Bethesda North Marriott Hotel and Conference Center

Feb 02, 2026 10:00 AM - Feb 04, 2026 12:45 PM

5701 Marinelli Road, North Bethesda, MD 20852

Regulatory Submissions, Information, and Document Management Forum

Don't miss the latest trends, innovations, and best practices in regulatory submissions, information, and document management (RSIDM)!

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Print Agenda

Day 1 Feb 02, 2026

10:00 AM — 5:05 PM — Ballroom Foyer (Upper Level)

Forum Registration

11:30 AM — 12:30 PM — Ballroom A-E

Networking Luncheon in the Exhibit Hall

12:30 PM — 1:00 PM Ballroom E-H

Welcoming Remarks and Presentation of the Excellence in Service Award

1:00 PM — 1:45 PM Ballroom E-H

Session 1: Opening Plenary - Achieving Regulatory Excellence: A Sponsor and Patient Perspective

Join a facilitated fireside chat where we will hear both a sponsor and patient perspective of what Regulatory Excellence means and how we achieve it. Our panelists will discuss how Regulatory Excellence has evolved in the digital age and how we expect it will change given ongoing transformations. In addition, we will be reminded of the patient impact of our work and how our day-to-day work is crucial in ensuring that life-saving products reach those that need them.
Track: General Session

Session Chair(s)

Jared Lantzy, PMP

Executive Director, Global Regulatory Operations
Novavax, United States

Mr. Lantzy has over 20 years experience solving technology and people problems in government, vendor, consulting, and industry environments. He is a former member of CDER's Electronic Submission Support Team at the US FDA and currently leads the Global Regulatory Affairs Operations team at Novavax, Inc. His current interest is on improving the exchange and review of data between industry and regulatory health authorities, to ultimately provide safer and more effective products to patients and for public health.

Noelia Plaza

Director of Process Excellence & Analytics
Daiichi Sankyo, United States

Noelia leads Daiichi Sankyo's Process Excellence & Analytics group for Global Regulatory Affairs. She is responsible for managing GRA's controlled procedural documents, optimizing global processes, ensuring compliance, and delivering metrics that support data-driven decision making in Regulatory. She began her career at Accenture and joined Daiichi Sankyo in December 2022. During her tenure at Accenture, Noelia partnered with a variety of sponsors on global transformation programs across Clinical and Regulatory, with a focus on improving processes with enabling technologies.

Speaker(s)

Speaker

Henrietta N. Ukwu, MD, FACP

Executive Vice President and Chief Regulatory Officer
Novavax, United States

Speaker

Representative Invited

Eli Lilly and Company, United States

Executive leader for Global Regulatory Affairs for Eli Lilly and Company. The organization is responsible for the regulatory leadership and strategic and operational support for human drugs, medical devices, and global manufacturing for Eli Lilly and Company. Dr. Garner leads Lilly's external engagement with global regulatory authorities and other stakeholders to share the goal of improving public health by delivering medicines that make life better for people around the world. In this role, Dr. Garner provides executive leadership to Lilly drug discovery, development, and manufacturing governance committees.

Speaker

Jamey Galione

Director, CMC Submission Management
Bristol Myers Squibb, United States

Jamey Galione is a seasoned Regulatory Affairs leader with over 25 years of experience driving excellence in Chemistry, Manufacturing, and Controls (CMC), Regulatory Operations, and Quality Assurance. Jamey's career spans leadership roles as Global Regulatory Strategist, Global CMC Specialist, and Regulatory Project Manager, with deep expertise in vendor management, eCTD submissions, and regulatory systems optimization. Skilled in implementing and enhancing content management and tracking platforms, Jamey streamlines global operations and ensures compliance. A cancer survivor, Jamey advocates for advancing early detection through biomarkers, diagnostics, and medical devices, reinforcing a lifelong commitment to improving patient outcomes.

1:50 PM — 3:05 PM

Session 2: FDA Electronic Submissions Update

This session will provide information related to electronic submissions. Topic areas will address eCTD, ESG, GSRS, CDER Nextgen Portal, and a proof of concept around modernizing the Information Request process. Experts from these areas will discuss recent updates and be available during the FDA Ask the Regulator session to answer questions.
Learning Objective :

- Discuss updates to FDA's eCTD program including eCTD v4.0, webpage edits, updates to specification and guidance, common validation issues
- Identify updates to CDER's NextGen Portal and when to use it
- Explain benefits of FDA's Global Substance Registration System
- Share updates to FDA's ESG program including transition to ESG NextGen, webpage edits, overall benefits
- Explain how the IR Modernization proof of concept can address pain points

Track: General Session

Session Chair(s)

Jonathan Resnick, PMP

Project Management Officer, OBI, OSP, CDER
FDA, United States

Jonathan Resnick is a member of CDER's Division of Data Management Services and Solutions, with a focus on eCTD and has been with FDA for 15 years. Prior to joining FDA, Jonathan spent 18 years working in IT project management supporting federal and private sector clients.

Seyoum Senay, MS

Supervisory Operations Research Analyst, CDER/OBI
FDA, United States

Mr. Senay is a visionary leader with a focus on innovation and positive change. At the heart of his mission is the widespread adoption of cutting-edge Informatics solutions, aimed at ensuring the availability of safe, effective, and new medicines for patients. As a U.S Excellence in Government Leadership Fellow, Mr. Senay is recognized for his excellence in delivering impactful results. Holding a master's degree from The Johns Hopkins University and being a Certified Program Manager, he brings extensive knowledge and expertise to advance the FDA CDER mission.

Speaker(s)

ESG

Representative Invited

FDA, United States

Jessica Bernhardt currently is the Program Manager for the Electronic Submissions Gateway (ESG) and AdminApps programs at the Food and Drug Administration (FDA). She took on the role of ESG Program Manager at the start of 2023 and oversaw the successful completion of the ESG AWS Migration. Jessica joined the FDA in 2020 as the AdminApps Program Manager, which she has successfully managed for the past three years. Jessica started her career in Government nine years ago when she joined the Social Security Administration (SSA) as an IT Specialist. After a year working as an IT Specialist for a year, was assigned to lead and manage an IT Modernization project, promoting the use of the Agile development lifecycle. In 2016 she was promoted

Updates to eCTD for v3.2.2 and v4.0

Representative Invited

FDA, United States

Heather Crandall has been with the FDA since 2012, working in CDER's Office of Business Informatics. She currently focuses on standards and processes around electronic submissions.

Global Substance Registration System (GSRS) and submitting Structure Data File (SDF) to FDA

Representative Invited

FDA, United States

Siba Bhattacharyya, PhD Health Scientist, ODAR(HIS), ODT, OC, FDA, United States Siba completed his undergraduate degree in Chemistry followed by master's and PhD in Biochemistry. He went on thereafter to complete 3 years of postdoctoral research in Microbiology. After serving for 5 years as a visiting scientist at the NIH/NIAID Immunology program, Siba became a chemist for 12 years in CBER at FDA focusing on blood products, vaccines and live biotherapeutics, followed by another 10 years in CDER focusing on chemically synthesized drugs and fermentation derived drugs. Siba published several papers in immunology, virology, JBC and on the regulation of probiotics. Currently, he is working on Global Substance Registration System (GSRS) at FD

3:05 PM — 3:50 PM Ballroom A-E

Refreshement and Networking Break in the Exhibit Hall

3:50 PM — 5:05 PM Ballroom E-H

Session 3: FDA - Ask the Regulators

Dedicated to sharing the latest information on new guidance's, this session will allow open discussion between the audience and an esteemed panel of regulatory experts. This session provides attendees the opportunity to ask regulators questions directly.

Please note: Due to the high volume of questions, not all will be answered live at the forum. We encourage participants to consider the regulators' backgrounds and expertise when directing their questions to ensure a more tailored and focused discussion. Note: Please hold all questions on eCTD v4.0 until Session 4.

