical trials.**
- **It may therefore be applied to conventional vaccine production in order to replace in vivo tests with in vitro tests indicative of the quality and quantity of the product whilst maintaining the highest quality and safety standards.**

The logo for the European Pharmaceutical Association (epaa) is written in a white, cursive script on a red-to-orange gradient background.

## Workshop Objectives

- **To discuss the applicability of the consistency approach for routine release of human and veterinary vaccines with all stakeholders**
- **To give recommendations on the implementation of the consistency approach**
- **To publish a workshop report**

**Note:** *A survey of ongoing activities relevant to the consistency approach was performed. The results will be presented and discussed at the workshop.*

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- **Organising committee:**  
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The logo for the European Petri Animal Association (EPA) is located in the bottom right corner of the slide. It features the lowercase letters "epaa" in a white, cursive script font, set against a background of a horizontal gradient from orange to yellow.