Animal testing replacement for vaccines
A One Health View: global outlook and future strategy

An Animal-Free Safety Assessment (AFSA) Collaboration conference co-organized by Humane World for Animals and IABS

Hotel Westin Grande Sukhumvit, Bangkok, Thailand | 2-4 December 2025

https://events.iabs.org/afsa/

Humane World for Animals and the International Alliance for Biological Standardization have been collaborating together since the 2019 IABS conference "Animal Testing for Vaccines Implementing Replacement, Reduction and Refinement: Challenges and Priorities" (Akkermans et al.) and through the AFSA Collaboration since 2020. They successfully organized online and face to face meetings (AFSA Collaborations Events) to promote dialogue and joint actions on animal testing replacement for both human and veterinary vaccines. This conference brings together again all the stakeholders in the field with the scope to concretely discuss about future projects and policy changes that need to be implemented to successfully phase out the reliance on animal testing within the vaccines testing control strategy, including the importance of vaccines' supply chain sustainability and continuity and the benefits of this in supporting the role of vaccines in One Health (ensuring animal health and food chain security, addressing zoonosis and emergency disease situations as well as the critical role of vaccines in reducing antimicrobial resistance (AMR)).

TUESDAY, DECEMBER 2, 2025
DAY 1

8.30am **Opening remarks**

- Joris VANDEPUTTE, IABS, Belgium
- Sarawut BOONSUK, Director General, Department of Medical Sciences, Ministry of Public Health, Thailand
- Laura VIVIANI, SciEthiQ for Humane World for Animals and AFSA, Italy

9.00am **Opening Lecture: Importance of investments in Asia and Thailand for vaccine R&D, state of the art quality testing and regulatory harmonization. Ongoing initiatives and opportunities to consider.**
Nakorn PREMSRI, National Vaccine Institute of Thailand

Session

OneHealth approach to advance vaccine control strategies

Moderator: Catherine Milne, EDQM, France

The session aims to present and discuss how the OneHealth vision could place a further emphasis in the transformation of vaccines' control strategies. The focus on the final batch release testing is switching toward the control of the product's life cycle based on the knowledge of the critical quality attributes and transitioning away from non-validated animal-based testing.

9.30am **One Health drives for New Approach Methodologies (NAMs) approaches for Vaccine Batch release**
Catrina STIRLING, Zoetis (remote), UK

9.50am **Panel Discussion**
Pradip DAS, Biological E, India
Lorenzo TESOLIN, Sciensano, Belgium
Corinne PHILIPPE, Boehringer Ingelheim, France
Dean SMITH, IABS, Canada

10:30am **Coffee-break**

Session

Industry perspective on phasing in non-animal testing and efforts to promote global alignment

Moderator: Laura Viviani, SciEthiQ, Italy

Speakers from both human and veterinary vaccines manufacturers present their ongoing efforts to promote regulatory acceptance and alignment of non-animal testing strategies for the release of their products, with an emphasis on how coordinated efforts and updated guidelines might benefit the overall products' value chain and public health.

10.45am **Animal Testing Replacement: Global Human Vaccine Manufacturer Perspectives**
Emmanuelle COPPENS, Sanofi, France

Implementation of non-animal testing and efforts to promote global alignment - An Industry Perspective
Sunil GOEL, Serum Institute of India, India

Implementing non-animal testing
Corinne PHILIPPE, Boehringer Ingelheim/HealthforAnimals, France

11.30am **Panel discussion**
Emmanuelle COPPENS, Sanofi, France
Sunil GOEL, Serum Institute of India, India
Corinne PHILIPPE, Boehringer Ingelheim/HealthforAnimals, France

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Session
Regulatory perspective - Ongoing progress in methods acceptance

Moderator: Henk-Jan Ormel, Dutch Competent Authority for Animal Procedures, Netherlands

Panelists representing National Regulatory Agencies, Pharmacopoeias and international organizations share their current work on accepting non animal testing for the release of human and veterinary vaccines and discuss about their future plans and outstanding issues.

