WHAT IS CASSS?

We are an agile, non-profit scientific organization whose strength is in bringing together professionals from industry, academia and regulatory agencies to solve scientific and technical problems in order to advance the development of biopharmaceuticals.
COMMITMENT TO INCLUSION

We are committed to diversity, equity, and inclusion in all aspects of what we do. Diverse perspectives drive innovative thinking and better solutions that advance our mission of regulatory capacity building, knowledge-sharing and global access. We advance together in the direction of dignity, respect, scientific truth, and the betterment of humanity.
KNOWLEDGE SHARING

• Our **purpose** is to discuss best practices and trends in the field of biopharmaceutical development and regulation.

• Our **community** is fostering a neutral venue for **collaboration** amongst industry professionals, subject matter experts, health authorities, academia and instrument developers

• Our future includes the next generation of talent, opening doors to unexplored career path opportunities.

1. Community
2. Peer to peer learning
3. Industry & regulatory trends
4. Next generation investigator awards
OUR KNOWLEDGE SHARING EVENTS INCLUDE:

CE in the Biotechnology & Pharmaceutical Industries
Symposium on the Practical Applications for the Analysis of Proteins, Nucleotides & Small Molecules

CMC Strategy Forum
Advancing Biopharmaceutical Development

BIOAASSYS
Scientific Approaches and Regulatory Strategies

Cell & Gene Therapy Products
Manufacturing, Quality and Regulatory Considerations

AT Europe
Analytical Technologies in the Biopharmaceutical Industry

Symposium on the Practical Applications of Mass Spectrometry in the Biotechnology Industry

CASSS Discussion Groups

CASSS Regional Forums

WCBP

Meeting dates & locations: www.casss.org
More than 5,200 members participate in CASSS’ interest-based symposia and fora.
GLOBAL ACCESS

• Encouraging **communities** around the world to exchange best practices.

• Live streaming **distinct** content for premier meetings and virtual sessions.

• Providing speaker slides, roundtable notes, workshop summaries and white papers that hold up the **integrity** of information without borders.

“Prior to this, I thought that my company was the only one working on this issue. It was great to see the various companies engaging in conversation with the regulators in attendance on this.”

– Bill W.
CAPACITY BUILDING

- **Collaboration** on the **integrity** of guidance implementation and application at all levels to foster global alignment and scientifically sound biologically derived medicines.

- Facilitate agency to agency, agency to industry and industry to industry dialogue to create **distinct** alignment.

> Everyone in the field struggles with the same problems, but we are not behind any other player. We are asking the right questions and doing the right things to get answers.

— Patrick S.
The CMC Strategy Forum was launched in 2002 from the well-established WCBP Symposium.

The CMC Forum Europe was launched in 2007 with support from the Biotech Working Party/EMA.

The CMC Forum Japan was launched in 2012 with support from PMDA and JPMA.

The CMC Forum Latin America was added in 2014 and has been held in both Brazil and Mexico.

Launch of the first CMC Strategy Forum China Pilot Program.
SCIENTIFIC PROGRAM ORGANIZING COMMITTEE

• Andrew Chang, *Novo Nordisk Inc.*
• Liuquan (Lucy) Chang, *Merck & Co., Inc.*
• Irene Deng, *Sanofi China*
• Sunny Hui Gao, *Janssen China R&D Ltd.*
• Emily Hernandez, *Biogen*
• Dinesh Khokal, *Amgen Singapore*
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SPECIAL THANKS TO...

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Emerging Global Regulatory Trends
The “New Normal”: Emerging from a Global Pandemic

Covid-19 Pandemic forced regulators to experiment with unprecedented degree of collaboration among themselves and industry, appreciation of technological/digital tools, recalibration of risk-benefit mindset and focus on what really matters.

As we emerge from the Covid-19 pandemic a “new normal” a more dynamic means of oversight is emerging that leverages these learnings

• Tightening of relations between global Health Authorities and industry (e.g., ICRMA pilots)
• Increased interest in collaboration, convergence, and reliance
• Focus on post-approval and lifecycle management
• Implementation of ICH guidelines
What is needed to meet the challenge of the “New Normal”

Leveraging pandemic lessons learned to enable modernization of regulatory frameworks in the biopharmaceutical industry:

• Enabling rapid global introduction of new *manufacturing/testing technological innovations*

• Enabling real time *cloud based structured DATA* exchange

• Increased *supply chain resilience & flexibility*, and further simplification of life cycle management regulatory requirements

• Acceptance of *virtual inspections* and mutual recognition of PIC/S member’s inspections

• Expansion of work-sharing, *joint reviews* among core ICH countries

• Expansion of *reliance* & mutual recognition in emerging markets
WELCOME
CMC STRATEGY FORUM
ADVANCING BIOPHARMACEUTICAL DEVELOPMENT
CHINA 2022
23-24 AUGUST