



WELCOME

cmc STRATEGY
FORUM

ADVANCING BIOPHARMACEUTICAL DEVELOPMENT

CHINA 2022

23-24 AUGUST



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**.



CORE VALUES

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.



Community



Peer to peer
learning



Industry &
regulatory trends



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

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BIOASSAYS
SCIENTIFIC APPROACHES AND REGULATORY STRATEGIES

AT ANALYTICAL
TECHNOLOGIES IN THE
BIOPHARMACEUTICAL
INDUSTRY
Europe

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

**CELL & GENE
THERAPY
PRODUCTS**
MANUFACTURING, QUALITY AND REGULATORY CONSIDERATIONS

HOS
BECAUSE STRUCTURE MATTERS

CASSS DISCUSSION
GROUPS

CASSS
REGIONAL FORUMS

WCBP

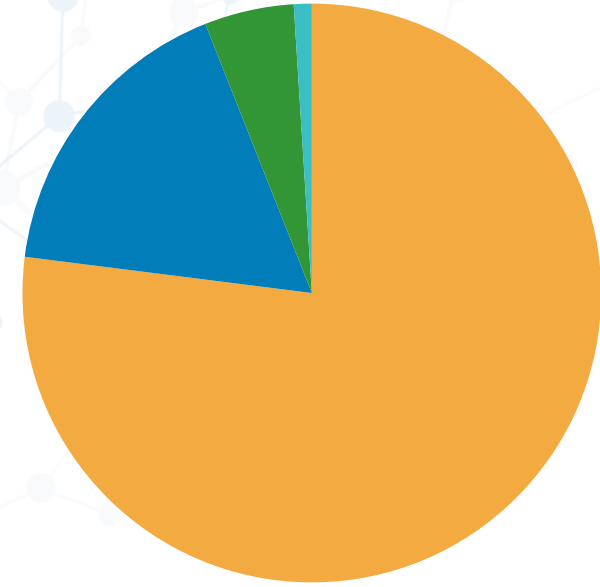
Meeting dates & locations: www.casss.org

More than 5,200 members participate in CASSS' interest-based symposia and fora.

CASSS
SHARING SCIENCE SOLUTIONS

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.



Global Reach: Current Demography



“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.

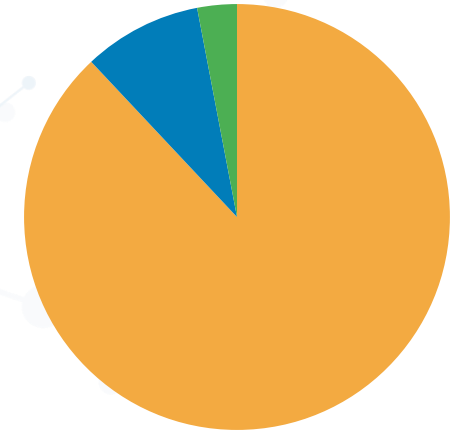
CAPACITY BUILDING

- **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.

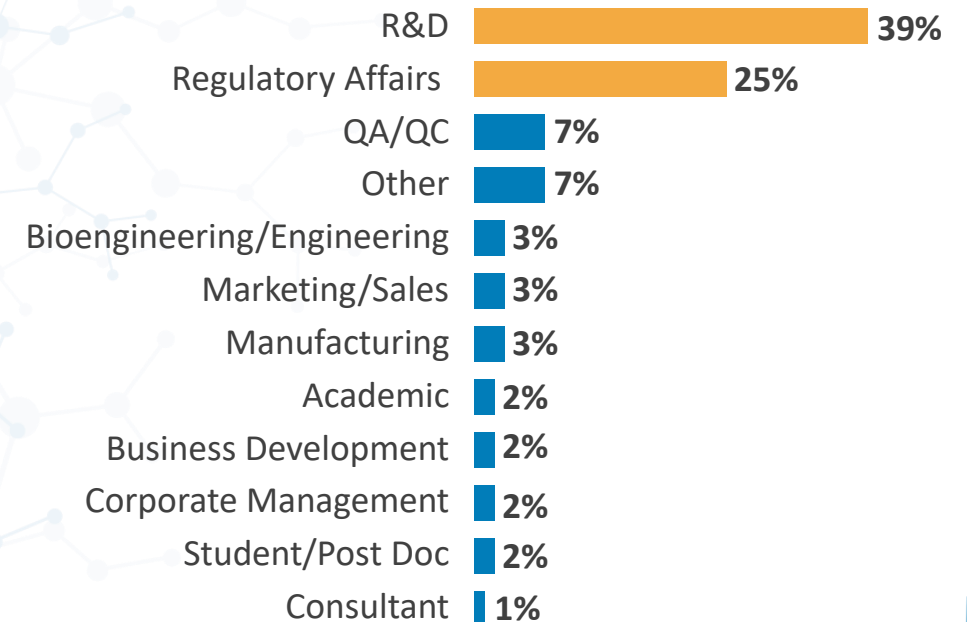
“ *Everyone in the field struggles with the same problems, but we are not behind any other player. We are asking the right questions and doing the right things to get answers.* ”

– Patrick S.

