

MIT Center for Biomedical Innovation's
2023 BioMAN Summit

December 6 – 7, 2023 • Samberg Conference Center

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Now!



Controlling Quality for Cell, Gene, and Complex Biologic Products

Keynote Speakers:

Dr. Peter Marks
USFDA

Dr. Isabelle Rivière
Takeda

Ensuring quality is a key challenge for the goal of delivering revolutionary biotherapeutics to the patients who need them. This Summit explores how a broad range of stakeholders are advancing their ability to ensure the quality of these innovative product modalities.

MIT's Center for Biomedical Innovation will host the **2023 BioMAN Summit**, which brings together thought leaders from industry, academia, and government for a series of invited presentations to investigate:

- What process designs are being used to maintain key product quality attributes of complex biologic products and to minimize introduction and formation of process- and product-related impurities?
- How are manufacturers ensuring safety of novel product modalities when traditional unit operations such as affinity purification, filtration, and viral inactivation cannot be used?
- What analytical platforms are being developed to provide rapid measurement of critical process parameters and product quality attributes?
- How are manufacturers approaching setting specifications for their complex biologic products?
- How are manufacturers addressing the impact of raw materials and supply chain characteristics on product quality attributes for these products?
- What efforts are underway to digitalize quality control and quality assurance for these products?