BOOK NOW!

Proventa International's 1st Annual

CHEMISTRY, MANUFACTURING & CONTROLS

STRATEGY MEETING EAST COAST USA 2023

18th May 2023, Thursday | **Le Meridien Cambridge**

The premier meeting for all East Coast USA CMC professionals

Featuring Industry Leaders and Decision Makers:

Mahesh Padval
Chief Pharmaceutical Development Officer
Relay Therapeutics

Seshu Tyagarajan
Chief Technical and Development Officer
Candel Therapeutics

Sheila Mathias
Chief Scientific Officer
Virpax Pharmaceuticals, Inc.

Niels Svenstrup
Senior Vice President, Chemistry & Manufacturing
PepGen

George Wu
Vice President, CMC
Enanta Pharmaceuticals

Kristen Manion
Vice President, Head of Regulatory Affairs, Quality and Manufacturing
Paratek Pharmaceuticals

Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

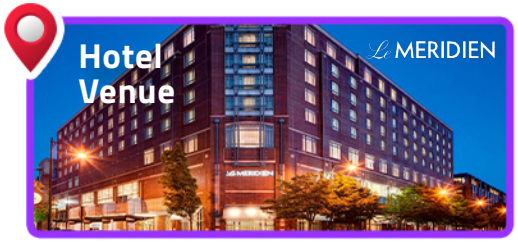
Pradeep Sharma
Global Head, Pharmaceutical & Technical Ops, Small Molecule & Oligonucleotides
Takeda

20 ROUNDTABLE DISCUSSIONS

5 TRACKS

2 KEYNOTE PRESENTATIONS

1 LOCATION



What Makes Our Strategy Meetings So Unique?

Proud to Partner with: aragen, alcami, indena, PORTON, Glenmark, Kingchem, cytiva, eurofins, GlycoSyn, MilliporeSigma, 浙江天宇药业股份有限公司

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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.

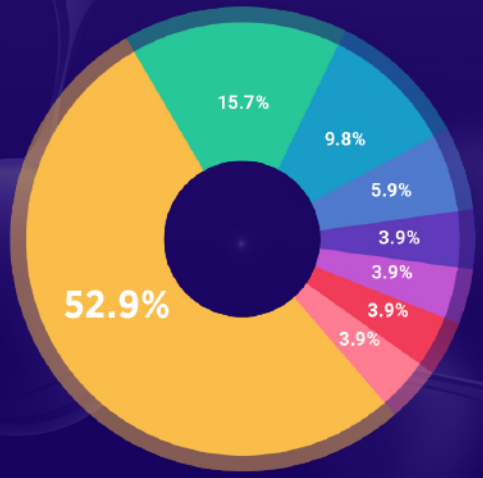
PERSONALISED AGENDA
Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time spent is focused and well-utilised.

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

Facilitator Faculty

Ian O'Reilly
Vice President, Head of Quality
Tessera Therapeutics

Seshu Tyagarajan
Chief Technical and Development Officer
Candel Therapeutics

Ganfeng Cao
Vice President and Head of Process Chemistry, CMC
Prelude Therapeutics

George Wu
Vice President, CMC
Enanta Pharmaceuticals

Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

Abizer Harianawala
Vice President, CMC
Cyteir Therapeutics

Jamie Gillette
Vice President, Head of Regulatory
Cullinan Oncology

Kelly Neelon
Vice President, CMC and Technical Operations
Vigil Neuroscience

Kristen Manion
Vice President, Head of Regulatory Affairs, Quality and Manufacturing
Paratek Pharmaceuticals

Mahesh Padval
Chief Pharmaceutical Development Officer
Relay Therapeutics

Niels Svenstrup
Senior Vice President, Chemistry & Manufacturing
PepGen

Pradeep Sharma
Global Head, Pharmaceutical & Technical Ops, Small Molecule & Oligonucleotides
Takeda

Art Faulkner
Vice President, Regulatory CMC
TG Therapeutics, Inc.

Sheila Mathias
Chief Scientific Officer
Virpax Pharmaceuticals, Inc.

