International Alliance for Biological Standardization

Animal Testing Replacement for Vaccines.
A One Health View: Global Outlook and Future Strategy

December 2-4, 2025
Bangkok, Thailand

Animal Testing Replacement: Global Human Vaccine Manufacturer Perspectives
Session 4 – Industry perspective on phasing in non-animal testing and efforts to promote global alignment

Emmanuelle COPPENS, Sanofi, France

A general introduction will give an overview of the Sanofi strategy and current situation for quality control analytical testing with scientifically relevant non animal based analytical testing. The presentation will then present what are the key challenges a global manufacturer still faces and what efforts are being made to promote worldwide alignment and acceptance for removal and replacement of animal testing and how reliance mechanisms also contribute to more reliable vaccine supply.

How Industry is Implementing in vitro Alternatives for Pyrogenicity testing
Session 7 - A new pyrogenicity strategy: How MAT and recombinant BET are changing the approach to pyrogenicity

Emmanuelle COPPENS, Sanofi, France

In the context of transitioning to non-animal based analytical testing Sanofi will present its strategy to avoid the rabbit pyrogen test (RPT), based on a pyrogens risk-assessment to determine which pyrogenicity test method is applicable between using a bacterial endotoxin test (BET) and/or a monocyte activation test (MAT). The current situation in regard to the implementation of the alternative non animal reagents for BET and the phasing out of RPT will be shared, as well as the remaining challenges and next steps for their implementation.

How industry is Phasing Out in vivo Safety Testing
Session 12 - Safety Testing: from development to implementation and regulatory acceptance

Emmanuelle COPPENS, Sanofi, France

In the context of transitioning to non-animal based analytical testing Sanofi will present its strategy to avoid in vivo safety testing and give an overview of the current situation on deleting obsolete or redundant testing and on what basis. We will then illustrate with some examples how industry and regulatory collaboration can contribute to the replacement of in vivo safety tests.

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From in vivo to in vitro Testing for DTaP (Diphtheria, Tetanus, acellular Pertussis) Potency Testing

Session 13 - Potency Testing: Achievements and next steps for implementation

Emmanuelle COPPENS, Sanofi, France

After highlighting the drawbacks and complexity to use in vivo methods for potency testing of DTaP combination vaccines, we will present how the IMI Vac2Vac consortium allowed to develop immunoassays and reagents intended to replace these in vivo assays. Then we will share how Sanofi, in conjunction with IMIVac2Vac, developed antigenicity assays for their products, how suitability is demonstrated and how validation is performed. We will briefly present the current status, the remaining challenges and next steps.