BOOK NOW!

Proventa International's 4th Annual

REGULATORY AFFAIRS

STRATEGY MEETING EAST COAST USA 2023

17th May 2023, Wednesday Le Meridien Cambridge

The premier meeting for all East Coast USA Regulatory Affairs professionals

Featuring Industry Leaders and Decision Makers:

Chitkala Kalidas
Vice President, Global Head Oncology & IVD Regulatory Affairs and Oncology Sustainability
Bayer

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

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

Jamie Gillette
Vice President, Head of Regulatory
Cullinan Oncology

Guilin Huang
Vice President, Head of Regulatory Affairs
Relay Therapeutics

Lauren DiPetrillo
Vice President, Head of Regulatory Affairs
Keros Therapeutics

Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

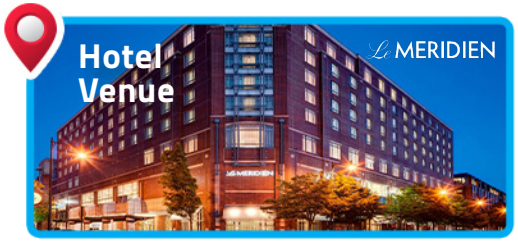
Joe McLaughlin
Head, Regulatory Business Process & Innovation
Sanofi

20 ROUNDTABLE DISCUSSIONS

5 TRACKS

3 KEYNOTE PRESENTATIONS

1 LOCATION



What Makes Our Strategy Meetings So Unique?

Proud to Partner with:

ESKO Adlib Glemser

Scan to register

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.

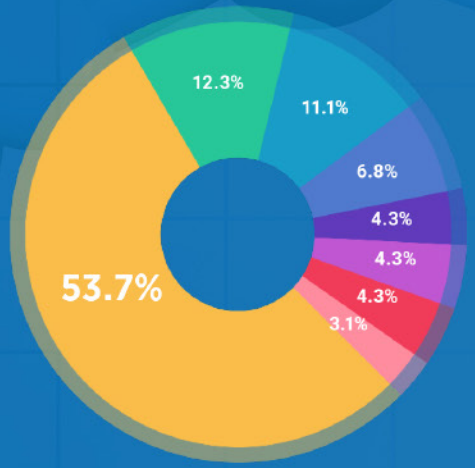
PERSONALISED AGENDA
Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time spent is focused and well-utilised.

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



Regulatory Affairs

- Regulatory Affairs
- Regulatory Operations
- RIM & IT Business Leads
- CMC
- Delivery Management
- Submission Management
- Global Strategy
- eSubmission/eCTD/eTMF
- Dossier Lead
- Policy & Intelligence

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

Jackie Leslie
Category Specialist
Life Sciences
ESKO

Samantha Thompson
Strategic Account Executive
Pharmaceutical
ESKO

Pawan Gandhi
Director, Global Research
and Development
Glemser Technologies

Jamie Morisco
Director, Sales
Glemser Technologies

Harry Chopra
Chief Client Officer
ADLIB

Anthony Vigliotti
Chief Product Officer
ADLIB

Chitkala Kalidas
Vice President,
Global Head Oncology &
IVD Regulatory Affairs and
Oncology Sustainability
Bayer

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

Joe McLaughlin
Head, Regulatory
Business Process &
Innovation
Sanofi

Gopi Vudathala
Global Head,
Regulatory Affairs CMC
Incyte Corporation

Guilin Huang
Vice President, Head of
Regulatory Affairs
Relay Therapeutics

Jamie Gillette
Vice President,
Head of Regulatory
Cullinan Oncology

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

Lauren DiPetrillo
Vice President, Head of
Regulatory Affairs
Keros Therapeutics

Margaret Woo
Vice President, Head of
Regulatory Affairs and
Quality
Scorpion Therapeutics

Ramola Bhandarkar
Vice President, Head of
Regulatory Affairs
Omega Therapeutics

Sheila Mathias
Chief Scientific Officer
**Virpax Pharmaceuticals,
Inc.**

Stan Russell
Former Vice President,
Quality
TCR² Therapeutics Inc.