Vimal Patel
Vice President, Head of CMC
Orum Therapeutics

Yanhuai (Richard) Ding
Head, Purification Process Development, Gene Therapy
Biogen

How Has Our STRATEGY MEETINGS Benefit The Life Science Industry

> *One-to-one meeting was useful that I could throw-in a lot of detailed questions and have clearer insights about offerings. I totally appreciate that."*
>
> **Sakthivel Sekar** - *Chief Executive Officer*, Sinopsee Therapeutics

> *I think in the small group setting where we were located a roundtable, it was really interesting to hear the perspective from the rest of industry."*
>
> **Serene Ong** - *Vice President, Commercial operations,Asia Pacific*, Marken

2023 Sponsors

CO-HOST SPONSORS

Aragen Life Sciences is a leading R&D and manufacturing solutions provider for the life sciences industries worldwide. We offer end-to-end integrated or standalone solutions for small and large molecules. Established in 2001, we now operate through our network of sites located globally with a team of 3700+ scientists and 475+ PhDs. Our expertise and experience have enabled over 450+ customers in advancing their research programs from discovery through commercialization. Aragen's innovative mindset, infrastructure, flexible business models have enabled us to serve large pharma or biotech, agrochemical, animal health and performance chemical industries globally. All our facilities conform to stringent regulatory standards. Our infrastructure has a built-up area of 1.2 million square feet, housing chemistry and biology labs, AAALAC-accredited animal houses, analytical labs, formulation development labs, kilo labs, pilot plants and manufacturing facilities. Aragen has been inspected by all leading regulatory agencies of the world, including USFDA, WHO, PMDA, EDQM and EMEA. Aragen has submitted its letter of intent to the Science Based Targets initiative (SBTi) and is part of a growing list of organizations that are committed to setting emission reduction targets in line with the Paris Agreement to limit global warming. It is also a signatory to the GRI South Asia Charter on Sustainability Imperatives, a framework that helps to realize the 17 Sustainable Development Goals (SDGs) defined by the United Nation. We are proud to be a Great Place to Work® (GPTW) certified company for the third consecutive year in 2022. This recognition confirms our High-Trust, High-Performance Culture™ and places us among 'companies with the best culture' to work with. For more details, visit www.aragen.com

Alcami and Masy BioServices serve pharmaceutical and biotech companies of all sizes for small molecules and biologics, providing customizable and innovative solutions for analytical development, clinical to commercial sterile and oral solid dose drug product manufacturing, packaging, microbiology, cGMP biostorage, environmental monitoring, and pharmaceutical support services, leveraging 675,000 ft^2 across five US-based scientific campuses. Visit us online at alcaminow.com and masy.com.

Indena is the leading company dedicated to the identification, development and production of high quality active principles derived from plants, for use in the pharmaceutical industry. CDMO activities are the priority in Indena's strategic vision. Today, Indena has a multipurpose GMP plant equipped with reactor ranging from 250 lt to 10,000 lt (Stainless Stell, Hastelloy, Glass-lined); a kilo lab LK2 to offer different capacities for products at the highest containment level (OEL 20 ng/m3 or OEB5); two spray dryers, large and a mid-size, working with organic solvents; a 20-liter hydrogenator being complemented by a 250-liter hydrogenator (ready at the end of 2023) to satisfy a wider demand for this kind of chemistry.

Porton Pharma With over 5,000 customer-centric employees, operations and commercial offices across the US, EU and China, Porton Pharma Solutions Ltd. provides global pharmaceutical companies with innovative, reliable and end-to-end process R&D and manufacturing services across small molecule APIs, dosage forms and biologics.

Our Process Technology Centers and Manufacturing Facilities feature state-of-the-art equipment, highly flexible cGMP-compliant production assets, and a proven program management system dedicated to seamlessly delivering successful outcomes for your unique project requirements.

By efficiently advancing development and enabling commercialization of multiple high-impact therapies, Porton is proud to have earned the trust of some of the world's leading and most innovative pharmaceutical companies and many biotechnology companies across the world.

GLS's CDMO services compliments the core strength in chemical synthesis of API's .GLS focusses upon catering to only the drug substance of the pharma value chain leveraging the prior experience in small molecule heterocyclic chemistry, Chiral chemistry, High Potent & Oncology products.
GLS goal is to provide value addition to its partner organizations –

- Chemistry solutions to critical problems in product development
- life cycle management
- identifying high value intermediates, KSM
- cost leadership in select products
- Early entrant to key products

In the process of product development, the IP generated will belong to the customer and it is at the customer's discretion to recognise GLS efforts in the patents. This approach illustrates GLS flexibility to work with external customers who are involved in creating IP around their product.

