International Workshop on Alternatives to the Murine Histamine Sensitization Test (HIST) for Acellular Pertussis Vaccines: Progress and Challenges in the Replacement of HIST

Hotel Hilton
Prague, Czech Republic
August 24, 2014

Organized by:

NICEATM	National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
ICCVAM	Interagency Coordinating Committee on the Validation of Alternative Methods
EURL ECVAM	European Union Reference Laboratory for Alternatives to Animal Testing
Health Canada	
EDQM	European Directorate for the Quality of Medicines and HealthCare

Sponsored by:

NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research

Workshop Objectives

1. Discuss the implementation of *in vitro* assays as replacements for the murine histamine sensitization test (HIST) for acellular pertussis (aP) vaccines on the basis of the consistency approach (i.e., the efficient functioning of a Quality System since the product licensing, involving process and testing validation. This approach ensures that the licensed manufacturing produces batches that are consistent with those that fulfilled the criteria of quality, safety and efficacy defined for the batches included in the marketing authorization):
    a. For licensed/registered products: Discuss the importance of Relevance of an *in vitro* assay to replace the HIST from the product profile of an aP vaccine – The high-level element that, along with Reliability, is required to validate a method.
    b. For new products: Discuss the requirements leading to the inclusion of one or more *in vitro* assays as replacements for the HIST in the product profile for licensing/registration.
2. Discuss the necessary framework for regulatory acceptance of a harmonized approach that uses *in vitro* assays instead of the HIST.
3. Discuss recent international efforts towards the development of *in vitro* assays to replace the HIST.

Draft Agenda

— Day 1 —
Sunday, August 24, 2014

9:30-9:45 **Welcoming Remarks, Announcements, and Introductions**

Juan Arciniega, DSc, Center for Biologics Evaluation and Research (CBER), U.S. FDA
Katie Lidster, PhD, National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), United Kingdom
Warren Casey, PhD, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), NIH, USA

9:45-10:05 **Prague, Pertussis, and Vaccines**

Roman Prymula, PhD, Czech Vaccinology Society, Czech Republic
Peter Sebo, PhD, Czech Academy of Science, Institute of Microbiology, Czech Republic

10:05-10:25 **The Road to Prague 2014**

Richard Isbrucker, PhD, Health Canada

10:25-11:45 **Session 1**
The Murine Histamine Sensitization Test (HIST)

Co-chairs:
Leslie Wagner, Center for Biologics Evaluation and Research (CBER), U.S. FDA
Blaise Descampe, DVM, GlaxoSmithKline, Belgium

10:25-10:45 **Introduction**

10:45-11:45 **Roundtable Discussion**

11:45-12:45 **Lunch**

12:45-1:15 **Animal Use for the HIST and the Impact of *In Vitro* Alternatives**

Coenraad Hendriksen, PhD, IntraVacc, Netherlands
Marieke Hoonakker, IntraVacc, Netherlands

1:15-1:30 **Discussion**

1:30-3:10 **Session 2**
***In Vitro* Assays as Replacements for HIST: Challenges to Regulatory Acceptance**

Co-chairs:
Sue Nelson, PhD, Sanofi Pasteur, Canada
Richard Isbrucker, PhD, Health Canada

1:30-1:40 **Introduction**

1:40-3:10 **Roundtable Discussion**

3:10-3:25 **Break**

3:25-4:15 **Final Discussion, Conclusions and Recommendations**

Juan Arciniega, DSc, Center for Biologics Evaluation and Research (CBER), U.S. FDA
Warren Casey, PhD, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), NIH, USA

4:15 **End of Meeting**