Proventa International's 2nd Annual

CHEMISTRY, MANUFACTURING & CONTROLS

STRATEGY MEETING EAST COAST USA 2025

Wednesday, 7th May 2025 | **Le Méridien Boston Cambridge**

The premier meeting for all East Coast USA CMC professionals

Visit our website for future ← events

Featuring Industry Leaders and Decision Makers:

Mahesh Padval
Chief Pharmaceutical Development Officer
Relay Therapeutics

Gregory Papastoitsis
Chief Process and Manufacturing Officer
Ankyra Therapeutics

Caitlyn Harvey
Vice President, Head of CMC
Convergent Therapeutics, Inc.

Debasis Patra
Vice President, Head of CMC
OliX Pharmaceuticals, Inc.

Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

Stephan Krause
Executive Director, Cell Therapy Global Quality
Bristol Myers Squibb

Erin O'Brien
Head, Process Chemistry, Synthetic Molecule Process Development
Takeda

Suresh Tipparaju
Director, Product Development and Clinical Supply
Alexion-AstraZeneca Rare Disease

21 ROUNDTABLE DISCUSSIONS

6 TRACKS

1 KEYNOTE PRESENTATIONS

1 PANEL DISCUSSION

1 LOCATION

What Makes Our Strategy Meetings So Unique?

Proud to Partner with:

Zifo | RG DISCOVERY | SEQENS OUR SCIENCE FOR YOUR FUTURE | BioDuro | sapio sciences | OpusRegulatory | HIPRA BIOTECH SERVICES | ARDENA | Cambrex | REDOX SCIENTIFIC | HARMONY PHARMA GROUP | VIVA | Wilmington PharmaTech

PROVENTA INTERNATIONAL

proventainternational.com

UK: +44 (0)208 124 6417
US: +1 (617) 614 0377

info@proventainternational.com
Proventa International
@proventaintl
@proventainternational

Proventa International's Strategy Meetings are a completely unique experience.

We're committed to delivering long-term value across our extensive life science network. Through our carefully crafted meetings, collaborative experiences and services Proventa International can offer you the perfect opportunity to meet your business goals, whatever they may be.

Our Vision

To be a platform for creating life-saving therapies and to facilitate the creation of a completely patient centric pharmaceutical industry.

Our Mission

By encouraging key leaders and their companies to put the patient at the very heart beat of every innovation. Sharing valuable insights and strategies to assist in the discovery, development and commercialisation of life saving therapies.

Our Unique Meeting Format

ROUNDTABLE DISCUSSIONS

These interactive and informal discussion groups are the hallmark of the meeting. The brightest minds in the industry are brought together in 60-minute sessions that enable participants from all over the world to share ideas, challenges and lessons learned.

PERSONALISED AGENDA

Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time spent is focused and well-utilised.

INNOVATIVE SOLUTIONS

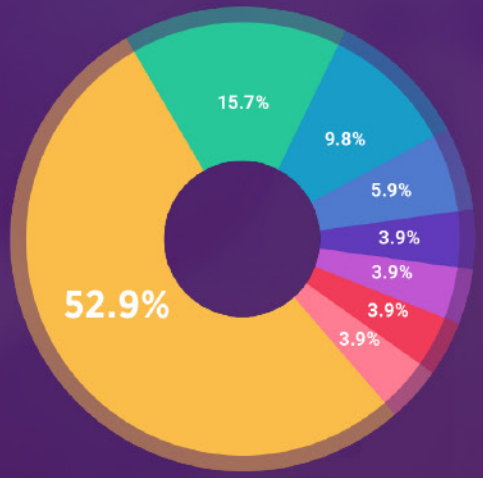
The most effective and time efficient way to assess potential partners at a strategic level. Identify key solution providers that can take your business to the next level and we will help arrange private meetings so you can connect.

STRATEGIC NETWORKING

Strategic networking opportunities form a key benefit of the meeting. Our proven format for building and strengthening alliances to make lasting connections that benefit you.

Seniority of Attendees

- Director Level
- Scientist
- Other
- C-level
- Department Head
- President / VP
- Team Lead
- Manager



CMC

- CMC
- Small Molecule
- Scale Up
- Manufacturing
- Medicinal Chemistry
- Drug Development
- Tech Transfer
- API
- Process Chemistry
- Analytical Development

Meet Investors

- Venture Capital
- Private Equity
- Large Pharma/Biotech
- Corporate Venture Capital
- Institutional
- High Net Worth
- Family Office/Private Wealth
- Government Organisation/ Sovereign Wealth Fund
- Angel

proventainternational.com
UK: +44 (0)208 124 6417
US: +1 (617) 340 2564
info@proventainternational.com
Proventa International
@proventaintl
@proventainternational
PROVENTA INTERNATIONAL

Facilitator Faculty

Johan Evenäs
Chief Executive Officer
RG Discovery

Fabien Bonhoure
Global Business Project Director
SEQENS

Caitlyn Harvey
Vice President, Head of CMC
Convergent Therapeutics, Inc.

Daniel Peng
Vice President, Regulatory Affairs CMC
Checkpoint Therapeutics

Debasis Patra
Vice President, Head of CMC
OliX Pharmaceuticals, Inc.

Erin O'Brien
Head, Process Chemistry, Synthetic Molecule Process Development
Takeda

Fue Vang
Director, Analytical Development
Candel Therapeutics

Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

Gregory Papastoitsis
Chief Process and Manufacturing Office
Ankyra Therapeutics

Kwame Nti-Addae
Executive Director, Head of CMC
Frontier Medicines

Mahesh Padval
Chief Pharmaceutical Development Officer
Relay Therapeutics

Matt Barrows
Senior Vice President, CMC & Technical Operations
Aviceda Therapeutics

Niels Svenstrup
Former Senior Vice President, Chemistry & Manufacturing
PepGen

Paul Peng
Vice President, CMC
City Therapeutics

Robert Gabriel
Board Member, Managing Partner
Ashur Capital

Suresh Tipparaju
Director, Product Development and Clinical Supply
Alexion-AstraZeneca Rare Disease

Stephan Krause
Executive Director, Cell Therapy Global Quality
Bristol Myers Squibb

Vikram Sadineni
Vice President, Technical Development & Manufacturing
Generate:Biomedicines

Yu Qian
Director, Head of Analytical Project Leads, Cell Therapies
Novartis

Yumiko Mizuno
Head, Plasma-Derived Therapies (PDT) Drug Product Development
Takeda

2025 Sponsors

CO-HOST SPONSORS

Zifo is a global provider of R&D solutions and services for research led businesses and, specifically, for Pharmaceutical and BioTech companies. Our expertise covers Clinical Data Management, Genome Informatics and Discovery & Lab Informatics. Zifo has an expanding team which delivers bioinformatics support, NGS data analysis and solutions development for personalized medicine and pharmacogenomics to our customers. From our offices across Europe, US, Japan and Asia we provide local contact and a high quality of service to meet the needs of the Bio-Pharma industry.

RG Discovery provides premium services within two major areas: Analytical Services & Advanced Chemistry and Drug Discovery. Our expertise and focus are small molecules, macrocycles and peptides. We are based in the vibrant Medicon Valley region close to Copenhagen. Analytical Services & Advanced Chemistry highlights Qualitative and quantitative analysis, structure identification, and conformational studies Separation services for purification of substances and isolation of impurities including chiral separation by SFC Synthesis of small molecules, peptides, macrocycles, carbohydrates, conjugates & linkers, and polymers Extensive experience supplying custom made impurities for major peptide products NMR for in-depth structure elucidation of complex molecules

Seqens is a global leader in the pharmaceutical industry, with over 30 years' experience in the development and manufacturing of APIs, intermediates and polymers. Our state-of-the-art R&D facilities in Europe and in the US and our network of 8 Western manufacturing sites (GMP and nonGMP) enable us to innovate, develop and industrialize the most demanding molecules, and implement the best available technologies. Seqens supports its customers from early-stage development to commercial production, offering tailored solutions for complex molecules. As a trusted partner to over 1,000 customers worldwide, Seqens is backed by a strong CMC project management team, offering the highest level of service and commitment.