11.45am **Brief Introduction of WHO Guidelines on the replacement or removal of animal tests for the quality control of biological products**
Dianliang LEI, WHO, Switzerland

EDQM's support for the 3Rs – status update and insights into Ph. Eur. General Chapter 5.2.14
Mihaela BUDA, EDQM, France

VICH concept paper on principles for technical guidance for the transition to in-vitro methods for batch potency tests in veterinary immunologicals
Kota SATO, National Veterinary Assay Laboratory, Japan

Indian Pharmacopoeia perspectives on alternatives to animal methods in testing of vaccines for human and animal use
Muthusamy KALAIVANI, Indian Pharmacopeia Commission, India

Implementation of 3Rs to quality control of biologicals and lot release tests in Japan
Masaaki IWAKI, JIHS (Japan Institute for Health Security), Japan

ANVISA's regulatory perspectives on progress in alternative method acceptance
Evelin BALBINO, ANVISA, Brazil

Korea's Strategy for NAMs Adoption: Harmonizing Regulatory Science and Innovation
In-Sook PARK, Korea Regulatory Science Centre, South Korea

Advancing 3rs implementation:badan pom strategy for animal testing replacement in vaccine quality control
Fitra DELVIONA, BADAN POM, Indonesia

1.15pm **Lunch Break**

Workshop

How to build competence in new testing strategies in National Control Laboratories?

Moderator: Dean Smith, IABS, Canada, & Janette Turner, Humane World for Animals, UK

The workshop allows the audience to discuss in groups about the possible approaches to build competence and confidence in non-animal testing strategies after key stakeholders from international organizations and manufacturers share their experience.

2.30pm **How to build competence in new testing strategies in National Control Laboratories? - A WHO perspective**
Alexandrine MAES (remotely) & Alain FAUCONNIER, WHO, Switzerland

Building competence in new testing strategies in National Control Laboratories
Sunil GOEL, Serum Institute of India, India

EU OMCL network experience contributes to method implementation and reduced animal use
Catherine MILNE, EDQM, France

How to Build NCL Competences? A Case Study from the Belgian National Control Laboratory
Lorenzo TESOLIN, Sciensano, Belgium

Building Competence in Non-Animal Testing Strategies for Vaccine Quality Control
Luca PORFIRI, FAO, Thailand

3.00pm **Discussion groups (30min) and reporting (30min)**

- Difficulties in implementation of new technologies (for NCL: expectations from companies)
- Successful cases of implementations
- Which mechanisms have been used or can be used to support competence's building, like the use of reliance for example? What are the barriers to use reliance (or similar mechanism)?

4.00pm **Coffee-Break**

Session

A new pyrogenicity strategy

How MAT and recombinant BET are changing the approach to pyrogenicity

Moderator: Juliana Gutierrez, bioMérieux, Japan

Speakers present how the use of the Monocyte Activation Test and the recombinant Bacterial Endotoxin Test are changing pyrogenicity testing, providing examples of their implementation and regulatory acceptance.

4.15pm **An EDQM update on pyrogenicity in European Pharmacopoeia**
Mihaela BUDA, EDQM, France

Bacterial Endotoxin Testing: Progressive Science and Sustainability
Jay BOLDEN, Eli Lilly & Company, USA

Transition from LAL test for endotoxin to rFC methods (12min/speaker)
Corinne PHILIPPE, Boehringer Ingelheim/HealthforAnimals, France

Navigating the Transition: Regulatory and Practical Perspectives on Implementing the Monocyte Activation Test
Bernhard ILLES, Microcoat, Germany

Advancing 3Rs in Quality Control of Immunobiologicals: Butantan's Strategy for Implementing MAT and Recombinant Endotoxin Testing
Juliana GALVÃO DA SILVA, Fundação Butantan, Brazil

How Industry is Implementing in vitro Alternatives for Pyrogenicity testing
Emmanuelle COPPENS, Sanofi, France

Waive and Replace the Rabbit Pyrogen Test in Lifecycle Vaccine Release
Shahjahan SHAID, GSK (remote), Germany

Panel Discussion
Mihaela BUDA, EDQM, France
Jay BOLDEN, Eli Lilly & Company, USA
Corinne PHILIPPE, Boehringer Ingelheim/HealthforAnimals, France
Bernhard ILLES, Microcoat, Germany
Juliana GALVÃO DA SILVA, Fundação Butantan, Brazil
Emmanuelle COPPENS, Sanofi, France
Shahjahan SHAID, GSK (remote), Germany

6.15pm **Closing of Day 1**
Laura VIVIANI, SciEthiQ, Italy & Joris VANDEPUTTE, IABS, Belgium

WEDNESDAY, DECEMBER 3, 2025

DAY 2

PATH WORKSHOP

Sustainable endotoxin testing: Developing a roadmap for LMIC

Part 1 – Cost Modelling Session

Moderator: Sampal Pal & Joe Little, PATH

This session focuses on identifying and discussing the cost drivers associated with transitioning from limulus amebocyte lysate (LAL) to recombinant Factor C (rFC) for endotoxin testing, specifically within the context of low and middle-income countries (LMICs).

