EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
In vitro Methods Unit –
European Centre for the Validation of Alternative Methods

Ispra, 8 July 2009

ECVAM/EPAA Workshop on
The Consistency Approach for Quality Control of Vaccines – a 3Rs opportunity
Brussels, 11-12 January 2010

Dear Colleague,

On behalf of ECVAM[1] and the EPAA[2] we would like to invite you to participate in the above workshop, which will bring together representatives from various disciplines to discuss the consistency of production approach and the opportunities this presents for reducing animal testing in vaccine quality control for release purposes.

Enclosed is a brief outline of the objectives of the workshop, as well as a preliminary programme and a list of proposed participants. Please let us know as soon as possible, and before 1 September 2009, whether you (or a representative of your organisation/institute) will participate. Responses should be sent to Marlies Halder (e-mail: *marlies.halder@jrc.ec.europa.eu*).

If you plan to participate and there are specific topics that you would like to address, please do suggest these to us.

Finally, we would like to take this opportunity to ask you to participate in our survey of ongoing activities relevant to the consistency of production approach. The survey will be circulated in September/October and the results will be presented and discussed at the workshop.

Yours sincerely

Marlies Halder (ECVAM), Imke Kross (Intervet), Cecile Ponsar (GSK), Nick Jarrett (EMEA), Coenraad Hendriksen (NVI), Fabrizio de Mattia (Intervet), Johan Hanselaer (Sanofi Pasteur)

[1] ECVAM: European Centre for the Validation of Alternative Methods European, Institute of Health and Consumer Protection, Joint Research Centre

[2] EPAA: European Partnership for Alternative Approaches to Animal testing, http://ec.europa.eu/enterprise/epaa/index_en.htm

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

Venue: Centre Borschette, Brussels
Start: 09:00; 11 January 2010
End: 16:00; 12 January 2010

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.

Objectives:

- To discuss the applicability of the consistency of production approach for routine release of human and veterinary vaccines with all stakeholders
- To give recommendations on the implementation of the consistency of production approach

Draft programme:

Day 1:
- Introduction
- Scope of the workshop
- Presentations on the views of the various stakeholders
- Presentations on technical aspects, possible methods, candidate vaccines
- Presentation of the results of the questionnaire

Day 2:
- Break-out groups for human and veterinary vaccines
- Reports of the break-out group sessions
- Conclusions, recommendations, follow-up projects

Potential participants

Regulators
Representative(s) of OMCLs
Representative(s) of EMEA & working parties
Representative(s) of European Commission DG Enterprise
Representative of EDQM
Representative of FDA-CBER
Representative of USDA
Representative of WHO (CH)

Industry
Representative(s) of EFPIA/EVM
Representative(s) of IFAH
Representative(s) of non-European trade associations
Representative(s) of individual manufacturers

European Commission Joint Research Centre
Representative of ECVAM

Animal welfare organisations
Eurogroup