

Accelerating Regulatory Excellence

Where domain expertise, digital innovation and data intelligence converge



October 22, 2026



09:00 AM – 05:30 PM ET



Hyatt Regency, Princeton, NJ

Agenda



09:00 – 09:15 AM

Welcome note – Setting the stage for the future of regulatory excellence

Regulatory organizations are facing unprecedented pressure to accelerate innovation, navigate increasing complexity, and extract greater value from data. This opening address will explore why incremental improvements are no longer enough and why regulatory transformation has become a strategic business imperative.

Sudhir Kandarth

Chief Revenue Officer
Freyr Solutions



09:15 – 09:45 AM

Keynote – The regulatory imperative: R&D, Regulatory & AI

As AI becomes embedded across the life sciences value chain, regulatory teams have an opportunity to move from operational support functions to strategic enablers of innovation. This keynote will explore how regulatory, R&D, and digital functions can work together to accelerate development, improve decision-making, and deliver better business outcomes.

Chris Lee

VP, Regulatory Affairs Innovation
and Strategic Operations
Gilead Sciences



09:45 – 10:45 AM

Presentation – The future of regulatory excellence

What does the next-generation regulatory enterprise look like? This session will present a vision for connecting domain expertise, digital capabilities, and enterprise data into a unified operating model. Through real-world use cases, platform demonstrations, and customer perspectives, attendees will see how AI, intelligence, and connected workflows can help organizations improve productivity, compliance, and business agility.

Suren Dheenadayalan

Chief Executive Officer
Freyr Solutions



10:45 – 11:00 AM

Conversations over coffee Networking and innovation zone



11:00 AM – 12:00 PM

Demo: Delivering enterprise regulatory intelligence at scale

Regulatory organizations generate enormous amounts of data, but turning that data into actionable intelligence remains a significant challenge. This session will showcase how modern intelligence platforms, analytics, and AI agents can transform fragmented information into meaningful business insights. Through an end-to-end scenario, attendees will see how organizations can move from reporting historical activity to driving proactive decisions and strategic actions.

Wajeed Abdul

Vice President,
Strategy & Growth,
Freyr Solutions



12:00 – 01:00 PM

Panel Discussion: Driving regulatory excellence

Regulatory leaders from across industries will discuss the challenges shaping today's operating environments and the lessons they are carrying into the future. Topics will include workforce evolution, operating models, technology adoption, organizational readiness, and leadership priorities. The session will provide insights into what is working today, what organizations continue to struggle with, and how leading companies are preparing for the future.

Boris Reznichenko

Senior Director, Head of Global Regulatory Operations and Clinical Transparency
Otsuka Pharmaceutical

Ryan McNeely

Senior Director - Regulatory Affairs Human Capital
Gilead Sciences

Lauren Orme

Senior Director, Regulatory Affairs
West Pharma

Andres Del Rio

Global Director of Regulatory Affairs & Health Science
LIPTON Teas and Infusions

Moderator: Sudhir Kandarath

Chief Revenue Officer
Freyr Solutions



01:00 – 02:00 PM

Lunch & networking

Interactive experience zones showcasing Freyr offerings and capabilities



02:00 – 02:30 PM

Fireside Chat - Rethinking Regulatory Information Management

This session will examine how leading organizations are rethinking the role of RIM to support greater agility, intelligence, and cross-functional collaboration. The discussion will cover emerging business needs, adoption challenges, and the capabilities required to unlock greater value from regulatory information investments.

Coming Soon

Expert from leading biopharma organization

Moderator: Sameer Siddiqui

AVP, FDL FreyaFusion
Freyr Solutions



02:30 – 03:00 PM

Demo - Agentifying post-approval change management

Post-Approval Change Management remains one of the most complex and resource-intensive regulatory processes. This session will demonstrate how agentic AI can automate planning, impact assessments, workflow orchestration, and execution across the PACS lifecycle. Attendees will experience an end-to-end demonstration that illustrates how intelligent agents can augment regulatory teams, reduce manual effort, and accelerate decision-making.

Harshith Subramanian

Senior Manager
Freyr Solutions



03:00 – 03:30 PM

Conversations over coffee

Networking and innovation zone



03:30 – 04:15 PM

Panel Discussion - Reimagining the regulatory operating model

The future of regulatory organizations will not simply be defined by technology, but by how people, processes, data, and AI work together. Industry leaders will discuss how operating models must evolve to support greater speed, scalability, intelligence, and business alignment. Topics will include organizational design, talent transformation, governance, data strategy, and the role of AI in shaping the regulatory function of the future.

Jack Cohen

Executive Director and Global Head of Regulatory Business Operations
Takeda

Andrew Robertson

SVP and Head of Regulatory Affairs and Quality
Denali Therapeutics

Sathya K

Chief Domain Officer
Freyr Solutions

Moderator: Abhishek Rajan Desai

VP, Strategy & Partnerships
Freyr Solutions



4:15 – 04:30 PM

Wrap-up & closing remarks

The next chapter begins here. The day concludes with a reflection on the themes, insights, and calls to action that emerged throughout the summit. Attendees will leave with a clearer understanding of where regulatory transformation is headed and how they can begin applying these ideas within their own organizations. The session will reinforce the key takeaways from FreyrOne and outline the journey ahead.

Suren Dheenadayalan

Chief Executive Officer
Freyr Solutions