With a highly experienced chemistry team, GLS is confident of value addition to its partners and maintain a long term relationship. The strong R&D team which is well supported by a strong regulatory, IP and manufacturing teams, GLS is hopeful to create a meaning full impact in the CDMO segment.

KEY OPINION LEADERS

Agenda at a Glance

CHEMISTRY, MANUFACTURING & CONTROLS
STRATEGY MEETING EAST COAST USA 2023
18th May 2023, Thursday | Le Meridien Cambridge

TIME ET	TRACK 1 INTERMEDIATES & API	TRACK 2 TECHNOLOGY TRANSFER & ANALYTICAL	TRACK 3 INTEGRATED DRUG DEVELOPMENT	TRACK 4 PROCESS RESEARCH & SCALE-UP	TRACK 5 OUTSOURCING
BOARDROOM ►	Jerome C. Hunsaker C	Jerome C. Hunsaker B	Jerome C. Hunsaker A	Lan Jen Chu	Margaret L.A. Macvicar
08:00 - 08:30	BREAKFAST & REGISTRATION				
08:30 - 09:00	OPENING KEYNOTE PRESENTATION Proactive Leadership in the Sciences  PRESENTER: Ian O'Reilly, *Vice President, Head of Quality*, Tessera Therapeutics				
09:00 - 10:00	**Evolution of CMC: Tackling the Challenges and Opportunities of Rare Disease Drug Development**  Niels Svenstrup, *Senior Vice President, Chemistry & Manufacturing*, PepGen	**Finding Tactical Approaches in Accelerating CMC Filing and Review Activities**  Seshu Tyagarajan, *Chief Technical and Development Officer*, Candel Therapeutics	**Lessons Learned and Ongoing Effort: Development of Vaccines and Therapeutics in Response to Covid-19**  Gopi Vudathala, *Global Head, Regulatory Affairs CMC*, Incyte Corporation	**Key Considerations for Sterile Drug Product Development for the Marketplace**  Vimal Patel, *Vice President, Head of CMC*, Orum Therapeutics	**Strategies for Monitoring the Quality of Outsourced Work – The Vulnerabilities Involved and How to Identify New Strategic Partnership**  Kelly Neelon, *Vice President, CMC and Technical Operations*, Vigil Neuroscience
10:00 - 10:10	REFRESHMENT BREAK				
10:10 - 10:30	NETWORKING / 1-1 MEETINGS				
10:30 - 10:50	NETWORKING / 1-1 MEETINGS				
10:50 - 11:10	NETWORKING / 1-1 MEETINGS				
11:10 - 12:10	**Mitigating Risks Associated with API Suppliers**  Pradeep Sharma, *Global Head, Pharmaceutical & Technical Ops, Small Molecule & Oligonucleotides*, Takeda	**What Are the Key Success Factors for a Timely and Successful Technology Transfer?**  Abizer Harianawala, *Vice President, CMC*, Cyteir Therapeutics	**Early Stage CMC Development Strategy to Speed IND**  Sheila Mathias, *Chief Scientific Officer*, Virpax Pharmaceuticals, Inc.	**Building an Effective CMC Strategy for Commercial Readiness in Clinical Stage Companies**  Mahesh Padval, *Chief Pharmaceutical Development Officer*, Relay Therapeutics	**How to Create a Partnership for "One-Stop-Shop" with a CDMO in the Current Landscape (considering post-COVID, etc.)**  Kristen Manion, *Vice President, Head of Regulatory Affairs, Quality and Manufacturing*, Paratek Pharmaceuticals
12:10 - 13:10	NETWORKING LUNCH				
13:10 - 14:10	**What is "Fit for Purpose" Process Research & Scale-Up of Small Molecule API?**  Ganfeng Cao, *Vice President and Head of Process Chemistry, CMC*, Prelude Therapeutics	**Innovations in Quality Technology - What's Worth Investing In and What Isn't?**  Jamie Gillette, *Vice President, Head of Regulatory*, Cullinan Oncology	**Exploring CMC Regulatory Challenges in Accelerated Product Development and Commercialization**  Art Faulkner, *Vice President, Regulatory CMC*, TG Therapeutics, Inc.	**Effective Scale-Up Strategies for Transition from Development to Manufacturing Scale**  Yanhuai (Richard) Ding, *Head, Purification Process Development, Gene Therapy*, Biogen	**Speeding Up Discovery with the Right CRO Partner**  George Wu, *Vice President, CMC*, Enanta Pharmaceuticals
14:10 - 14:20	REFRESHMENT BREAK				
14:20 - 14:40	NETWORKING / 1-1 MEETINGS				
14:40 - 15:00	NETWORKING / 1-1 MEETINGS				
15:00 - 15:20	NETWORKING / 1-1 MEETINGS				
15:20 - 15:50	CLOSING KEYNOTE PRESENTATION Establishing a Comprehensive, Reliable CMC Strategy to Develop Robust Cell and Gene Therapy Products  PRESENTER: Seshu Tyagarajan, *Chief Technical and Development, Officer*, Candel Therapeutics				
15:50 - 16:50	DRINKS & CANAPES RECEPTION				

