

# Transitioning DTwP containing vaccines to animal-free batch release testing strategy. Strategies for implementation.

AFSA Collaboration and Humane Society  
International Global Workshop  
January 29<sup>th</sup>, 2025

A close-up photograph of a multi-channel pipette dispensing a pink liquid into a 96-well microplate. The pipette tips are white and arranged in a grid. The liquid is being dispensed into several wells, creating a series of small droplets. The background is a soft, out-of-focus blue and green.

Strategies for updating  
current animal-based  
safety testing

# Our Interaction Today



Participants are muted and without video automatically



If you wish to speak, raise your hand or put your question in SLIDO



Please introduce yourself (name, organisation, role) when interacting in person or via SLIDO



Use SLIDO for your questions or comments – TEAMS Q&A and Chat will be monitored as well, but prioritize SLIDO



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# Context of the Workshop

- This is another event part of the Humane Society International (HSI) Project “Accelerate non-animal batch release testing for human vaccines”
- The project allows stakeholders to have dedicated discussions with experts in the field and join local or global workshops to fill any knowledge gaps and allow additional discussions on prioritizations of non animal testing strategies for batch release and understand the resources needed.
- The workshop has been created in collaboration with some members of the Project International Steering Committee – **Many thanks!**



<https://www.afsacollaboration.org/event/>



# Objectives

- The main objective of this workshop is to engage all the industry and regulatory stakeholders in a discussion on the possible strategies to facilitate introduction and acceptance of non animal testing strategies (or animal reduction ones) for the batch release of DTwP containing vaccines, whenever scientifically possible.
- Speakers will provide a quick update on the **SAFETY testing** available opportunities, and the ones that are in development, that can substitute the current animal-based testing strategies.
- You're invited to share:
  - your knowledge on those opportunities,
  - your view or experience on the introduction of such opportunities in your local routine testing,
  - what it is needed to move towards updating current strategies but also local regulations, pharmacopoeias and guidances.

# Agenda

Time in CET	Topic	Speakers
11-11:10	Welcome and objectives	Laura Viviani, SciEthiQ for Humane Society International
11:10-11:30	Overview of the opportunities for testing deletion for DTP vaccines	Catherine Milne, EDQM
11:30-12:50	<p>Overview of the opportunities for testing replacement.</p> <p>Diphtheria - Absence of toxin Irreversibility of toxoid: Vero-cells assay</p> <p>Tetanus toxicity: BINACLE</p> <p>Tetanus toxicity: cell-based assay opportunity and readiness</p> <p>The value of the MWGT for wP</p>	<p>Pradip Das, Biological E</p> <p>Shahjahan Shaid, GSK</p> <p>Andrew Peden, Ciara Doran, Sheffield University, and Shalini Rajagopal, MHRA</p> <p>Pradip Das, Biological E</p>
12:50-13:50	Interactive discussion with speakers and experts and the attendees	All speakers, Ivana Knezevic and Dianliang Lei, WHO Norms and Standards for Biologicals Moderated by Laura Viviani and Heidemarie Schindl, AGES
13:50-14:00	Closing Remarks	Laura Viviani, SciEthiQ for Humane Society International

# Let's Discuss



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# Closing Remarks

What we discussed today



# Agenda

Time in CET	Topic	Speakers
11-11:10	Welcome and objectives	Laura Viviani, SciEthiQ for Humane Society International
11:10-11:40	DT single dilution or not? Pros and cons of an animal reduction opportunity. NCL and manufacturer's perspectives.	Morgane Florens, Sciensano Pradip Das, Biological E Silvio Bandiera, Sanofi
11:40-12:20	DTaP in vitro potency test Multiplex Assay ELISA Assay	Maxime Vermeulen, Sciensano Paul Strickings, MHRA
12:20-12:40	Manufacturers approaches to implementations	Sunil Goel, Serum Institute of India with a DCVMN perspective on future implementation
12:40-13:10	wP potency test. Perspective on future potency testing wP bacteria characterization	Laura Viviani, SciEthiQ for Humane Society International Nicholas Mantis, Wadsworth Center, NY State Department of Health
13:10-13:50	Interactive discussion with speakers and experts and the attendees	All speakers, Ivana Knezevic and Dianliang Lei, WHO Norms and Standards for Biologicals - Moderated by Laura Viviani and Heidemarie Schindl, AGES
13:50-14:00	Closing Remarks	Laura Viviani, SciEthiQ for Humane Society International



# **SAVE THE DATES!**

- **Webinar on «Replacing the monkey neurovirulence test: challenges and opportunities for the future» - Q1 2025**
- **AFSA – IABS Conference about Animal testing replacement for vaccines: A One Health View: global outlook and future strategy  
December 2-4, 2025 – Bangkok, Thailand**



**Thank you!**

<https://www.afsacollaboration.org/biologicals/>