7.30am Leader: Sampa PAL & Joe LITTLE, PATH, Scientific Program Officer

7.40am **Implementation of rFC: cost considerations**
Juliana GALVAO DA SILVA & Debora FERARRIN, Fundação Butantan, Brazil

7.50am **Recombinant methods for endotoxin testing in India - Cost and market analysis**
Surat PARVATAM, Humane World for Animals India, & K. V. S. Narayana RAJU, Consultant for DLR, India

8.00am **The Cost of Innovation: Comparative Analysis of LAL vs. rFC/rCR in Butantan's Flu Vaccine Production**
Juliana GALVAO DA SILVA & Debora FERRARIN, Fundação Butantan, Brazil

9.30am **Coffee-break**

Presentation

In vitro Analytical Characterization based Quality and Potency Assessment of mRNA Vaccines

Moderator: Paul Sticking, MHRA, UK

The speaker presents how robust in vitro assays (especially potency) have been developed for different classes of vaccines, especially protein and mRNA, and gained widespread regulatory approvals.

9.45am **In vitro Analytical Characterization based Quality and Potency Assessment of mRNA Vaccines**
Gautam SANYAL, Vaccine Analytics, USA

Session

Safety Testing: from development to implementation and regulatory acceptance

Moderator: Sarah Sheridan, Merck, UK

Speakers present concrete examples on how the review of the traditional animal-based assays allowed deletion of obsolete or redundant testing and pushed forward the implementation and acceptance of in vitro approaches.

10.15am **Safety tests for vaccines; Strategies to remove and replace animal tests in the European Pharmacopoeia (Ph. Eur.)**
Catherine Milne, EDQM, France

Next Generation Sequencing (NGS)- An alternative to animal based neurovirulence testing (NVT) for polio vaccines
Kutub MAHMOOD, PATH, USA

Next generation sequencing as an alternative to neurovirulence tests in animals for the quality control of live-attenuated viral vaccines
Javier MARTIN, MHRA, UK

A cell-based assay for tetanus toxin as an alternative to animal models used in safety testing of tetanus toxoid
Paul STICKINGS, MHRA, UK & Ciara DORAN, Sheffield University

TABST/LABST waiver… and more in veterinary vaccines
Laure MARTINEZ, Virbac, France

How industry is Phasing Out in vivo Safety Testing
Emmanuelle COPPENS, Sanofi, France

Path To Remove and Replace Safety Testing In India
Pradip DAS, Biological E, India

Panel discussion
All speakers

Session

Roles of global health stakeholders in funding, cost sharing for capital investment, training and shaping global agendas

Moderator: Joris Vandeputte, IABS, Belgium

Transitioning from in vivo to in vitro testing strategies is a major transformation requiring investment in innovation, training, and alignment of regulations. The panelists discuss the role that global health stakeholders might have to support the change.

12.15pm **Panel Discussion**
Dianliang LEI, WHO, Switzerland
Meenu BATOLAR, CEPI, Singapore
Ole OLESEN, Independent Expert, Belgium
Naree KETUSING, WOAH, Thailand

1.00pm **Lunch**

Session
Potency Testing: Achievements and next steps for implementation

Moderator: Heidemarie Schindl, AGES, Austria

Speakers present the successful transition from in vivo to in vitro potency testing in both new and legacy vaccines, highlighting how different approaches to method development and validation have been worked and what are the remining challenges to overcome.

2.00pm **Potency Testing for Adjuvanted Vaccines: Progress, Roadblocks and a Vision for Non Animal testing**
Badiaa BOUZYA, GSK, Belgium (remote)

Potency testing of aluminium adjuvanted tick borne encephalitis virus vaccines
Dieter PULLIRSCH, AGES, Austria

Gyrolab-Based In Vitro Immunoassay for Potency and Quality Control of Chikungunya VLP Vaccine: A Sensitive Alternative to Animal Models
Katarzyna OSETEK-MÜLLER, Bavarian Nordic, Germany

Replacing the in vivo potency test for human rabies vaccines: a global collaborative initiative.
Jean-Michel CHAPSAL, Consultant & Project Manager BSP149, France

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

Application of VP2 & VP4 mAb-based Indirect ELISA for Potency and Stability Assessment of Indian Trivalent Vaccine Formulations
Rabindra PRASAD SINGH, ICAR-National Institute on Foot and Mouth Disease, India (remote)

The next challenge – a fully in vitro approach to ensure quality and consistency of whole-cell pertussis vaccines
Paul STICKINGS, MHRA, UK