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**

Proactive Leadership in the Sciences

- Humanistics in the 21st century biotech
- How to show up, motivate and engage
- CMC: the whole is the sum of all parts

Ian O'Reilly
Vice President, Head of Quality
Tessera Therapeutics

ABOUT THE SPEAKER

Ian O'Reilly, Vice President, Head of Quality at Tessera Therapeutics, spent the last two decades refining his approach to Quality and CMC, working on increasingly novel approaches with the therapeutic goal of curing humans of disease. Ian has lived and worked in the U.S., Europe, and Asia, focusing on how to best foster a QMS and CMC ecosystem to support end users' successes. With science continuing to outpace regulatory guidance and precedents, a united quality-minded scientific community is more important than ever.

When not running and hiking very long distances, Ian can be found with his amazing family and team.

15:20 - 15:50 ET **CLOSING KEYNOTE PRESENTATION**

Establishing a Comprehensive, Reliable CMC Strategy to Develop Robust Cell and Gene Therapy Products

- Explore and understand the importance of having a clear CMC strategy in the development and commercialization of cell and gene therapies (CGT)
- Addressing key CMC issues in CGT to ensure regulatory compliance
- Best practices to achieve regulatory and pre-launch success
- Developing an integrated plan and executing on the plan
- The commercial outlook

Seshu Tyagarajan
Chief Technical and Development Officer
Candel Therapeutics

ABOUT THE SPEAKER

Dr. Seshu Tyagarajan is the Chief Technical and Development Officer at Candel Therapeutics. She has two decades of technical, manufacturing and development experience in Biologics and Cell & Gene therapies. Prior to Candel, she was Global Head, CMC Strategy for CGT at Novartis where she developed the clinical and commercial manufacturing strategy for T-Charge™(CAR-T). She successfully led several BLAs and INDs and was a key contributor to the groundbreaking BLA submission for Kymriah®.

Seshu held roles of increasing responsibility at Merck, Roche, Phyton, Biogen and Lilly. She holds a Ph.D. in Chemical and Biochemical Engineering (Rutgers), and MS in Bioengineering (Purdue).

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**

Evolution of CMC: Tackling the Challenges and Opportunities of Rare Disease Drug Development

- In exploring and developing new modality drugs to treat rare diseases, how do you build the necessary know-how (internally and externally), and how do you balance the need for speed in development with the foundational work needed to prepare a new modality drug for IND?
- What are the challenges of Rare Disease CMC development (e.g. in terms of material planning, stability, batch size, distribution and so on)
- What are the challenges from a CMC perspective of running trials in rare diseases?
- Are there any regulatory hurdles that are putting Rare Disease programs at a disadvantage compared to non-Rare indications, and how do you deal with those?

Niels Svenstrup
Senior Vice President, Chemistry & Manufacturing
PepGen

ABOUT THE SPEAKER

Niels Svenstrup currently serves as Senior Vice President of Chemistry and Manufacturing at PepGen. Niels has more than 20 years of Pharma and Biotech industry experience in Pharmaceutical Research & Development and his work has resulted in the invention of numerous drug candidates of which several are currently in clinical development. Prior to joining PepGen he served in a variety of R&D leadership roles including SVP Development at Cydan, Director of CMC at Ascendis Pharma, Head of Department, Medicinal Chemistry at H. Lundbeck A/S, and R&D Project Leader at Bayer Pharma.

