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)!

Print Agenda

Day 1 Feb 02, 2026

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

Forum Registration

10:50 AM — 11:20 AM — Swarthmore AB

Case Study Sponsored by AlphaLife Sciences AI-Orchestrated Authoring and QC across the R&D Document

Network

This session presents practical approaches to AI-orchestrated authoring and quality control for regulatory and medical writing across the R&D document lifecycle, spanning clinical, non-clinical, quality, safety, labeling, and regulatory submission–related documents. We demonstrate how teams can work in familiar environments—such as a Microsoft Word add-in and a web portal—while automating up to 90% of first-draft content in alignment with regulatory guidance. The approach streamlines review comment incorporation, document finalization, quality control, and subsequent updates to accelerate submission timelines. The workflow integrates with enterprise systems, including Veeva RIM, supporting the end-to-end lifecycle of regulatory submissions alongside existing document management and review processes. Finally, we introduce an R&D document-network model for change intelligence, enabling automated change detection, dependency mapping for impact assessment, visible change lineage, and downstream propagation—supporting cross-document consistency and scalable QC

Learning Objective :

- How AI Orchestration Supports Authoring and QC Across the R&D Network
- AI-Assisted Authoring and Change Management for CSR, Module 2.7.3/2.7.4, Non-Clinical, and CMC
- Integrating AI into Enterprise Authoring Environments: Microsoft Word and Veeva RIM

Track: Exhibitor Event

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

William Chen

Principal Business Solution Architect
AlphaLife Sciences, United States

Will Chen is a Principal Business Solution Architect at AlphaLife Sciences, where he designs AI-driven solutions to transform clinical development and life sciences workflows. With over 15 years of healthcare technology leadership, Will specializes in bridging cutting-edge innovation with strategic commercial execution. Previously, Will held leadership roles at McKinsey & Company, Elsevier and Syapse, where he led cross-functional teams and drove strategic growth within the pharmaceutical sector. He is an expert in navigating the intersection of deep science and digital transformation. Will holds a Ph.D. in Genetics from Stanford University School of Medicine and a B.S. in Biology from MIT.

Sharon Chen

Founder and CEO
AlphaLife Sciences, United States

Sharon Chen is a visionary leader at the intersection of computer science and life sciences, boasting over 25 years of pioneering software development experience. As the Founder and CEO of AlphaLife Sciences, she drives innovation in generative AI-powered clinical development solutions, transforming the way the industry approaches drug development. Previously, Sharon served as the APAC

General Manager at Verily Life Sciences, an Alphabet company, where she led groundbreaking initiatives integrating advanced technology with life sciences. Sharon's visionary leadership and innovative spirit continue to profoundly impact AlphaLife Sciences and the broader life sciences sector.

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.
Henrietta N. Ukwu, Novavax Inc

Carlos Garner, Eli Lilly and Company

Jamey Ann Galione, Bristol-Myers Squibb Company

Track: General Session

Session Chair(s)

Jared Lantzy, PMP

Executive Director, Global Regulatory Operations
Novavax, Inc., 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

Dr. Ukwu is a physician, pharmaceutical industry executive and author of the Global Regulatory Systems - A Strategic Primer and ABCs of Leadership books. She is named to the 2022 & 2011 PharmaVoice 100 most inspiring industry leaders, 2012 TOPRA award for most Inspiring Leaders, 2019 Top Blacks in Health Care. She joined Novavax in January 2021, is currently EVP and Chief Regulatory Officer, has over two decades of regulatory leadership delivering many products approvals including the Novavax COVID 19 vaccine. Prior to Novavax, she was chief regulatory officer at Otsuka Pharmaceuticals and held positions at Merck, Pfizer, PPD. She is Fellow of the Regulatory Affairs Professional Society, and Fellow of the American College of Physicians.

Speaker

Carlos Garner, PHD, MSC

Senior Vice-President Global Regulatory Affairs and Head, Lilly Regenerative Med
Eli Lilly and Company, United States

Dr. Garner is executive leader for Global Regulatory Affairs for Eli Lilly and Company. The organization is responsible for the regulatory leadership, strategic and operational support for human drugs, medical devices, and global manufacturing for Eli Lilly and Company. Additionally, Dr Garner leads Lilly's Regenerative Medicine business responsible of the development and commercialization of gene therapies to treat rare and sensory diseases. Dr. Garner and his teams lead Lilly's external engagements with global regulatory authorities, regenerative medicines key opinion leaders, and other stakeholders to share the goal of improving public health by creating medicines that make life better for people around the world.

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 Ballroom E-H

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.

Update on eCTD v3.2.2 & v4.0 Submissions
Jessica Bernhardt, FDA

Updates to eCTD for v3.2.2 and v4.0
Heather Crandall, FDA

FDA CDER NextGen Portal
Seyoum Senay, FDA

FDA'S Global Substance Registration System (GSRS) and Submitting Structure Data (SD) File to have Unique Ingredient Identifiers (UNIIs) for FDA-regulated Products
Siba Bhattacharyya, FDA

FDA CDER Information Request (IR) Modernization: PDUFA VII IR Demonstration Project
Jonathan Resnick, FDA