PARTNERING SPONSORS

Founded in 1996 and headquartered in Irvine, California, **BioDuro-Sundia** is a leading US-based CRDMO. With 2,000+ scientists, we have 7 sites across the US and China. We provide fully integrated services spanning drug discovery to commercial manufacturing, covering medicinal chemistry, biology, DMPK, drug substance, and drug product development. Our expertise includes various modalities such as small molecules, peptides, oligonucleotides, and antibody-drug conjugates (ADCs). The drug discovery team, with 1,100+ chemists, serves 330+ global clients annually, offering accelerated project timelines with <5 days per step and a 99%+ on-time delivery record.

Sapio Sciences' mission is to improve life in the lab - because science is complex, Sapio makes technology simple. Sapio is a global business offering an all-in-one science-aware (TM) lab informatics platform combining cloud-based LIMS, ELN, and data solutions. Sapio serves some of the largest global and niche brands, including biopharma, CRO's and clinical diagnostic labs across NGS genomic sequencing, bioanalysis, bioprocessing, stability, clinical, histopathology, drug research, and in vivo studies. Our customers love Sapio's platform because it is robust, scalable, and with no-code configuration, can quickly adapt to meet unique needs.

Opus Regulatory is a niche Regulatory Affairs consulting firm providing experts in Regulatory Strategy, CMC, Labeling, and Ad Promo. Our clients range from development stage biotech companies to mid-size and large pharmaceutical companies. Our team is made up of biopharmaceutical leaders and innovators. Our mission is to provide the highest-level Regulatory Affairs consulting service in the industry and to continually exceed the expectations of our clients.

HIPRA Biotech Services is a CDMO supporting pharmaceutical and biotech companies across the full life cycle of biologic and vaccine products. Backed by over 50 years of scientific and technical excellence including our internally commercialized and marketed COVID vaccine, we offer end-to-end development and GMP manufacturing solutions across a wide range of expression platforms, from viral to mammalian to microbial platforms, to make clinical and commercial drug substance and drug product for our clients. With a team of 400+ R&D scientists and over 1,000 professionals in Manufacturing, QA and QC, state-of-the-art facilities, and a strong regulatory track record, we deliver both clinical and commercial programs with speed, quality, and flexibility. We continuously invest in innovation and capacity expansion, making us a trusted partner that will grow with our clients for their long-term success.

KEY OPINION LEADERS

EXHIBITORS

Agenda at a Glance

CHEMISTRY, MANUFACTURING & CONTROLS
STRATEGY MEETING EAST COAST USA 2025
Wednesday, 7th May 2025 | Le Meridien Cambridge

TIME EST	TRACK 1 INTERMEDIATES & API	TRACK 2 TECHNOLOGY TRANSFER & ANALYTICAL	TRACK 3 OUTSOURCING / PROCESS RESEARCH & SCALE-UP	TRACK 4 INTEGRATED DRUG DEVELOPMENT	TRACK 5 EMERGING / NEW MODALITIES	TRACK 6 DRUG SUBSTANCE, DRUG PRODUCT, DRUG DELIVERY
BOARDROOM ►	Jerome C. Hunsaker A	Jerome C. Hunsaker B	Jerome C. Hunsaker C	Edward Pennell Brooks	Margaret L.A. Macvicar	Lan Jen Chu
08:00 - 08:30	REGISTRATION & WELCOMING					
08:30 - 09:00	OPENING KEYNOTE PRESENTATION: Managing a Complex Global Network for Internal and External QC Testing for Autologous Cell Therapies PRESENTER: Stephan Krause, *Executive Director, Cell Therapy Global Quality*, Bristol Myers Squibb					
09:00 - 10:00 PHARMA/ BIOTECH	**The Role of Intermediates in API Synthesis and Their Impact on CMC Regulatory Submissions** Niels Svenstrup, *Former Senior Vice President, Chemistry & Manufacturing*, PepGen	**Key CMC Considerations for Effective Planning and Collaboration in Complex Site Transfers** Paul Peng, *Vice President, CMC*, City Therapeutics	**Global Outsourcing: Strategies for Uncertain Times** Matt Barrows, *Senior Vice President, CMC & Technical Operations*, Aviceda Therapeutics	**Developing Robust Analytical Methods for Integrated CMC** Fue Vang, *Director, Analytical Development*, Candel Therapeutics	**Navigating CMC for Biologic/Small Molecule Hybrid Therapies** Caitlyn Harvey, *Vice President, Head of CMC*, Convergent Therapeutics, Inc.	**Enhancing Drug Solubility, Stability, and Drug Delivery** Mahesh Padval, *Chief Pharmaceutical Development Officer*, Relay Therapeutics
10:00 - 10:05	REFRESHMENT BREAK					
10:05 - 10:25	NETWORKING / 1-1 MEETINGS					
10:25 - 10:45	NETWORKING / 1-1 MEETINGS					
10:45 - 11:05	NETWORKING / 1-1 MEETINGS					
11:10 - 12:10 SOLUTION/ PHARMA/ BIOTECH	**De-Risking Small Molecules Development: Strategies to Maximize Success and Boost Your Company's Value** Fabien Bonhoure, *Global Business Project Director*, SEQENS SEQENS		**Effective Strategies for Managing Impurities During API Production of Peptides and Macrocycles** Johan Evenäs, *Chief Executive Officer*, RG Discovery RG DISCOVERY		**Exploring Emerging Oligonucleotide Modalities and Their Implications for Therapeutic Development** Debasis Patra, *Vice President, Head of CMC*, OliX Pharmaceuticals, Inc.	**Understanding the Growing Role of Drug-Device Combination Products and Delivery Systems** Vikram Sadineni, *Vice President, Technical Development & Manufacturing*, Generate:Biomedicines
12:15 - 13:15 PHARMA/ BIOTECH	**Implementing Robust Strategies to Mitigate Risks in the Supply Chain** Erin O'Brien, *Head, Process Chemistry, Synthetic Molecule Process Development*, Takeda	**Identifying Key Success Factors for Effective Biologics Technology Transfer** Gopi Vudathala, *Global Head, Regulatory Affairs CMC*, Incyte Corporation	**Evaluating the Pros and Cons of Outsourcing CMC Activities** Gregory Papastoitsis, *Chief Process and Manufacturing Officer*, Ankyra Therapeutics	**Collaboration Between CMC and Clinical Teams for Seamless Development** Daniel Peng, *Vice President, Regulatory Affairs CMC*, Checkpoint Therapeutics	**Cell and Gene Therapies: CMC Challenges and Potential Solutions** Yu Qian, *Director, Head of Analytical Project Leads, Cell Therapies*, Novartis	**CMC for Oral Drug Delivery: Navigating the Challenges of Bioavailability and Controlled Release** Suresh Tipparaju, *Director, Product Development and Clinical Supply*, Alexion-AstraZeneca Rare Disease
13:15 - 14:00	NETWORKING LUNCH					
14:00 - 14:20	NETWORKING / 1-1 MEETINGS					
14:20 - 14:40	NETWORKING / 1-1 MEETINGS					
14:20 - 14:40	NETWORKING / 1-1 MEETINGS					
15:10 - 16:10 PHARMA/ BIOTECH	**Building a Successful Overall Development Plan for Producing Sufficiently Formulated API** Suresh Tipparaju, *Director, Product Development and Clinical Supply*, Alexion-AstraZeneca Rare Disease	**Best Industry Practice for Late-Stage and Commercial Analytical Method Transfer (AMT)** Stephan Krause, *Executive Director, Cell Therapy Global Quality*, Bristol Myers Squibb	**Optimizing Process Research & Scale-Up in CMC: From Early-Stage Development to Commercial Production** Vikram Sadineni, *Vice President, Technical Development & Manufacturing*, Generate:Biomedicines	**Digital Transformation in CMC: Revolutionizing Drug Development & Manufacturing** Kwame Nti-Addae, *Executive Director, Head of CMC*, Frontier Medicines		**CMC Strategies to Reduce Dosing Frequency: Overcoming Challenges in Drug Substance Formulation and Delivery** Yumiko Mizuno, *Head, Plasma-Derived Therapies (PDT) Drug Product Development*, Takeda
16:10 - 16:30	AFTERNOON REFRESHMENT BREAK					
16:30 - 17:00	PANEL DISCUSSION: What Do Investors and Partners Consider the "Must-Have" Value Drivers for CMC in a New Modality? CHAIRPERSION: Caitlyn Harvey, *Vice President, Head of CMC*, Convergent Therapeutics, Inc. PANELIST: Robert Gabriel, *Board Member, Managing Partner*, Ashur Capital PANELIST: Gregory Papastoitsis, *Chief Process and Manufacturing Officer*, Ankyra Therapeutics PANELIST: Gopi Vudathala, *Global Head, Regulatory Affairs CMC*, Incyte Corporation					
17:00 - 18:00	DRINKS & CANAPES RECEPTION					

