10 NOV

Le Meridien Cambridge Boston

Le MERIDIEN

REGULATORY AFFAIRS

STRATEGY MEETING EAST COAST USA 2022

The premier meeting for all East Coast USA Regulatory Affairs professionals

- RIM and Data Management
- Regulatory Strategy
- Change Control
- Regulatory Submissions
- Medical Devices
- Regulatory Operations
- Quality Management
- Labelling
- API intermediates
- Product Lifecycle

Featuring Industry Leaders and Decision Makers

Ramola Bhandarkar
Vice President, Head of Regulatory Affairs
Omega Therapeutics

Guilin Huang
Vice President, Head of Regulatory Affairs
Relay Therapeutics

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

Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

Patrick Guinn
Executive Director and Head, Regulatory Affairs & CMC
Mitsubishi Tanabe Pharma Development America, Inc.

Tara Baer
Global Head, Labeling Quality and Excellence
Takeda

Colleen McGraw
Senior Director, Global Regulatory Affairs Labeling
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STRATEGY MEETINGS!

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PROVENTA INTERNATIONAL

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

REGULATORY AFFAIRS
STRATEGY MEETING
EAST COAST USA 2022

10 NOV

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.

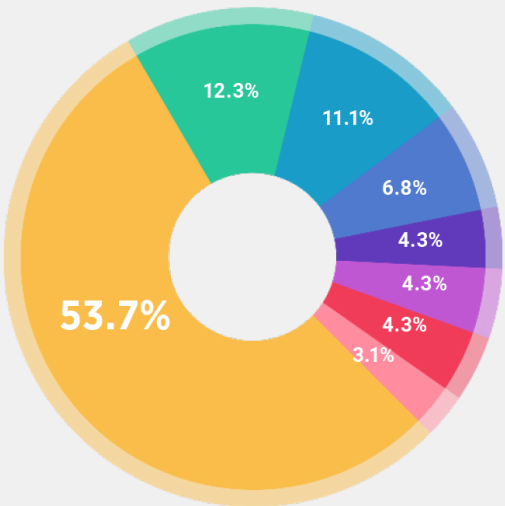
STRATEGIC NETWORKING

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.

Why this strategy meeting is a MUST ATTEND FOR YOU AND YOUR TEAM!

- Examine the current state of the regulatory landscape and explore how you can streamline complex regulatory processes throughout the product life cycle chain
- Engage and collaborate with regulatory teams, global health authorities and decision makers to reduce costly duplication effort, share experience and knowledge, optimize use of limited resources and expand capabilities
- Constructive roundtable discussions will address how leading pharma and medtech companies are driving continuous transformation and responding faster to ever changing regulatory environments
- Address the organizational, data and process challenges to streamline regulatory activities and fully benefit from an end-to-end RIM visibility Share best industry practices on accelerating development, registration, submission, and market tracking of globally unified products and creating profound synergy among global regulatory authorities And pharmaceutical community
- Learn strategies in leveraging RWE Towards Accelerated Medical Device Development and Innovation To shorten the product life cycle of Medical devices across the global supply chain and overcome increasing regulatory scrutiny
- Discuss the best approaches to accelerate the true implementation and utilization of AI/ML to reduce the length of timelines for faster approval
- Unique one-day interactive strategy meeting allows decision makers in pharma and medtech companies to benchmark and forecast the future product approval milestones more accurately
- Focus on the success stories and discuss the lessons learned from end-to-end submission process of COVID-19 vaccines to reshape the future submission processes for novel drugs
- Develop roadmaps to strategic adoption of structured content management to generate, manage, and reuse content at a rapid pace

SENIORITY OF ATTENDEES



Facilitator Faculty

Michelle Gyzen
Senior Director, Strategic Solutions, Regulatory Affairs and Drug Development Solutions
IQVIA

Samantha Thompson
Strategic Account Executive – Pharmaceutical
ESKO

David Meister
PreSales Solution Consultant - Brand Management Solutions
ESKO

Stan Russell
Vice President, Quality
TCR² Therapeutics Inc.