Track: General Session

Session Chair(s)

Jonathan Resnick, PMP

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5:05 PM — 6:05 PM Ballroom A-E

Networking Reception in the Exhibit Hall

Day 2 Feb 03, 2026

7:45 AM — 4:30 PM | Ballroom Foyer (Upper Level)

Forum Registration

7:45 AM — 8:15 AM | Ballroom E-H

Networking Breakfast in the Exhibit Hall

8:15 AM — 8:30 AM | Ballroom E-H

Welcome to Day Two and DIA Community Update

8:30 AM — 10:00 AM | Ballroom E-H

Session 4: eCTD 4.0 in Action: Readiness and Alignment Across Global Health Authorities

As health authorities worldwide move toward eCTD 4.0 implementation, global collaboration and harmonization are key to realizing its full potential. This session will bring together global regulators to share updates on regional progress, highlight opportunities to strengthen global alignment, and discuss how eCTD 4.0 can improve the quality, consistency, and efficiency of regulatory submissions. Participants will gain a high-level understanding of current timelines, readiness activities, and the broader vision for how eCTD 4.0 supports digital transformation and more agile regulatory review processes.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Describe the overarching goals and expected benefits of eCTD 4.0 implementation across regions

Track: General Session

Session Chair(s)

Lorelle Leonienco, PMP

Product Manager
LORENZ Life Science Group, United States

Lorelle Leonienco, PMP Product Manager, Global Regulatory Agencies, LORENZ Life Sciences Group, Canada With over 20 years in Life Sciences, Lorelle has held roles across Commercial, Regulatory, Medical, Clinical, and IT in both Generic and Brand Pharma. Her career has focused on implementing technology to modernize operations, drive efficiency, and support regulatory compliance. As Product Manager for Global Regulatory Agencies at LORENZ Life Sciences Group, she steers the development of strategic RIM solutions designed to meet the evolving needs of Health Authorities, ensuring they are aligned, user-focused, and impactful across the global regulatory landscape.

Tamei Elliott, MS

Director, Global Scientific Content
DIA, United States

Tamei Elliott, MS, serves as the Associate Director of Scientific Programs for the Americas region at DIA. In this pivotal role, she is responsible for identifying and prioritizing content areas and topics crucial to DIA constituents. Tamei assesses the implications of significant regulatory and health policy changes, seamlessly integrating relevant content into the development and advancement of DIA conferences and courses. Her responsibilities extend to overseeing content development and strategy within the Americas region.

Speaker(s)

Speaker

Jonathan Resnick, PMP

Project Management Officer, OBI, OSP, CDER
FDA, United States

Jonathan Resnick is a member of CDER's Division of Data Management Services and Solutions, with a focus on eCTD and has been with FDA for 15 years. Prior to joining FDA, Jonathan spent 18 years working in IT project management supporting federal and private sector clients.

Speaker

Kristiina Puusaari, MBA, PMP

Digital Business Transformation Programme eSubmission Senior Coordinator
European Medicines Agency, Netherlands

Kristiina joined the European Medicines Agency in January 2002 and is responsible for the implementation, coordination and maintenance of the eSubmission systems and processes at the agency. Kristiina is a Product Owner and a subject matter expert for eCTD v3.2.2, eCDT v4.0, the electronic Application Forms (eAFs), the eSubmission Gateway and Web Client, the Common Repository, the PSUR Repository and the business processes related to the eSubmissions. Kristiina works closely with the EMA business and technical colleagues and the development teams, the colleagues from the European Medicines Network (EMRN) and pharmaceutical industry. Kristiina represents the EMA in eSubmissions related stakeholder groups and is a co-chair of the ICH M8.

Speaker

Representative Invited

Health Canada, Canada

Marcin Boruk has been with Health Canada since 2005 and has worked in the areas review, legislation and business transformation. Currently he is an acting Director in the Business

Facilitation and Modernization Directorate, Health Canada supporting the branch in projects related to secure technology platforms, data governance, stewardships and standards.

Speaker

Andrea Johnson

Deputy Director Future Systems Business Requirements
Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Andrea began her career in genetic toxicology before joining the MHRA in 1996. She has worked in diverse roles including product licensing, system development, and various and various business architecture roles. Her responsibilities have included working with International Partnerships on several projects such as IDMP and eSubmissions. For the past three years she has been Deputy Director in the Health Quality and Access Group, managing teams including those handling eCTD. Most recently her work has focussed on aligning business needs with system development.

10:00 AM — 10:45 AM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

10:45 AM — 12:00 PM

Session 5, Track 1: Enhancing Data Reliability and Acceptability of RWD to support Harmonized Regulatory Decision Making Across US, China and EU

Session 5, Track 1: Enhancing Data Reliability and Acceptability of RWD to support Harmonized Regulatory Decision Making Across US, China and EU
Track: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Jillian E. Carinci, MS

Senior Director, Head of Submission Sciences
Biogen, United States

Jillian Carinci is Sr. Director, Head of Submission Sciences group at Biogen. Jillian leads Biogen's Global Delivery Managers and is responsible for overseeing global submissions, establishing processes, ensuring compliance, robust submission planning, tracking metrics, high quality submission delivery and process improvements. Jillian began her career at Octagon Research Solutions before transitioning to Accenture. During her tenure at Accenture Jillian partnered with sponsors to manage numerous

regulatory submission projects, ensuring compliance with global regulatory requirements, delivering within scope, on time, and with the highest quality.

Speaker(s)

Enhancing Data Reliability and Acceptability of RWD to support Harmonized Regulatory Decision Making Across US, China and EU

David Ross, MBA, MSc, PMP, RAC

Senior Director, Digitial Advocacy and Policy
AstraZeneca, United States

David Ross (Senior Director, Regulatory Data and Submissions, AZ) has undergraduate degrees in Chemical Engineering, and Biochemistry with an MBA and Engineering Management graduate degrees. He led global complex Business Transformation projects in the Pharmaceutical and Biologics industry. In his Global Regulatory Policy role, David is actively involved in Reliance and Collaboration efforts at AZ. David is Bio Representative in the ICH Task Force for PQKM Feasibility Assessment. As the GSO IRISS Lead (2016 to present) David hosts monthly meetings on Regulatory Submission and Data innovation. As AZ Lead for PhRMA IT Group (2014 to 2023), David helped lead the PhRMA IT White Paper on Cloud based computing with global collaboration.

Speaker

Brian Gillette, PhD

VP, Data
Droice Labs, United States

10:45 AM — 12:00 PM

Session 5, Track 2: Successful Digital Implementation: Demystifying the Submissions Journey to Automation, AI & Data Content Transformation

Session 5, Track 2: Successful Digital Implementation: Demystifying the Submissions Journey to Automation, AI & Data Content Transformation
Track: Optimizing Processes and Procedures
Level: Advanced

Session Chair(s)

Maria Sagoua, MHA

United States

Maria Barhams Sagoua joined Accumulus Synergy as Director, Regulatory Innovation where she is responsible for translating regulatory requirements into practice within the Accumulus Platform. Prior to joining the Accumulus team, Maria served as SAS' Principal Consultant to the U.S. FDA where she was responsible for partnering with the Agency to advance digital transformation goals across regulated products.Throughout her career, Maria has worked across the biomedical research (NIH), regulatory (FDA), technology (DrFirst) and clinical (Kaiser Permanente) ecosystem to support the design, development, and delivery of innovative solutions. Maria holds a BS-Biology from Ball State University and MHSA from the George Washington University.

Speaker(s)

Speaker

Kevin O'Leary

VP of R&D, Quality and Regulatory
Dassault Life Sciences, Ireland

Speaker

Kathleen Vieson, PharmD

Principal
Sage Content Solutions, United States

Kathleen has spent over 25 years in the life sciences digital content space as an editor, product manger, Editor in Chief, and leader of integrated content teams. Over her career, Kathleen has led teams to embrace new ways of working supported by innovative content operations including structured content authoring. Recently, Kathleen has worked with several pharmaceutical regulatory affairs groups as part of their journey to data-integrated, digital solutions.

10:45 AM — 12:00 PM

Session 5, Track 3: Has Cloud Innovation Stalled in Regulatory Exchange — And Why We Can't Afford to Let It Stay That Way

Has Cloud Innovation Stalled in Regulatory Exchange — And Why We Can't Afford to Let It Stay That Way
Learning Objective :

- Examine if cloud adoption for regulatory exchange has stalled despite clear technical benefits
- Explore the organizational, cultural, and compliance challenges impeding progress
- Learn from case studies where cloud-enabled regulatory workflows are beginning to take hold
- Identify key enablers for building a sustainable, cloud-ready regulatory infrastructure

Track: Adopting Innovative Technologies
Level: Intermediate

Session Chair(s)

Jared Lantzy, PMP

Executive Director, Global Regulatory Operations
Novavax, United States

Mr. Lantzy has over 20 years experience solving technology and people problems in government, vendor, consulting, and industry environments. He is a former member of CDER's Electronic Submission Support Team at the US FDA and currently leads the Global Regulatory Affairs Operations team at Novavax, Inc. His current interest is on improving the exchange and review of data between industry and regulatory health authorities, to ultimately provide safer and more effective products to patients and for public health.

Speaker(s)

Sandra Krogulski, MA

Director, GRSO Innovation and Business Operations Lead
Bristol Myers Squibb, United States

Sandy Krogulski is an experienced and solution-oriented individual with over 10 years of submission and regulatory experience. Sandy joined BMS in 2018, working on global submissions and process evolution. In her current role, Sandy is focusing on digitalization and automation of processes to improve submission strategy and business operations.

