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.

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.
• Organising committee:
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