

CMC STRATEGY FORUM[®]

ADVANCING BIOPHARMACEUTICAL DEVELOPMENT

JAPAN 2025



KNOWLEDGE SHARING AND CAPACITY BUILDING

- Collaborative review projects (e.g., ICMRA, ACCESS) draw major interest; however, regulators noted some *operational challenges in meeting common timeliness*, as well as regulatory modernization needs.
- Implementation of AI/advanced manufacturing technologies requires continuous dialogue with regulatory authorities to *establish best practices and drive global regulatory harmonization*.
- Flexible manufacturing brings patient benefits and supply stability, but it's essential to *promote innovation while ensuring safety* under appropriate regulatory frameworks.

CMC STRATEGY FORUM JAPAN 2025 BY THE NUMBERS



First-Time Attendees

41



Regulators Participation

20



Company Participation

35



Country Participation

14

Austria | Canada | Denmark | France | Germany | Ireland | Italy | Japan | Netherlands | Singapore | Sweden | Switzerland | United Kingdom | United States

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