## CELL&GENE THERAPY DIVIDED 2024 PRODUCTS MANUFACTURING, QUALITY AND REGULATORY CONSIDERATIONS

## KNOWLEDGE SHARING AND CAPACITY BUILDING

- There is a need for speed, but we cannot compromise quality.
- Potency assurance strategy is more than potency testing.
- To ensure safe and efficacious administration of gene edited products to patients, minimizing unintended effects is paramount.
- There is an **evolution of product understanding**, particularly in the application of analytical methods used to support process development and characterize or monitor product attributes.
- ICH provides a harmonized approach to ensure that *safe*, *effective and high-quality medicines are developed, registered, and maintained* in a resource efficient manner whilst meeting high standards.

## Cell & Gene Therapy Products 2024 BY THE NUMBERS



First-Time Attendees

126



Regulators Participated

5



**Company Participation** 

129



## **Country Participation**

18

Austria | Belgium | Canada | China | Denmark | Finland | France | Germany | Ireland | Italy | Japan | Netherlands | Portugal | Saudi Arabia | Spain | Sweden | United Kingdom | United States