3.20pm **Panel Discussion**
Badiaa BOUZYA, GSK, Belgium (remote)
Dieter PULLIRSCH, AGES, Austria
Katarzyna OSETEK-MÜLLER, Bavarian Nordic, Germany
Jean-Michel CHAPSAL, Consultant & Project Manager BSP149, France
Emmanuelle COPPENS, Sanofi, France
Rabindra PRASAD SINGH, ICAR-National Institute on Foot and Mouth Disease, India (remote)
Paul STICKINGS, MHRA, UK

4.00pm **Coffee-Break**

Session
Availability of critical reagents and use of reference standards
Lesson learnt and open challenges

Moderator: Dean Smith, IABS, Canada

The development of new products and testing strategies based on different and product specific assays and tests might require a revision on the concept and use of reference standards. Panelists share their view on the current and future scenarios.

4.15pm **Introduction: Setting the scene on critical reagents**
Kutub MAHMOOD, PATH, USA & Paul STICKINGS, MHRA, UK

4.25pm **Panel Discussion on Critical Reagents**
Paul STICKINGS, MHRA, UK
Javier MARTIN, MHRA, UK
Kutub MAHMOOD, PATH, USA
Dianliang LEI, WHO, Switzerland
Mihaela BUDA, EDQM, France

4.45pm **Introduction: Setting the scene on use of reference standards**
Dean SMITH, IABS, Canada

4.55pm **Panel Discussion on Use of Reference Standards**
Paul STICKINGS, MHRA, UK
Javier MARTIN, MHRA, UK
Kutub MAHMOOD, PATH, USA
Dianliang LEI, WHO, Switzerland
Mihaela BUDA, EDQM, France

5.45pm **Closing of Day 2**
Laura VIVIANI, SciEthiQ, Italy & Joris VANDEPUTTE, IABS, Belgium

THURSDAY, DECEMBER 4, 2025

DAY 3

PATH WORKSHOP

Sustainable endotoxin testing: Developing a roadmap for LMIC

Part 2 – Regulatory session

Moderator: Joe Little PATH & Sampa PAL

This session focuses on identifying and discussing the regulatory challenges associated with transitioning from limulus amebocyte lysate (LAL) to recombinant Factor C (rFC) for endotoxin testing, specifically within the context of low and middle-income countries (LMICs).

7.30am Leader: Sampa PAL & Joe LITTLE, PATH, Scientific Program Officer

7.40am **Overcoming challenges to advance modern methods and ensure the safe supply of medicine**
Jay BOLDEN, Eli Lilly & Company, USA

7.50am **Bacterial Endotoxin Test-Indian Pharmacopeia perspectives**
Muthusamy KALAIVANI, Indian Pharmacopeia Commission, India

8.00am **Discussion in working groups and reporting**

9.00am **Coffee-break**

Session

How future proof regulations could support vaccines' release paradigm's change

Moderator: Corinne Philippe, Boehringer Ingelheim, France

Panelists present their experience and vision on how future proof regulations could be conducive to the change in vaccines' release testing, highlighting their approaches to global alignment and reliance, and discussion on the challenges to overcome

9.45am **Panel Discussion**
Dianliang LEI & Alain FAUCONNIER, WHO, Switzerland
Luca Porfiri, FAO, Thailand
Laure MARTINEZ, Virbac, France
Charles SANDY, AUDA-NEPAD, South Africa
Meenu BATOLAR, CEPI, Singapore
Dean SMITH, IABS, Canada

Session

Future outlook on vaccines development, manufacturing and release strategies. How NAMs are going to change the field

Moderator: Colleen Pike, Humane World for Animals, USA

10.45am **The Pre-clinical (and Clinical) Utilities of Microphysiological Systems as In Vitro NAMs in Drug and Vaccine Development**
Danilo TAGLE, NIH (remote), USA

EU initiatives to advance NAMs in research and regulatory testing
Ole OLESEN, Independent Expert, Belgium

11.45am **Panel Discussion**
Danilo TAGLE, NIH (remote), USA
Ole OLESEN, Independent Expert, Belgium
Gautam SANYAL, Vaccine Analytics, USA
Dean SMITH, IABS, Canada
Lorenzo TESOLIN, Sciensano, Belgium

12.15pm **Closing remarks**

- Joris VANDEPUTTE, IABS, Belgium
- Sarawut BOONSUK, Director General, Department of Medical Sciences, Ministry of Public Health, Thailand
- Laura VIVIANI, SciEthiQ for Humane World for Animals and AFSA, Italy