

CGTP SUMMIT 2025

KNOWLEDGE SHARING AND CAPACITY BUILDING

- Start early. ***Try multiple approaches***, especially if your product is complex. ***Focus on complimentary assays***, not redundant assays.
- Obtain early regulatory input, and ***grow the agency's understanding*** with your understanding.
- ***Gradual maturation*** of potency strategy is possible.
- There still isn't an agreement on where in the cascade to stop assessing the potency of a drug. If you can, ***start with the end in mind*** and develop a functional potency assay.
- ***Industry and regulators should continue working together*** to provide general guidance on how to balance the need for a QC-friendly assay and a functional assay.

CGTP Summit 2025 BY THE NUMBERS



First-Time Attendees

77



Regulators Participated

6



Companies Represented

63



Countries Collaborated

12

Austria | Belgium | Canada | Denmark | France | Japan |
Netherlands | Saudi Arabia | South Korea | Sweden |
United Kingdom | United States

CASSS RESOURCES

Looking for more past meeting content?

Speaker slides, roundtable notes, and video presentations can be accessed through **Papers and Presentations** and **CASSS On Demand** on our website. www.casss.org