VENTURE CAPITAL & PRIVATE EQUITY STRATEGY MEETING EAST COAST USA 2025

Wed/Thurs, 7-8th May 2025 | **Le Méridien Boston Cambridge**

Investment Challenges and Opportunities in Emerging Biotech Markets

Scan to Register

Featuring Industry Leaders and Decision Makers:

Claire Elizabeth Smith
Partner
SpringTide Ventures

Doug Zingale
Managing Partner
Blue Goose Capital

David Sherris
CEO
Attivare Therapeutics

	DAY 1	DAY 2
TIME / EST	INVESTMENT IN CLINICAL TRIALS & MANUFACTURING	INVESTMENT IN DRUG DISCOVERY & BIOTECH
ROOM►	Robert R Taylor	Robert R Taylor
08:00 - 08:30	REGISTRATION AND WELCOME	
08:30 - 09:00	OPENING KEYNOTE PRESENTATION: Managing a Complex Global Network for Internal and External QC Testing for Autologous Cell Therapies Stephan Krause, *Executive Director, Cell Therapy Global Quality* **Bristol Myers Squibb**	OPENING KEYNOTE PRESENTATION: Scaling Biotech Ventures: Challenges and Opportunities for Investors in Drug Discovery Startups
09:00 - 10:00	Balancing Cost-Effectiveness with Data Reliability in Decentralized Models	What Are the Emerging Trends in Venture Capital for Drug Discovery and Biotech Startups? David Sherris, *CEO*, **Attivare Therapeutics**
10:00 - 10:05	REFRESHMENT BREAK	
10:05 - 11-05	NETWORKING / 1-1 MEETINGS	
11:10 - 12:10 SOLUTION	Can the Boom and Bust Cycle of Biotech Investing be Changed? Doug Zingale, *Managing Partner*, **Blue Goose Capital**	2025 Investment Trends: Transforming Drug Discovery Ventures
12:15 - 1:15 Pharma/ Biotech	Exploring the Key Strategies for Improving the Cost-Efficiency of Clinical Trials and Increasing ROI for Investors? Robert Gabriel, *Board Member, Managing Partner*, **Ashur Capital**	Scaling Biotech Ventures: Challenges and Opportunities for Investors in Life Science Startup Tomasz H. Zastawny, PhD, DSc, *Strategic Advisor*, **Auxilius Pharma**
13:15 - 14:00	REFRESHMENT BREAK	
14:00 - 14:40	NETWORKING / 1-1 MEETINGS	
15:10 - 16:10 Pharma/ Biotech	Global Expansion of Clinical Trials: Opportunities and Challenges	Investment Challenges and Opportunities in Emerging Biotech Markets Claire Elizabeth Smith, *Partner*, **SpringTide Ventures**
16:10 - 16:30	AFTERNOON REFRESHMENT BREAK	
16:30 - 17:00	PANEL DISCUSSION: What Do Investors and Partners Consider the "Must-Have" Value Drivers for CMC in a New Modality? Caitlyn Harvey, *Vice President, Head of CMC*, **Convergent Therapeutics, Inc.**	PANEL DISCUSSION: Venture Strategies for Biotech Startups: Building Scalable Innovations in Drug Discovery
17:00 - 18:00	DRINKS & CANAPES RECEPTION	

proventainternational.com
UK: +44 (0)208 124 6417
US: +1 (617) 614 0377
info@proventainternational.com
Proventa International
@proventaintl
@proventainternational
PROVENTA INTERNATIONAL

Event Day | Keynote Presentations

A great way to open the roundtable discussions is through a timely presentation from a top-tier biotech/pharmaceutical company. Listen as we hear this 30-minute exposition on this meeting's pressing topic.

08:30 - 09:00 ET **OPENING KEYNOTE PRESENTATION**

Managing a Complex Global Network for Internal and External QC Testing for Autologous Cell Therapies

Stephan Krause
Executive Director, Cell Therapy Global Quality
Bristol Myers Squibb

ABOUT THE SPEAKER

Dr. Stephan Krause is the Executive Director, Cell Therapy Global Quality at Bristol Myers Squibb. He is a recognized industry leader for advancing best practices for analytical method lifecycle steps to support acceleration of product development. Stephan is currently chair of PDA's ATMP Advisory Board (since 2021), chair of the ANSI task force for standardizing analytical lifecycle steps and conditions (since 2022), and chair of TR56 R1 Annex ATMP for phase-appropriate QMS (since 2024). He has won numerous innovation, advocating, and publication awards. Based on his high-impact publications and advocacy, Stephan was invited multiple times in recent years to present an industry perspective to the FDA and other regulatory agencies to support the implementation of ICH Q2(R2), Q12, and Q14.

16:30 - 17:00 ET **PANEL DISCUSSION**

What Do Investors and Partners Consider the "Must-Have" Value Drivers for CMC in a New Modality?

CHAIRPERSON
Caitlyn Harvey
Vice President, Head of CMC
Convergent Therapeutics, Inc.

PANELIST
Robert Gabriel
Board Member, Managing Partner
Ashur Capital

PANELIST
Gregory Papastoitsis
Chief Process and Manufacturing Officer
Ankyra Therapeutics

PANELIST
Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

ABOUT THE SPEAKER

Caitlyn Harvey is the Vice President and Head of CMC at Convergent Therapeutics. She has over 20 years of development, manufacturing and regulatory experience across multiple modalities including radioligand, VLP, CGT, and antibody therapies. Caitlyn has led the CMC filings for over 15 successful INDs and has been a key contributor to 4 BLA submissions.

Event Day

TRACK 1

Intermediates & API

Developing and distributing a safe and effective vaccine and therapeutic since the Covid-19 outbreak has garnered immense global interest. Exploring common CMC issues posed by the development of these products, CMC perspectives and relevant case studies that provide solutions to enable regulatory compliance, shorter review timelines, and support post-approval maintenance will be discussed in this track.