Tara Baer
Former Global Head,
Labeling Quality and
Excellence
Takeda

How Has Our STRATEGY MEETINGS Benefit The Life Science Industry

> *"I think the roundtable meeting format was very interesting and really encouraged a lot of participation by all of the participants and sharing of ideas and and much more so than any kind of lecture format would have."*
>
> **Adrian Dana -** *Vice President, Global Patient Safety and Risk Management*, **Alnylam**

> *"The one-to-one meeting is very good. It was an interesting experience, it felt a little bit like speed dating, I never done that before. It worked well, you had a chance to connect with someone for a good conversation."*
>
> **Richard Schaaf -** v*Vice President, Technology & Operations*, **Commonwealth Informatics**

2023 Sponsors

THOUGHT LEADER

Esko, part of the Danaher group, is the worldwide market leader within packaging and labelling software for workflow automation, quality assurance and online collaboration. Esko packaging and labeling management solutions helps pharmaceutical and life sciences companies manage their packaging preproduction specifications, regulatory content and artwork portfolio in a compliant and secure way, helping raise productivity, reduce time-to-market, lower costs, expand business and improve profitability. Esko offers a common online communications platform that: • Provides security and control • Enforces compliancy (GMP compliant) • Creates and maintains an audit trail of all activities • Brings control to the graphics and content process • Helps each department & function manage their tasks and approval management process proactively. Company Website: https://www.esko.com/en/solutions/brand-solutions/webcenter

Since 1987, **Glemser** has played a critical role in developing industry-leading IT solutions and services that are essential for global life science companies to solve their most pressing challenges in quality, compliance, and efficiency. Glemser has modernized Global Labeling with ComplianceAuthor™, a system designed to aggregate your existing RIM systems and data repositories to allow for streamlined labeling capabilities. We leverage advancements in natural language processing, machine learning, artificial intelligence, and natural language generation to make product labeling easy and content finable, accessible, interoperable, and reusable.

Adlib is a document conversion and transformation platform that delivers unsurpassed accuracy, automation, and third-party integration. Companies trust Adlib to access and convert multiple file types from multiple sources, automate manual data entry processes, and generate submission-ready, technically compliant documents of record.

Global Sponsorship Opportunities

Proventa's end-to-end consulting division gather real-time business intelligence on the industry's **needs, challenges, budgets** and **investment areas**. We combine this information with your specific needs to enhance your business development strategy. With the wealth of intel we provide, Proventa guarantees tangible results for your business within twelve months of the event.

For Sponsorship Opportunites please contact:
SPONSORSHIP TEAM: info@proventainternational.com | +44 (0)20 3314 0100