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 strategic leader specializing in healthcare informatics innovation and regulatory science advancement. He focuses on implementing transformative informatics solutions that accelerate the development and approval of safe, effective medicines for patients. His work directly supports the FDA's mission to protect and promote public health through evidence-based regulatory decision-making. As a U.S. Excellence in Government Leadership Fellow, Mr. Senay has demonstrated exceptional capability in leading complex initiatives that deliver measurable outcomes for public health. He holds a Master's degree from The Johns Hopkins University and maintains certification as a Program Manager, bringing both academic rigor and practical exp

Speaker(s)

Update on eCTD v3.2.2 & v4.0 Submissions

Jessica Bernhardt, MS

IT Project Manager ODT
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

Heather Crandall, MA

Business Informatics Specialist, OBI, FDA
FDA, United States

Heather Crandall has been with the FDA since 2012, working in the 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

Siba P Bhattacharyya, PHD

Health Scientist, OC/ODT/ODAR/HIS
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-D

Refreshment and Networking Break in the Exhibit Hall

3:10 PM — 3:40 PM Swarthmore AB

Case Study Sponsored by InteliNotion LLC

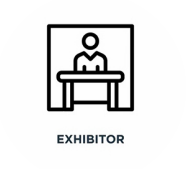
Generative AI (GenAI) has emerged as a transformative technology for innovation in the medical writing space, offering unprecedented opportunities for growth and efficiency. However, amidst the excitement, key challenges must be addressed, including implementation in a regulated environment, ensuring compliance and governance, managing the proliferation of diverse language models, maintaining human oversight and intervention. This comprehensive case study is an update from last year's presentation and chronicles the continuing journey of a leading global biopharmaceutical company as it leverages GenAI and Structured Component Authoring (SCA), addressing the complexities and opportunities in medical writing, and pioneering a path to Intelligent Content creation.

Featured Topics:

- Implementation Strategy: Best practices for integrating GenAI with Componentized Content in a regulated environment
- Harnessing the power of a combined GenAI/SCA system: Determining where to leverage the benefits of SCA's structured governance vs. precise content generation from agent-driven GenAI technology
- Precision Prompting: How to craft prompts and evaluate generated outputs
- Content Structure and Governance: Enhance content compliance and quality through effective organization and architecture
- Automated Authoring: opportunities for implementing automated processes to drastically reduce the time it takes to generate key documents like CSRs, while increasing throughput and quality
- Content Transformation and Reuse: Maximize efficiency through reuse and adaptation across diverse document types

Track: Exhibitor Event

Session Chair(s)



Sponsored Sessions

United States

Speaker(s)

GenAI in a Global Biopharmaceuticals Company – Progress Update

Matthew Renda, PHD, MS

Senior Director Medical Writing Operations
Alexion, United States

Matt Renda He has 13 years of academic research experience focused on gene therapy and 18 years of pharmaceutical development experience providing regulatory submission management and medical writing leadership to optimize cross-functional processes, implement innovative technologies and efficiently develop clinical documents. Matt joined Alexion in 2016 and leads a team focused on evaluating and implementing new technologies for Medical Writing. He received Platinum accreditation for completing the AstraZeneca Generative AI Accreditation Programme and has presented on Structured Content Authoring at Industry user forums, DIA Global, AMWA, RAPS and RSIDM.

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.

- ESG: Jessica Bernhardt, FDA
- Updates to eCTD for v3.2.2 and v4.0: Heather Crandall, FDA
- CDER NextGen Portal: Seyoum Senay, FDA
- FDA'S Global Substance Registration System (GSRS) of Structure Data (SD) File to have Unique Ingredient Identifiers (UNIIs) for FDA-regulated Products: Siba Bhattacharyya, FDA
- Jonathan Resnick, FDA

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.

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FDA, United States

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Speaker(s)

ESG

Jessica Bernhardt, MS

IT Project Manager ODT
FDA, United States

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

Siba P Bhattacharyya, PHD

Health Scientist, OC/ODT/ODAR/HIS
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

5:05 PM — 6:05 PM

Ballroom A-D

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 A-D

Networking Breakfast in the Exhibit Hall

8:15 AM — 8:30 AM | Ballroom E-H

Welcome to Day Two

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.

eCTD v4.0 Implementation Update

Jonathan Resnick, FDA

Kristiina Puusaari, European Medicines Agency, Netherlands

eCTD 4.0 in Action

Andrea Johnson, Medicines and Healthcare Products Regulatory Agency (MHRA)

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)

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.

Lorelle Leonienco, PMP

Product Manager
LORENZ Life Sciences 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)

eCTD v4.0 Implementation Update

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.

eCTD 4.0 in Action

Andrea Johnson

Deputy Director of Future System 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 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

10:05 AM — 10:35 AM Swarthmore AB

Case Study Sponsored by Weave Bio

Regulatory teams are under increasing pressure to deliver high-quality, submission-ready documents quickly, yet many workflows still rely heavily on manual, repetitive steps that slow timelines and introduce avoidable inconsistencies. This session will highlight how Weave's AI-native, human-driven platform applies automation to streamline key aspects of regulatory document development, including structuring source information, auto-generating content, and improving workflow visibility. The case study will draw on Weave's work with Parexel as an example of how automation can support real-world regulatory workflows, reducing manual effort and improving consistency across documents. These insights will help illustrate how Weave enables teams to work more efficiently and achieve more predictable document timelines. Attendees will gain practical guidance on modern, AI-enabled approaches that enhance quality and reduce operational burden within regulatory operations.