Ramola Bhandarkar
Vice President, Head of Regulatory Affairs
Omega Therapeutics

Tara Baer
Global Head, Labeling Quality and Excellence
Takeda

Nanita Cranford
Executive Director, Head of Global Regulatory Operations
Regeneron Pharmaceuticals, Inc.

Lauren DiPetrillo
Executive Director, Head of Regulatory Affairs
Keros Therapeutics

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

Patrick Guinn
Executive Director and Head, Regulatory Affairs & CMC
Mitsubishi Tanabe Pharma Development America, Inc.

Jamie Gillette
Vice President, Head of Regulatory
Cullinan Oncology

Guilin Huang
Vice President, Head of Regulatory Affairs
Relay Therapeutics

Kristen Manion
Vice President, Regulatory Affairs and Quality
Paratek Pharmaceuticals

Colleen McGraw
Senior Director, Global Regulatory Affairs Labeling
Moderna

Shrinivas (Cheenu) Murti
Head, Global CMC Business Process Excellence and Systems
Takeda

Kristen Sauter
Global Head, Regulatory Affairs, Information Management & Digital Innovation
Takeda

Franklin Vairinhos
Vice President, Regulatory Affairs
Axcella Health Inc.

Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

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

Intimate format events where senior leadership discuss the biggest challenges facing the industry.

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Co-host Sponsors

IQVIA is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. IQVIA creates intelligent connections to deliver powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients. Using global experts in over 100 countries, dedicated cloud-based safety technology, proven processes, advanced analytics including the market-leading NLP platform, IQVIA provides customers with improved compliance performance at lower cost, better predictive planning and visibility across the complete compliance landscape.

VISIT WEBSITE

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

VISIT WEBSITE

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.

VISIT WEBSITE

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:
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WHO SHOULD ATTEND?

- Chief Executive Officers
- Senior Vice Presidents
- Executive Vice Presidents
- Vice Presidents
- Global Heads
- Directors
- Executive Director

RESPONSIBLE FOR:

- Regulatory Affairs
- CMC
- Safety & Compliance
- Quality Assurance/Compliance
- Labeling Management & Compliance
- RIM & Data Management
- Regulatory Operations

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** - *Vice President, Technology & Operations*, Commonwealth Informatics

How it Works?

Real insights are shared in conversations, not lectures. That's why our unique **roundtable** format guarantees real learning and ensures you only attend discussions that deliver value to you.

Join as many as four roundtable discussions, each with up to 20 other subject experts, networking with top-level peers in an informal, relaxed and sociable environment.

Simply follow the steps below to select your roundtable discussions and we'll create your own personalised agenda for the day:

01 EXPLORE THE FULL AGENDA

Select which roundtable discussions you would like to join. Our sessions are divided among 6 themed tracks for easy selection - you can choose to join any session you like.

02 COMPLETE YOUR SCHEDULING FORM

Select your preferred roundtable discussion for each time slot. We will send this form out via email a few weeks before the event - be sure to get your first choice by completing the form quickly.

03 ENJOY YOUR PERSONALISED EXPERIENCE

Join your selected roundtable sessions on the day. We will give you your personalised agenda containing the time and room assignments of your chosen roundtable discussions so you won't miss it.

Agenda at a Glance

Regulatory Affairs Strategy Overview 10th of November, 2022 – Cambridge, Boston - Le Meridien Hotel