Speaker

Representative Invited

Pfizer Inc, United States

David Isom is Senior Director, Global Regulatory Policy at Pfizer where he leads policy and advocacy for priorities that include innovative use of technology and data to transform regulatory submission and review, and global regulator collaboration. Before his focus on policy, David led several Pfizer regulatory information management, real world data, and clinical trial data services. Prior to joining Pfizer in 1999, David served at the U.S. FDA as a regulatory project manager in CDER's Division of Antiviral Drug Products, and later as Head of CDER's Office of IT and e-submission programs. Before FDA, David worked in healthcare outpatient and surgical settings as a U.S. Navy Hospital Corpsman. David has a B.Sc from University of Maryland.

Speaker

Representative Invited

Astellas Pharmaceuticals, United States

Peter is the Executive Director of Regulatory Data and Document Operations for Astellas. This global group has responsibility for submissions, product registrations and labeling operations. Peter has been involved in multiple global programs targeting process improvements in product change control, document and submission management, and sourcing strategies. Prior to moving into Regulatory Operations, Peter worked in IT at Astellas focusing on informatics in the areas of RA, QA and document management. He is a strong advocate for gender parity and empathy in the workplace. Peter has a Bachelor's degree in Mathematics from Austin College in Sherman, TX, and an MBA from the Lake Forest Graduate School of Management.

10:45 AM — 12:00 PM

Session 5, Track 4: The Future of Regulatory: Reimagining Operating Models for the Digital and AI Revolution

With a focus on real-world experience and multi-company perspectives, the discussion will delve into how organizations are adapting their operating models and capabilities to a digital future with transformed submissions. Panelists will share practical strategies for aligning global operations, overcoming challenges of fragmented data ownership, and the importance of cross-functional collaboration to reduce cycle times and improve submission quality—all while integrating new digital tools and AI capabilities. By blending insights on operating model redesign with the realities of technology adoption, the session will highlight:

Practical approaches to structuring regulatory teams and governance to support both global consistency and local agility

The impact of AI and automation on regulatory workflows, decision-making, and cycle times

Lessons learned from implementing digital solutions and managing change across complex organizations

Learning Objective :

- Gain actionable strategies for leading technology-driven transformation in regulatory affairs
- Learn practical approaches to optimizing regulatory operating models in the digital era
- Employ guidance on integrating AI and automation while maintaining compliance and business continuity
- Use insights from industry leaders on overcoming common challenges and driving sustainable change

Track: Strategic Leadership and Organizational Readiness

Level: Advanced

Session Chair(s)

Cindy Chiu

Senior Director, Regulatory Affairs Operations and Quality Management
Merck & Co., United States

Cindy Chiu is a Senior Director in Global Regulatory Affairs and Clinical Safety group at Merck & Co. She has over 20 years of experience in the pharmaceutical and energy industries, focusing on post-merger process integration and operations excellence. She has served in various leadership roles overseeing project management, business process improvement and change management initiatives. In her current role at Merck & Co., she is the Lead of the Regulatory Content Authoring and Archiving Management group. Prior to Merck, she worked as a management consultant, where she assisted clients with change management and business process redesign as a result of merger activity or technology integrations.

Speaker(s)

Speaker

Mukesh Singhal, MBA

Partner
Deloitte, United States

Mukesh Singhal is a leader in Deloitte's R&D and Regulatory practices, with over 15 years of industry experience shaping and leading digital transformations across the industry. Mukesh has led a cross-industry

Regulatory Intelligence forum since 2018, helping to shape an industry vision for a next gen regulatory intelligence capability. Mukesh is the product owner of Deloitte's next gen regulatory intelligence industry solution.

12:00 PM — 1:15 PM Ballroom A-E

Networking Luncheon in the Exhibit Hall

1:15 PM — 2:30 PM

Session 6, Track 1: Shaping the Future of Regulatory: Trends, AI, and Practical Success

This session highlights how regulatory functions are evolving through global technology trends, artificial intelligence, and smarter data strategies. We'll explore regulatory tech expectations in clinical research, focusing on intelligence and practical implementation. Key insights will cover AI adoption in regulatory, including considerations for success, and the strategic management of regulatory data to enable structured submissions, governance, and analytics. Together, these perspectives provide a clear roadmap for modernizing regulatory operations and achieving practical success.
Learning Objective :

- Spot emerging global regulatory trends and understand how they're reshaping the future of clinical research
- Gain practical insights into AI adoption in regulatory work, with clear considerations for driving success in their own organizations
- Leverage smarter strategies for managing regulatory data to streamline submissions, strengthen governance, and unlock the power of analytics

Track: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Nimesh Patel

Director of Global Regulatory Systems
Eisai Pharmaceuticals, United States

Director of Global Regulatory Systems, overseeing the implementation, support and development Eisai's Regulatory technology strategy. Active member of IRISS and Committee Member in PhRMA's Regulatory IT Workstream. Prior to Eisai, performing similar roles in supporting the Regulatory functions at Big Pharma, Consultancies and mid-size biotech's for the past 20+ years.

Speaker(s)

Global Regulatory Tech Expectations: Trends, Intelligence, and Practical Implementation in Clinical

Research

Sara Saunders, MHA

Sr. Manager Regulatory Afffairs
Florence Healthcare, United States

Implementing AI in Regulatory: Key Considerations for Success

Sean Carpenter

Project Manager
Ennov, United States

USE CASE: Strategic Management of Regulatory Data: Enabling Structured Submissions, Governance, and Analytics

Donna Yosua

Director, Master Data Management & Data Governance
Merck & Co., United States

Donna Yosua leads the Merck Data Harmonization & Interoperability program which includes the implementation of a regulatory data hub and canonical data model with reusable data publications, reporting and analytics dimensional data model, and corresponding regulatory data governance framework. Donna is a seasoned Life Sciences Strategist/Business Architect and an expert in Regulatory Information Management with 25 years of experience guiding organizations toward improved business performance by leading the development and deployment of new strategies, processes, and enabling technologies. She has global experience in the pharmaceutical, technology development, and consulting industries.

1:15 PM — 2:30 PM

Session 6, Track 2: Strategies to Transform Regulatory Affairs

Join us to explore how to evolve regulatory affairs with forward-looking approaches, key foundations, and strategic tech implementation. This session will focus on how to move beyond the legacy processes of the past to successfully enable modern frameworks for aligned, efficient, and automated procedures across regulatory. Ways to apply content governance, structured data, automation, and more will be examined along with their prospective benefits.
Learning Objective :
At the conclusion of this session, participants should be able to:

- Identify the risks of fragmented or improperly implemented processes on regulatory affairs
- Recognize the benefits of structured data and content governance in regulatory

- Discuss the strategic approaches and technological practices to bolster regulatory affairs for the future

Track: Optimizing Processes and Procedures

Session Chair(s)

Rachel Bombara

Sr. Regulatory Services Manager
Certara, United States

Rachel has 13+ years of experience in regulatory operations and helping sponsors achieve their eCTD submission goals. She has led the eCTD submission publishing of a variety of application types for different regions, from small amendments to large-scale original marketing applications, as well as mentored and trained others in eCTD publishing and submission management. She has also spoken at industry conferences on topics pertinent to investigational and marketing related submissions and produced a variety of blogs, presentations, and other materials to share valuable industry insights.

Speaker(s)

Beyond the Spreadsheet: The Silent Cost of Data Chaos in Regulatory Affairs

John Popp, PhD

Manager – Regulatory Information Management
Celegence, Netherlands

John is a skilled and versatile life science professional with 5 years of industry experience and a robust scientific background, including over a decade of research in chemistry with conference presentations and journal publications. As a certified change practitioner with (agile) project management certifications, John combines strong analytical skills, a hands-on mentality, and a solution-focused mindset helping regulatory teams manage data more effectively, drive digital transformation, and stay ahead in a changing industry.

Data + Content Governance: The Missing Foundation for Scalable-AI in Regulatory Affairs

Vanni Carapetian, MPH

Director, Regulatory Data
Genentech, A Member of the Roche Group, United States

Vanni brings nearly 20 years of life sciences and technology expertise drawn from team and leadership roles at Roche, J&J, and Amgen. Their experience spans clinical development, manufacturing, and regulatory and their principal interest lies in setting and executing strategies that enable organisations to generate value from data. In their current role, Vanni is the Regulatory Data Lead at Roche and is based in South San Francisco.