Agenda at a Glance

TIME ET	TRACK 1 RIM AND DATA MANAGEMENT	TRACK 2 REGULATORY OPERATIONS & REGULATORY STRATEGY	TRACK 3 LABELLING, ARTWORK, AND REGULATORY CONTENT MANAGEMENT	TRACK 4 REGULATORY SUBMISSIONS/ECTD	TRACK 5 COMPLIANCE
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 The Post-Pandemic Era in Regulatory Affairs Landscape: The State-of-the-Art and Emerging Trends PRESENTER: Chitkala Kalidas, *Vice President, Global Head Oncology & IVD Regulatory Affairs and Oncology Sustainability*, Bayer				
09:00 - 10:00	**Streamlining Global Regulatory Compliance and Information Management** Sheila Mathias, *Chief Scientific Officer*, Virpax Pharmaceuticals, Inc.	**Navigating the New CT Regulations and Operationalizing the New EU CTA Process via EU CTIS** Margaret Woo, *Vice President, Head of Regulatory Affairs and Quality*, Scorpion Therapeutics	**Utilizing Dynamic Labeling Management Technologies for Effective Content Management, Workflow, and Structured Authoring** Tara Baer, *Former Global Head, Labeling Quality and Excellence*, Takeda	**Collaboration with Regulatory Authorities and Agencies: How to Secure Early Engagement and Dialogue?** Lauren DiPetrillo, *Vice President, Head of Regulatory Affairs*, Keros Therapeutics	**How to Overcome the Common Pitfalls Around Operational Complexities in Mergers and Acquisitions with Ownership Transfer of Such Highly Regulated Drugs?** Guilin Huang, *Vice President, Head of Regulatory Affairs*, Relay Therapeutics
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 SOLUTION		**Reducing the "Work" in Paperwork: Automation & Auto-Classification in Regulatory Submission Processes** Harry Chopra, *Chief Client Officer*, ADLIB ADLIB	**Bridging Disciplines with Structured Content and End-to-End Labeling** Samantha Thompson, *Strategic Account Executive Pharmaceutical*, ESKO (Co-facilitating) Jackie Leslie, *Category Specialist Life Sciences*, ESKO ESKO	**How Documents of Record Clear the Path to More Efficient Regulatory Compliance** Anthony Vigliotti, *Chief Product Officer*, ADLIB ADLIB	**How Natural Language Processing Can Reduce Global Labeling Timelines by up to 50%** Pawan Gandhi, *Director, Global Research and Development*, Glemser Technologies GLEMSER
12:10 - 12:40	KEYNOTE PRESENTATION Regulatory Content Transformation : The "Whys" and the "Hows" of Structuring content end to end - from labeling to esubmission PRESENTER: Samantha Thompson, *Strategic Account Executive Pharmaceutical*, ESKO				
12:40 - 13:40	NETWORKING LUNCH				
13:40 - 14:10	KEYNOTE PRESENTATION Improve Regulatory Content Generation Timelines with Component Based Authoring PRESENTER: Jamie Morisco, *Director, Sales*, Glemser Technologies				
14:10 - 15:10	**Examining the Advantages of an Innovative End-to-End Regulatory Information Management Platform** Lauren DiPetrillo, *Vice President, Head of Regulatory Affairs*, Keros Therapeutics	**Exploring Strategies to Revamp Your Regulatory Infrastructure for Faster, Better, and Stronger Processes** Jamie Gillette, *Vice President, Head of Regulatory*, Cullinan Oncology	**Understanding the Need for End-to-End Visibility to Labeling Changes** Kristen Manion, *Vice President, Head of Regulatory Affairs, Quality and Manufacturing*, Paratek Pharmaceuticals	**eCTD 4.0: Definition, Key Changes, and Effect on Submission Content Preparation** Gopi Vudathala, *Global Head, Regulatory Affairs CMC*, Incyte Corporation	**Utilization of External Vendors to Support Regulatory Activities** Stan Russell, *Former Vice President, Quality*, TCR² Therapeutics Inc.
15:10 - 15:20	REFRESHMENT BREAK				
15:20 - 15:40	NETWORKING / 1-1 MEETINGS				
15:40 - 16:00	NETWORKING / 1-1 MEETINGS				
16:00 - 16:20	NETWORKING / 1-1 MEETINGS				
16:20 - 17:20	**What Are the Distinctions and Similarities Between Data Governance and Data Management, and How Do They Interact?** Stan Russell, *Former Vice President, Quality*, TCR² Therapeutics Inc.	**Innovative Approaches to Clinical Development Programs and Trial Design, Including a Discussion on Experience with Acceptance by Regulatory Agencies** Ramola Bhandarkar, *Vice President, Head of Regulatory Affairs*, Omega Therapeutics	**The Future of Structured Content Authoring: Why Are We in Need of It?** Joe McLaughlin, *Head, Regulatory Business Process & Innovation*, Sanofi	**Looking Into the Pivotal Role of AI to Improve the Efficiency of Reviewing Regulatory Submissions** Jamie Gillette, *Vice President, Head of Regulatory*, Cullinan Oncology	**Ensuring Global Compliance in a Complex Regulatory Landscape: Best Practices and Tools for Regulatory Affairs Professionals** Art Faulkner, *Vice President, Regulatory CMC*, TG Therapeutics, Inc.
17:20 - 18:20	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**

The Post-Pandemic Era in Regulatory Affairs Landscape: The State-of-the-Art and Emerging Trends

- **Emerging trends in Oncology regulatory science: clinical trial diversity, dose optimization and evidence generation**
- **Integration of feedback from multiple regulatory authorities into a cohesive global regulatory strategy**
- **How to integrate the voice of the patient into the drug development program and regulatory strategy?**
- **Use of diagnostics, decentralized trials and their impact on regulatory strategy**
- **The role of the regulatory professional in global drug development**

Chitkala Kalidas
Vice President, Global Head Oncology & IVD Regulatory Affairs and Oncology Sustainability
Bayer

ABOUT THE SPEAKER

Chitkala Kalidas, PhD, is the Global Head of Oncology Regulatory Affairs and Oncology Sustainability at Bayer. Dr. Kalidas and her team of global regulatory affairs professionals are responsible for developing global regulatory strategies for programs in all stages of drug development and for the registration of drugs as well as in vitro diagnostics. Programs in her group include VITRAKVI® (larotrectinib), STIVARGA® (regorafenib), XOFIGO® (radium-223), ALIQOPA® (copanlisib), NEXAVAR® (sorafenib) and NUBEQA® (darolutamide), among others. Precision medicine is an area of interest for her group as well as novel development strategies including tissue agnostic development, novel clinical trial designs, pediatric development in Oncology and drug development in special populations. Dr. Kalidas also leads the Oncology Sustainability Initiative at Bayer. This initiative, which is focused on Global Health Equity in underserved communities around the globe, reflects Bayer's commitment to remedy disparities in access to quality cancer care and bring to life Bayer's vision of Health for All.

