

ECVAM/EPAA Workshop on The Consistency Approach for Quality Control of Vaccines – a 3Rs opportunity

Brussels, 11-12 January 2010
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.

The consistency approach is based upon the principle that the quality of a vaccine is the consequence of the strict application of a quality system and of a consistent production of batches. Through the application of this principle, which has been implemented for some novel human vaccines, 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. The concept of consistency 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.

For a discussion of general and specific technical aspects of the consistency approach the reader is referred to the following two ECVAM reports: Metz et al. 2007 ATLA 35, 323-331; Hendriksen et al. 2008, Biologicals 36, 73-77.

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

Participants

Participants (invitation only) are representatives of OMCLs, EMEA, European Commission services, EDQM, FDA-CBER, USDA, Industry, EFPIA/EVM, IFAH, Animal welfare organisations and the Eurogroup for Animals