Featured Topics:

- Applying AI and automation to reduce manual effort in regulatory document development
- Using structured information and auto-generated content to improve consistency and accuracy
- Enhancing workflow visibility and predictability for IND, CTA, and other key submissions
- Real-world example: learnings from Weave's work with Parexel
- Practical strategies for integrating human-driven AI into regulatory operations

Track: Exhibitor Event

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Human + AI -- Weave + Parexel: Revolutionary Collaborations in 2026

Brandon Rice

CEO and Co-founder
Weave Bio, United States

Brandon leads Product at Weave, overseeing the development of AutoIND, an AI-powered platform streamlining IND preparation. His work focuses on building products that impact lives, deliver value, and enhance user experience. With a background in life science startups, he has worked in drug manufacturing, discovery, and diagnostics, including CRISPR-based target identification and multi-omic cancer detection. He co-founded a genomics services company, commercializing bioinformatics technology that continues to advance genome building. Driven by a passion for emerging technologies, he transforms innovative ideas into impactful solutions.

10:45 AM — 12:00 PM White Oak (Lower Level)

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

The definition of data sources from the US FDA, EU and China will be surveyed for specific descriptions. Provide a market consultation and global road map (focusing on China, US, and European Union) and literature survey for the future of Regulatory Decision Making using RWD, proposing solutions for consistency of decision making across regions. AI as an enabler of data reliability will be explored. References to AI (predictive/ generative) will be contextualized to support the data referenced. AI is usable in a defined context. AI approaches assume data is reliable. Data can be reliable only if it is appropriately structured. AI can help with data standardization. [We will explain the roles that AI plays in generating data standards). Different stages of a product lifecycle will be studied in terms of expanding indications, geographies, and requirements of HTAS and payers. The findings for this paper will be a good reference point for Regulators, HTAs and industry members.

EU Focus
David Sidney Ross, AstraZeneca

Real-World Data (RWD) in Regulatory Submissions in the US: Challenges and Solutions
Brian Gillette, Droice Labs

China Focus

Tong Guo, GoBroad Healthcare Group

Learning Objective :

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

- Define how to improve consistency between FDA, EMA, and China
- Identify global use cases for regulatory collaboration (e.g., multinational and non-interventional study data)
- Acknowledge RWD will be used regionally and is unlikely to be shared globally

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)

EU Focus

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.

Real-World Data (RWD) in Regulatory Submissions in the US: Challenges and Solutions

Brian Gillette, PHD

VP, Data
Droice Labs, United States

Brian is a biomedical engineer specializing in clinical and translational research in advanced therapy modalities, clinical data science, and machine learning/artificial intelligence with extensive experience working with health systems, pharma, biotech, and medical device companies on clinical trials and real-world evidence. At Droice Labs, he helps biopharma teams drive highly efficient evidence generation for FDA, CMS, EMA, and other regulatory

approvals by combining modern clinical trial study designs with regulatory-grade AI middleware. Prior, Brian was an Assistant Professor at NYU Long Island School of Medicine in the Departments of Surgery and Foundations of Medicine, where he led research in regenerative medicine and wound healing.

China Focus

Tong Guo, PHD

Strategic Advisor
GoBroad Healthcare Group, China

Dr. Tong Guo serves as Strategic Advisor at Gobroad Healthcare Group. Early in his career, he served as Principal Biostatistician at Bristol-Myers Squibb in US. After returning to China, he served as VP at WuXiPRA, Executive Director of Data Science Asia at Bayer, Head of Biometric Asia and Africa at Quintiles, and Head of Sales at IQVIA. Dr. Guo also serves as multiple high-level advisory and leadership roles including: Advisor to the Clinical Oncology Committee and Deputy Director of the Clinical Trial Committee of the China Pharmaceutical Innovation Promotion Association; Lead to ICH M14 Guiding Principles. Dr. Guo holds a master's and a Ph.D. degree in biostatistics from McGill University, Canada.

10:45 AM — 12:00 PM Brookside AB (Lower Level)

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

The shift from document-driven to data-centric submissions is upon us and it is redefining how organizations prepare, manage, and deliver regulatory content. This session explores what it truly takes to enable a connected, end-to-end data journey that unlocks automation, AI, and digital efficiencies within the regulatory function.

Drawing from real-world use cases and lessons learned, expert panelists will share practical insights on how regulatory and cross-functional teams are laying the foundation for sustainable digital transformation. The discussion will highlight both the strategic vision and the operational realities behind this evolution, offering a grounded look at the people, processes, and data required to make digital regulatory transformation work.

Key themes include:

- Data Readiness and Modeling: How data standards, structured content, and FAIR data principles create the backbone for automation and AI-enabled submissions
- Cross-Functional Collaboration: Best practices for aligning Regulatory Affairs, Clinical, Safety/Quality, Product, and IT teams around a unified data strategy that drives consistent, high-quality outputs
- Culture and Change Management: Shifting from a legacy document mindset to a data-driven culture that encourages agility, transparency, and continuous learning
- Governance and Strategy: Building frameworks that connect regulatory data initiatives to enterprise goals—without dependency on specific vendors or technologies

Participants will leave with actionable insights, guidance and tactics to accelerate progress toward data-driven submissions and digital-first operations. The discussion will emphasize what can be done to move transformation forward within your organization spanning data curation, process alignment, and workforce capability building.