Dr. Kalidas is active in the area of multi-stakeholder collaboration to enhance access to cancer clinical trials as well as regulatory science and innovation to expedite availability of innovative cancer therapies to patients. She represents Bayer at several multi-stakeholder forums to accelerate cancer drug development and improve cancer care equity in underserved communities.

Dr. Kalidas has over 20 years of experience in drug development. Prior to joining Bayer, Dr. Kalidas was at Merck & Co. Inc. where she worked on drug development programs across multiple therapeutic areas and geographic regions. Prior to joining the pharmaceutical industry, she was a Management Consultant at the Boston Consulting Group. Dr. Kalidas has a PhD in Microbiology from Cornell University.

12:10 - 12:40 ET **KEYNOTE PRESENTATION**

Regulatory Content Transformation: The "Whys" and the "Hows" of Structuring Content End to End—From Labeling to eSubmission

Samantha Thompson
Strategic Account Executive Pharmaceutical
ESKO

ABOUT THE SPEAKER

Samantha is responsible for developing Esko's Life Science Vertical as a Strategic Account Executive NA | Life Sciences. Samantha joined Esko Brands in October 2015 as an Account Executive and previously covered the Southeast territory. Samantha resides in Mount Pleasant, SC with her husband, daughter, and fur baby. Prior to joining Esko Brands, Samantha worked as an Inside Sales Representative for 2 years at Esko serving Printers./ Converters. Prior to Esko, Samantha was an account executive at Erwin Penland.

Samantha graduated from Clemson University in 2012. She has a BS in Graphic Communications/Packaging with a minor in Business Administration. Samantha also obtained her MBA from the University of Phoenix.

13:40 - 14:10 ET **KEYNOTE PRESENTATION**

Improve Regulatory Content Generation Timelines with Component Based Authoring

- **Evolving regulatory requirements and advancements in technology are causing the life sciences industry to modernize their content generation processes**
- **Component based authoring allows for the use and re-use of data to be applied to document generation, reducing the time required to create submission ready documents**
- **Sustain compliance and improve quality with component based authoring**

Jamie Morisco
Director, Sales
Glemser Technologies

ABOUT THE SPEAKER

Jamie serves as a Director of Sales for Glemser. In this role, Jamie draws from his extensive background in technology and business transformation to assist clients along their modernization journey. Jamie has a proven track record leading clients and team through complex technology enabled transformations delivering benefits across time, quality, cost and compliance.

Event Day

TRACK 1

RIM and Data Management

The complexity in harmonizing processes, data, systems and workflows within a product life cycle is still one of the key challenges of regulatory teams. Unlocking the potential of disconnected data stored in disparate systems and technologies can help regulatory teams effectively navigate the complexity and expand capabilities. Pharma and medical device companies are constantly seeking innovative ways to align cross-functional teams, streamline regulatory activities, unifying systems through holistic view of regulatory information and process continuity. This track explores robust strategies in leveraging RIM by interconnecting quality datasets, regulatory processes, technology and people to enhance operational excellence and decision-making throughout the entire product life cycle.

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

Streamlining Global Regulatory Compliance and Information Management

- Regulated information is scattered across various systems, making it hard to adapt and slowing time to market
- "Single source of truth" gives Regulatory (as well as clinical, medical affairs and quality) teams access to reliable data and the unification of systems increases efficiency
- Optimization of Regulatory content – collaboration and reuse of content across functional (clinical, regulatory, and quality) domains improves data quality and consistency within the application/ dossier

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. Sheila has held increasing roles of responsibilities, entering the pharmaceutical industry at Merck US Human Health in the position of Medical Science Liaison. Dr. Mathias transitioned into Regulatory Affairs at Aventis Pharmaceuticals and has successfully brought multiple products through regulatory approval.

Dr. Mathas received a B.S in Zoology from Howard University, a PhD in Neurophysiology from Meharry Medical College, an executive MBA from Saint Joseph's University, and a JD from Northwestern California University School of Law. Since 2018 she has served on the Advisory Board for Tennessee State University Department of Biology

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

12:10 - 12:40 ET KEYNOTE PRESENTATION
See Page 6

12:40 - 13:40 ET NETWORKING LUNCH

13:40 - 14:10 ET KEYNOTE PRESENTATION
See Page 6

14:10 - 15:10 ET ROUNDTABLE 3

Examining the Advantages of an Innovative End-to-End Regulatory Information Management Platform

- How to set yourself up for success – Metadata and how quality metadata leads to quality reporting and locating of information
- Impact to version control with regulatory information management platform
- Lessons learned from implementing a regulatory information management platform (i.e. migration considerations, naming conventions etc.)