1:15 PM — 2:30 PM

Session 6, Track 3: Drive Global Safety with Semantic Alignment: Implementing IDMP Ontology and FHIR for Smarter Pharmacovigilance

As pharmacovigilance evolves into a globally coordinated, data-driven discipline, aligning medicinal product data across jurisdictions becomes critical. This session explores how the IDMP Ontology and FHIR API enable semantic interoperability between regulatory authorities and sponsors, overcoming challenges in substance naming, dose forms, and terminologies. Through real-world case studies, attendees will learn how harmonized IDMP concepts and global identifiers support accurate signal detection, product matching, and scalable data exchange. The session will also highlight strategies for deploying IDMP within sponsor cloud platforms and national regulatory systems to enhance global safety collaboration.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Explain how the IDMP Ontology supports semantic interoperability across regulatory and sponsor systems
- Demonstrate the use of the global IDMP FHIR API to align product data for improved signal detection
- Identify implementation strategies for integrating IDMP into cloud-based pharmacovigilance platforms

Track: Adopting Innovative Technologies

Session Chair(s)

Matthias Sijtstra

Senior Consultant
Main5 GmbH & Co. KGaA, Netherlands

Matthias works as a Senior Consultant at Main5 GmbH & Co. KGaA. The focus of his work is Data Management, where he provides consultancy and subject matter expertise for implementation of Regulatory Information Management (RIM) solutions and compliance projects (e.g. IDMP). In these projects, he is looking to gain more for the client than just compliance, by engaging people, processes, and tools, he is working to improve the client's data quality and processes. Additionally, Matthias has experience in software development and validation in a highly regulated environment.

Speaker(s)

Speaking the Same Language: Leveraging the IDMP ontology and FHIR to Enhance Global Pharmacovigilance and Collaboration

Magnus Wallberg, MSc

Technology Evangelist
Uppsala Monitoring Centre, Sweden

Magnus Wallberg completed his M.Sc. degree in Engineering Physics from Uppsala University, School of Engineering. Since 1999 Magnus has worked in the area of pharmacovigilance informatics. Magnus has for many years had the overall responsibility for the Systems Development Strategies of internal and external development projects at the Uppsala Monitoring Centre. Magnus now has the role of Technology Evangelist focusing on harmonization and beter use of technology to enhance patient safety.

Speaker

Representative Invited

FDA, United States

Speaker

Representative Invited

Pfizer Inc , Canada

Craig Anderson, Director of Data Standards & Continuous Improvement at Pfizer, oversees global Labeling projects, focusing on electronic labeling, drug product details, AI, digital health, and data standards. With industry experience and a regulatory background from Health Canada, he led projects on Structured Product Labeling, IDMP, and AE reporting. Craig also co-leads HL7 FHIR initiatives, including ePI, PQI, Structured Regulatory Correspondence, and API Exchange of Medicinal Product Information.

1:15 PM — 2:30 PM

Session 6, Track 4: Achieving Regulatory Operational Excellence: People, Process, Data, Tech

The session will blend key insights and learning from the fall Gens & Associates Regulatory Operational Excellence and World Class RIM study with experiences from two different sized sponsors. The session will minimally focus on 6 key areas that contribute to regulatory operational excellence: 1) process optimization / maturity, 2) KPI/Metric program effectiveness, 3) advanced technology investment priority and ROI, 4) Data Governance practices leading to high data quality levels, 5) authoring transformation (e.g. GenAI usage / ROI and 6) Regulatory Digitization progress.
Learning Objective :
At the conclusion of this session, participants should be able to:

- Recognize what constitutes a high performing Regulatory organization
- Explain which advanced technology use cases are getting the best ROI
- Implement practical approaches for improving a regulatory KPI/Metrics Program

Track: Strategic Leadership and Organizational Readiness

Session Chair(s)

Noelia Plaza

Director of Process Excellence & Analytics
Daiichi Sankyo, United States

Noelia leads Daiichi Sankyo's Process Excellence & Analytics group for Global Regulatory Affairs. She is responsible for managing GRA's controlled procedural documents, optimizing global processes, ensuring compliance, and delivering metrics that support data-driven decision making in Regulatory. She began her career at Accenture and joined Daiichi Sankyo in December 2022. During her tenure at

Accenture, Noelia partnered with a variety of sponsors on global transformation programs across Clinical and Regulatory, with a focus on improving processes with enabling technologies.

Speaker(s)

Achieving Regulatory Operational Excellence: People, Process, Data, Tech

Steve Gens, MS

Managing Partner
Gens & Associates Inc., United States

Steve Gens (MSOD) is the Managing Partner of Gens & Associates Inc., a global Life Science benchmarking and advisory firm specializing in performance improvement, strategy, industry analysis, benchmarking and organizational transition. His early career was spent at Johnson & Johnson in a variety of management positions and then transitioned to consulting where he lead global Life Science consulting practices for First Consulting Group and Booz Allen Hamilton. His organization is well known for their insightful industry benchmarks and World Class RIM thought leadership. Steve has a Bachelor's of Science in Business Computer Science and a Master in Organizational Development and Performance.

2:30 PM — 3:15 PM

Refreshement and Networking Break in the Exhibit Hall

3:15 PM — 4:45 PM

Session 7, Track 1: Data-driven Submissions - How Pharmaceutical Companies are Getting Ready for a New Era

As regulatory agencies implement structured, modular, and digital-first requirements, leading pharmaceutical organizations are confronting unprecedented regulatory convergence. Initiatives such as ICH M4Q(R2), CDISC USDM, ICH M11, and ePI are reshaping content creation, more as data, across clinical, CMC, and labeling domains—demanding both operational and organizational transformation. This session will have transformation leaders from multiple pharmaceutical companies and providers to share how they are designing future-state operating models, building scalable governance for cross-functional content collaboration, sequencing technology implementation for maximum impact, and overcoming organizational resistance to digital transformation. Attendees will hear from organizations at varying stages of adoption, from early pilots to mature programs. This collaborative session provides actionable strategies for pharmaceutical leaders building comprehensive digital content ecosystems that position their organizations for regulatory modernization initiatives including FDA KASA requirements, EMA SPOR implementation, and emerging global harmonization standards driving the future of pharmaceutical operations. Speakers will share practical insights on establishing Centers of

Excellence, managing change across regulatory affairs, clinical operations, and manufacturing quality teams, while addressing technical challenges including enterprise system integration and metadata standardization.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Understand How Leading Pharma Companies Are Implementing Structured Content Strategies to Improve Regulatory Agility
- Gain Practical Strategies for Building Scalable Governance and Future-State Operating Models
- Explore How to Overcome Organization Resistance and Enable Digital Transformation Through Effective Change Management and System Integration

Track: Building and Sustaining Successful RSIDM Foundations

Level: Intermediate

Session Chair(s)

Venkatraman Balasubramanian, PhD, MBA

Healthcare and Life Sciences Strategic Advisor
VB Insights, LLC, United States

Bala heads VB Insights, an advisory firm for the Healthcare and Life Sciences sector. Bala brings over 35 years of experience. During his long tenure, he has been responsible for the introduction of Web, document management, global team collaboration, and regulatory information management applications to large pharma. Until recently, Bala was Head of the Healthcare and Life Sciences Industry Solutions Group at Orion Innovation. As an entrepreneur and a thought leader, he has been involved in initiatives to transform regulatory affairs from a document-centric function to a data-driven function. Bala has been associated with DIA for more than 14 years, most recently as the DIA RIM Working Group subteam lead for the RIM Reference Model.

Speaker(s)

Data-driven Submissions - How Pharmaceutical Companies are Getting Ready for a New Era

Niklas Jaenich, PhD, RPh

Head of Global Labeling Operations and Digitization
Boehringer Ingelheim, Germany

Niklas Jänich serves as the Head of Global Labeling Operations & Digitization at Boehringer Ingelheim. In this role, he oversees the end-to-end labeling process, ensuring system efficiency, regulatory compliance, and driving digital transformation. His key focus areas include advancing structured content management within the GxP-regulated labeling framework and championing the global rollout of electronic Product Information. Niklas is a licensed pharmacist with a PhD in medicinal chemistry and a Master's degree in Drug Regulatory Affairs, combining scientific expertise with regulatory insight to shape the future of pharmaceutical labeling.

Speaker

Madhavi Gidh-Jain, PhD

Global Medical Writing and Document Management Head
Sanofi, United States

Madhavi Gidh-Jain is the Global Head of Medical Writing and Document Management for all therapeutic areas and regions at Sanofi. Madhavi has more than 20 years of experience in designing, writing, and reviewing medical and regulatory documents for pharmaceuticals, biologics, devices, and combination healthcare

products. Her work at various pharmaceutical and biotech companies includes digital innovation, process management, and preparation of marketing applications for Health Authorities.

