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Health for Animals
global animal health association

Regulatory and Scientific Perspectives: Case Studies in Replacing Animal Tests for Veterinary Vaccine Batch Release

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Webinars Rules for Q&A

All participants will be in "Listening only" mode.

Only the speakers and panelists will be able to speak

We will have an interpreter providing **consecutive translation into Spanish**

Questions will be discussed after each presentation and during the final panel

Apologies if all questions cannot be answered due to lack of time

For any questions, please use the chat function

This webinar is recorded – presentations and recordings will be available on the AFSA event page

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Why this webinar?

- AFSA and Humane World for Animals have been working to promote the implementation of innovative nonanimal based testing and relevant regulatory transformation for both human and veterinary products https://www.afsacollaboration.org/biologicals/

- SENASA (Argentina) and MAPA (Brazil) expressed interest in a webinar showcasing regulatory approval of rabies, clostridial and leptospira vaccines and VICH/potency topics for LATAM countries. This webinar has brought experts in these areas together to share knowledge, experience and concrete case studies on successful implementation and regulatory acceptance: https://www.afsacollaboration.org/event/

- We built this webinar program through collaboration with HealthforAnimals, veterinary vaccines manufacturers and regulatory authorities aiming to support others to consider and planning the implementation of novel approaches to batch release testing and regulatory transformation

Brazil as a Case Study: Advancing Non-Animal Methods

Sustained regulatory dialogue

- Engagement with Ministry of Agriculture (MAPA) since 2018
- Focus on non-animal methods for veterinary products

Concrete regulatory outcome

- Ordinance No. 560 (2022)
- Waiver of animal-based innocuity tests
- Applies to veterinary biological products

What this represents

- Regulatory modernization
- Multi-stakeholder collaboration
- Alignment with international trends

Why this matters today

- Change underway in Latin America
- Informs today's discussions:
  - Case studies
  - Regulatory challenges
  - Implementation pathways

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Today's Objectives

1. Provide real world examples of technical and regulatory hurdles in the adoption and implementation of nonanimal methods in veterinary vaccine batch release testing and how these have been overcome for successful product approval
2. Provide key insights and references to representatives of regulatory agencies and public and private testing laboratories, and manufacturers in LATAM countries
3. Key representative case studies will be presented highlighting the scientific, technical, and data driven rationale for the substitution of the animal methods, and some of the available mechanisms of dialogue and collaboration between industry and regulatory agencies to achieve regulatory harmonization

Thank you and Enjoy the Webinar

- Thank you to HealthforAnimals 3Rs Task Force for helping shape this webinar and to WOAH for the support in sharing this event within its global network!
- Thanks to you in advance for your active participation

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on LinkedIn (linkedin.com/company/afsacollaboration)

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