## CELL&GENE THERAPY DUM 2023 PRODUCTS MANUFACTURING, QUALITY AND REGULATORY CONSIDERATIONS

## KNOWLEDGE SHARING AND CAPACITY BUILDING

- There is *no "one size fits all" approach* for CGT products given the broad diversity of modalities and corresponding properties.
- Developing CGTP for ultra/rare diseases has many challenges.
   The cost of manufacturing AAV GT is extremely high. There is a call for CMC expertise to drive down the cost of production.
- Cellular starting materials (CSM) need to be characterized and,
  to the extent possible, their variability understood and taken
  into account when the sponsor sets specifications and conducts
  comparability assessments. We are beginning to see developers
  undertake the complex task of characterizing CSM.

## Cell & Gene Therapy Products 2023 BY THE NUMBERS



Attendee Participants

In-Person - 256

Virtual - **147** 

First Time - 165



Regulators
Participation

30



Company Participation

135



**Country Participation** 

20

Afghanistan | Austria | Belgium | Canada | China | Denmark | Finland | France | Germany | Ireland | Israel | Italy | Netherlands | Portugal | Singapore | South Korea | Spain | Switzerland | United Kingdom | United States