Speaker

Laurent Lefebvre

RA CMC Director
Novartis, Switzerland

Speaker

Murali Menon, MS

Chief Revenue Officer
Docuvera, United States

Murali Menon is Chief Revenue Officer at Docuvera, where he leads business strategy and partnerships focused on transforming how life sciences organizations create, manage, and deliver clinical and regulatory content. With over 20 years of experience in technology and digital transformation, Murali is passionate about helping teams move from document-based to data-driven processes. His leadership combines deep domain expertise with a vision for interoperability, automation, and compliance across the clinical lifecycle.

3:15 PM — 4:45 PM

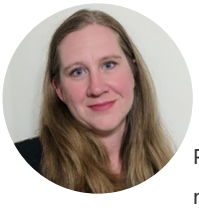
Session 7, Track 2: Interactive Workshop: Using Hackathons to Identify Regulatory Process Bottlenecks and Develop AI-Enabled Solutions

Join us for an interactive workshop designed to empower regulatory affairs, regulatory operations, and IT leaders with practical approaches to drive innovation, enhanced business performance and compliance through hackathons. This session will begin with insights from the 2025 DIA RIM Intelligent Automation Survey. Speakers will then introduce the concept of hackathons — what they are, when to use them, how they can accelerate problem solving and cross-functional collaboration, and share their experiences using hackathons in pharmaceutical organizations.
Learning Objective :
At the conclusion of this session, participants should be able to:

- Identify when and how to use hackathons to address regulatory business challenges, improve business process efficiency and quality
- Define regulatory problems and brainstorm artificial intelligence and automation solutions collaboratively
- Apply a structured hackathon approach to optimize regulatory business processes and generate business value

Track: Optimizing Processes and Procedures
Level: Intermediate

Session Chair(s)



Lindsay Fitzgerald

Delivery Manager
Astrix, United States

Regulatory Affairs Business Solution expert with proven industry experience in project management, advisory services, business analysis and business support of the Department. With her 10 years' experience at AstraZeneca leading Regulatory IT projects, spanning business/technology analysis, project management, validation/testing, business training development and delivery she has credibility speaking with both IT and Regulatory business stakeholders. As an end-to-end RIM process data and system expert with 9 years' experience in Regulatory consulting for top pharma clients she has led business process optimization, RFP and vendor selection, implementation, and migration projects.

Speaker(s)

Using Hackathons to Identify Regulatory Process Bottlenecks and Develop AI-Enabled Solutions

Cary Smithson, MBA

Managing Partner
LeapAhead Solutions, Inc., United States

Cary is the Managing Partner of LeapAhead Solutions and has over 30 years of experience in life sciences focused on leading strategic initiatives to drive increased business productivity, enhance regulatory compliance, and simplify information management and the use of technology. Her areas of expertise include regulatory information management, artificial intelligence, data strategy/governance, clinical/R&D and GxP content management, IT strategy, enterprise architecture, Agile, business process optimization, and project/program/portfolio management. Cary co-leads the DIA RIM Working Group, leads the DIA RIM Intelligent Automation Topic Team, co-leads the RAPS AI Community, and regularly serves as an industry thought leader.

Speaker

Gayatri Tadinada

Life Sciences AI Consultant
SLICKBIT Technologies, India

With over 15 years at the intersection of Digital Innovation and Life Sciences, I have spent my career shaping how technology can accelerate drug development, regulatory operations, and commercialization. An IIT alumna and former Novartis professional, I've worked across the full value chain of pharma from R&D and Regulatory to Clinical, Safety, and Commercial helping global organizations modernize how they manage data, content, and decisions. Today I lead a rapidly growing AI services startup Slickbit focused exclusively on building custom GenAI and automation solutions for Life Sciences. At Slickbit, our mission is to help pharma and biotech companies translate the promise of AI into practical, compliant and high-impact outcomes.

Speaker

Keith Michael Parent, MS

CEO
Court Square Group, United States

Keith founded and has led the IT & Life Science Strategy for Court Square since it's inception in 1995. Keith understands the intersection between IT and Quality within the Life Science industry and continues to drive FDA Compliant IT Solutions. Instrumental in creating the Audit Ready Compliant Cloud (ARCC) platform

specifically used for qualified and validated applications from pre-clinical to manufacturing with a specialty in Clinical and Regulatory systems. Keith is also co-founder of both RegDocs365, a regulatory content management repository and EmpiraMed, an ePRO, EDC and Registry software solutions company.

3:15 PM — 4:45 PM

Session 7, Track 3: Beyond Faster: Humans + AI and the Next Chapter of Regulatory Writing

AI promises speed, but its real impact on regulatory writing goes deeper. AI is reshaping roles, responsibilities, and how humans and machines collaborate. This session will explore how writers and reviewers can adapt from authors and checkers to generators, orchestrators and validators in AI-enabled workflows. Speakers will share lessons from early implementations, discuss emerging behaviors and skills, and highlight practical steps regulatory, quality and IT teams can take to build trust, lead change, and thrive through stronger human–AI collaboration.
Learning Objective :

- Evaluate examples of AI-human collaboration in regulatory writing, distinguishing between tasks suited for automation vs. those requiring human oversight
- Identify ways AI is changing roles and how readiness and role enablement can ease adoption in current workflows
- Apply practical strategies and change leadership to adapt team behaviors and skillsets within the next 12-18 months to prepare for AI-enabled regulatory writing and review

Track: Adopting Innovative Technologies

Session Chair(s)

Aliza Nathoo

Senior Director, Content Strategy
F. Hoffmann-La Roche Ltd., Canada

Aliza began her career on molecular teams and leading complex regulatory submissions. Over her 20+ years in biopharmaceuticals, she has expanded her focus into automation-assisted content authoring, generation, and management. Today, she leverages her foundation to drive content innovation within Roche, transforming theoretical strategies into scalable, sustainable operations. Known for her collaborative leadership, Aliza partners across regulatory, technology, and business units to shape, standardize, and implement solutions that anticipate the future of work. She is passionate about building adaptive, compliant systems and processes that empower teams to deliver in an ever-evolving regulatory landscape.

Speaker(s)

Streamlining Regulatory Processes with AI Similarity Scoring System: The Future of Content Mapping, Propagation and Document Management

Sharon Kim, PharmD

CEO

MPilotAI, United States

Sharon Kim, PharmD, is CEO and founder of MPilot, an AI company transforming how clinical and regulatory documents are designed, authored, and reviewed. With extensive experience at Pfizer, Genentech, and Gilead, she founded MPilot to make AI a true collaborator for medical writers, enhancing accuracy, consistency, and compliance while preserving human oversight. A recognized advocate for ethical and practical AI adoption, Sharon has led sessions at DIA, AMWA, and in academia, advancing industry understanding of how AI can improve regulatory workflows, accelerate research, and strengthen confidence in data integrity across the life sciences.

What it Really Takes to get AI Tech Implemented in Regulatory Space

Kruti Shah, MBA, MS

Senior Consultant
Astrix, United States

Kruti is a Senior Consultant at Astrix, where she helps life sciences organizations rethink how regulatory content is created and delivered. Her recent work focuses on implementing AI-powered solutions that not only automate processes but also inspire people to work differently. With a background in project management and organizational change, Kruti believes true transformation happens when technology meets human adaptability.

3:15 PM — 4:45 PM

Session 7, Track 4: Leading Regulatory Transformation: Strategic Change, Data Innovation, and Human-Centered Leadership

This session brings together three practical perspectives on how regulatory teams can lead meaningful change during times of disruption and digital transformation. Presenters will share strategies for evolving roles, launching cross-functional data initiatives, and building resilient teams all with a focus on achieving regulatory excellence. A key theme is embedding change not just as a support function, but as a strategic capability that enables regulatory organizations to adapt, innovate, and stay compliant. Attendees will gain tools and insights they can apply immediately to improve collaboration, readiness, and leadership impact across their teams and functions.
Learning Objective :
At the conclusion of this session, participants should be able to:

- Apply practical change and transition management strategies to balance current regulatory responsibilities with future innovation
- Develop approaches to lead cross-functional data projects by fostering alignment and collaboration across teams
- Demonstrate leadership tools that support team resilience, psychological safety, and adaptability during disruption

Track: Strategic Leadership and Organizational Readiness

Session Chair(s)

Lorelle Leonienco, PMP

Product Manager
LORENZ Life Science Group, United States

Lorelle Leonienco, PMP Product Manager, Global Regulatory Agencies, LORENZ Life Sciences Group, Canada With over 20 years in Life Sciences, Lorelle has held roles across Commercial, Regulatory, Medical, Clinical, and IT in both Generic and Brand Pharma. Her career has focused on implementing technology to modernize operations, drive efficiency, and support regulatory compliance. As Product Manager for Global Regulatory Agencies at LORENZ Life Sciences Group, she steers the development of strategic RIM solutions designed to meet the evolving needs of Health Authorities, ensuring they are aligned, user-focused, and impactful across the global regulatory landscape.