TIME EST	TRACK 1 RIM AND DATA MANAGEMENT	TRACK 2 REGULATORY OPERATIONS & REGULATORY STRATEGY	TRACK 3 CHANGE CONTROL	TRACK 4 LABELLING, ARTWORK, AND REGULATORY CONTENT MANAGEMENT	TRACK 5 REGULATORY SUBMISSIONS
ROOM ▶	Jerome C. Hunsaker C	Jerome C. Hunsaker C	Jerome C. Hunsaker C	Lan Jen Chu	Margaret L.A. Macvicar
08:00 - 08:30	REGISTRATION AND WELCOME				
08:30 - 09:00	OPENING KEYNOTE PRESENTATION A Comprehensive View and Vision of the Future: Exploring the Current Regulatory Landscape and Learning Outcomes from the COVID-19 Pandemic				
09:00 - 10:00	Leveraging End-to-End RIM Visibility Across Cross-functional Teams to Expand Regulatory Capabilities and Streamline Regulatory Processes Throughout the Product Life Cycle	Accelerating Development, Registration, Submission, and Market Tracking of Globally Unified Products and Create Profound Synergy Among Global Regulatory Authorities and the Pharmaceutical Industry	Enterprise Change Control	A Roadmap Towards Strategic Adoption of Structured Content Management to Generate, Manage, and Reuse Content at a Rapid Pace	The Success Stories: Lessons Learned from End-to-End Submission Process of Oncology Therapies to Reshape the Future of Submission Processes for Novel Drugs
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		Overview of Tools to Ensure a Competitive, Aligned Regulatory Strategy Across Regulatory Submissions		End to End Labelling with Automated Artwork and Regulatory Structured Content (Topic TBC) ESKO ESKO BRAND SOLUTIONS	The Evolution of Regulatory Outsourcing and the Role of Technology IQVIA IQVIA
12:10 - 13:10	NETWORKING LUNCH				
13:10 - 13:40	ESKO BRAND SOLUTIONS	KEYNOTE PRESENTATION Enterprise Structured Content | End-to-End Labelling		ESKO BRAND SOLUTIONS	
13:40 - 14:40	Utilizing Robust Integrated Regulatory Information Management Systems to Ensure Compliance and Efficiency Throughout the Product Lifecycle	The Impact of COVID-19 on Regulatory Workflows from Clinical Data Management to Trial Monitoring and Outsourcing Decisions	Performing Regulatory Change Management Using an Efficient and Sustainable Model	Structured Content and End-to-End Labeling from Regulatory Trigger to Automated Creation of Print, Device and Digital Components	Latest Technology and Trends for Creating Automated, Traceable, Data-driven Submission
14:40 - 14:50	REFRESHMENT BREAK				
14:50 - 15:10	NETWORKING / 1-1 MEETINGS				
15:10 - 15:30	NETWORKING / 1-1 MEETINGS				
15:30 - 15:50	NETWORKING / 1-1 MEETINGS				
15:50 - 16:50	Strategies to Develop a Data-driven Mindset and Culture to Increase Data Integration, Data Standards and Governance	Best Practices in Building Customizable Regulatory Strategies for Gene Editing CRISPR Technologies	Effective Implementation of Post-approval Change Globally to Shorten Approval Time	Addressing the Quality, Compliance, and Operational Challenges Paired with the Constantly Changing Scope of Regulations in Global Pharmaceutical and Device Labeling	Streamlining Global Regulatory Strategy and Submission Processes
16:50 - 17:50	DRINKS & CANAPES RECEPTION				

Event Day

OPENING KEYNOTE PRESENTATION

8:30 – 9:00 EST

A Comprehensive View and Vision of the Future: Exploring the Current Regulatory Landscape and Learning Outcomes from the COVID-19 Pandemic

- Discussing the effective outcomes we can use from the global regulatory success of COVID-19 vaccine development as a blueprint to plan, design and streamline future regulatory processes
- Accelerating the continuous collaboration among health authorities, regulatory teams, governments and pharma companies in order to foster life-changing therapies and reduce time to market time
- Leveraging the momentum to catalyze the other areas of unmet medical need to benefit patients, drug developers, manufacturers and regulators towards proactive strategies

Stan Russell
Vice President, Quality
TCR² Therapeutics Inc.

KEYNOTE PRESENTATION

13:10 - 13:40 EST

Enterprise Structured Content | End-to-End Labelling

- With continually evolving regulations, global expansion, mergers & acquisitions and product growth, data management challenges for Life Sciences Companies continue to increase
- Redefine your labeling content management strategy and reimagine the change process with content reuse, automation, and rules-based processing

Samantha Thompson
Strategic Account Executive – Pharmaceutical
ESKO

ESKO

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.