08:00 - 08:30 ET **BREAKFAST & REGISTRATION**

08:30 - 09:00 ET **OPENING KEYNOTE PRESENTATION**
See Page 6

09:00 - 10:00 ET **ROUNDTABLE 1**

The Role of Intermediates in API Synthesis and Their Impact on CMC Regulatory Submissions

- Risk management in a risk-averse industry: Dealing with changes to the global supply chain and how to future-proof your manufacturing
- In-sourcing vs. outsourcing: What developments could drive a reanalysis of the equation?
- Driving innovation in drug development: Where to turn to for insights when developing novel API modalities?
- Complex APIs: Hurdles to entering development and how to overcome them

Niels Svenstrup
Former Senior Vice President, Chemistry & Manufacturing
PepGen

ABOUT THE SPEAKER

Niels Svenstrup has over 20 years of experience in the pharma and biotech industry across various leadership roles in chemistry and manufacturing. He recently founded Creative Molecular Consulting, where he is advising early-stage companies on navigating the transition from discovery to preclinical and clinical development from a CMC, regulatory, and business perspective. Niels has a master's in cell biology and chemistry, a Ph.D. in organic chemistry, and did his postdoctoral training at The Scripps Research Institute in La Jolla, CA. He joined the pharmaceutical industry as a laboratory leader in medicinal chemistry at Bayer Pharma in Germany in 2000. He later went on to become Head of Department, Medicinal Chemistry at H. Lundbeck's Neuroscience Drug Discovery Center in Copenhagen, Denmark, before joining Ascendis Pharma as Director of CMC and leader of the team that invented and developed TransCon PTH (now YorviPath), an approved drug in the EU and US for the treatment of hypoparathyroidism. Niels moved to the U.S. in 2017 to take on the role of Senior Vice President, Development at Cydan, a rare disease accelerator located in Cambridge, MA. Most recently, Niels was SVP of Chemistry and Manufacturing at PepGen Inc. from 2021 to 2025

10:00 - 11:05 ET **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

11:10 - 12:10 ET **SOLUTION FOCUS ROUNDTABLE 2**

De-Risking Small Molecules Development: Strategies to Maximize Success and Boost Your Company's Value

- Navigating Regulatory Challenges – Identify and address critical checkpoints early in the process to streamline approvals
- Strengthen your molecule's competitive edge - Leverage formulation enhancement and intellectual property protection
- Optimizing Efficiency & Value – Optimize timelines, reduce variability, and increase the value of your molecules thanks to scale-up and supply expertise

Fabien Bonhoure
Global Business Project Director
SEQENS

ABOUT THE SPEAKER

Fabien Bonhoure is Global Business Project Director at SEQENS, where he oversees the development of innovative and generic molecules for pharmaceutical and biotech companies of all sizes. With over 20 years of experience in healthcare, he has held leadership roles at global companies such as BD and Leica Microsystems. He specializes in managing complex projects with a strong client focus and is skilled at identifying client needs, improving operational performance, and transforming risks into opportunities throughout the innovation development lifecycle. He holds an MBA from INSEAD and a Doctorate in Pharmacy, blending scientific expertise with strategic acumen to deliver impactful results for his clients.

12:15 - 13:15 ET **ROUNDTABLE 3**

Implementing Robust Strategies to Mitigate Risks in the Supply Chain

- Diversify Suppliers: What are effective strategies for establishing relationships with multiple suppliers of critical raw materials to reduce reliance on a single source and enhance supply chain resilience?
- Regulatory Starting Materials or Intermediates: What approaches can companies adopt to mitigate risks associated with manufacturing key intermediates for validation when the regulatory starting material has not yet received approval in all countries?
- Strengthen Regulatory Compliance: What are best practices for ensuring strict adherence to international regulatory standards (e.g., GMP, ICH guidelines) to reduce risks of non-compliance or approval delays?
- Implement Predictive Analytics: How are organizations utilizing AI-driven tools to forecast demand, identify potential disruptions, and optimize inventory management for streamlined operations? Are these strategies being applied specifically to APIs and intermediates?

Erin O'Brien
Head, Process Chemistry, Synthetic Molecule Process Development
Takeda

ABOUT THE SPEAKER

Erin O'Brien is a collaborative, strategic, and solutions-oriented leader responsible for the development and manufacturing of small molecule drug candidates through clinical development and commercial life cycle management. Currently serving as the Head of Process Chemistry at Takeda Pharmaceuticals, she spearheads the development of synthetic molecule drug substances. Before joining Takeda, Erin held significant roles at Biogen, including Executive Director, Head of Small Molecule Development, where she led initiatives in drug product process development, technology transfer, and strategic collaborations. Erin's career began as a research scientist at Roche Palo Alto, LLC. She then advanced through various roles at Millennium: The Takeda Oncology Company, eventually becoming a Group Leader. Her leadership expanded further at Biogen, where she oversaw the chemical Process Development group, focusing on innovative manufacturing processes and green chemistry. Erin holds a Ph.D. in Organic Chemistry from the University of Pennsylvania and a B.S. in Chemistry from Mount Allison University. She is active in professional circles, including International Consortium of Quality, contributing to developments in green chemistry and pharmaceutical manufacturing. Her published works span multiple journals and book chapters, reflecting her commitment to advancing sustainable and efficient chemical processes.

13:15 - 15:10 ET **NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS**

15:10 - 16:10 ET **ROUNDTABLE 4**

Building a Successful Overall Development Plan for Producing Sufficiently Formulated API

- Current state of the art and emerging technologies to improve oral bioavailability of and delivery of BCS Class 2 (high permeability with low aqueous solubility) small molecules, with some discussion on technologies like amorphous spray dried dispersion (SDD), forming API nano particles using nano-crystallization technologies etc
- Improvements in technologies to enhance oral bioavailability of peptide therapeutics-use of permeation enhancers-their advantages and disadvantages
- Challenges and approaches in OSD drug product development to tailor DP presentations to patients of different ages [neonates-2 year olds (suspensions?), 2-18 (mini-tabs?), >18, seniors etc]
- Challenges in integration of DS and DP development in light of continuous manufacturing

Suresh Tipparaju
Director, Product Development and Clinical Supply
Alexion-AstraZeneca Rare Disease

ABOUT THE SPEAKER

See Page 13

16:10 - 16:30 ET **AFTERNOON REFRESHMENT BREAK**

16:30 - 17:00 ET **PANEL DISCUSSION**
See Page 6

17:00 - 18:00 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 2

Technology Transfer & Analytical

As drug development progresses, the analytical methods are refined and expanded, and if done right it gives the opportunity to deliver better results. Effective execution of a technology transfer can greatly impact the success of product's development and ultimately of CMC success. Join this track to gain practical insights on executing a successful technology transfer and leveraging advanced technology and tools for data exchange.

08:00 - 08:30 ET BREAKFAST & REGISTRATION

08:30 - 09:00 ET OPENING KEYNOTE PRESENTATION
See Page 6

09:00 - 10:00 ET ROUNDTABLE 1

Key CMC Considerations for Effective Planning and Collaboration in Complex Site Transfers

- Legal contracting process
- Vendor qualification and management
- What are the key technical challenges in method transfer?
- What are the key considerations in acceptance criteria setting (spec setting in general) during method qualification/validation?
- Sample shipping logistics for stability testing at different sites

Paul Peng
Vice President, CMC
City Therapeutics

ABOUT THE SPEAKER
Paul Peng, Ph.D., has about 20 years of experience in the oligonucleotide industry. Dr. Peng is currently leading the CMC function at City Therapeutics for second generation siRNA therapeutics. In his previous roles he made key CMC contributions to support early and late stage development and regulatory filings for oligonucleotide therapeutics (siRNAs, ASOs and RNA editing oligonucleotides) in small and large biotechnology companies including Alnylam, Stoke, Biogen and Korro. With a Ph.D. in nucleoside/nucleotide chemistry from McGill University, he is dedicated to

10:00 - 11:05 ET REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

12:15 - 13:15 ET ROUNDTABLE 2

Identifying Key Success Factors for Effective Biologics Technology Transfer

- Communication and planning
- Facility systems & suitability
- Equipment & Process considerations
- Process controls (CPPs& CQAs)
- Process Qualification/Verification & Validation

Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

ABOUT THE SPEAKER
Dr. Vudathala, Ph.D., is currently Global Head, RA CMC at Incyte Corporation. He was Formerly Executive Director of RA CMC at Intarcia Therapeutics, Head of Quality Advocacy at GSK Vaccines and Global Head of Regulatory CMC at Novartis Vaccines. He was also Associate Vice President of Regulatory Affairs CMC at Sanofi-Aventis. He has extensive experience in CMC regulatory strategy for Global Development and Life-Cycle Management Projects and contributed to over 30 NDA and BLA approvals and 60 INDs. Dr. Vudathala has had numerous interactions with global regulators on project related CMC matters as well as on key ICH initiatives. He has published extensively on drug development and regulatory CMC topics. He was on the Regulatory and Quality Advisory Board at the Parenteral Drug Association and a member of the PDA core team on ICHQ12/ Post Approval Changes. He was also previously Vice Chair of the Technical Development and Operations Committee at PhRMA and an active member of the PhRMA CTD Quality Task Force, Genotoxic Impurities Task Force, and a working group member of the FDA Subcommittee for Pharmaceutical Sciences on Process Analytical Technologies and Quality-by-Design. He was also the Chair of the Regulatory Sciences Section of AAPS. Dr. Vudathala is a well-recognized expert on Regulatory CMC and Quality matters and has made several presentations at AAPS, PDA, IIR, Barnett & Proventa International workshops and conferences on CMC, Regulatory, CTD, Drug Device Combination Products and Genotoxic Impurities topics. Dr. Vudathala graduated from the University of Alberta with a Ph.D. in Pharmaceutics and held positions with the Health Protection Branch, Canada, and Procter & Gamble Pharmaceuticals

13:15 - 15:10 ET NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS

15:10 - 16:10 ET ROUNDTABLE 3

Best Industry Practice for Late-Stage and Commercial Analytical Method Transfer (AMT)

- When to apply which AMT approach and condition(s)?
- Co-validation vs. traditional AMT
- When and how to use/justify AMT waivers (ex., same Platform Analytical Procedure (PAP) exists already at both sites (Sending and Receiving)
- Internal AMT (QC-QC) versus external AMTs (CTL-QC or QC-CTL)
- ICH Q2R2 Total Analytical Error comparison integrated in AMT study execution and acceptance criteria
- Enhanced AMT studies that include critical analytical performance criteria and continuous post-AMT monitoring
- When does an initially intended AMT become a method comparison study?

Stephan Krause
Executive Director, Cell Therapy Global Quality
Bristol Myers Squibb

ABOUT THE SPEAKER
Dr. Stephan Krause is the Executive Director, Cell Therapy Global Quality at Bristol Myers Squibb. He is a recognized industry leader for advancing best practices for analytical method lifecycle steps to support acceleration of product development. Stephan is currently chair of PDA's ATMP Advisory Board (since 2021), chair of the ANSI task force for standardizing analytical lifecycle steps and conditions (since 2022), and chair of TR56 R1 Annex ATMP for phase-appropriate QMS (since 2024). He has won numerous innovation, advocating, and publication awards. Based on his high-impact publications and advocacy, Stephan was invited multiple times in recent years to present an industry perspective to the FDA and other regulatory agencies to support the implementation of ICH Q2(R2), Q12, and Q14.

16:10 - 16:30 ET AFTERNOON REFRESHMENT BREAK

16:30 - 17:00 ET PANEL DISCUSSION
See Page 6

17:00 - 18:00 ET DRINKS & CANAPES RECEPTION

Event Day

TRACK 3

Outsourcing / Process Research & Scale-up

Outsourcing partnerships play an important role in enabling an organization to address key business strategies and respond to emerging trends effectively. With the growing demand of CDMOs and CMOs in the market, pharmaceutical and biotechnology companies are increasingly turning to collaborate to reduce overheads and overall costs, and speed up the drug development timelines. This track explores strategic actions and present challenges in building a successful partnership.

08:00 - 08:30 ET BREAKFAST & REGISTRATION

08:30 - 09:00 ET OPENING KEYNOTE PRESENTATION
See Page 6

09:00 - 10:00 ET ROUNDTABLE 1

Global Outsourcing: Strategies for Uncertain Times

- Managing clinical supply
- If/when/how to Tech Transfer to US

Matt Barrows
Senior Vice President, CMC & Technical Operations
Aviceda Therapeutics

ABOUT THE SPEAKER
Matt has over 25 years of leadership in CMC and is the SVP of Quality and Technical Operations at Aviceda Therapeutics. Most recently, Matt was CTO at Tome Biosciences, responsible for quality, manufacturing, and process/analytical development for the cell and gene therapy company. Prior to Tome, Matt was Executive Director, Manufacturing at Moderna, where he led the manufacturing scale-up of Spikevax and clinical manufacturing for Moderna's Personalized Cancer Vaccine, among other clinical programs. Matt served as Upstream Manufacturing Lead & Head of Operational Readiness at Alexion Pharmaceuticals and held leadership roles at Genzyme/Sanofi in Manufacturing, Process Engineering, and Quality System Remediation. He received his MBA from Northeastern University and BS in Biotechnology from Worcester Polytechnic Institute.

10:00 - 11:05 ET REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

11:10 - 12:10 ET SOLUTION FOCUS ROUNDTABLE 2

Effective Strategies for Managing Impurities During API Production of Peptides and Macrocycles

- Analytical techniques used for impurity identification and profiling
- Managing impurities during API production: workflows and strategies
- Synthesis optimization
- The role of an external partner

Johan Evenäs
Chief Executive Officer
RG Discovery

ABOUT THE SPEAKER
Johan Evenäs is CEO and co-founder of RG Discovery. He has 25 years of industrial drug discovery and development experience from AstraZeneca and RG Discovery with focus on drug discovery, medicinal chemistry, NMR and IPR. Johan holds a PhD in biophysical chemistry from Lund University, Sweden, and performed postdoctoral research at Univ. of Toronto, Canada.

12:10 - 13:10 ET NETWORKING LUNCH

12:15 - 13:15 ET ROUNDTABLE 3

Evaluating the Pros and Cons of Outsourcing CMC Activities

- Large vs. Small Biotech company considerations in outsourcing activities to CDMOs
- Access to skilled professional (and in different geographies)
- Reduce capital investment, operational and labor cost and focus to core business functions (i.e., development of pipeline)
- Identify organizations with high quality standards and regulatory compliance
- Managing timelines and other risks (i.e., delays, biosecurity act)

Gregory Papastoitsis
Chief Process and Manufacturing Officer
Ankyra Therapeutics

ABOUT THE SPEAKER
Dr. Gregory Zarbis-Papastoitsis is the Chief Process and Manufacturing Officer at Ankyra Therapeutics, an immune-oncology company, where he is responsible for all CMC activities. Prior to Ankyra, he was the EVP of Process and Manufacturing at Compass Therapeutics where he oversaw all CMC activities for a CD137 agonist, which is currently in Phase 1/2 clinical studies. Before he was the SVP of development and manufacturing at Eleven Biotherapeutics where he worked on an IL-1 inhibitor that reached pivotal clinical studies for Dry Eye Disease, and an anti-IL6 antibody (successful IND), for Macular Edema. Earlier, he was Associate Director of Process and Analytical Development at Syntonix Pharmaceuticals, where he was responsible for the early development of a long-lasting Factor IX (ALPROLIX®). He also worked on the commercial process of HUMIRA® (Abbott/Abbvie), on the purification process of ONTAK® , an IL2-diphtheria toxin fusion protein (Seragen), on the early development of an antibody-toxin conjugate (aPSMA-DM1) that reached Phase I clinical trials for prostate cancer and an aCCR2 antibody that was in Phase II clinical trials for autoimmune diseases (Millenium Pharma). He received his PhD in Biology at Binghamton University followed by 3 years of post-doctoral studies at Boston University School of Medicine investigating proteases in Alzheimer disease.