Speaker(s)

Balancing the Now and the Next: Change Management as a Strategic Lever in Regulatory Role Evolution

Jennifer Ann Carlino, MSc

Senior Director, Regulatory Information & Submission Management
Bristol Myers Squibb, United States

Jennifer Carlino is a Senior Director of Regulatory Information Submission Management at Bristol-Myers Squibb, with 25+ years in the pharmaceutical industry. She leads global eCTD submissions, guiding teams through complex regulatory requirements in the US and beyond. Jennifer holds a Master's in QA/RA from Temple University and is committed to advancements in submission strategy and regulatory science through operational excellence and innovation.

From Regulatory Data Office to an Enterprise Product Master Data Initiative: A Case Study for Driving Regulatory Excellence

Kumar Sancheti, MS

Associate Director
AbbVie, United States

A self-motivated, committed, and diligent individual with leadership experience in regulatory product management and initiative management. I am keen on learning and help transform regulatory information landscape.

Leading Through Disruption: Building a Culture of Regulatory Excellence and Innovation

Angela Dyer, PhD

Founder & Principal Consultant
Innovative Regulatory Inc, Canada

Angela Dyer brings over 30 years of experience in the biopharma industry. A seasoned Regulatory Affairs leader and executive leadership coach, key roles include Department Head of Regulatory Affairs Cangene Corporation, VP & Global Head of Regulatory Affairs Emergent BioSolutions Inc. and Chair of the Canadian Association of Professionals in Regulatory Affairs (CAPRA). Angela has overseen product licensure and maintenance for 11 products across 30+ countries. Her regulatory technical experience spans across various modalities including anti-toxins, small molecules, vaccines, therapeutics, and combination products. A 2x founder, Angela embraces a 'can-do' mindset and is driven to translate scientific data into drug approvals for patients.

Day 3 Feb 04, 2026

7:15 AM — 12:45 PM

Forum Registration

7:15 AM — 7:45 AM Ballroom A-E

Networking Breakfast in the Exhibit Hall

7:45 AM — 9:00 AM

Session 8, Track 1: Preparing for and Implementing eCTD 4.0 Implementation: Strategies, Challenges, and Lessons Learned

This session provides a comprehensive exploration of the global implementation landscape and practical strategies for eCTD 4.0. We will begin by delving into the European Medicines Agency's (EMA) eCTD v4.0 journey, sharing valuable insights from its pilot program and exploring its connections to future global standards. Next, based on the first-hand experiences from technical pilots with the US FDA and Japan's PMDA, we will analyze key implementation challenges from an industry perspective, such as metadata harmonization, managing multiple versions, and tool interoperability. Finally, the session will leverage lessons learned from the transition to eCTD 3.3 to offer specific preparation strategies and best practices for submitters, including those in advertising and promotion. By integrating perspectives from Europe, North America, and Asia, this session aims to provide a holistic roadmap and practical guide for a successful transition to eCTD 4.0.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Understand the EMA's eCTD v4.0 implementation path and its impact on the life sciences landscape
- Analyze key challenges and practical experiences from the FDA and PMDA technical pilots
- Learn preparation strategies and best practices derived from previous eCTD v4.0 transitions

Track: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Shenqi (Handsome) Ji

Publishing Regional Director, Asia, Global Regulatory & International Operations
Pfizer, China

Handsome Ji is a recognized expert in regulatory operations and eCTD. Since 2015, Ji has chaired DIA China Annual Meeting sessions, including ICH Theme Day and CTD/eCTD workshops. He served as advisor to the DIA China Young Professionals Committee and co-lead of the RA Community Core Working Group. Ji co-led the RDPAC China Regulatory Requirements Working Group and lectures at the NMPA Institute of Executive Development. He also leads industry courses at Fudan University and contributes to global DIA programs. Ji holds a bachelor's degree in Computer Science and Technology from Fudan University.

Speaker(s)

Evolution in Action: The EMA eCTD v4.0 Journey and Its Impact on the Life Sciences Landscape

Anjana Pindoria

Director Product Strategy
EXTEDO GmbH, Germany

Anjana is a passionate advocate for patient empowerment. With over 20 years of experience in the Pharmaceutical and Global Health Authority sector, she possesses strategic insights into the medicinal product journey, from development to patient care. As the Director of Product Strategy at EXTEDO, Anjana has a strong track record of successfully launching software products into the market. Her role involves actively listening to industry challenges, identifying areas for innovation, and spearheading transformative initiatives within the global network. Anjana's expertise extends beyond the present; she scans the horizon for future changes that could impact our work today.

eCTD 4.0: How to Prepare and Lessons Learned from eCTD 3.3 Transition

Jason Cober, MPA

Director Regulatory Review, AI, Digital Transformation
ProPharma Group, United States

Jason Cober is the Director - Regulatory Review, AI, and Digital Transformation at ProPharma Group. He previously led FDA/OPDP's eCTD implementation and has 17 years' experience with the Agency's eCTD specification and guidance development process.

eCTD 4.0 Analysis Based on First Experience with US FDA and JAPAN; Based on RAPS Publication

Calyn Stanfill

Senior Manager, Regulatory Publishing
Gilead Sciences, United States

Calyn Stanfill is a Senior Manager at Gilead Sciences with 12+ years submission experience. She has been a leader in leveraging submission tools to cut rework and streamline the global submission process. With a focus on compliance and collaboration, Calyn has a deep technical expertise and a passion for process innovation to strengthen global team capabilities.

7:45 AM — 9:00 AM

Session 8, Track 2: Global Submissions Without Borders: Harmonizing Processes, Data, and Technology Across Diverse Health Authorities

Session 8, Track 2: Global Submissions Without Borders: Harmonizing Processes, Data, and Technology Across Diverse Health Authorities

Track: Optimizing Processes and Procedures

Session Chair(s)

Vladimir Penkrat, MBA

Associate Vice President – Regulatory Affairs
Indegene, United States

Vladimir Penkrat is AVP of Regulatory Affairs at Indegene. With an MBA in International Business, Vladimir has provided strategic leadership throughout his career across clinical development, biometrics, biostatistics, medical writing, pharmacovigilance, and regulatory affairs. Over the past three decades Vlad worked across top pharma, biotech startups, CROs, and consulting firms. Within the recent 10 yrs, Vlad's passion for regulatory excellence has established process leadership in Regulatory Writing, Submissions Management, Publishing, Labelling, CTT, Consulting, & GenAI innovation as a business. Vlad's leadership has enabled businesses to prepare for digital adeptness & as a business leader he has scaled R&D operations to >500 FTE.

Speaker(s)

Global Submissions Without Borders: Harmonizing Processes, Data, and Technology Across Diverse Health Authorities

Lucie Svobodova, PharmD

Regulatory Affairs Senior Manager
Novavax, Czech Republic

7:45 AM — 9:00 AM

Session 8, Track 3: Industry Lessons Learned from FDA GenAI Community Challenge

The FDA issued a GenAI challenge for the public to demystify the use of GenAI to promote innovation and enhance processes within the FDA. This session will share lessons learned from industry and the FDA who participated in this challenge using both commercial off-the-shelf and custom LLM solutions. The session will focus on highlighting experiences with different technologies and methodologies as LLM technology continues to evolve quickly and it's impact on industry.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Understand the impact that LLM solutions are having on our industry
- Evaluate the difference between off-the shelf and custom solutions
- See where the evolution of LLM technology continues to grow

Track: Adopting Innovative Technologies

Session Chair(s)

Kevin Tompkins, MBA

Executive Director, Regulatory Information & Submission Management
Bristol Myers Squibb, United States

Kevin Tompkins is the Executive Director, Regulatory Information and Submission Management at Bristol Myers Squibb. He joined BMS in 2018 and has over 20 years of experience in different roles leading regulatory operations teams. In his current role, Kevin is responsible for the strategic direction and delivery of regulatory submissions, product data, and regulatory systems for BMS. He holds a B.S. in Information Systems and a M.B.A. from LaSalle University.

Speaker(s)

Speaker

Venkatraman Balasubramanian, PhD, MBA

Healthcare and Life Sciences Strategic Advisor
VB Insights, LLC, United States

Bala heads VB Insights, an advisory firm for the Healthcare and Life Sciences sector. Bala brings over 35 years of experience. During his long tenure, he has been responsible for the introduction of Web, document management, global team collaboration, and regulatory information management applications to large pharma. Until recently, Bala was Head of the Healthcare and Life Sciences Industry Solutions Group at Orion Innovation. As an entrepreneur and a thought leader, he has been involved in initiatives to transform regulatory affairs from a document-centric function to a data-driven function. Bala has been associated with DIA for more than 14 years, most recently as the DIA RIM Working Group subteam lead for the RIM Reference Model.

