



BioNCiD 2027

**5th International Congress BIOPHARM
NONCLINICAL DEVELOPMENT**

SYMPOSIA

May 23 to 27, Varadero

■ **From Lab to Journal: Effective Communication of Nonclinical Data**

Transforming data into a scientific text. Interaction with reviewers and Ethical considerations. Visibility, and increasing the impact of publications. Trends in nonclinical outcome publications.

■ **Nonclinical Case Studies: De-Risking Biotech Products from Discovery to IND**

Nonclinical Development Programs of Drugs and Biotechnological Products and Trends in Pharmacokinetic and Toxicology development.

■ **Navigating the Regulatory Pathway**

Strategic Design of the Nonclinical Program for Biotechnological Products. Constructing the Nonclinical Modules for an IND/CTA Application. Specific Challenges in the Characterization of Biotechnologicals and Interacting with Regulatory Agencies and Managing Queries.

■ **The Next Generation of Animal Models: Scientific Rigor Meets Ethical Responsibility in Biopharmaceutical Development**

Novel and Traditional Animal Models: Development and use of genetically engineered animals. Challenges and perspectives. Staff training and Facilities accreditation. IACUC and its role on the nonclinical development. Home Cage Monitoring Technologies. Improving nonclinical to

clinical translation. Animal welfare, behavior management and implementation of the culture of care under nonclinical regulatory requirements and the application of 3 Rs. Recognizing compassion fatigue and human-animal interaction.

■ **Zebrafish as a robust biomedical research model and its high potential for translational applications**

Use of the zebrafish as a model for scientific research: from management, reproduction, and ecotoxicological approaches, as well as new technologies related to pharmacology and human diseases.

■ **Alternative Methods: Accelerating the Adoption of Non-Animal Technologies in Drug Development**

Next generation advanced in vitro models for mAbs and other health products for nonclinical safety evaluation. Better approaches for implementing 3Rs methods for vaccines QC. Alternatives and simulation in education. Regulatory acceptance of alternatives to animal testing.

■ **OMICS and Nonclinical Studies**

Methods for sample preparation, characterization of peptides/proteins/conjugates, crosslinking, pharmacokinetic studies, biomarkers identification, technologies for OMICS data generation, mass spectra data processing and database search engines, computational proteomics, functional network analysis, integrative OMICS data analysis, and system biology based bioinformatics software development.