9:00 – 10:00 EST

ROUNDTABLE 1:
Leveraging End-to-End RIM Visibility Across Cross-functional Teams to Expand Regulatory Capabilities and Streamline Regulatory Processes Throughout the Product Life Cycle

- Addressing organizational, data and process challenges to streamline regulatory activities and fully benefit from a comprehensive RIM strategy
- Exploring the best practices to accelerate the true implementation and utilization of AI/ML to automate workflows and reduce the length of timelines for faster approval
- Innovative approaches to align internal and external regulatory processes and IT systems to improve the speed, compliance and the reliability of the processes

Kristen Sauter
Global Head, Regulatory Affairs, Information Management & Digital Innovation
Takeda

13:40 – 14:40 EST

ROUNDTABLE 3:
Utilizing Robust Integrated Regulatory Information Management Systems to Ensure Compliance and Efficiency Throughout the Product Lifecycle

- What are the obstacles currently facing companies that have grown over time to include different document and data systems throughout the organization?
- How do we move from silos of information to a single source of truth throughout the Product Lifecycle?
- What business intelligence can be gained from a defragmented approach to data rather than silos of information held across functional areas?
- What are keys to success to moving forward and adopting a robust Regulatory Information Management system?

Nanita Cranford
Executive Director, Head of Global Regulatory Operations
Regeneron Pharmaceuticals, Inc.

15:50 – 16:50 EST

ROUNDTABLE 4:
Strategies to Develop a Data-driven Mindset and Culture to Increase Data Integration, Data Standards and Governance

- Exploring novel approaches to unify a global data framework across regions, functions, and disconnected systems by standardizing terminology and relationships between information
- Leveraging cloud technologies to accelerate data integration, data governance, and data quality monitoring terminology and relationships between
- How can we enable data quality by interlinking people, process and technology within data quality strategy?
- Sharing the best practices, considerations, processes for the true RIM implementation

Kristen Manion
Vice President, Regulatory Affairs and Quality
Paratek Pharmaceuticals

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.

09:00 – 10:00 EST

ROUNDTABLE 1:
Accelerating Development, Registration, Submission, and Market Tracking of Globally Unified Products and Create Profound Synergy Among Global Regulatory Authorities and the Pharmaceutical Industry

- Discussing the persistent barriers to facilitate centralized procedures and labels aiding the simultaneous launch of new products in multiple markets
- Exploring the complexities in accelerating the process of bringing compliant products to global markets while adhering to country-specific registration/ submission requirements to meet diverse patient needs worldwide
- Discussing the latest updates and ongoing ICH processes to accelerate global harmonization through less cumbersome approval processes across countries, reduce product development time
- Building a steady bridge between emerging and developed countries in order to fill the gap in regulatory capacity and expertise
- Discussing the international agreements on rapid data sharing and harmonized standards to enable all aspects of product life cycle benefiting from increasing globalization

Patrick Guinn
Executive Director and Head, Regulatory Affairs & CMC
Mitsubishi Tanabe Pharma Development America, Inc.

11:10 – 12:10 EST

ROUNDTABLE 2:
Overview of Tools to Ensure a Competitive, Aligned Regulatory Strategy Across Regulatory Submissions

- Best practices to ensure internal alignment on core messaging across regulatory documents
- Creative tools to ensure you are staying up to date with current precedence (i.e., regulatory approvals, labels, etc.).
- Overview of tools available to review publicly available competitor documents (i.e., clinical study protocols, SAPs, eCTD Sections, etc.)

Lauren DiPetrillo
Executive Director, Head of Regulatory Affairs
Keros Therapeutics

13:40 – 14:40 EST

ROUNDTABLE 3:
The Impact of COVID-19 on Regulatory Workflows from Clinical Data Management to Trial Monitoring and Outsourcing Decisions

- **New end-to-end process from linking clinical data flow to submission of information to sites and regulators during COVID and beyond?**
- **Less ore more outsourcing decisions during the pandemic and beyond?**
- **Any evidence observed due to the sudden change in business operations that regulatory compliance is not equipped to handle under the significant pressure?**

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

15:50 – 16:50 EST

ROUNDTABLE 4:
Navigating the Regulations of Gene and Cell Therapy, Gene Editing, and Novel Gene Therapy Products and Delivery Platforms

- Exploring the current FDA/EMA framework for cell and gene therapy regulation including human genome editing
- CRISPR gene editing & rise of novel gene editing technologies
- Novel gene therapy technologies for regulation of gene expression
- Do the FDA's expedited programs (e.g., breakthrough therapy designation, RMAT designation, accelerated approval) speed up the process for these novel therapies?
- How manufacturing strategies impact the development of cell & gene therapy programs?