Speaker

Representative Invited

FDA, United States

Speaker

Representative Invited

Life Science Integration Partners, United States

As an Informatics leader and consultant in Life Sciences, Jim has broad experience across the R&D spectrum. He has designed and delivered systems ranging from Computer Aided Drug Design, LIMS, Clinical Trial Management, Clinical Data Management, Regulatory Submission Planning, Publishing and Delivery. An area of specialization is automated content analytics and quality assurance utilizing a spectrum of technologies including natural language generation, machine and deep learning. Jim is founder and president of Life Science Integration Partners.

7:45 AM — 9:00 AM

Session 8, Track 4: Co-Managing a Complete Regulatory Program with AI: A Sponsor–Technology Co-Design Case Study

This session explores a biotech sponsor's integration of AI across its regulatory program, from pre-IND planning to submission, to streamline workflows, reduce manual effort, and ensure compliance while managing multiple assets. It describes a co-design approach, where sponsor subject matter experts and technology partners mapped regulatory workflows, leveraging large language models for narrative drafting, automated document management, structured data extraction and metrics managed to achieve significant time savings and improved cross-functional alignment. Attendees will have the opportunity to participate in a live workflow mapping exercise to identify automation opportunities in their own programs and gain a practical framework for AI adoption in regulatory management.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Apply co-design principles to integrate AI into sponsor-led regulatory programs
- Map end-to-end submission workflows to identify automation opportunities
- Evaluate metrics for efficiency, compliance, and collaboration in AI-enabled regulatory management

Track: Strategic Leadership and Organizational Readiness

Session Chair(s)

Kunal Lal, MBA

Consultant - Strategy & Change
Red Nucleus, United Kingdom

Kunal Lal is a UK-based Consultant with Red Nucleus and a subject matter expert in Regulatory Information Management and IDMP/XEVMPD. He has over 13 years of experience working across the Regulatory, Pharmacovigilance, Clinical and Supply Chain functions of pharmaceutical organizations, with robust knowledge of related regulations, processes, and systems. Kunal has led and contributed to many projects for regulatory readiness, process assessment, definition and optimization, data maturity assessment and governance and application support and maintenance.

Speaker(s)

Sponsor Perspective: How a Biotech Built an AI-Enabled Regulatory Program

Sigrid Selberg, PhD

Chief Scientific Officer
Chemestmed OÜ, Estonia

Sigrid Selberg is the Chief Scientific Officer at Chemestmed, a role she has held for nearly two years. She is responsible for leading the company's GLP toxicity studies, coordinating IND preparation, and managing international collaborations with CROs and academic partners to further develop Chemestmed's comprehensive epitranscriptomic pipeline. Dr. Selberg holds a Ph.D. in Analytical and Physical Chemistry, with her doctoral research focusing on organic synthesis and acidity studies in biphasic, cell membrane–like systems. Her multidisciplinary background bridges chemistry and biomedical innovation, supporting Chemestmed's mission to translate cutting-edge science into safe and effective therapeutic solutions.

Co-Managing a Complete Regulatory Program with AI: A Sponsor–Technology Co-Design Case Study

Meelis Lootus, PhD, MS, MSc

Founder & CEO
Tehistark, United Kingdom

9:10 AM — 10:25 AM

Session 9, Track 1: Federating the Forgotten: Content as a Data Asset in Your Enterprise Data Strategy

The biopharma industry sits at the intersection of immense data volumes, stringent regulatory demands, and increasingly complex scientific narratives. Protocols, CSRs, labels, and various dossiers represent not only critical artifacts for submission and compliance but also are repositories of corporate and scientific knowledge. Yet, current enterprise data strategies primarily focus on patient records, trial results, and real-world evidence, often neglecting lifecycle management of high-value scientific and regulatory content.

Traditional content management approaches treat these artefacts as siloed documents, managed by small, domain-specific teams such as regulatory, clinical operations, and safety, each with bespoke workflows. This model results in redundant effort, inconsistent quality, and inefficient integrations for content flow across domains. Moreover, this model hinders the application of modern data governance to narrative content, which needs to be structured, discoverable, and interoperable to leverage AI and advanced analytics.

On the other hand, a federated architecture based on Data Mesh principles offers a compelling blueprint for transforming how organizations author, review, and repurpose narrative. This architecture reframes content as a first-class data asset, distributes ownership to domain teams, and enforces cross-enterprise standards for metadata and governance. As a result, bottlenecks of monolithic data lakes are avoided while consistency and compliance are preserved.

This session will define content as a data asset, introduce the concept of a Common Content Model, illustrate federated governance, explore real-world biopharma use cases, and demonstrate business impact.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Understand how regulatory content can be treated as governed data assets within a federated architecture
- Demonstrate how a shared content metamodel (like a data model) enables consistency, discoverability & interoperability across decentralized domains
- Learn how applying a federated architecture to content supports reuse, efficiency, AI-driven content generation & data submissions

Track: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Jennifer Dames

Director, RA Submission Management
AbbVie, United States

Jennifer Dames is Director, Regulatory Submissions at AbbVie. She has over 10 years experience in Regulatory. Jennifer has experience with implementation of a Regulatory Information Management system, Document Management, Submission Management, Publishing, and system support.

Speaker(s)

Speaker

Christopher James Dowdall

Business Transformation Leader - Content Reuse & Automation
Roche, United Kingdom

Chris Dowdall is a Principal Data Sciences Product Leader at Roche, where he drives enterprise efficiency through transformative data, content, and AI initiatives. With over 15 years of experience, Chris is an expert in analysis, lineage, modelling methodologies, and implementation of content and data governance frameworks. Chris is the lead architect of the Roche Content Model (RCM), a semantic framework for enterprise content management. The RCM provides a unified content modelling language that ensures interoperability and powers data-driven automation across distributed application ecosystems.

Speaker

Representative Invited

Deloitte, United States

9:10 AM — 10:25 AM

Session 9, Track 2: Structured Content Implementations across the Drug Development Lifecycle

Written content will still be a core requirement of regulatory submissions, labels, and R&D documents. What we do with that content, how it is formatted, reused, repurposed, where it is stored and where it goes; remains critical. The case studies in this session demonstrate two diverse individual roadmaps. Both organizations employ structured content and strong processes to not only achieve regulatory compliance, but to reduce risk, build a framework for flexibility, and manage change.

Preparing the regulatory organization of the future requires alignment of process, preparedness of the organization, readiness of technology, and consideration of data centric approaches. As the industry aligns to data centricity and changing/updated standards committees like FIHR; regulatory teams look for ways to stay flexible.

Learning Objective :

- Reduce patient safety and counterfeit risks via digital formats
- Increase regulatory compliance with FDA 21CFR11, EU Falsified Medicines Directive (FMD) and Good Manufacturing Practices (GMP) through an e-labeling initiative
- Prepare for changes and reduce workloads by using structured content to reuse content or re-purpose content
- Assess challenges in continued content management in labelling and benefits of what labeling can provide

Track: Optimizing Processes and Procedures

Session Chair(s)

Theresa Pinnell, MLS

Director of Regulatory Solutions
Kivo, United States

Theresa has over 20 years of experience in the life sciences industry, where she has developed and delivered innovative and user-friendly solutions for regulatory, clinical and QA processes. She is currently the Director of Regulatory Solutions at Kivo, a company that provides a unified cloud-based platform for managing regulatory activities and content, TMF and QMS documents. She is passionate about empowering emerging life science groups to accelerate their research and development and bring their products to market faster and safer. She fosters a culture of inclusion and collaboration within teams, leveraging her diverse background in library and information science, business and her global experience with various pharmaceutical clients.

Speaker(s)

Unified by Design: Centralizing R&D Document Services to Improve Agility in an Evolving Regulatory Environment

Samantha Lighting, MS

Functional Lead, Submission Ready Documents
Sanofi, United States

Implications of Global Regulatory Momentum Toward Electronic Labeling (e-Labeling) in Pharmaceuticals

Eric Randel, MBA, PMP

Associate Director, CCDS & Labeling Lead
Astellas Pharmaceuticals, United States

Regulatory Labeling professional with 20 years experience in Biotech and Pharma. Skilled PM having led multiple cross-functional and cross-cultural teams. Currently responsible for leading US, EU, Japan, and China Labeling activities for five global products. Led an internal initiative to develop and implement a standard global process for implementation of Electronic Labeling (e-Labeling) at Astellas Pharma Inc. Additionally, skilled automation and validation engineer having designed and built multiple automated systems, including GxP validation where applicable, which drive efficiency in global processes.