This session is designed for regulatory and RIM professionals, data and information managers, and transformation leaders who are driving or supporting modernization efforts within their organizations. Whether you're just beginning your digital journey or advancing toward AI-enabled capabilities, this conversation will provide practical strategies to advance your organization's readiness and success.

By sharing tangible examples and hard-won lessons from industry peers, this session will help attendees understand how regulatory data strategy serves as both a foundation and a catalyst for broader enterprise innovation—ultimately enabling faster, more intelligent, and globally harmonized regulatory submissions.

The Digital Knowledge Transformation Journey
Kathy Vieson, Sage Content Solutions

End to End: From Data to Publication at Scale
Kevin O'Leary, Dassault Systemes

Understanding and Improving Your Data Readiness
Justin Porth, Amgen

Learning Objective :

- Illustrate the organization-wide change coordination required to align a strategy between regulatory, data management, operations, & other functions to transform knowledge flow
- Distinguish the criticality of designing proper data models: key element to this strategy
- Define a scalable & achievable implementation framework to mitigate key barriers to the shift from document to data driven practice

Track: Optimizing Processes and Procedures
Level: Advanced

Session Chair(s)

Maria Sagoua, MHA

Chief Operating Officer
Breaking Barriers, United States

Maria Barhams Sagoua is a recognized leader in innovation and digital transformation. As Director of Regulatory Innovation at Accumulus Synergy, she supported the develop meant of the HL7 FHIR PQI standard, developed and scaled a 0-1 regulatory platform serving 70+ global regulators and leading life sciences companies. She's orchestrated cross-industry collaboration to transform regulatory operations, integrations systems with data standards to support harmonization. Maria's career spans the FDA, NIH, SAS, and health tech companies where she advanced AI/analytics initiatives, modernizations, and stakeholder collaboration. She holds an MHSA from George Washington University and is certified in process improvement and change management.

Speaker(s)

End to End: From Data to Publication at Scale

Kevin O'Leary

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

Kevin has been providing Regulatory and Quality solutions to the Biopharma for 30 years. Previously as founder and CEO of QUMAS and then as VP in Dassault Sytemes for the last ten years, he has worked with most of the top 20 companies to deliver solutions that have scaled up to 100,000 users at a single company. He manages a large R&D team focused on the challenges of the industry and in particular the alignment of AI with the

need for certainty and accuracy in Regulatory and Quality data usage. Kevin studied Computer Science in Munster Technological University, with Post grad in Industrial Management and is an Alumni of Stanford University Business School. He has served as an Adjunct Prof in University College Cork for several years.

The Digital Knowledge Transformation Journey

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.

Understanding and Improving Your Data Readiness

Justin Porth, MBA

Principle Data Engineer (Senior Manager Information Systems)
Amgen, United States

Justin Porth is an Associate Director of Information Systems in Tampa, FL, leading cross-functional programs that modernize data and regulatory workflows. He drives Regulatory Filing initiatives, including CMC Data Automation for Module?3, building pipelines from source systems to structured authoring to accelerate submissions and improve data integrity. Known for pragmatic strategy and delivery, Justin champions governance, semantic modeling, and end-to-end automation to reduce authoring time and raise quality across filings.

10:45 AM — 12:00 PM Ballroom FGH

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

Session 5, Track 3: 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

Session Chair(s)

Jared Lantzy, PMP

Executive Director, Global Regulatory Operations
Novavax, Inc., 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)

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

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

David Isom

Senior Director, Global Regulatory Policy and Intelligence, Global Product Devel
Pfizer, 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

Peter Terbeek, MBA

Executive Director, Regulatory Data and Document Operations
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 Brookside C (Lower Level)

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
Merck & Co., Inc., 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

Helena Corte-Real Correia, PHD

VP, Regulatory Data and Content Lead
F. Hoffmann-La Roche Ltd., Switzerland

Helena Corte-Real Correia is the VP, Regulatory Data and Content Lead within Product Development at Roche. With a PhD in Marine Genetics from the University of Liverpool and over 10 years of research in molecular genetics at Oxford University, the Portuguese National Institute of Health, and Basel University, she transitioned to the pharmaceutical industry to apply her scientific knowledge and skills to advance healthcare. She joined the Regulatory Affairs group at Roche in 2003 and has had various roles of increasing responsibility as Late Stage Head for Regulatory Documentation, Global Head of Regulatory Operations and Regulatory Data and Content Leader.

Speaker

Tim Twells

VP of Regulatory Affairs, Enabling Functions
Novartis, United Kingdom

I am a transformative leader who is passionate about implementing digitalisation, innovative thinking and operational optimisation across the full E2E Regulatory lifecycle. My current role at Novartis brings together a broad range of capabilities for impact across the Development organisation and beyond. I strategically lead a highly skilled and large group of individuals and leaders to deliver against the Enterprise vision of reimaging medicine to improve and extend people's lives.

Speaker

Mukesh Singhal, MBA

Partner
Deloitte, United States

Mukesh Singhal is a partner in Deloitte's R&D practice, co-leading the Regulatory practice, with over 20 years of industry experience shaping and leading digital transformations across the industry. Mukesh has led a cross-industry Future of Regulatory forum, helping to shape an industry vision for the future of Regulatory.