Lauren DiPetrillo
Vice President, Head of Regulatory Affairs
Keros Therapeutics

ABOUT THE SPEAKER

Lauren DiPetrillo is Vice President, Head of Regulatory Affairs at Keros Therapeutics, Inc. She is responsible for Regulatory Affairs, Medical Writing and Clinical QA at Keros. Her career began as a clinical pharmacologist before transitioning to a clinical scientist to eventually a regulatory affairs' role at Alkermes, Inc. She was the regulatory lead for LYBALVI® (olanzapine/ samidorphan) for the treatment of schizophrenia and bipolar I disorder. She helped drive the overall regulatory strategy for LYBALVI® as well as the NDA filing and successful FDA Advisory Committee. Lauren received her Ph.D. in Clinical Pharmacology from Tufts University Graduate School of Biomedical Sciences and a B.S in Biology from University of Richmond.

15:10 - 16:20 ET REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

16:20 - 17:20 ET ROUNDTABLE 4

What Are the Distinctions and Similarities Between Data Governance and Data Management, and How Do They Interact?

- Aside from the need for a comprehensive/all-encompassing scope, what other similarities do the two share?
- If we agree that Governance is the more strategic side and Management the tactical one, what are the aspects of a) Governance that are tactical and b) Management that are strategic?
- What are the top 3 priorities for each that the owner/steward must ensure?
- Has anyone had to back-engineer either/both from an audit citation for data privacy or data integrity gaps and associated corrective actions?

Stan Russell
Former Vice President, Quality
TCR² Therapeutics Inc.

ABOUT THE SPEAKER

Stan Russell is a 30+ year Life Sciences veteran, working in Engineering, Manufacturing, Quality, Supply Chain, and IT. He has advanced formulations, technologies, and therapeutic areas from discovery through commercial production; playing critical roles in submission, approval, and launch of therapies, diagnostics, and nutritionals. His career progression includes individual contributor roles at Abbott Laboratories and management to executive positions with Automated Systems, Baxter/Baxalta/Shire, Alexion, Sebela, and TCR2.

Stan serves on the board of Playworks and will soon take a short-term missionary trip supporting Children's Impact Network in Honduras. He holds both BS-Chemical Engineering and Executive MBA degrees from Northwestern University.

17:20 - 18:20 ET DRINKS & CANAPES RECEPTION

Event Day

TRACK 2

Regulatory Operations & Regulatory Strategy

Despite the unprecedented collaboration and communication globally over the course of COVID-19 crisis, there are still challenges in accelerating the process of bringing compliant products to global markets while adhering to country-specific registration/submission requirements to enhance the approval of potential life-saving therapeutics for patients worldwide. On the other hand, emerging technologies such as gene editing CRISPR technologies still remain unfavorable from a regulatory standpoint, and are not yet fully developed toward delivering all of their promises due to the unclear legal regulations at the national and international levels. This track aims to address the challenges in development, registration, submission, and monitoring strategies of globally unified therapeutics as well as persistent operational barriers to formulate frameworks and define regulatory strategies for emerging gene editing CRISPR technologies.

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 the New CT Regulations and Operationalizing the New EU CTA Process via EU CTIS

- What are the operational hurdles to bring trials to patients in EU?
- What are alternatives to CTIS/EMA help desks when no resolution is insight?
- Any lessons learned as best practices to effectively use EU CTIS

Margaret Woo
Vice President, Head of Regulatory Affairs and Quality
Scorpion Therapeutics

ABOUT THE SPEAKER
Margaret is Vice President, Head of Regulatory Affairs and Quality at Scorpion Therapeutics in Boston. Prior to joining Scorpion Therapeutics, she headed the Regulatory function at C4 Therapeutics. Her pharmaceutical career began as a clinical pharmacologist before transitioning to a career in regulatory affairs at Novartis Oncology and subsequently with EMD Serono. She completed her post-doctoral training at St. Jude Children's Research Hospital, followed by being a Research Associate at Washington University in St Louis. She earned a Master's in Bioscience Regulatory Affairs from Johns Hopkins University, a PharmD from University of Southern California, and went to college at UC Berkeley majoring in Molecular and Cell Biology.

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

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

Reducing the "Work" in Paperwork: Automation & Auto-Classification in Regulatory Submission Processes

- How would you describe the maturity of your organization's regulatory submission preparation journey, from the time clinical trials are commenced to the time the completed regulatory application is ready for submission?
- Where do you see the largest set of inefficiency in this process and what is your perspective on characteristics that need the most attention?
- As you look at the workload of regulatory operations management for your organization, what are the most complex aspects of the journey, as well as preparing the documentation to support that journey?
- As you look forward, what are some of the technology advances you see or would like to see happen in this space to drive efficient outcomes for the business?