9:10 AM — 10:25 AM

Session 9, Track 3: Enabling Efficient Regulatory Submissions: A Cloud-Based Approach to Structured CMC Dossiers

This session will provide an in-depth overview and demonstration of the CMC use case within Project PRISM, illustrating progress in digital CMC submissions. Participants will see the workflow beginning with the submission of a CMC dossier in PDF format to a secure, cloud-based environment. Advanced AI tools are employed to deconstruct the PDF, extract unstructured CMC data, and convert it into a structured dataset based on a CMC data standard. The demonstration will highlight how leveraging structured data reduces manual effort and builds a foundation for faster, more reliable regulatory submissions and review.
Learning Objective :
At the conclusion of this session, participants should be able to:

- Understand how AI tools can extract and structure CMC data from PDF submissions to support digital transformation in regulatory processes
- Identify how cloud-based platforms enable real-time collaboration, data traceability, and integrity throughout the CMC dossier lifecycle
- Discover how structured data approaches can reduce manual effort and potentially accelerate reviews

Track: Adopting Innovative Technologies

Session Chair(s)

Rita Algorri, PhD, MS

Associate Director, Global Regulatory Affairs (CMC)
Amgen, United States

Rita Algorri, PhD is an Associate Director, Regulatory Affairs CMC at Amgen Inc. in Thousand Oaks, CA. In this role, she leads and orchestrates internal and external activities relating to regulatory modernization, digitization, automation, and emerging technologies. She also serves within Amgen's Advocacy and External Engagement function which fosters collaboration with multiple internal and external cross-functional teams to coordinate and progress company and industry initiatives. Rita is a microbiologist by training and holds a PhD in Clinical and Experimental Therapeutics and M.S. in Regulatory Science from the University of Southern California.

Speaker(s)

Enabling Efficient Regulatory Submissions: A Cloud-Based Approach to Structured CMC Dossiers

Ciby Joseph Abraham, PhD

Senior Director and Group Manager, Project and Product Leadership
AstraZeneca, United States

Ciby Abraham is a Senior Director and Group Manager, Project and Product Leadership in CMC Regulatory Affairs at AstraZeneca. Prior to his role with AstraZeneca, Ciby worked at the for several years FDA as a Team Leader. In addition, Ciby worked in the industry as a formulator, analytical method development scientist, and a manufacturing specialist. He was also licensed by the New York State Board of Pharmacy to release compounded products to the market. Ciby holds a Ph.D. in chemistry from Johns Hopkins University, Master's degree in chemistry from St. John's University, and a Bachelor's degree in chemistry from Binghamton University.

Speaker

Vada Perkins, DrSc, MSc

Vice President, Global Head of Regulatory Intelligence & Policy
Boehringer Ingelheim, United States

Vada A. Perkins is Vice President. Global Head of Regulatory Policy & Intelligence for Boehringer Ingelheim. He is a former FDA Senior Advisor for Regulatory Science with international regulatory policy and strategy expertise in promoting convergence for the assessment of medicinal products worldwide. He received his degrees from Johns Hopkins University, University of Southern California, and the University of Maryland.

Speaker

Representative Invited

DNAnexus, United States

General Manager and Lead Architect for DNAnexus' Regulatory Solutions. Expertise working at the intersection of cloud technology, genomic science, and regulatory science. Leading the vision and formation of Trusted Regulatory Spaces (TRS) in the cloud for global regulatory stakeholder interaction. Transforming regulatory research and review at the FDA as lead architect of precisionFDA and the PRISM platform for regulatory stakeholder interaction in the cloud. Managed the AWS Elastic Compute Cloud (EC2). Architected and operated the cloud infrastructure for crowd-sourced search and spam-fighting solutions at Topsy Labs (acquired by Apple) and Cloudmark (acquired by Proofpoint). Bachelor of Science in Chemistry from UC Berkeley.

9:10 AM — 10:25 AM

Session 9, Track 4: Cross-functional Collaboration: Integration Programs and Inspections

Session 9, Track 4: Cross-functional Collaboration: Integration Programs and Inspections
Track: Strategic Leadership and Organizational Readiness

Session Chair(s)

Katherine Novak, MS

Director
Epista Life Science, United States

Katherine Novak provides experience as a strategic consultant across the full drug product lifecycle, including Clinical Operations, Regulatory Operations, Regulatory Informatics, Pharmacovigilance, and large-scale Manufacturing. Katherine supports clients in global Regulatory strategy, digitalization, system implementation, process development, and data quality. Her passion is in data standard harmonization and collaboration, specifically submission data and optimization for Regulatory decision-making.

Speaker(s)

Winning with Integrations: Aligning Regulatory and Technology Teams for Scalable Impact and Success

Danny Bradford

Director of Integration Services
Acumulus Technologies, United States

Inspection-Ready by Design: Digital Strategies to Support Hybrid and Remote Regulatory Inspections

Andrea Bastek, PhD, MS

VP Market Strategy
Florence Healthcare, United States

Andrea Bastek, Ph.D., is VP of Market Strategy at Florence Healthcare. Her team works to drive transformation in the eClinical industry in order to improve the site experience and the collaboration between sites and Sponsors/CROs. Prior to Florence she spent 15 years supporting sites running cardiac medical device studies working with and leading a unique sponsor field team. She holds a Ph.D. in Bioengineering from The Georgia Institute of Technology as well as a BS and MS in Biomedical Engineering from Tulane University.

10:25 AM — 11:10 AM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

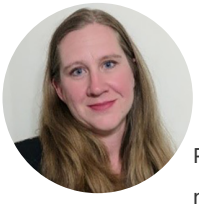
11:10 AM — 12:30 PM

Session 10: Global Regulators in Focus: Key Updates Shaping the Future of Regulation

Receive the latest updates from international regulators about recent and future developments. This session provides attendees the opportunity to ask regulators questions directly. Please note: due to the high volume of questions, not all will be answered live at the forum. We encourage audience members to submit questions in advance via the DIA mobile app.

Track: General Session

Session Chair(s)



Lindsay Fitzgerald

Delivery Manager
Astrix, United States

Regulatory Affairs Business Solution expert with proven industry experience in project management, advisory services, business analysis and business support of the Department. With her 10 years' experience at AstraZeneca leading Regulatory IT projects, spanning business/technology analysis, project management, validation/testing, business training development and delivery she has credibility speaking with both IT and Regulatory business stakeholders. As an end-to-end RIM process data and system expert with 9 years' experience in Regulatory consulting for top pharma clients she has led business process optimization, RFP and vendor selection, implementation, and migration projects.

Tamei Elliott, MS

Director, Global Scientific Content
DIA, United States

Tamei Elliott, MS, serves as the Associate Director of Scientific Programs for the Americas region at DIA. In this pivotal role, she is responsible for identifying and prioritizing content areas and topics crucial to DIA constituents. Tamei assesses the implications of significant regulatory and health policy changes, seamlessly integrating relevant content into the development and advancement of DIA conferences and courses. Her responsibilities extend to overseeing content development and strategy within the Americas region.

Speaker(s)

Speaker

Kristiina Puusaari, MBA, PMP

Digital Business Transformation Programme eSubmission Senior Coordinator
European Medicines Agency, Netherlands

Kristiina joined the European Medicines Agency in January 2002 and is responsible for the implementation, coordination and maintenance of the eSubmission systems and processes at the agency. Kristiina is a Product Owner and a subject matter expert for eCTD v3.2.2, eCDT v4.0, the electronic Application Forms (eAFs), the eSubmission Gateway and Web Client, the Common Repository, the PSUR Repository and the business processes related to the eSubmissions. Kristiina works closely with the EMA business and technical colleagues and the development teams, the colleagues from the European Medicines Network (EMRN) and pharmaceutical industry. Kristiina represents the EMA in eSubmissions related stakeholder groups and is a co-chair of the ICH M8.

Speaker

Representative Invited

Health Canada, Canada

Marcin Boruk has been with Health Canada since 2005 and has worked in the areas review, legislation and business transformation. Currently he is an acting Director in the Business

Facilitation and Modernization Directorate, Health Canada supporting the branch in projects related to secure technology platforms, data governance, stewardships and standards.

Speaker

Andrea Johnson

Deputy Director Future Systems Business Requirements
Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Andrea began her career in genetic toxicology before joining the MHRA in 1996. She has worked in diverse roles including product licensing, system development, and various and various business architecture roles. Her responsibilities have included working with International Partnerships on several projects such as IDMP and eSubmissions. For the past three years she has been Deputy Director in the Health Quality and Access Group, managing teams including those handling eCTD. Most recently her work has focussed on aligning business needs with system development.

12:30 PM — 12:45 PM

Closing Remarks and Forum Adjourned