13:15 - 14:40 ET NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS

15:10 - 16:10 ET ROUNDTABLE 4

Building Scalable and Flexible CMC Strategies: Leveraging CDMO Partnerships and Digital Tools from Early Development to Commercialization

- Process Scalability Across Development Stages: How can we effectively scale up from lab to commercial manufacturing while maintaining product quality and compliance? What role can digital tools like AI, modeling, and data analytics play in reducing risk and accelerating this process?
- Adapting to Evolving Program Needs and Modalities: Designing flexible CMC strategies that can accommodate shifts in product formats, dose strengths, or device configurations across the lifecycle
- Navigating Global Regulatory and Supply Chain Complexities: Coordinating global filings and tech transfers with multiple CDMOs while addressing regional regulatory requirements, supply chain risks, and geopolitical variability
- Scaling for Global Supply: Balancing Speed, Compliance, and Cost in a Fragmented Regulatory Landscape

Vikram Sadineni
Vice President, Technical Development & Manufacturing
Generate:Biomedicines

ABOUT THE SPEAKER
Accomplished Biologics Development Leader with over 20 years of technical and strategic CMC experience spanning early-stage development through commercialization. Led development efforts for WINREVAIR®, EMPLICITI®, OPDIVO®, and KENALOG-80®. Proven track record in formulation, process development, tech transfer, and regulatory strategy for biologics and combination products. Experienced in leading high-performing teams and collaborating with global regulatory agencies to support successful IND and BLA filings. Currently Vice President of Technical Operations at Generate Biomedicines, with prior leadership roles at Merck, Acceleron, and BMS. Holds a Ph.D. in Pharmaceutical Chemistry.

16:10 - 16:30 ET AFTERNOON REFRESHMENT BREAK

16:30 - 17:00 ET PANEL DISCUSSION
See Page 6

17:00 - 18:00 ET DRINKS & CANAPES RECEPTION

Event Day

TRACK 4

Integrated Drug Development

Developing and distributing a safe and effective vaccine and therapeutic since the Covid-19 outbreak has garnered immense global interest. Exploring common CMC issues posed by the development of these products, CMC perspectives and relevant case studies that provide solutions to enable regulatory compliance, shorter review timelines, and support post-approval maintenance will be discussed in this track.

08:00 - 08:30 ET **BREAKFAST & REGISTRATION**

08:30 - 09:00 ET **OPENING KEYNOTE PRESENTATION**
See Page 6

09:00 - 10:00 ET **ROUNDTABLE 1**

Developing Robust Analytical Methods for Integrated CMC

Analytical Development Strategy:
- Phase appropriate analytical methods
- Integrated approach to developing analytical methods
- Developing platform analytical technologies
- Benefits of implementing a platform approach
- Ex: Case study

Fue Vang
Director, Analytical Development,
Candel Therapeutics

ABOUT THE SPEAKER
Speaker TBC

10:00 - 11:10 ET **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

12:15 - 13:15 ET **ROUNDTABLE 2**

Collaboration Between CMC and Clinical Teams for Seamless Development

- Strategy towards commercial filing
- Route of administration, dosage form(s), and number of patients per phase of clinical trial
- Stability constraints to help inform treatment window
- Incomplete understanding of CQAs and clinical efficacy

Daniel Peng
Vice President, Regulatory Affairs CMC
Checkpoint Therapeutics

ABOUT THE SPEAKER
Dr. Daniel Peng is currently a Vice President, Regulatory Affairs CMC at Checkpoint Therapeutics, where he is responsible for company-wide CMC regulatory strategies, global submissions and CMC regulatory compliance for both biological and small molecule programs. Prior to this, Daniel served as Director in Global Regulatory Affairs CMC at Merck for commercial biologic products post-approval global submissions. From 2010 to 2016, Daniel served as primary and secondary CMC reviewer for various types of regulatory submissions in FDA/CDER/Office of Pharmaceutical Quality (OPQ). Daniel has also worked in leading pharmaceutical companies (AstraZeneca and Shire) for product development and commercial manufacturing for 7 years. He also served as a faculty member at the College of Pharmacy, University of Tennessee Health Science Center (Memphis, TN) for 6 years. Daniel obtained his Ph.D. in Pharmaceutics from West China University of Medical Sciences (Chengdu, China).

13:15 - 14:40 ET **NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS**

15:10 - 16:10 ET **ROUNDTABLE 3**

Digital Transformation in CMC: Revolutionizing Drug Development & Manufacturing

- Data Integration and Interoperability - Legacy systems and siloed data across R&D, manufacturing, and quality units hinder seamless integration and real-time decision-making
- Change Management and Cultural Resistance - Implementing digital tools often faces pushback from teams accustomed to traditional workflows, requiring strategic change management and upskilling
- Data Integrity and Regulatory Compliance - Ensuring digital systems meet stringent GxP requirements and data integrity standards (e.g., ALCOA+) is critical but complex
- Cybersecurity and IP Protection - As more systems go online, protecting sensitive data, including proprietary formulations and process knowledge, becomes a growing concern
- Cost and ROI Uncertainty - High upfront investments in digital infrastructure and uncertainty around measurable returns can delay or limit adoption

Kwame Nti-Addae
Executive Director, Head of CMC
Frontier Medicines

ABOUT THE SPEAKER
Kwame is a pharmaceutical executive with over 15 years of experience in CMC, formulation, and process development. As Executive Director at Frontier Medicines, he leads Drug Substance, Drug Product, Analytical, and Supply Chain functions. At Lyndra Therapeutics, he played a key role in advancing long-acting oral dosage forms through pivotal trials. He has also held key roles at Ironwood, Cyclerion, and Vertex, driving preclinical and clinical programs and regulatory submissions. Known for his technical expertise, strategic leadership, and dedication to innovation and inclusion, Kwame delivers impactful results across early-stage development through to commercial readiness.

16:10 - 16:30 ET **AFTERNOON REFRESHMENT BREAK**

16:30 - 17:00 ET **PANEL DISCUSSION**
See Page 6

17:00 - 18:00 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 5

Emerging / New Modalities

Despite the reinvigorated R&D engine and reinstated productivity, challenges and opportunities remain unanswered, such as optimized druggability, pharmacokinetics and safety, enhanced bioavailability, delivery, and more. This track aims to tackle these current barriers, formulate an outlook strategy and explore the emerging modality space.

08:00 - 08:30 ET BREAKFAST & REGISTRATION

08:30 - 09:00 ET OPENING KEYNOTE PRESENTATION
See Page 6

09:00 - 10:00 ET ROUNDTABLE 1

Navigating CMC for Biologic/Small Molecule Hybrid Therapies

- Designing a phase appropriate CMC strategy
- Clinical considerations: How much, how fast, for how long?
- Regulatory strategy: Can you establish CQAs early to ease requirements in late stage?

Caitlyn Harvey
Vice President, Head of CMC
Convergent Therapeutics, Inc.

ABOUT THE SPEAKER
See Page 7

10:00 - 11:10 ET REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

Exploring Emerging Oligonucleotide Modalities and Their Implications for Therapeutic Development

- Interest has grown significantly with the recent approval of various oligos (ASO, PMO, siRNA, etc.). Since these are typically manufactured by chemical synthesis, is the existing knowledge (e.g., with small or large molecules) still applicable?
- Initial approvals are primarily in rare disease indications, so the demands are relatively low. Is the industry ready to deliver much larger quantities needed for higher patient populations (metabolic, cardiovascular, etc.)?
- Will new manufacturing technologies be needed to meet higher demands (beyond current solid-phase synthesis technology)?
- Are sufficient regulatory guidelines available to address this unique field (oligo molecules are quite large but still can be chemically synthesized like small molecules)?