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

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

Mitigating Risks Associated with API Suppliers

- Key starting material supply risks
- Manufacturing issues
- Quality and compliance issues
- Meeting the timelines

Pradeep Sharma
Global Head, Pharmaceutical & Technical Ops, Small Molecule & Oligonucleotides, Takeda

ABOUT THE SPEAKER

Pradeep Sharma is an accomplished CMC leader in pharmaceutical industry with experience in CDMOs, Generic drug manufacturing, New Chemical entities (NCEs) including commercial process development, preformulation studies, solid oral dosage development, optimization, managing product life cycle etc. Authored multiple DMFs, INDs, IMPDs, CTAs, NDAs, MAAs, PMDAs, etc. for Global market approvals. Recently led CMC teams for submissions and approvals of multiple NCEs: Ridaforolimus, ponatinib, brigatinib, mobocertinib, maribavir. Presently employed at Takeda Pharmaceuticals Co. Intl. Co. Ltd., Cambridge, MA.

12:10 - 13:10 ET **NETWORKING LUNCH**

13:10 - 14:10 ET **ROUNDTABLE 3**

What is "Fit for Purpose" Process Research & Scale-Up of Small Molecule API?

- Start process research activities as early as the preclinical/prenomination stages
- Build your process research team (internal/external) early
- Regulatory and Quality colleagues are always best friends
- Budgeting can be harder than Chemistry

Ganfeng Cao
Vice President and Head of Process Chemistry, CMC
Prelude Therapeutics

ABOUT THE SPEAKER

Ganfeng Cao is Vice President and Head of Process Chemistry, CMC at Prelude Therapeutics. Prelude Therapeutics is a public, and clinical-stage biopharmaceutical company designing and developing a pipeline of novel, small molecule therapies that precisely target the key drivers of cancer cell growth and resistance.

Prior to Prelude, he worked for Incyte Corporation for over 14 years as a medicinal chemist and then process chemist. Ganfeng received his Ph.D. in organic chemistry from the University of Michigan, Ann Arbor.

14:10 - 15:20 ET **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

15:20 - 15:50 ET **CLOSING KEYNOTE PRESENTATION**
See Page 6

15:50 - 16:50 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**

Finding Tactical Approaches in Accelerating CMC Filing and Review Activities

- Accelerated approval means shortened CMC Pathways
- Phase appropriate CMC concerns with no impact to safety, efficacy, quality
- Specific topics: small scale models, methods, comparability, stability

Seshu Tyagarajan
Chief Technical and Development Officer
Candel Therapeutics

ABOUT THE SPEAKER

Dr. Seshu Tyagarajan is the Chief Technical and Development Officer at Candel Therapeutics. She has two decades of technical, manufacturing and development experience in Biologics and Cell & Gene therapies. Prior to Candel, she was Global Head, CMC Strategy for CGT at Novartis where she developed the clinical and commercial manufacturing strategy for T-Charge™(CAR-T). She successfully led several BLAs and INDs and was a key contributor to the groundbreaking BLA submission for Kymriah®. Seshu held roles of increasing responsibility at Merck, Roche, Phyton, Biogen and Lilly. She holds a Ph.D. in Chemical and Biochemical Engineering (Rutgers), and MS in Bioengineering (Purdue).

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

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

What Are the Key Success Factors for a Timely and Successful Technology Transfer?

- Best practices for a successful technology transfer
- Importance of gap analysis and risk assessments
- Challenges and possible solutions for successful transfer
- When should technology transfer occur?

Abizer Harianawala
Vice President, CMC
Cyteir Therapeutics

ABOUT THE SPEAKER

Abizer Harianawala is currently the Vice president of CMC at Cyteir Therapeutics. He has 25 plus years of extensive CMC experience in development and commercialization of oral and parenteral products. He has led CMC and supply chain activities for nine products across a range of therapeutic areas that are sold globally. Prior to joining Cyteir, he worked at Stevanato, Taris Biomedical, Ariad, Zalicus, Genzyme and Bristol-Myers Squibb. He received his Ph.D. in Pharmaceutics from the University of Connecticut.