12:00 PM — 1:15 PM Ballroom A-E

Networking Luncheon in the Exhibit Hall, hosted by Generis

1:15 PM — 2:30 PM White Oak (Lower Level)

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

Senior Director of Global Regulatory Systems
Eisai Co., Ltd., United States

Senior 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

Kim Gallop

Global Regulatory Specialist
Florence Healthcare, United States

Kimberly Gallop is the Global Regulatory Analyst at Florence Healthcare, bringing 13 years of clinical research experience with a strong foundation in global regulatory affairs and clinical trial start-up operations at a major CRO. In her role, she oversees the Regulatory Compliance Library, ensuring alignment with international standards such as ICH GCP E6(R2), FDA 21 CFR Part 11, EMA Annex 11, and MHRA guidance. Kimberly provides regulatory insight and consultation to software development teams, guiding product compliance with both internal policies and external regulations. She collaborates with subject matter experts to research and interpret global clinical research requirements, and plays a critical role in internal audits.

Implementing AI in Regulatory: Key Considerations for Success

Sean Carpenter

Director of Product
Ennov, United States

Sean Carpenter is a Director of Product at Ennov. With more than 25 years experience in life sciences, Mr. Carpenter's primary focus is Ennov's RIM for pharmaceuticals and medical devices. For the last 2 years, Mr. Carpenter has led

Ennov's efforts in developing and releasing integrated AI capabilities. In addition, Mr. Carpenter led the development and release of Ennov's Medical Device RIM, developed from the ground up with guidance from medical device companies big and small.

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

Donna Yosua

Director, Global Regulatory Data Management
Merck & Co., Inc., 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 Brookside AB (Lower Level)

Session 6, Track 2: Moving Beyond Fragmentation through Integrated Data and Content for Modern Regulatory Processes

Under pressure to meet today's regulatory demands, many pharmaceutical organizations struggle with inefficiencies from outdated manual processes or rush to implement the latest technology without the requisite key foundations. This session will focus on how to successfully move beyond the fragmented legacy processes of the past to enable modern, data-centric frameworks for improvements across regulatory. Ways to apply content governance, structured data, automation, and more will be shared along with their practical uses and 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
- • Formulate a practical next step for improving governance maturity using session frameworks and examples
- 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 14+ 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 6 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

Senior 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 Ballroom FGH

Session 6, Track 3: Drive Global Safety with Semantic Alignment: Implementing IDMP Global Identifiers 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.

Driving Interoperability: Publication of Global Identifiers using FHIR and their role in IDMP Use Cases
Magnus Wallberg, Uppsala Monitoring Centre, Sweden

Implementing Interoperability: Requesting and Using Global PhPIDs in (Cross-Border) Health Care
Bernd Moeske, Freelance Strategy Consultant & Information Architect

FDA and Global Pharmaceutical Product and Substance Identifiers
Tyler Peryea, FDA

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, IDMP-Ontology). 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.

Speaker(s)

Driving Interoperability: Publication of Global Identifiers using FHIR and their role in IDMP Use Cases
Magnus Wallberg, MSC

Solution Architect
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 Solution Architect focusing primarily on pharmacovigilance systems within Uppsala Monitoring Centre but also solutions around IDMP (Identification of Medicinal Products).

Implementing Interoperability: Requesting and Using Global PhPIDs in (Cross-Border) Health Care
Bernd Moeske, MSC

Freelance Strategy Consultant & Information Architect
Aedify AS, Norway

Independent consultant based in northern Europe. Specializing in implementing strategic initiatives and IT solutions across diverse industries. My recent focus has been on supporting government institutions in adopting international standards mandated by regulatory frameworks, such as the EU's EESSI initiative and emerging standards like ISO IDMP, HL7 FHIR, ISO 27269 IPS, and EEHRxF within the EU's EHDS initiative. With master's degrees in both computer science and technology management, I bridge the gap between strategic planning and technical execution. Industry Experience Telecommunications, public sector, healthcare, pharmaceuticals, banking & finance, automotive, transportation, and software development.

FDA and Global Pharmaceutical Product and Substance Identifiers

Tyler Peryea

Chemist
FDA, United States

Tyler Peryea is a chemist and technical leader within the Office of Data Transformation at the U.S. FDA, where he serves as GSRS Program Lead and co-chair of the Data Standards Advisory Board. He was the lead developer of the Global Substance Registration System (GSRS), an open-source platform implementing ISO IDMP 11238 standards now deployed at FDA, EMA, Uppsala Monitoring Centre, bFarm, and MHRA. With over 15 years of experience in cheminformatics and regulatory science, he has pioneered innovations including MolVec and Featurize-Nitrosamines, and spearheaded acceptance of SD files as machine-readable submission formats. Tyler focuses on practical implementation of data standards that enable global regulatory collaboration.

1:15 PM — 2:30 PM

Brookside C (Lower Level)

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.

Achieving Regulatory Operational Excellence: People, Process, Data, Tech
Steve Gens, Gens & Associates Inc.

DATA
Joerg Stueben, Boehringer Ingelheim International GmbH

RIM Technology Investment Priority
Sasikanth Godavarty, Otsuka

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, 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.

DATA

Joerg Stueben, DRSC

Head of Regulatory Information Management
Boehringer Ingelheim, Germany

Dr Joerg Stueben works as "Head of Regulatory Information Management and Senior Expert" for Boehringer Ingelheim. He oversees all typical activities of a RIM group with a focus on Data Management incl modelling, IDMP/SPOR and Data Quality questions and on working on AI usage and guidance documentation. He has a record of successfully leading cross-functional and compliance critical, global projects and consults his business in complex process questions. With over 25 years of extensive experience in pharmaceutical industry, Joerg is an acknowledged expert in project and process management. He is a member of Efpia ERAO IDMP, IFPMA IDMP group co chair, GIDWG & GAMP DACH SC. He is a licensed pharmacist and six sigma black belt.

