

### KNOWLEDGE SHARING AND CAPACITY BUILDING

- Innovative computation design at *the sequence level enables for an extremely fast time* (3 weeks) from DNA to confirmed nanoparticles for vaccine development.
- The same basic principles for comparability are used for WCBPs, novel protein modalities, microbiome, and mRNA vaccines. The devil is in the *details of product and process understanding*.
- When comparability data are outside the comparability criteria, companies can:
  - *Optimize the process to achieve product quality* that meets the comparability criteria
  - *Justify changes in product quality* based on platform or product specific knowledge; evaluation should include an assessment of efficacy, safety, and PK.

### CMC STRATEGY FORUM NORTH AMERICA 2023 BY THE NUMBERS



#### Attendee Participants

In-Person - **350**

Virtual - **590**

First Time - **339**



#### Regulators Participation

**66**



#### Company Participation

**136**



#### Country Participation

**21**

Austria | Brazil | Canada | China | Denmark | Finland |  
Germany | India | Ireland | Israel | Japan | Netherlands |  
Portugal | Singapore | Slovenia | South Korea | Spain |  
Sweden | Switzerland | United Kingdom | United States