Harry Chopra
Chief Client Officer
ADLIB

ABOUT THE SPEAKER
Harry Chopra is the Chief Client Officer of Adlib Software and brings over 30 years of experience in a sales and marketing function across multiple industries. Harry's background spans, manufacturing, telecommunications, financial services, financial market intelligence, and regulatory reporting. Over the last five years Harry has been involved in regulatory reporting and understands the exacting requirements of regulatory bodies across the globe.

12:10 - 12:40 ET **KEYNOTE PRESENTATION**
See Page 6

12:40 - 13:40 ET **NETWORKING LUNCH**

13:40 - 14:10 ET **KEYNOTE PRESENTATION**
See Page 6

14:10 - 15:10 ET **ROUNDTABLE 3**

Exploring Strategies to Revamp Your Regulatory Infrastructure for Faster, Better, and Stronger Processes

- Getting to the root of it – what is slowing us down?
- Regulatory change management and anticipating changes that will rock the system
- What does a "good" Regulatory Infrastructure look like?
- How can a well-defined Regulatory Infrastructure streamline processes and fill gaps?

Jamie Gillette
Vice President, Head of Regulatory
Cullinan Oncology

ABOUT THE SPEAKERS
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.

15:10 - 16:20 ET **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

16:20 - 17:20 ET **ROUNDTABLE 4**

Innovative Approaches to Clinical Development Programs and Trial Design, Including a Discussion on Experience with Acceptance by Regulatory Agencies

- Exploring innovative trial designs including adaptive designs
- FDA's draft guidance on Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics
- Success with regulatory acceptance of novel biomarkers and surrogate endpoints
- Use of Real-World Evidence
- Dose optimization in oncology (Project Optimus)

Ramola Bhandarkar
Vice President, Head of Regulatory Affairs
Omega Therapeutics

ABOUT THE SPEAKER
Ramola Bhandarkar is Vice President and Head of Regulatory Affairs at Omega Therapeutics, which is pioneering a new class of epigenomic medicines using mRNA-based therapeutics. Prior to Omega, she was the Head of Regulatory Strategy for bluebird bio's Oncology Business Unit and was the bluebird bio global regulatory lead for ABECMA®, which is the first cell-based gene therapy approved by the FDA for the treatment of multiple myeloma. Prior to bluebird bio, Ramola held positions of increasing responsibility at ImmunoGen, Inc., an antibody drug conjugate company to treat cancer, where she led the regulatory strategy group.

17:20 - 18:20 ET **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 3

Labelling, Artwork, and Regulatory Content Management

Regulatory teams are shifting towards adopting structured content management strategies to integrate, orchestrate and optimize content workflows. Accelerating the optimization of content, labeling and artwork processes, enabling crossfuntional teams to work together efficiently, reducing manual steps and reusing regulatory content will be the main focus of this track. Here, we will address the regulatory challenges in authoring, reviewing, submission and compiling troves of documents and exploring the best practices in adoption of structured content authoring and reuse strategy to minimize errors and repetitive cycles.

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**

Utilizing Dynamic Labeling Management Technologies for Effective Content Management, Workflow, and Structured Authoring

- What does effective content management look like?
- Language, how to move it from the creative College of Arts into the structured College of Science and Mathematics?
- AI, can it change the way we work in Labeling?

Tara Baer
Former Global Head, Labeling Quality and Excellence
Takeda

ABOUT THE SPEAKER
Tara Baer is an experienced leader in Medical Device and Pharmaceutical labeling. Tara has worked at such industry leaders as Takeda, AbbVie, Boston Scientific, Wyeth, PRA, and Navitas, where she developed a passion for End-to-End Labeling Management, from safety through distribution. An experienced leader and motivator she has led diverse teams of professionals towards collaborative solutions.

She specializes in content development, automated tracking/process integration, translation management, workflow and asset management. Tara is a founder of Leaders in Labeling, a LinkedIn group of thought leaders in labeling for regulated products, pharmaceutical, biologics and medical devices.

