

CMC STRATEGY FORUM

ADVANCING BIOPHARMACEUTICAL DEVELOPMENT

NORTH AMERICA 2022

KNOWLEDGE SHARING AND CAPACITY BUILDING

- Modelling is a *valuable tool to develop a target process* and analytical control strategy design, but is *not a substitute* for real-time data to validation.
- Legomics *accelerates product development* and is useful for modular facility buildout with subunits that can be technology-agnostic.
- Novel modalities may be *pivotal to serve patient-centric* approaches by *increasing the probability of success* for long-term treatments by simplifying dose administration and accessibility to patients.
- Potency assays should account for *ALL biologically active* constituents of the product (BsAb, ADC, etc...).

CMC STRATEGY FORUM NORTH AMERICA 2022 BY THE NUMBERS



**Attendee
Participants**

130



**Regulators
Participation**

17



**Company
Participation**

33



Country Participation

6

Canada | China | Denmark | Japan | Switzerland | United States