12:10 - 13:10 ET **NETWORKING LUNCH**

13:10 - 14:10 ET **ROUNDTABLE 3**

Innovations in Quality Technology - What's Worth Investing In and What Isn't?

- Where do we find the most value for new technology? If you could automate any portion of your job, what would it be?
- What's the value of AI over people? Where does AI really make the best sense?
- Can evolution in lab technology seamlessly connect to existing QA/QC systems and is it worth the cost to retrofit?

Jamie Gillette
Vice President, Head of Regulatory
Cullinan Oncology

ABOUT THE SPEAKER

Jamie Gillette is Vice President, Head of Regulatory Affairs at Cullinan Oncology of Cambridge, Massachusetts. She is responsible for Regulatory strategy and operations for all Cullinan pipeline products. Jamie possesses 20+ years of global drug development, clinical trials, and Regulatory experience and has held leadership positions at multiple organizations in the biopharmaceutical industry. She has experience throughout the product life cycle, from INDs through Marketing Applications and across multiple therapeutic areas including oncology, inflammation, and vaccines. As a community leader, Jamie has been an instructor and avid student in Budo Taijutsu for over 10 years. She is also Vice President of the Howard County Veterans Foundation whose mission is to develop and construct the Howard County Veterans Monument in Columbia, Maryland.

14:10 - 15:20 ET **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

15:20 - 15:50 ET **CLOSING KEYNOTE PRESENTATION**
See Page 6

15:50 - 16:50 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 3

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

Lessons Learned and Ongoing Effort: Development of Vaccines and Therapeutics in Response to Covid-19

- Discovery to Development to Commercial
- Speed to Market
- What lessons have we learned?
- How do we position ourselves for the next crisis?

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 25 NDA and BLA approvals and 50 INDs. Dr. Vudathala has had numerous interactions with global regulators on project related CMC matters as well as on key ICH initiatives.

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

11:10 - 12:10 ET ROUNDTABLE 2

Early Stage CMC Development Strategy to Speed IND

- Early Evaluation of genotoxic impurities
- Robust Quality Systems for effectively manage Corrective and Preventive Actions (CAPAs)
- Identify a (optimized) chemical lead early.
- Druggability assessment
- Early CMC risks assessments

Sheila Mathias
Chief Scientific Officer
Virpax Pharmaceuticals, Inc.

ABOUT THE SPEAKER

Dr. Sheila A. Mathias has more than 20 years of leadership experience in the pharmaceutical industry accelerating drug development. She brings extensive global regulatory affairs strategic guidance and clinical development experience having worked across a range of therapeutics areas, including pain management, addiction medicine, and dermatology. This experience has spanned across big pharma, mid-sized, to start-up biotechnology companies. Most recently, she held the position Senior Director Global Regulatory Affairs at Sun Pharma Advanced Research Company.

12:10 - 13:10 ET NETWORKING LUNCH

13:10 - 14:10 ET ROUNDTABLE 3

Exploring CMC Regulatory Challenges in Accelerated Product Development and Commercialization

- Establishing acceptance criteria with limited data set
- Use of limited stability data to support expiry period
- Establishing process controls with limited manufacturing experience
- Managing a product formulation that may not be optimized
- Potential use of clinical/pilot manufacturing sites for commercial launch

Art Faulkner
Vice President, Regulatory CMC
TG Therapeutics, Inc.

ABOUT THE SPEAKER

Art Faulkner is a Vice President Regulatory CMC at TG Therapeutics. Previously, he was a Sr. Director Regulatory CMC at Edge Therapeutics and at Hurley Consulting. Prior to this, he was a Director in Global CMC at Pfizer, and he worked at Merck prior to joining Pfizer. He has worked in the pharmaceutical industry for over 35 years with 25 years of experience in Regulatory CMC. He managed CMC strategy and execution to support global registrations of antibody products and small molecules in various dosage forms, with complimentary experience with devices.

