

cmc STRATEGY FORUM

ADVANCING BIOPHARMACEUTICAL DEVELOPMENT

NORTH AMERICA 2023

KNOWLEDGE SHARING AND CAPACITY BUILDING

- Tools to facilitate digital structured content are *being developed* and will come online soon.
- Specifications are *set for a purpose*; the role of specifications is evolving from “ensuring” to “confirming” - QbD should be applied to the product and process, not testing – ICH Q8.
- The generation of real-time stability data is the *bottleneck for accelerated product development* and lifecycle management.
- Use prior knowledge and Bayesian statistics in model generation for extrapolation of existing data to *support product shelf life*, post-approval.

CMC STRATEGY FORUM NORTH AMERICA 2023 BY THE NUMBERS



**First-Time
Attendees**

28



**Industry
Participation**

79



**Company
Participation**

38



Country Participation

6

Austria | Canada | Germany | Japan |
Switzerland | United States