RIM Technology Investment Priority

Sasikanth Godavarty

Senior Director, Head of Regulatory Technology
Otsuka, United States

As Senior Director and Head of Regulatory Technology at Otsuka Pharmaceutical Companies (U.S.), heads the Regulatory Technology team to deliver innovative, compliant solutions for Global Regulatory Affairs (GRA). Expertise lies in technology strategy, regulatory technology operations, and business process improvement, with a focus on optimizing core platforms like EDMS, RIMS, and publishing systems. Pioneer in multiple AI initiatives to enhance automation and improve regulatory processes. With over 18 years of pharmaceutical industry experience, contributes to cross-functional collaboration, stakeholder engagement, and data-driven strategies to support Otsuka's mission of advancing global health through cutting-edge products.

2:30 PM — 3:15 PM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

2:35 PM — 3:05 PM Swarthmore AB

Case Study Sponsored by Veeva Systems: Veeva AI for Regulatory: Agentic AI for Next Gen Submissions

This case study showcases how Veeva is bringing Agentic AI directly into the Vault Platform and Veeva RIM applications to accelerate the industry's path toward Next-Gen Submissions

Attendees will see how deeply embedded AI Agents - secure, application-specific, and continuously advancing - unlock transformative gains in speed, compliance, and global submission readiness.

• The session will feature a preview of the first few use cases of Veeva AI in Regulatory - AI Agents for Health Authority (HA) correspondence intake, question response creation and insight generation from information in documents and data in Veeva RIM.

• The session will close with thoughts about regulatory operations of the future, reimagined with zero based design and practical value realization framework for Agentic AI

Featured Topics:

What agentic AI means for Regulatory: How unified data, content, and AI Agents within Veeva RIM eliminate integration complexity and unlock secure, in-context automation

Case study: Health authority (HA) interactions automation

- Automating correspondence intake

- Drafting and refining HA responses

- Generating insights from information in Veeva RIM

- Demonstrating the end-to-end workflow

? The era of Next Gen Submissions: A vision of 100+ interoperable AI Agents assisting regulatory to enable predictive planning, optimal dossier strategy, simultaneous global filings and proactive upstream and downstream visibility to

regulatory status, while also improving resource productivity.

Track: Exhibitor Event

Session Chair(s)

Pratyusha Pallavi, MBA

Executive Director, Regulatory AI Strategy
United States

3:15 PM — 4:45 PM White Oak (Lower Level)

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.

Data-driven Submissions from a Labeling Perspective
Niklas Jaenich, Boehringer Ingelheim

Clinical Data Driven Submissions: Human-Data Partnership
Madhavi Gidh-Jain, Sanofi

CMC - ICH Structured Product Quality Submissions
Laurent Lefebvre, Novartis

Structured, Governed, Reusable: Moving Beyond Static Documents to Data-Centric Velocity Murali Menon, Docuvera

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 from a Labeling Perspective

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.

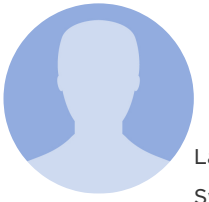
Clinical Data Driven Submissions: Human-Data Partnership

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.

CMC - ICH Structured Product Quality Submissions



Laurent Lefebvre, PHARMD, MPHARM

Head RA Data & Technology
Novartis, Switzerland

Laurent is a pharmacist working as Head RA Data & Technology at the Novartis HQ in Basel, Switzerland. He accumulated 15 years of experience working as worldwide Regulatory CMC Project Lead including blockbuster brands which helped to develop a good overview of the entire CMC product lifecycle in a global regulatory environment while progressively moving to digitalization topics. He is involved in regular collaborations cross-industry, digital initiatives, contributor to ISO IDMP guidelines and regulatory intelligence discussions regarding telematics (EMA SPOR, KASA-PQ/CMC, G-SRS). He is currently acting as EFPIA Alternate Expert in the ICHM4Q(R2) EWG, topic lead on M16 EWG and industry co-lead on ISO IDMP CMC.

Structured, Governed, Reusable: Moving Beyond Static Documents to Data-Centric Velocity

Murali Menon, MS

Chief Revenue Officer, SVP Sales and Services
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

Brookside AB (Lower Level)

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.

- Using Hackathons to Identify Regulatory Process Bottlenecks and Develop AI-Enabled Solutions: Cary Smithson, LeapAhead Solutions, Inc
- Gayatri Tadinada, SLICKBIT Technologies
- Keith Parent, Court Square Group

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

Experienced Regulatory Affairs Delivery Manager & Business Solutions Expert with a strong background in project management, advisory services, business analysis, and departmental support within the pharmaceutical industry. Certified Veeva Vault Platform Associate Administrator and recognized Regulatory Operations Subject Matter Expert (SME). Skilled in managing and optimizing multiple electronic document management systems (eDMS), with a focus on business administration, cross-functional alignment, and industry best practices. Adept at stakeholder engagement across all organizational levels, consistently maintaining a a customer-centric approach and high attention to detail.

