

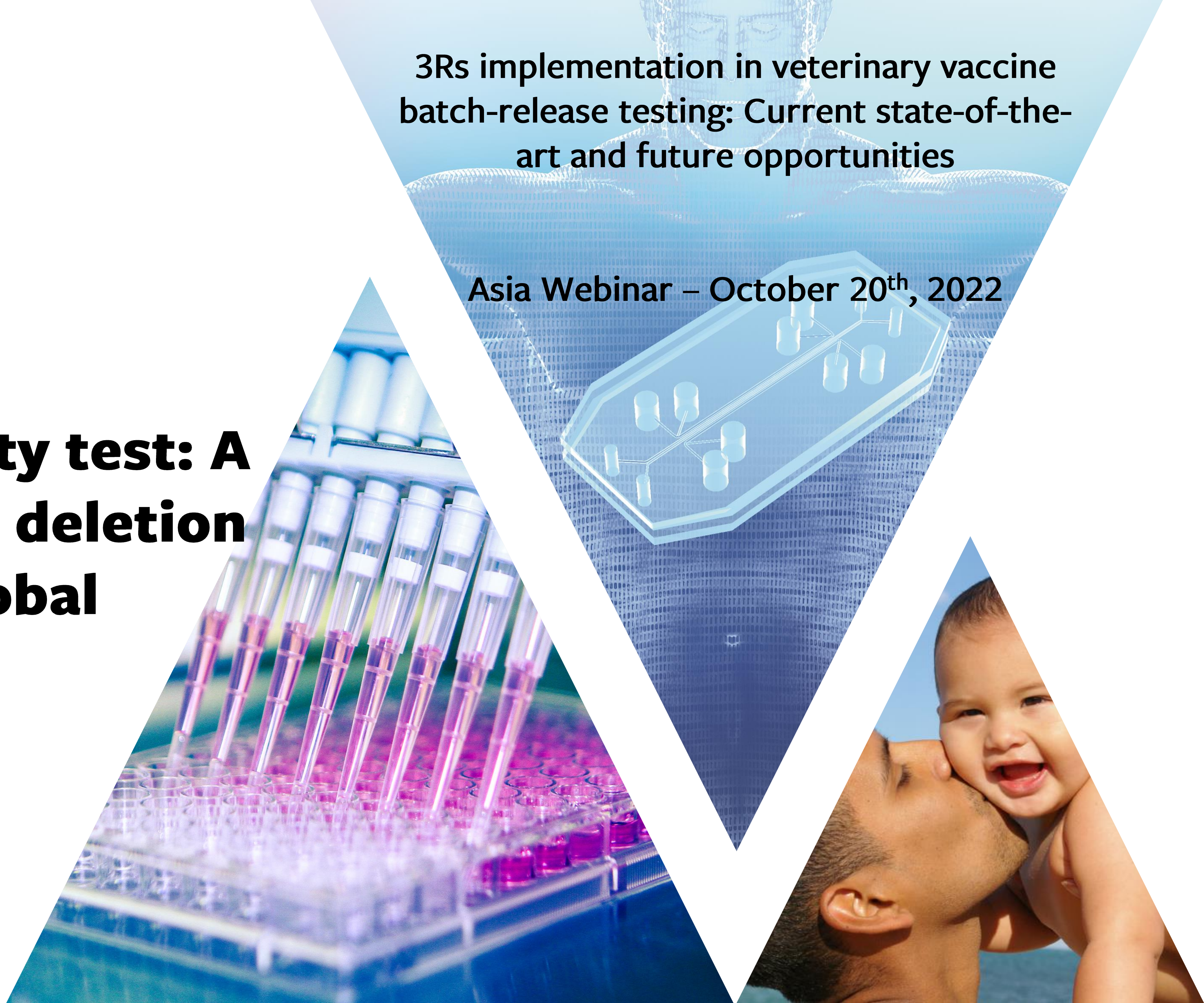


3Rs implementation in veterinary vaccine batch-release testing: Current state-of-the-art and future opportunities

Asia Webinar – October 20<sup>th</sup>, 2022

**Animal batch safety test: A case study on test deletion and (yet to be) global harmonization**

Laura Viviani







The Humane Society International coordinated **Animal-Free Safety Assessment (AFSA) Collaboration** works to accelerate global adoption of a modern, species-relevant approach to safety assessment that will better protect people and our planet, and hasten the replacement of animal testing

COSMETICS



CHEMICALS



BIOLOGICALS





# Current Members\*



\* Listed organizations are members of at least 1 AFSA workstream; listing does not imply participation in or endorsement of other work areas



# Deletion and Replacement of Obsolete Animal

Global



Target animal batch safety test



The image displays three VICH guidelines documents and a world map. The documents are:

- VICH GL50 (BIOLOGICALS: TABST)** May 2017, Revision at Step 9, For Implementation at Step 7 - Final. Title: **HARMONISATION OF CRITERIA TO WAIVE TARGET ANIMAL BATCH SAFETY TESTING FOR INACTIVATED VACCINES FOR VETERINARY USE**. Adopted at Step 7 of the VICH Process by the VICH Steering Committee in May 2017 for implementation by May 2018.
- VICH GL55 (BIOLOGICALS: TABST LIVE VACCINES)** May 2017, For Implementation at Step 7 - Final. Title: **HARMONISATION OF CRITERIA TO WAIVE TARGET ANIMAL BATCH SAFETY TESTING FOR LIVE VACCINES FOR VETERINARY USE**.
- VICH GL59 (BIOLOGICALS: LABST VETERINARY VACCINES)** November 2020, For Implementation at Step 7. Title: **HARMONISATION OF CRITERIA TO WAIVE LABORATORY ANIMAL BATCH SAFETY TESTING FOR VACCINES FOR VETERINARY USE**. Adopted at Step 7 of the VICH Process by the VICH Steering Committee in November 2020 for implementation by November 2021.

The world map shows purple dots indicating the implementation of these guidelines in various regions, including Europe, Asia, and South America.



# Drivers & barriers to waiver or deletion implementation worldwide

## Barriers

- Non animal testing not prioritized by some manufacturers and regulators
- Heterogenous experience among laboratories on GMP compliance, PACs and non animal testing
- Diverse regulatory requirements and risk averse approach

## Drivers

- Increased agreement among industry and regulatory stakeholders on the concrete possibility to delete/waive and replace obsolete tests
- Significant scientific and technical progresses achieved in production and *in vitro* testing
- Successful case studies and increase experience sharing

# Our strategy, Activities and Successes

**Multi-stakeholders  
dialogue to act together  
at the global and local  
level.**

Accelerating Global Deletion of the Abnormal Toxicity Test  
*Planning common next steps*  
October 14<sup>th</sup> 2021 • 12:30 – 16:30 CEST  
- ON ZOOM -

An AFSA Collaboration workshop organized  
by HSI and EFPIA in collaboration with IABS



TODAY WE WELCOME



In collaboration with



AFSA EFPIA Workshop October 2021  
Publication in Biologicals submitted



**Specific  
secure  
atory**



ABST

laboratory  
release  
the field is  
ers have

ST  
hs,







**Thank you!**

Wish to learn more and collaborate?

Laura Viviani – [lviviani@hsi.org](mailto:lviviani@hsi.org)