Ramola Bhandarkar
Vice President, Head of Regulatory Affairs
Omega Therapeutics

TRACK 3:
CHANGE CONTROL

Overcoming the ever-changing data, technology, process and regulatory requirements and responding to the change faster in regulatory affairs remains a significant hurdle and a top priority for the pharma and medical devices companies. Effectively managing change begins with establishing a comprehensive change control process from drug discovery to post-market approval throughout the product life cycle value chain. This track explores effective strategies to drive continuous transformation and foster an integrated approach among people, technology and processes to adopt change and stay ahead of the curve.

09:00 – 10:00 EST

ROUNDTABLE 1:
Enterprise Change Control

- Integrated across all CMC groups in the organization
- Integrated across all phases of development i.e. pre and post-approval
- Automation opportunities for tracking metrics, etc.
- Agency expectations and experiences

Shrinivas (Cheenu) Murti
Head, Global CMC Business Process Excellence and Systems
Takeda

Event Day

13:40 – 14:40 EST

ROUNDTABLE 3:
Performing Regulatory Change Management Using an Efficient and Sustainable Model

- Change controls through clinical phases
- Change Management Philosophies
- Managing changes made at CMOs/CROs
- Optimized change management
- Management of changes in Regulatory submissions (INDs/IMPDs/CTAs & NDAs/BLAs/MAAs)

Gopi Vudathala
Global Head, Regulatory Affairs CMC
Incyte Corporation

15:50 – 16:50 EST

ROUNDTABLE 4:
Effective Implementation of Post-approval Change Globally to Shorten Approval Time

- The challenges and risks that drug manufacturers are facing due to the complexity of post-approval change
- Efficiently managing changes resulting from supply chain constraints
- Discussion on the latest PACMP framework
- Exploring the current tools to manage changes globally and accelerate post-approval change implementation, particularly through the use of protocols/change management plans
- Strategies on a transformational shift towards faster implementation of new knowledge, continual improvement, and innovation through post-approval changes
- Best practices to streamline the process for requesting, creating, editing, approving, and tracking change requests to shorten approval time

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

TRACK 4:
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.

09:00 – 10:00 EST

ROUNDTABLE 1:
A Roadmap Towards Strategic Adoption of Structured Content Management to Generate, Manage, and Reuse Content at a Rapid Pace

- Addressing the regulatory challenges through authoring, reviewing, publishing and compiling troves of documents
- Key drivers to accelerate the shift towards adopting robust data-driven regulatory document management
- Exploring content reuse strategies to automate repetitive tasks and minimize time consuming processes
- Exploring a case study to demonstrate a roadmap through adoption of structured content authoring strategy to minimize errors and repetitive cycles

Franklin Vairinhos
Vice President, Regulatory Affairs
Axcella Health Inc.

11:10 – 12:10 EST

SOLUTION FOCUS ROUNDTABLE 2:
End to End Labelling with Automated Artwork and Regulatory Structured Content (Topic TBC)

Samantha Thompson
Strategic Account Executive – Pharmaceutical
ESKO

David Meister
PreSales Solution Consultant - Brand Management Solutions
ESKO

ESKO

13:40 – 14:40 EST

ROUNDTABLE 3:
Structured Content and End-to-End Labeling from Regulatory Trigger to Automated Creation of Print, Device and Digital Components

- Exploring company approaches to planning for and implementing Structured Content Authoring (SCA)
- Challenges and successes of tracking end-to-end labeling (CCDS updates through to printed PIs/PILs)
- Diving in to capacities to increase digital labeling initiatives (use of QR codes, websites, etc.)

Colleen McGraw
Senior Director, Global Regulatory Affairs Labeling
Moderna

Event Day

15:50 – 16:50 EST

ROUNDTABLE 4:
Addressing the Quality, Compliance, and Operational Challenges Paired with the Constantly Changing Scope of Regulations in Global Pharmaceutical and Device Labeling

- Strategies to increase the accuracy, consistency and traceability of medical device labeling in shorter cycles to ease the barriers for device users
- The importance of real-world device data to create UDI (Unique Device Identification) systems and the importance of the device label to a global UDI system
- Innovative approaches to smoothly incorporate new languages, suppliers and product into the existing production workflows
- The latest efforts of International Medical Device Regulators Forum (IMDRF) to harmonize the regulations and promote consistency in global labeling requirements

Tara Baer
Global Head, Labeling Quality and Excellence
Takeda

TRACK 5:
REGULATORY SUBMISSIONS

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.