Speaker(s)

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

Cary Smithson, MBA

Managing Partner and Owner
LeapAhead Solutions, Inc., United States

Cary is the Managing Partner and Owner 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, 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 AI & Automation Team, is a leader in the DIA AI Consortium, and regularly serves as an industry thought leader.

Speaker

Bryan Reynolds

CEO / Founder
Docxonomy, United States

Mr. Reynolds has over 30 years of experience as a successful entrepreneur, senior executive, and managing consultant with core competencies focused on enterprise content management, mobility, business process engineering, imaging, and records management. Currently, Mr. Reynolds is the Founder and CEO of Docxonomy. The breadth of his knowledge includes the architectural design and development as well as project management of numerous global, large-scale document/records management initiatives across multiple industries including pharmaceutical, biotechnology, medical devices, financial services, insurance, healthcare, and the public sector.

Speaker

Gayatri Tadinada

CBO - Business & Growth
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.

3:15 PM — 4:45 PM

Ballroom FGH

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.

- Streamlining Regulatory Processes with AI Similarity Scoring System: The Future of Content Mapping, Propagation and Document: Sharon Kim, MPilotAI
- Arju Sangal, Amgen
- What it Really Takes to get AI Tech Implemented in Regulatory Space: Kruti Shah, Astrix

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
Hoffmann-La Roche Limited, 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)

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.

From Redlines to Risk Scores: AI-Powered QC for Regulatory Writing

Arju Sangal, MPHARM

Global Safety Director
Amgen, Sweden

Implementing AI in Regulatory, Beyond the Technology

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 Brookside C (Lower Level)

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 transformation and change during times of disruption and digital AI innovations. Presenters will share strategies for evolving roles, launching cross-functional data initiatives, and building resilient teams all with a focus on achieving regulatory excellence. Organizations should see 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, achieve team readiness, and develop leaders across their teams and functions.

- Balancing the Now and the Next: Change Management as a Strategic Lever in Regulatory Role Evolution: Jennifer Carlino, Bristol Myers Squibb
- From Regulatory Data Office to an Enterprise Product Master Data Initiative: A Case Study for Driving Regulatory Excellence: Pankajkumar Sancheti, AbbVie
- Leading Through Disruption: Building a Culture of Regulatory Excellence and Innovation: Angela Dyer, Innovative Regulatory Inc

Learning Objective :

- Apply practical program, change and transition management strategies to balance current regulatory responsibilities with future innovation
- Develop approaches to lead cross-functional data initiatives by creating operational models fostering alignment and collaborating across teams and functions
- 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 Sciences 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)

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.

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, PMP

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.

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 White Oak (Lower Level)

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.

The EMA eCTD v4 Journey and the Impact on the Life Sciences Landscape
Anjana Pindoria, EXTEDO GmbH

eCTD 4.0: How to Prepare and Lessons Learned from eCTD 3.3 Transition
Calyn Stanfill, Gilead Sciences, Inc.

eCTD 4.0: How to Prepare and Lessons Learned from eCTD 3.2.2 Transition
Jason Cober, ProPharma Group

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)

The EMA eCTD v4 Journey and the 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 Analysis Based on First Experience with US FDA and JAPAN; Based on RAPS Publication

Calyn Stanfill

Senior Manager, Regulatory Publishing
Gilead Sciences, Inc., 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.

eCTD 4.0: How to Prepare and Lessons Learned from eCTD 3.2.2 Transition

Jason Cober, MPA

Director Regulatory Review, AI, Digital Transformation
ProPharma, 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.

7:45 AM — 9:00 AM Brookside AB (Lower Level)

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

This session provides real world case study experiences in multimarket filing to achieve accelerated approvals through the process of harmonizing content, processes and responsibilities. Through effective planning and alignment of content across market filings the submissions can be optimized toward multi market readiness. The session will further deep dive

into approaches where technology can enable a data centric model to further enable content harmonization through digital means as well as the use of Cloud Based Centralized Spaces for Health authorities to review filed applications.
Global Submissions Without Borders: Harmonizing Processes, Data, and Technology Across Diverse Health Authorities
Lucie Svobodova, Novavax

Smart Submission Publishing including Multi-Authority Collaboration
Schei Dattner, EXTEDO GmbH / cormeo GmbH

Accelerate Data Standard Compliance with an Enterprise Data Remediation Framework
Brooke Casselberry, Epista Life Sciences

Learning Objective :

- Apply a systematic approach to harmonizing global submission processes and content
- Build a scalable framework for managing regulatory information across markets with varying requirements
- Describe key data and process challenges in implementing data standards across global product portfolios
- Learn how cloud based regulatory spaces enable secure regulatory collaboration and data submission

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

Independent Consultant
A-REG Solutions, Czech Republic

Lucie Svobodova, PharmD, is the COO and Founder of A REG Solutions, a global regulatory strategy company. She brings extensive experience in regulatory affairs and pharmacovigilance, spanning early R&D through post-marketing phases – especially in the vaccines and biotechnology industry. With a doctoral degree in pharmacy from Charles University, Lucie is highly skilled in navigating diverse regulatory systems and is passionate about streamlining regulatory processes worldwide. Her leadership places A REG Solutions at the forefront of regulatory innovation in Europe and beyond.