14:10 - 15:20 ET REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

15:20 - 15:50 ET CLOSING KEYNOTE PRESENTATION
See Page 6

15:50 - 16:50 ET DRINKS & CANAPES RECEPTION

Event Day

TRACK 4

Process Research & Scale-up

Scaling up production remains one of the biggest challenges in pharma manufacturing. Designing processes and scale-up those processes from a process research, ensuring those processes are scaled-up efficiently. As such, it is important to ensure that the necessary steps and evaluations are carried out in order to manage complexities and reduce timelines. This track will take a closer look at effective strategies you will have to consider for a successful scale-up of your product's manufacturing process.

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 Considerations for Sterile Drug Product Development for the Marketplace

- Facility design and classified area considerations based on type of DP and container closure
- Formulation development and stability of drug product
- Sterilization process & validation
- Quality risk management
- Continuous improvement

Vimal Patel
Vice President, Head of CMC
Orum Therapeutics

ABOUT THE SPEAKER

Vimal is currently Vice President, Head of CMC at Orum Therapeutics. Orum is a clinical-stage biotechnology company whose goal is to bring life-changing therapies to patients by combining the power of the emerging field of protein degraders with precision of antibodies to generate a broad portfolio of highly differentiated product candidates.

Vimal brings over 20 years of experience in development and manufacturing of mAbs, ADCs, radiopharmaceuticals and small molecules. Previously, Vimal held roles of increasing responsibility with Process Development and Manufacturing Sciences at Daiichi Sankyo, Actinium Pharmaceuticals, Pfizer and Progenics Pharmaceuticals.

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

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

Building an Effective CMC Strategy for Commercial Readiness in Clinical Stage Companies

- How early do you start planning commercial readiness
- Mapping out DS and DP strategy during clinical development
- Selection of CMO/CDMO and their capabilities to align with potential clinical/commercial plans
- Cross functional inputs and alignment for CMC strategy
- Role of reg CMC and planned regulatory interactions during clinical development for commercial readiness

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 27 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.

12:10 - 13:10 ET **NETWORKING LUNCH**

13:10 - 14:10 ET **ROUNDTABLE 3**

Effective Scale-Up Strategies for Transition from Development to Manufacturing Scale

- What are current challenges and solutions from mAb, vaccine, and AAV from PD to MFG?
- What are unique properties for AAV process development from cell line development, upstream, downstream to analytic methods?
- Can platform process be applied for AAV purification?

Yanhuai (Richard) Ding
Head, Purification Process Development, Gene Therapy
Biogen

ABOUT THE SPEAKER

Yanhuai (Richard) Ding is currently the head of purification process development for gene therapy. He worked in multiple biotech companies such as ThermoFisher, Shire HGT, Lonza, AnaptysBio. He earned his Ph.D. in biochemistry and molecular biology in 2000 from Waikato University, New Zealand. He had over 20 years' experience in purification process development, technology transfer, manufacturing support, viral clearance (Phase I-III), process characterization & validation, regulatory filing (IND) from mAbs, Fabs, enzymes, vaccine, Collagen 7, biosimilars, and/or AAVs.

14:10 - 15:20 ET **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

15:20 - 15:50 ET **CLOSING KEYNOTE PRESENTATION**
See Page 6

15:50 - 16:50 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 5

Outsourcing

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

Strategies for Monitoring the Quality of Outsourced Work – The Vulnerabilities Involved and How to Identify New Strategic Partnership

- Outsourced development and manufacturing is usually time sensitive, choice of the wrong partner is not easily remedied
- Strategic partners are selected based on previous experience, real-world assessments outside of personal experience are hard to get due to confidentiality
- Sponsor is accountable for integrity of data and quality of work and product but may have limited visibility into quality system

Kelly Neelon
Vice President, CMC and Technical Operations
Vigil Neuroscience

ABOUT THE SPEAKER

Kelly Neelon, Vice President of CMC/Technical Operations at Vigil Neuroscience, is a product development professional with over 20 years of industry experience in biotech and pharmaceutical drug development. She has made significant contributions to the development and commercialization of multiple approved products throughout her career. Prior to joining Vigil Neurosciences, Dr. Neelon served as Vice President of Technical Operations at Phoenix Tissue Repair, where she was responsible for the CMC strategy for a rare disease therapeutic.

She held previous roles with increasing levels of responsibility at TESARO, Momenta Pharmaceuticals, and Dyax. Dr. Neelon earned her Ph.D. in biochemistry from Boston College and a master's degree in chemical engineering from the University of Massachusetts Lowell.