09:00 – 10:00 EST

ROUNDTABLE 1:
The Success Stories: Lessons Learned from End-to-End Submission Process of Oncology Therapies to Reshape the Future of Submission Processes for Novel Drugs

- Discussing the challenges throughout the global simultaneous submissions for oncology products and the solutions implemented to successfully bring to market
- The collaboration between global health authorities and the pharmaceutical companies simultaneously to maintain continuity and excel in two-way of communication horizontally and vertically
- Learning outcomes/strategies that can be applied to other diseases and corresponding modalities in terms of flexibility, speed and creativity
- Adopting best practices on optimizing submission process and getting new products to market faster

Guilin Huang
Vice President, Head of Regulatory Affairs
Relay Therapeutics

11:10 – 12:10 EST

SOLUTION FOCUS ROUNDTABLE 2:
The Evolution of Regulatory Outsourcing and the Role of Technology

- How far have we really come in terms of regulatory outsourcing in the last 20 year and what the market data tells us
- Can we/should we operationalize strategy?
- Share outsourcing experiences and lessons learned
- Health Authority considerations for expanding global presence using outsourcing
- Is there more we can do using technology, innovations, automation, and AI?

Michelle Gyzen
Senior Director, Strategic Solutions, Regulatory Affairs and Drug Development Solutions, IQVIA

IQVIA

13:40 – 14:40 EST

ROUNDTABLE 3:
Latest Technology and Trends for Creating Automated, Traceable, Data-driven Submission (Topic TBC)

