International Alliance for Biological Standardization

Animal Testing Replacement for Vaccines.
A One Health View: Global Outlook and Future Strategy

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Potency Testing for Adjuvanted Vaccines: Progress, Roadblocks and a Vision for Non-Animal testing

Adjuvanted vaccines play a critical role in enhancing immune responses, enabling dose sparing, and improving efficacy in vulnerable populations. However, traditional animal-based potency testing methods face significant scientific, operational, and ethical limitations, including high variability, slow turnaround, and growing ethical concerns under the 3Rs principles. This presentation explores the progress, challenges, and vision for transitioning to non-animal potency testing frameworks for adjuvanted vaccines.

Recent scientific advances offers innovative non-animal strategies, including mechanism-based analytical assays, in vitro functional assays, immunochemical assays, and systems-based characterization. These approaches provide robust, predictive, and scalable alternatives to traditional methods. Integrated potency platforms tailored to specific adjuvant types, such as aluminum salts, oil-in-water emulsions, TLR agonists, and saponin-based adjuvants, have demonstrated reliability in evaluating antigen-adjuvant interactions and immune activation mechanisms.

Despite advancements, roadblocks remain, including complex antigen-adjuvant interactions, regulatory challenges, and manufacturing constraints. Addressing these issues requires international collaboration, harmonized regulatory acceptance, and the adoption of digital and AI-driven predictive models.

This presentation outlines a vision for a fully non-animal potency testing framework, emphasizing mechanism-informed vaccine design, multi-assay strategies, and global regulatory convergence. By integrating analytical, immunochemical, and functional assays, the path forward aims to achieve 100% non-animal potency testing, ensuring ethical compliance and advancing vaccine development.