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

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

Bridging Disciplines with Structured Content and End-to-End Labeling

- Insights into the strategies toward digital transformation
- How to overcome change management challenges and get to an unified approach to managing structured content
- Overview of technology that exists to centralize and manage Regulatory, Labelling and Packaging Content from a single end-to-end platform

Samantha Thompson
Strategic Account Executive
Pharmaceutical
ESKO

(Co-facilitating)
Jackie Leslie
Category Specialist Life Sciences
ESKO

ESKO

ABOUT THE SPEAKER
See Page 6

12:10 - 12:40 ET **KEYNOTE PRESENTATION**
See Page 6

12:40 - 13:40 ET **NETWORKING LUNCH**

13:40 - 14:10 ET **KEYNOTE PRESENTATION**
See Page 6

14:10 - 15:10 ET **ROUNDTABLE 3**

Understanding the Need for End-to-End Visibility to Labeling Changes

- Numerous labels to manage, constant changes requested, expansion into more and more markets, multiple versions of labels to track, etc… Does this sound familiar? If so, this is the brainstorming session for you. Understanding the E2E labeling process is critical to success.
- Let's discuss current state of E2E Labeling Process. Such as what issues occur to make having visibility to E2E labeling?
- Evolving E2E Labeling Technology – company standards, integrations, and automaton
- Future of E2E Labeling
- Conclusions

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.

15:10 - 16:20 ET **REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS**

16:20 - 17:20 ET **ROUNDTABLE 4**

The Future of Structured Content Authoring: Why Are We in Need of It?

- Panel will extend into the overall transformation of "authoring" from assisted, to augmented, to autonomous
- What problems are the biggest opportunities and what could be the outcomes (art of the possible)?
- What are the different approaches companies are taking in defining strategies/ roadmaps and managing stakeholder expectations?

Joe McLaughlin
Head, Regulatory Business Process & Innovation
Sanofi

ABOUT THE SPEAKER
Joe McLaughlin is a passionate leader who fosters a "What if?" mindset to make the case for change with a proven ability to deliver the vision and outcomes. He has 25 years in Pharma partnering across Regulatory, Supply Chain and Quality to transform ways of working with a focus on user experience.

Joe led Sanofi's Global Regulatory Affairs Transformation Program to reimagine and simplify Regulatory information management which is foundational to enabling Sanofi's broader digital and data transformation. He currently heads Sanofi's GRA Business Process & Innovation team where they foster and drive new ways of working across process, data and digital.

17:20 - 18:20 PT **DRINKS & CANAPES RECEPTION**

Event Day

TRACK 4

Regulatory Submissions/eCTD

The success and speed of bringing COVID-19 vaccines to the global market has sparked improved collaboration among regulatory teams, global health authorities, manufacturers and patients. Using this success as a blueprint, this track will explore success stories and the best industry practices that help the regulatory ecosystem transform the end-to-end submission process and speed up the review process for the potentially life-changing therapeutics. Developing a roadmap from the earliest stages of research and development, through a sequence of global submissions, to market authorization/product maturation will be the focus of 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

Collaboration with Regulatory Authorities and Agencies: How to Secure Early Engagement and Dialogue?

- Discuss various regulatory pathways to seek early engagement with regulatory authorities
- Review experience with the novel engagement strategies as outlined PDUFA VII goals letter
- Discuss what is the optimal time to seek regulatory engagement with regulatory authorities and agencies worldwide

Lauren DiPetrillo
Vice President, Head of Regulatory Affairs
Keros Therapeutics

ABOUT THE SPEAKER
See Page 7

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

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

How Documents of Record Clear the Path to More Efficient Regulatory Compliance

- How would you describe the maturity of your organization's audit and documentation compliance journey?
- Where do you see the largest set of inefficiency in this process and what is your perspective on characteristics that need the most attention ?
- As you look forward, what are some of the technology advances you see or would like to see happen in this space to drive efficient outcomes for the business ?

Anthony Vigliotti
Chief Product Officer
ADLIB

ABOUT THE SPEAKER
Anthony Vigliotti is the Chief Product Officer of Adlib Software and has 20+ years of experience in the Business Workflow and Intelligent Document Processing segment with prior roles at Kofax, Nuance, Notable Solutions (NSi), and Xerox. Anthony brings a well-rounded set of experiences with solution-related roles in Product Management, Alliance and Partner Management, and Product Development. He holds a bachelor's degree in Mechanical Engineering and a Master's Degree in Information Technology, both from the Rochester Institute of Technology.

12:10 - 12:40 ET KEYNOTE PRESENTATION
See Page 6

12:40 - 13:40 ET NETWORKING LUNCH

13:40 - 14:10 ET KEYNOTE PRESENTATION
See Page 6

14:10 - 15:10 ET ROUNDTABLE 3

eCTD 4.0: Definition, Key Changes, and Effect on Submission Content Preparation

- Key challenges with changes
- Standard approaches on eCTD preparation
- Post-approval variations and updates to eCTD sections
- Inclusion of reports, batch records, etc.

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.