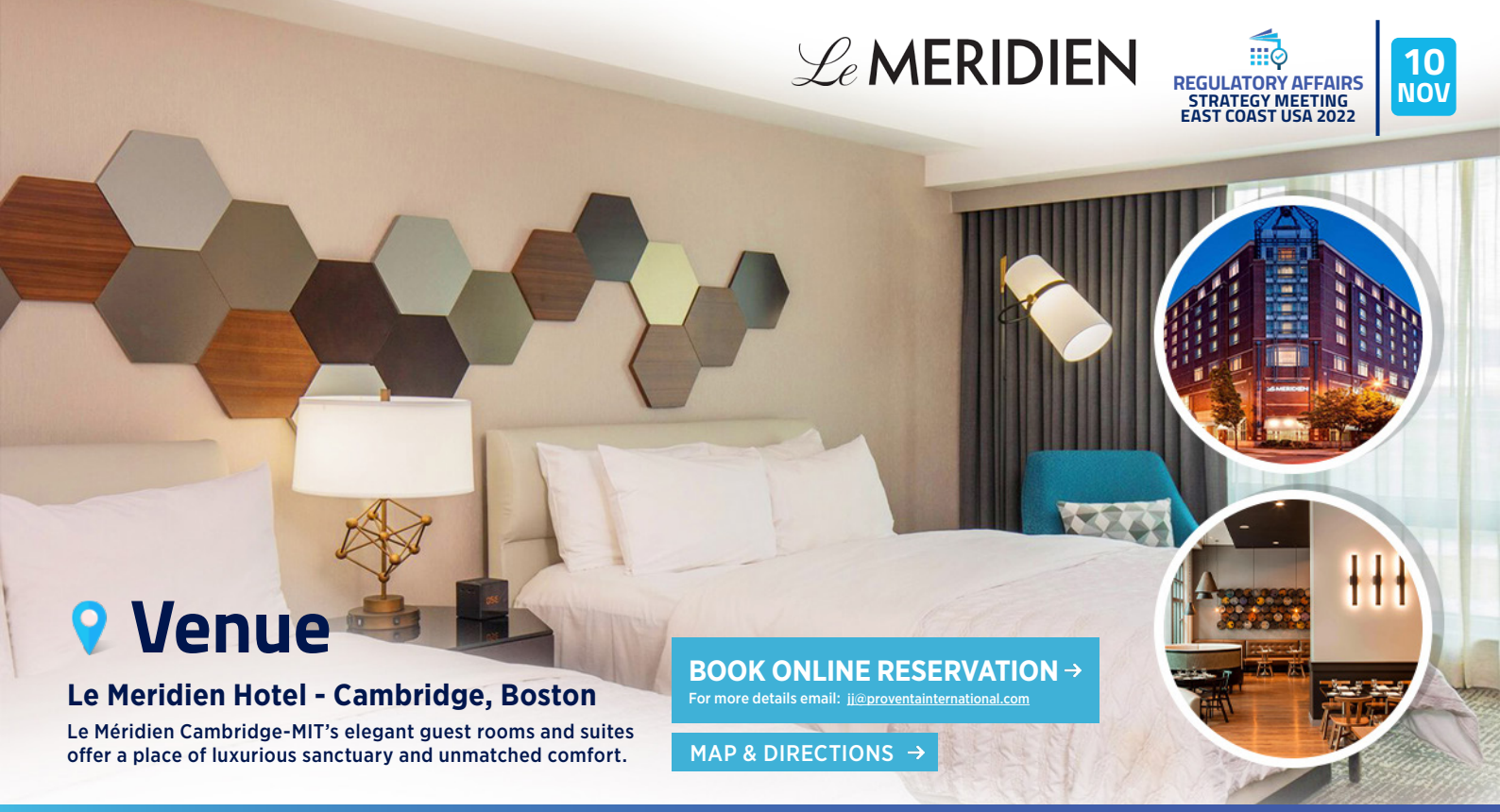
15:50 – 16:50 EST

ROUNDTABLE 4:
Streamlining Global Regulatory Strategy and Submission Processes

- Developing a roadmap from the earliest stages of research and development, through a sequence of global submissions, to market authorization/product maturation
- Exploring innovative tools and technologies to automate workflows, transform the submission creation and speeding up review process
- Strategies on adapting to the unpredictable requirements and responses of different regulatory authorities and increasing the quality and efficiency of data-driven regulatory submissions
- Identifying and implementing best approaches to better support global teams and submissions

Jamie Gillette
Vice President, Head of Regulatory
Cullinan Oncology

MEETING CONCLUDE



Venue

Le Meridien Hotel - Cambridge, Boston

Le Méridien Cambridge-MIT's elegant guest rooms and suites offer a place of luxurious sanctuary and unmatched comfort.

BOOK ONLINE RESERVATION →
For more details email: jj@proventainternational.com

MAP & DIRECTIONS →

OUR FACE-TO-FACE MEETING IN OCTOBER & NOVEMBER 2022

Strategy Meeting Zurich and Boston

Zurich - Europe

OCT 10 MON — CLINICALOPERATIONS
Clinical Operations Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 10 MON — CLINICALTRIALSUPPLYCHAIN
Clinical Trial Supply Chain Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 11 TUE — BIOMANUFACTURING
Biomanufacturing Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 11 TUE — CELLANDGENETHERAPY
Cell & Gene Therapy Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 12 WED — REGULATORYAFFAIRS
Regulatory Affairs Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 12 WED — CHEMISTRYMANUFACTURINGCONTROL
CMC Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 13 THUR — MEDICINALCHEMISTRY
Medicinal Chemistry Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

Boston/Cambridge MA - US East Coast

NOV 08 TUE — ONCOLOGY
Oncology Strategy Meeting 2022
Le Meridien Cambridge

NOV 09 WED — CLINICALOPERATIONS
Clinical Operations Strategy Meeting 2022
Le Meridien Cambridge

NOV 10 THUR — REGULATORYAFFAIRS
Regulatory Affairs Strategy Meeting 2022
Le Meridien Cambridge

NOV 14 MON — DRUG DISCOVERY BIOLOGY
Drug Discovery Biology Strategy Meeting 2022
Le Meridien Cambridge

NOV 15 TUE — MEDICINALCHEMISTRY
Medicinal Chemistry Strategy Meeting 2022
Le Meridien Cambridge

The premier meeting for all East Coast USA Regulatory Affairs professionals

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