Debasis Patra
Vice President, Head of CMC
OliX Pharmaceuticals, Inc.

ABOUT THE SPEAKER
Dr. Debasis Patra has doctoral and post-doctoral research experience in novel method development and total synthesis of natural products. He has been working in the pharma/biotech industry for the last 25 years, leading teams of scientists and engineers for the process development and manufacturing of small molecules, peptides, oligonucleotides, etc. Currently he is heading the CMC team at OliX Pharmaceuticals and is responsible for all activities related to drug substance and drug product development and manufacturing to support multiple clinical stage programs (Phase 1/2) in several disease areas, such as ophthalmology, metabolic, dermatology, hair loss, etc.

12:15 - 13:15 ET ROUNDTABLE 3

Cell and Gene Therapies: CMC Challenges and Potential Solutions

- Process variability: Cell and gene therapies often exhibit significant variability due to the biological nature of the products, making it difficult to establish consistent manufacturing processes
- Analytical development: Developing robust assays for potency, purity, and stability can be challenging due to the novel nature of these therapies
- Regulatory Compliance: Ensuring compliance with evolving regulatory requirements can be challenging, especially with the expedited development of breakthrough therapies

Yu Qian
Director, Head of Analytical Project Leads, Cell Therapies
Novartis

ABOUT THE SPEAKER
Yu is the Head of the Cell Therapy Analytical Project team at Novartis. With a background in Immunology and Cancer Immunology, Yu has extensive experience in Analytical Development for Cell Therapies. Yu has a proven track record in developing integrated analytical strategies and guiding teams in creating fit-for-purpose assays to drive innovation and support various cell therapy modalities at different stages. Before joining Novartis, Yu was the Director of Cell Therapy CMC Analytical Innovation and Product Sciences at Takeda Pharmaceuticals and co-founded a start-up prior to joining Takeda.

13:15 - 15:10 ET NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS

16:10 - 16:30 ET AFTERNOON REFRESHMENT BREAK

16:30 - 17:00 ET PANEL DISCUSSION
See Page 6

17:00 - 18:00 ET DRINKS & CANAPES RECEPTION

Event Day

TRACK 6

Drug Substance, Drug Product, Drug Delivery

Developing and distributing a safe and effective vaccine and therapeutic since the Covid-19 outbreak has garnered immense global interest. Exploring common CMC issues posed by the development of these products, CMC perspectives and relevant case studies that provide solutions to enable regulatory compliance, shorter review timelines, and support post-approval maintenance will be discussed in this track.

08:00 - 08:30 ET **BREAKFAST & REGISTRATION**

08:30 - 09:00 ET **OPENING KEYNOTE PRESENTATION**
See Page 6

09:00 - 10:00 ET **ROUNDTABLE 1**

Enhancing Drug Solubility, Stability, and Drug Delivery

- BCS classification: When does enhancing solubility help absorption/ exposure?
- Techniques to improve solubility and their pros/cons + solubility enhancement tools for early preclinical work vs. clinical/commercial planning
- Stability prediction tools
- Stability enhancement tools and their application
- Drug delivery toolkit for small and complex molecules and recent advances

Mahesh Padval
Chief Pharmaceutical Development Officer
Relay Therapeutics

ABOUT THE SPEAKER

As Chief Pharmaceutical Development Officer, **Mahesh Padval** guides transition of the Company's late research assets into development and oversees pharmaceutical development activities to support regulatory filings and product commercialization. Mahesh brings to Relay Therapeutics nearly 30 years of product development experience in the pharmaceutical industry. Prior to joining Relay Therapeutics, Mahesh was vice president of pharmaceutical sciences and product development at Verastem, Inc. There, he was responsible for preclinical development, CMC and clinical pharmacology activities in support of the company's development programs through non-clinical, clinical development and regulatory filings, including the approval and commercial launch of COPIKTRA TM. Prior to Verastem, Mahesh held roles of increasing responsibility at Zalicus, Inc., culminating in his role as vice president of preclinical development and formulations. He also held roles at Charles River Discovery and Development Services and Genzyme Transgenics Corporation. Mahesh holds a Ph.D. and M.S. in industrial pharmacy from Massachusetts College of Pharmacy, CSS in administration and management from Harvard University and a Bachelor of Pharmacy from the University of Bombay, India.

10:00 - 11:10 ET **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

11:10 - 12:10 ET **ROUNDTABLE 2**

Understanding the Growing Role of Drug-Device Combination Products and Delivery Systems

Vikram Sadineni
Vice President, Technical Development & Manufacturing
Generate:Biomedicines

ABOUT THE SPEAKER
See Page 10

12:15 - 13:15 ET **ROUNDTABLE 3**

CMC for Oral Drug Delivery: Navigating the Challenges of Bioavailability and Controlled Release

Suresh Tipparaju
Director, Product Development and Clinical Supply
Alexion-AstraZeneca Rare Disease

ABOUT THE SPEAKER

Dr. Suresh Tipparaju is Director of Product Development and Clinical Supply at Alexion-AstraZeneca Rare Disease. He leads development strategy for a portfolio of APIs comprising small molecules, synthetic peptides, and oligonucleotides from early clinical stages up to commercial validation. Over his 15 years of experience in pharmaceutical development and CMC, Suresh was a key contributor and author of marketing applications for four approved medicines currently helping patients in need: Onivyde, Livtencity, Voydeya, and Beyonttra. Before joining AstraZeneca, Suresh worked at Takeda, Shire, and Merrimack Pharmaceuticals. Dr. Tipparaju obtained his PhD in organometallics from the National Chemical Laboratory, India, and was a postdoctoral associate in Nobel laureate (late) Prof. Herbert C. Brown's lab at the Herbert C. Brown Center for Borane Research at Purdue University, IN. Dr. Tipparaju published over 20 research articles in prestigious peer-reviewed journals and is an inventor on 10 patents. His research interests are in all aspects of CMC and pharmaceutical development.

13:15 - 15:10 ET **NETWORKING LUNCH & NETWORKING / 1-1 MEETINGS**

15:10 - 16:10 ET **ROUNDTABLE 4**

CMC Strategies to Reduce Dosing Frequency: Overcoming Challenges in Drug Substance Formulation and Delivery

Reducing dosing frequency enhances patient adherence and convenience while unlocking differentiation, lifecycle management, and market access opportunities.
Key issues:

- **Optimizing drug substance properties for extended dosing intervals**
- **Developing formulations for controlled-release and high-volume solutions**
- **Innovating delivery devices to handle large doses with less invasiveness**
- **Aligning CMC strategies across drug substance, formulation, and devices**
- **Tackling regulatory, scalability, and commercialization challenges**

Yumiko Mizuno
Head, Plasma-Derived Therapies (PDT) Drug Product Development
Takeda