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

11:10 - 12:10 ET ROUNDTABLE 2

How to Create a Partnership for "One-Stop-Shop" with a CDMO in the Current Landscape (considering post-COVID, etc.)

- Is this concept real or is it a unicorn? Can you get a true One-stop-shop in the virtual CDMO space?
- If so, what are the pros? Reduction in time to market, focused oversight of one CDMO, building a true partnership, potential decrease in costs, etc.
- Do the pros outweigh the cons? The need to build capabilities (sponsor cost), may not have the right in house experts, decrease in technical experts, may increase tech transfer risks, reliant on one CDMO
- Size matters! Product complexity? What are the most important factors to creating a partnership for a One-stop shop?
- How is the current landscape impacted by the pandemic?

Kristen Manion
Vice President, Head of Regulatory Affairs, Quality and Manufacturing
Paratek Pharmaceuticals

ABOUT THE SPEAKER

I am the Vice President, Head of Regulatory Affairs, Quality, and Manufacturing at Paratek Pharmaceuticals, located in King of Prussia, PA. I am responsible for making regulatory, quality, and manufacturing strategic decisions across all products, from pre-IND to late-phase development and marketed products. I have over 20+ years of global drug development, quality, and regulatory experience and have held various positions at multiple organizations in the pharmaceutical industry. Key areas of expertise include: interacting and negotiating with FDA and other Health Authorities to achieve favorable resolutions; creation and execution of innovative regulatory/quality/manufacturing strategies for development and marketed products leading to timely submission and product approval; in-depth knowledge and expertise of drug development, early phase drug registration, product approvals, life cycle registration activities, and maintenance of dossiers, creation, execution, and maintenance of quality management system and lead health authority inspections.

12:10 - 13:10 ET NETWORKING LUNCH

13:10 - 14:10 ET ROUNDTABLE 3

Speeding Up Discovery with the Right CRO Partner

- The challenges of delivering product on time to support preclinical and clinical studies with the Right CRO partner
- How to manage and mitigate geopolitical risks with CROs in different parts of the world?
- How to reduce the cost of goods while mitigating other risks?
- How to manage QA and regulatory audits of CROs in a virtual environment?

George Wu
Vice President, CMC
Enanta Pharmaceuticals

ABOUT THE SPEAKER

George Wu has more than 33 years of experience leading CMC organizations. Currently, George is a Vice President, CMC, at Enanta Pharmaceuticals, overseeing DS, DP, analytical development, QC/QA, and clinical supply management. George was a Vice President (2011–2020), Pharmaceutical Sciences, at GSK/TESARO, where he led teams in developing and launching two oncology medicines. George worked for 22 years at Merck/Schering-Plough as a Distinguished Fellow (Sr. Scientific Director).

George received his postdoctoral training with Professor Negishi at Purdue University and his Ph.D. degree under the supervision of Professor Heck at the University of Delaware. Professors Negishi and Heck received the Nobel Prize in Chemistry in 2010.

14:10 - 15:20 ET REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

15:20 - 15:50 ET CLOSING KEYNOTE PRESENTATION
See Page 6

15:50 - 16:50 ET DRINKS & CANAPES RECEPTION

CHEMISTRY, MANUFACTURING & CONTROLS

STRATEGY MEETING EAST COAST USA 2023

18th May 2023, Thursday Le Meridien Cambridge

Hotel & Venue

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OUR FACE-TO-FACE MEETING IN MAY 2023

Strategy Meeting San Diego, Boston & Princeton USA

MAY 2023

San Diego - US West Coast

08th - Drug Discovery Biology Strategy Meeting
09th - Medicinal Chemistry Strategy Meeting
10th - Oncology Strategy Meeting
11th - Clinical Operations Strategy Meeting

MAY 2023

Boston/Cambridge MA - US East Coast

17th - Regulatory Affairs Strategy Meeting
18th - Chemistry, Manufacturing and Controls Strategy Meeting

MAY 2023

Princeton New Jersey - US East Coast

23rd - Drug Discovery Biology Strategy Meeting
24th - Medicinal Chemistry Strategy Meeting
25th - Clinical Operations Strategy Meeting

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