



International Alliance for  
Biological Standardization

## 10th Annual Statistics Workshop: Science & Statistics – Elevating CMC through Partnership

November 12-14, 2024  
IBBR, Rockville, USA

### **Session III: Enhancing Biologicals Development with Advanced Analytical Approaches**

This session will explore the transformative journey of analytical methods in the biologics sector, highlighting the shift from traditional control strategies to cutting-edge approaches. We will delve into the modernization of analytical characterization, which is crucial for the rapid development and approval of gene therapies, cell therapies, and novel vaccines. The session will discuss the challenges and opportunities presented by the ICH Q2(R2) and Q14 guidelines, emphasizing the role of CMC statisticians in ensuring the fitness for use of analytical procedures. Additionally, we will examine a patient-centric approach to cell therapy manufacturing, focusing on the link between CAR-T product attributes and clinical outcomes. Through examples from recent successful submissions and clinical trials, the session aims to stimulate Quality by Design thinking and showcase the lifecycle management of analytical methods. Join us for a comprehensive discussion on enhancing biologic development with advanced analytical approaches and the role of statisticians in shaping the future of biologics.

