

## **DIGITAL TRANSFORMATION IN BIOMANUFACTURING**

Amos Lu, MIT, USA  
amoslu@mit.edu  
Richard Braatz, MIT, USA

Key Words: First-principles Modeling, Data-based Modeling, Machine Learning

This presentation describes ways to leverage and implement digitalization technologies in biopharmaceutical manufacturing. An accelerated process development workflow is described that employs micro-scale technologies, modular unit operations with integrated process control and monitoring systems, systems integration, and full plant automation. The presentation describes how to best develop and transfer knowledge between steps in the workflow via first-principles models, data analytics, and machine learning. Case studies are described that illustrate the application of each of the above methods, including where process equipment was designed digitally by using first-principles models first, then the process equipment was constructed and implemented experimentally, with the experimental results confirming model predictions.