

KNOWLEDGE SHARING AND CAPACITY BUILDING

- Global informed reliance and collaboration have *rapidly evolved into a valuable regulatory strategic option* to get new medicines to global patients more quickly.
- Platform methods and the use of prior knowledge can significantly support development phase programs, with *ever-advancing support for biological products using pharmacopeial methods*.
- New regulations taking effect in 2026 will require *strategic prioritization and cross-industry collaboration*.
- Transitioning devices between clinical stages requires careful assessment of *which design differences are clinically meaningful*.

CMC STRATEGY FORUM EUROPE 2025 BY THE NUMBERS



First-Time Attendees

75



Regulators Participated

25



Companies Represented

71



Countries Collaborated

20

Austria | Belgium | Canada | China | Denmark | Finland |
France | Germany | Ireland | Israel | Italy | Japan | Netherlands |
South Africa | South Korea | Spain | Sweden | Switzerland |
United Kingdom | United States

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