



International Alliance for
Biological Standardization

**Animal Testing Replacement for Vaccines.
A One Health View: Global Outlook and Future Strategy**
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ANVISA's regulatory perspectives on progress in alternative method acceptance

The National Health Surveillance Agency (ANVISA) is the Brazilian regulatory agency that is responsible for regulating the quality control of vaccines. This presentation will provide an overview of the regulatory changes introduced by ANVISA and by the Brazilian Pharmacopoeia, which are working on the introduction of alternative methods to the use of animals. This implementation is aligned with the advances in alternative methods promoted by other regulatory agencies and organizations as World Health Organization (WHO), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and recognized Pharmacopoeias, and also aligned with the agenda of the National Council for the Control of Animal Experimentation (CONCEA). This presentation will also highlight the challenges that ANVISA, official laboratories and drug manufacturers needed to overcome to secure the introduction of those changes in the regulations and manufacture and how international collaboration has been key element to promote such changes. It is worth noting the complete deletion of the Abnormal Toxicity Test and the creation of a chapter dedicated to the Monocyte Activation Test to detect pyrogens in the 7th edition of the Brazilian Pharmacopoeia. Currently the revision of vaccine monographs is in progress and other changes are being considered, such as the introduction of the Recombinant Factor C (rFC) method for detection of bacterial endotoxins.