



International Alliance for  
Biological Standardization

## **12th Annual Statistics Workshop: From Data to Patients – CMC Statisticians' Contributions to Quality, Safety, and Efficacy of Pharmaceutical Products**

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### **Let Models Speak: Machine Learning Process Models with Interpretable AI Agents – Gang Wang, Moderna**

Historical process data has been collected from different programs at Moderna, making it feasible for the development of machine learning (ML) models that can be used to deepen process understanding, predict process performance of new sequences, and accelerate process development.

A structured database has been designed with historical data from process development experiments linked with metadata such as sequence and process attributes. Interpretable machine learning models were used to identify relationship among manufacturability, sequence attributes, and process parameters. Digital platforms and applications were created as an interface for scientists and engineers to utilize prior knowledge as reference and compare with new experiments, and as an advisory tool to recommend optimal processes with explanations.

One of the potential challenges of ML-based process models is the generalizability of such models when applied to new mRNA sequences. In this presentation, we will focus on the approaches taken to enhance interpretability and further the trust of AI/ML-based solutions, and extend the discussion into developing AI agents on top of interpretable workflows.

