

Virtual Lunch-N-Learn

NEW APPROACH METHODOLOGIES FOR IND SUCCESS

Securing FDA acceptance of New Approach Methodologies (NAMs) in an IND requires a thoughtful and well-structured regulatory strategy. NAMs can offer powerful and human-relevant insights, but they must be presented within a clear evidentiary framework that demonstrates scientific credibility, appropriate validation, and alignment with FDA expectations. This session will provide an overview of how to position NAMs for regulatory acceptance by mapping their outputs to IND requirements, developing transparent validation and benchmarking plans, and using targeted animal bridging studies to strengthen confidence in the NAM-based evidence package.

The workshop will also highlight key FDA engagement pathways, including ISTAND, the Model Informed Drug Development Paired Meeting Program, and Pre-IND meetings, and explore how sponsors can leverage these opportunities to obtain early feedback, reduce regulatory uncertainty, and build a more robust and defensible IND submission. This session is designed for participants with varying levels of regulatory experience and will emphasize practical strategies for integrating innovative methods into the FDA review process.

Speaker Details:

Anne Jones is an emerging Regulatory Affairs professional with over 20 years of experience in the pharmaceutical industry, including nonclinical research and early drug development. She recently completed her Master's degree in Regulatory Affairs at SDSU to transition from bench science into regulatory practice formally. She brings a strong foundation in IND-stage program support, documentation quality, and cross-functional collaboration. Anne has contributed to development programs spanning small molecule drugs, biologics, and adeno-associated virus gene therapies, gaining practical insight into how nonclinical data informs regulatory decisions. She is particularly interested in how regulatory strategy, scientific evidence, and compliance principles intersect to guide the advancement of innovative therapies.



Join Us January 26, 2026
at 11:00 am (Pacific)

Free Registration

Contact Kim Walker to
Register –
kawalker@sdsu.edu

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