

### Status of global implementation of MAT for biologicals. Product Specific Approaches and Regulatory Alignment

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#### Workshop's Rules for Q&A



All participants will be in "Listening only" mode.

Only the speakers and panelists will be able to speak



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 Q&A function. In case, it does not work, use the Chat box

This Webinar is recorded – Presentations and Recordings will be available on the AFSA event page



# **Today's Objectives**

- 1. Provide an overview of the activities and projects currently ongoing at a global and local level to implement the Monocyte Activation Test as replacement of the Rabbit Pyrogenicity Test for biological products
- 2. Provide a platform for the various stakeholders to have a practical exchange on the different MAT approaches, their products specificity, the associated challenges and implemented solutions
- 3. Allow you to interact with key experts in the field
- 4. Understand how the phasing out of the Rabbit Pyrogenicity Test might look like in local, regional and global context



## Why this workshop?

- Humane Society International (HSI) has been working since 2019 to promote the implementation of innovative non animal based testing for biologicals products and the relevant regulatory transformation: https://www.afsacollaboration.org/biologicals/
- This workshop is part of a series of events focused on the available innovations and wish to share knowledge, experience and concrete case studies on their successful implementation and regulatory acceptance: <u>https://www.afsacollaboration.org/event/</u>
- We built this workshop based on the HSI's bilateral conversations held across 2023 with industry and regulatory stakeholders on the topic and on the discussion held in the previous events dedicated to this subject, like the EDQM/EPAA 2023 "The future of pyrogenicity testing. Phasing out the rabbit pyrogen test" and on the recommendations proposed to WHO by the NC3Rs Report.



# **Our pre-registration Survey**

- Thank you for your answers!
- Your questions helped us to shape the presentations and helped our experts to learn about you and your experience
- We're a truly global community of stakeholders interested and committed to change
- We hope to give you the information, data and contacts to support your change



# Thank you and See you soon!

- Thanks a lot to the Scientific Committee that helped to shape this workshop
- Thanks to you for your active participation
- Our upcoming events:
  - Transition to non-animal based veterinary vaccine batch release testing. Policy and regulations theoretical aspects and case studies, October 8<sup>th</sup>, 2024
  - Workshop on DTP in vitro opportunities and future strategies, Q1 2025
  - Webinar on the opportunity offered by HTS to substitute the monkey neurovirulence test, Q1 2025
  - Global AFSA and IABS Conference, Bangkok, December 2025
  - Follow us here: <u>https://www.afsacollaboration.org/event/</u> or on LinkedIn

