15-16 September 2015: EPAA Workshop on international harmonisation of biologicals, Egmond an Zee, the Netherlands – Proceedings

General presentations

Setting the scene - Katrin Schutte

3Rs in product development and QC of biologicals - Catrina Stirling

Regulatory harmonisation of 3Rs in QC testing of biologicals - Iwona Wilk-Zasadna

Introduction to breakout sessions - Anna Szczepanska

Breakout session, case study 1: Deletion/waiving of general safety tests (ATT/GST) at WHO level and from national regulatory requirements

The Scientific Relevance of the ATT – Today and from a historical Perspective - Klaus Cussler

A case study of false-positive results & the ATT in the context of modern quality - Martin Bopst Garbe

Status of the General Safety Test (GST) in the United States - Robin Levis

ATT statement/Brasil - Klaus Cussler

CS1 - Summary - Marlies Halder

Breakout session, case study 2: Deletion/waiving of general safety tests (ATT/GST; TABST) at VICH level and from national regulatory requirements

Waiving the Target Animal Batch Safety Test at MSD Animal Health - Harrie Glansbeek

CS2 – Summary - Catrina Stirling

Breakout session, case study 3: Potential harmonization pathways for in vivo testing requirements for Diphtheria and Tetanus vaccines and perspectives for 3Rs implementation

Towards replacement of in vivo potency assays for Diphtheria and Tetanus vaccines - Sylvie Uhrlich

CS3 – Summary - Sylvie Uhlrich/Paul Sickings

Breakout session, case study 4: Swine Erysipelas vaccine

Swine Erysipelas vaccine In vitro ELISA assay to replace in vivo immunization-challenge test - Pieter-Jan Serreyn

CS4 - Summary - David John

Conclusions & recommendations from the workshop

Actions