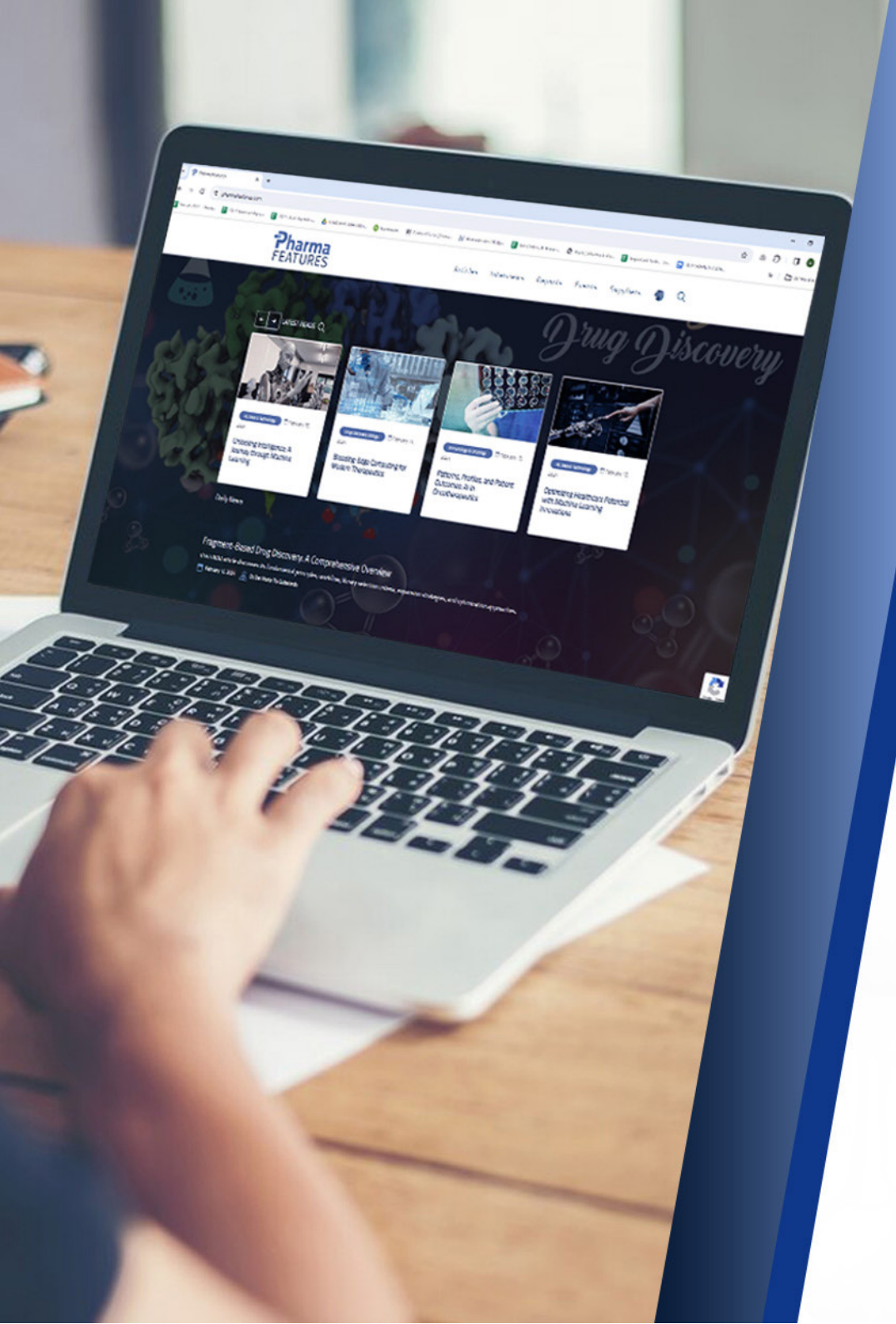
ABOUT THE SPEAKER

Dr. Yumiko Mizuno is the Head of Plasma-Derived Therapies Drug Product Development at Takeda, where she is responsible for all activities related to drug product and combination product development, as well as leading the early-stage portfolio. With over 14 years of experience in R&D CMC at Takeda, she brings deep expertise across all phases of development for a range of modalities. Dr. Mizuno has a proven track record of successfully leading diverse cross-functional and cross-regional teams, fostering collaboration, innovation, and excellence. Previously, she led global R&D strategic planning and change management at Takeda, developing practical skill sets in portfolio strategy and management.

16:10 - 16:30 ET **AFTERNOON REFRESHMENT BREAK**

16:30 - 17:00 ET **PANEL DISCUSSION**
See Page 6

17:00 - 18:00 ET **DRINKS & CANAPES RECEPTION**



Pharma
FEATURES

Find your new partner,
explore our digital storefronts

www.pharmafeatures.com

Contact us to discuss how we can help generate growth for your business

Dex Marco Guibelondo
Marketing Content Writer, Proventa International
Editor-in-Chief, PharmaFEATURES

dex@proventainternational.com

2025 Strategy Meeting Calendar

MAY

Boston/Cambridge MA - US East Coast

MAY 7 WED
CHEMISTRY MANUFACTURING CONTROL
CMC Strategy Meeting 2025
Le Meridien Boston Cambridge

MAY 8 THUR
MEDICINAL CHEMISTRY
Medicinal Chemistry Strategy Meeting 2025
Le Meridien Boston Cambridge

MAY 7-8 WED&THUR
VENTURE CAPITAL PRIVATE EQUITY
Venture Capital & Private Equity
Le Meridien Boston Cambridge

Princeton/New Jersey - US East Coast

MAY 14 WED
MEDICINAL CHEMISTRY
Medicinal Chemistry Strategy Meeting 2025
Hyatt Regency Princeton

MAY 15 THUR
CLINICALOPERATIONS & CLINICALTRIALSUPPLYCHAIN
Clinical Operations & Clinical Trial Supply Chain Strategy Meeting 2025
Hyatt Regency Princeton

MAY 14&15 WED&THUR
VENTURE CAPITAL PRIVATE EQUITY
Venture Capital & Private Equity
Hyatt Regency Princeton

OCTOBER

London/UK - Europe

OCT 9 THUR
CLINICALOPERATIONS & CLINICALTRIALSUPPLYCHAIN
Clinical Operations & Clinical Trial Supply Chain Strategy Meeting 2025
Crowne Plaza, London Docklands

OCT 15 WED
BIOINFORMATICS & DRUG DISCOVERY BIOLOGY
Bioinformatics & Drug Discovery Biology Strategy Meeting 2025
Crowne Plaza, London Docklands

OCT 16 THURS
MEDICINAL CHEMISTRY
Medicinal Chemistry Strategy Meeting 2025
Crowne Plaza, London Docklands

NOVEMBER

San Diego - US West Coast

NOV 12 WED
MEDICINAL CHEMISTRY
Medicinal Chemistry Strategy Meeting 2025
Hard Rock Hotel San Diego

NOV 13 THUR
CLINICALOPERATIONS & CLINICALTRIALSUPPLYCHAIN
Clinical Operations & Clinical Trial Supply Chain Strategy Meeting 2025
Hard Rock Hotel San Diego

Boston/Cambridge MA - US East Coast

NOV 18 TUE
CLINICALOPERATIONS & CLINICALTRIALSUPPLYCHAIN
Clinical Operations & Clinical Trial Supply Chain Strategy Meeting 2025
Le Meridien Boston Cambridge

NOV 19 WED
BIOINFORMATICS & DRUG DISCOVERY BIOLOGY
Bioinformatics Strategy Meeting 2025
Le Meridien Boston Cambridge

CHEMISTRY, MANUFACTURING & CONTROLS

STRATEGY MEETING EAST COAST USA 2025

Wednesday, 7th May 2025 Le Meridien Cambridge

Hotel & Venue

Le MERIDIEN

Le Méridien Boston Cambridge

Le Méridien Cambridge-MIT's elegant guest rooms and suites offer a place of luxurious sanctuary and unmatched comfort. Explore unique programs inspired by the brand's European heritage. Born in a glamorous era of travel, Le Méridien believes everyone should explore the world in style.

Hotel Details >

Map & Directions >

STRATEGY DINNER & INNOVATION SPOTLIGHT SESSION 2025

MAY 21-22

ESKO BRAND SUMMIT

INNNOVATION SPOTLIGHT 2025

Brussels, Belgium

JUNE 24

REVVITY SIGNALS

STRATEGY DINNER

STK San Francisco,1 Market St Suite M3,San Francisco,

Learn more about our Strategy Meetings

www.proventainternational.com