

International Alliance for
Biological Standardization

9th Annual IABS Statistics Workshop

Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

November 7-9, 2023

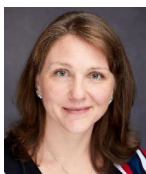
The impact of statistics and data science in Chemistry, Manufacturing & Controls (CMC) is constantly expanding, with the introduction of advanced statistical methods and the ability to mine "big data" in the development and lifecycle management of biological products.

Multiple aspects within the ever-evolving CMC landscape include: improving and developing innovative statistical methodologies to address key development decisions; addressing questions arising from yet unexplored modalities or technologies; advancing the regulatory framework through revised guidance; and implementation of harmonized statistical solutions.

This workshop will provide a forum for statisticians, data scientists, development engineers, and regulators to explore approaches that serve future generations of technical and regulatory innovation in biological development and lifecycle management.



Timo Bailer
co-Chair Boehringer
Ingelheim



Laura Pack
co-Chair Rezolute

Sessions:

- **Session I:** The Research Question: It's Importance in Achieving Successful Product Development and Regulatory Review
- **Session II:** Innovative statistical Methodologies in CMC
- **Session III:** Application of CMC Statistics to New Modalities and Technologies
- **Session IV:** Call to Action: Implementation of Statistical Solutions for CMC



Further information

Venue :

University of Maryland
Institute for Bioscience
and Biotechnology
Research (IBBR)
Rockville, MD, USA

www.iabs.org