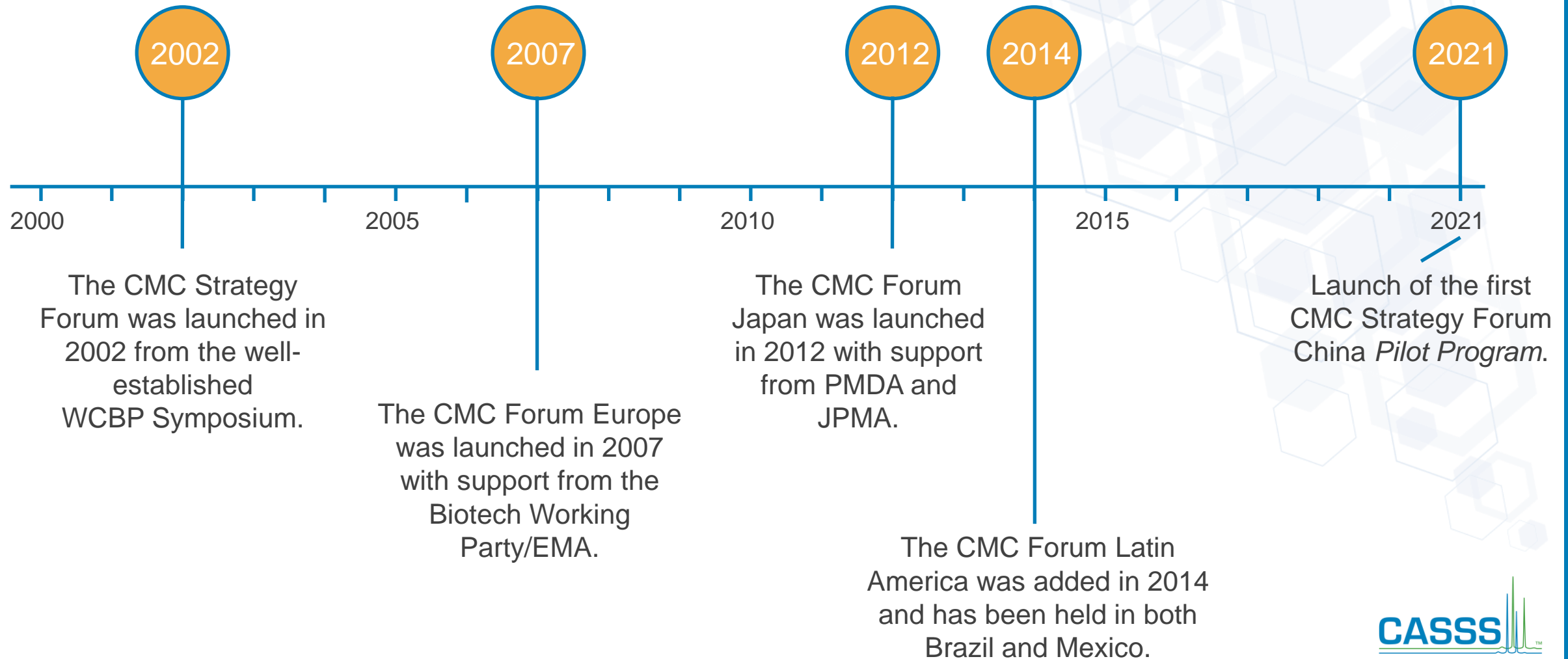
Professional Representation



Primary Job Function



CMC STRATEGY FORUM HISTORY



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*
- Yingying Liu, *CSL Behring Asia Pacific Ltd.*
- Frank Montgomery, *AstraZeneca*
- Wassim Nashabeh, *F. Hoffmann-La Roche Ltd.*
- Joey Studts, *Boehringer Ingelheim Pharma GmbH & Co. KG*
- **Patrick Swann, *CSL Behring***
- Yaying Wang, *Takeda Pharmaceutical Company Limited*
- Timothy Watson, *Pfizer, Inc.*
- Haifeng Wu, *Novartis Pharmaceuticals Corporation*
- Zero Wu Zhengyu, *Novo Nordisk (China) Pharmaceuticals Co., Ltd.*
- Xin Yao, *Sanofi China*
- Meng Yang, *Roche (China) Holding Ltd.*
- Zhongbing (Robin) Zhang, *Amgen China*

SPECIAL THANKS TO...

CASSS Staff

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STRATEGIC PROGRAM PARTNERS

Strategic Diamond



Genentech
A Member of the Roche Group

Strategic Gold





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*



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