15:10 - 16:20 ET REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

16:20 - 17:20 ET ROUNDTABLE 4

Looking Into the Pivotal Role of AI to Improve the Efficiency of Reviewing Regulatory Submissions

- What elements do we need to see with our own eyes, versus where can we use AI?
- End-to-end solutions, how to choose the best one for your organization
- Global AI vs Internal AI – how much to share for the "common good"
- Should FDA approve Regulatory Affairs-related AI?

Jamie Gillette
Vice President, Head of Regulatory
Cullinan Oncology

ABOUT THE SPEAKER
See Page 8

Event Day

TRACK 5

Compliance

Knowing about the latest changes in the world of compliance also allows your organization to tap into best practices and the latest technology to best prepare for and implement any change. Ultimately, this mitigates the risk of data breaches, violations, or security threats that are frequently hard to spot without tapping into expert knowledge. In this track, we'll provide you a tried-and-true method for making sure your company is aware of and comprehends any recent advancements in the field and the rules you have to follow.

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

How to Overcome the Common Pitfalls Around Operational Complexities in Mergers and Acquisitions with Ownership Transfer of Such Highly Regulated Drugs?

- Ownership transfer of highly regulated drug products following mergers and acquisitions (M&A) requires proactive planning and sophisticated execution to ensure regulatory compliance and operational efficiency
- Highlighting the common challenges, concerns and risks before, during and after the ownership transfer of such highly regulated drug products
- Discussing strategies and best practices to ensure smooth ownership transfer to satisfy regulatory requirements and enable subsequent efficient drug development

Guilin Huang
Vice President, Head of Regulatory Affairs
Relay Therapeutics

ABOUT THE SPEAKER
Guilin Huang oversees the regulatory efforts at Relay Tx. She brings over 18 years of experience in global regulatory affairs and drug development focusing on oncology and rare diseases. Prior to Relay Tx, Guilin accumulated and enriched her drug development expertise as an accomplished regulatory strategist at Takeda, ARIAD, Chugai and Vertex. She contributed to global clinical development of several breakthrough therapies from early stage through global approvals, and she was instrumental to delivering successful global simultaneous filings and regulatory approvals of Kalydeco® (ivacaftor) for cystic fibrosis with gating mutations and R117H mutation, Alunbrig® (brigatinib) for ALK-positive non-small cell lung cancer (NSCLC), and Exkivity™ (mobocertinib) for NSCLC with EGFR exon20 insertion mutations. Additionally, Guilin played a key role to secure successful approvals of companion diagnostics for Alunbrig® and Exkivity™ .

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

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

How Natural Language Processing Can Reduce Global Labeling Timelines by up to 50%

- Using automation to replace manual documentation processing to realize resource efficiencies and gain valuable insights from your dad
- NLP tools that are tailored for the life sciences industry are available to make an immediate impact on your business

Glemser

Pawan Gandhi
Director, Global Research and Development
Glemser Technologies

ABOUT THE SPEAKER
Pawan serves clients as the Director of Global Research and Development. He brings along extensive experience in designing and implementing enterprise compliance solutions for life sciences clients. Pawan directs and coordinates development activities for organizational products to deliver quality solutions catering to complex regulated use cases.

12:10 - 12:40 ET KEYNOTE PRESENTATION
See Page 6

12:40 - 13:40 ET NETWORKING LUNCH

13:40 - 14:10 ET KEYNOTE PRESENTATION
See Page 6

14:10 - 15:10 ET ROUNDTABLE 3

Utilization of External Vendors to Support Regulatory Activities

- What do you look for or look to avoid in hiring vendors for file assembly and publishing?
- Does anyone have experience putting together internal policies/procedures from scratch, and was that done internally or externally?
- What are the absolute "must-have's" in terms of hiring internally to retain institutional knowledge?
- What are the top factors in considering whether to outsource or perform functions in-house?

Stan Russell
Former Vice President, Quality
TCR² Therapeutics Inc.

ABOUT THE SPEAKER
See Page 7

15:10 - 16:20 ET REFRESHMENT BREAK & NETWORKING / 1-1 MEETINGS

16:20 - 17:20 ET ROUNDTABLE 4

Ensuring Global Compliance in a Complex Regulatory Landscape: Best Practices and Tools for Regulatory Affairs Professionals

- What Regulatory Compliance software tools does your company use?
- What are the pros and cons of the tools?
- What types of Regulatory information do you manage?
- How do you balance data entry/maintenance and compliance?
- Are the same practices applied globally?

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.

17:20 - 18:20 ET DRINKS & CANAPES RECEPTION

REGULATORY AFFAIRS

STRATEGY MEETING EAST COAST USA 2023

17th May 2023, Wednesday 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 >




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

Visit us on our website to know more about our meetings
www.proventainternational.com