Smart Submission Publishing including Multi-Authority Collaboration

Schei Dattner, MBA

CPO & CSO
cormeo GmbH, Germany

Schei has almost 30 years of business knowledge, around 25 years of experience in Sales and Marketing in the IT- and services industry and 3 years in Material Management. Today he has responsibility for sales and the product portfolio of the cormeo group including EXTEDO. His strengths lie in the areas of business thinking and acting and he is very experienced in solution selling and product management. Prior to joining EXTEDO, he was the owner and General Manager of a sales outsourcing provider. Before that, he was a Member of the Board and responsible for Sales, Marketing and Consulting at one of the leading German service providers for Technical Documentation and created a document factory. Based on structured components.

Accelerate Data Standard Compliance with an Enterprise Data Remediation Framework

Brooke Casselberry, MS, RAC

Vice President, Advisory and Delivery
Epista Life Science, United States

Brooke is known for her pivotal roles in collaborating with Sponsor Companies, Health Authorities, and Technology Developers. She has maintained focus on leveraging cutting-edge technologies as a catalyst for regulatory advancements, optimization, and collaboration for global go-to-market strategies and data harmonization. She was named PharmaVoice's top 100 most inspiring individuals for Mentorship and Team Development and received the esteemed Excellence in Service award from DIA. Brooke has an integral role in shaping the discourse surrounding data and technology in regulatory affairs through her work with DIA as programming chair for the Data & Technology Track and as the co-chair of the DIA RA Community.

7:45 AM — 9:00 AM Ballroom F-H

Session 8, Track 3: Lessons Learned from the 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.

The Precision FDA GenAI Challenge
Samir Lababidi, FDA

FDA GenAI Community Challenge: Low Code Participation
James Averback, Life Sciences Integration Partners

FDA GenAI Community Challenge Pro Code Tier: Lessons Learned

Venkatraman Balasubramanian (Bala), VB Insights, LLC

Learning Objective :

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

- Describe 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

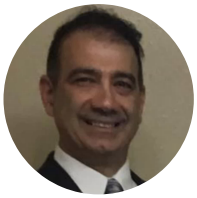
Session Chair(s)

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)



The Precision FDA GenAI Challenge

Samir Lababidi, PHD

Statistician
FDA, United States

Dr. Samir Lababidi is a mathematical statistician and bioinformatician in the Office of the Commissioner (OC) at the U.S. Food and Drug Administration (FDA). He has been for over 20 years at the FDA. He currently co-leads the FDA's precisionFDA Challenge Program, where he has played a central role for more than eight years in the development of AI/ML applications and the coordination of scientific challenges on the precisionFDA platform.

FDA GenAI Community Challenge: Low Code Participation

James Averback, MS

President
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.

FDA GenAI Community Challenge Pro Code Tier: Lessons Learned

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.

7:45 AM — 9:00 AM

Brookside C (Lower Level)

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.

Transforming IND Preparation with AI: A Biotech Perspective on Smarter Regulatory Documentation
Sigrid Selberg, Chemestmed OÜ

Co-Designing AI for Regulatory Teams: Building Trust, Traceability, and Efficiency
Meelis Lootus, Tehistark

The Life Sciences Lens: Unpacking the Need to for Sponsors to Evaluate, Validate, and Govern GenAI for Regulatory Use
Emily Lewis, UCB

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)

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

Meelis is the founder and CEO of Tehistark, where he leads the development of AutoDossier, an AI-powered regulatory authoring platform with a focus on CTD module 2 and CMC sections. He previously served as Director of AI Engineering at Sharecare Inc, developing production grade information systems for pharmaceutical and health insurance companies. He holds a Ph.D from Oxford's world-renown Visual Geometry group and has ten years industrial experience developing AI solutions primarily for life sciences and health sectors. He sits on an IEEE committee for standardising the development and use of novel digital biomarkers.

Transforming IND Preparation with AI: A Biotech Perspective on Smarter Regulatory Documentation

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.

The Life Sciences Lens: Unpacking the Need to for Sponsors to Evaluate, Validate, and Govern GenAI for Regulatory Use

Emily Lewis, MS

AI and Innovation Lead
UCB, United States

Emily Lewis is a trailblazing innovator and leader in the realm of digital health and AI. With nearly two decades of experience, she has made significant contributions to the development and adoption of cutting-edge digital health solutions. Her passion for using technology to improve patient outcomes and advance healthcare has earned her recognition as one of Fierce Healthcare's Rising Stars in HealthTech.

9:10 AM — 10:25 AM White Oak (Lower Level)

Session 9, Track 1: Federating the Forgotten: Unlocking the Content Supply Chain for AI and Data Submission

The pharmaceutical product development lifecycle relies on a complex content supply chain, where data inputs flow into protocols, study results feed CSRs, and regulatory decisions shape labeling. However, a critical disconnect remains; while clinical data is increasingly standardized, the narrative content wrapping it often remains trapped in static documents and siloed systems. This fragmentation creates a significant barrier to innovation, resulting in manual handoffs, inconsistent data propagation, and an inability to provide the structured context necessary to fully leverage the disruption promised by Generative AI.

Previous attempts at automation through monolithic structured content systems often failed by forcing unsustainably rigid compromises on authors. Today, the challenge has evolved: organizations are rushing to deploy AI for summarization and generation, only to find that without a foundational way to codify this interconnected ecosystem outputs are inconsistent or require heavy rework. To scale AI beyond simple tasks, the industry requires a shift away from rigid templates toward a flexible, data-driven methodology that treats content as a network of interrelated, reusable components.

This session introduces the Unified Content Modelling Language (UCML), a methodology for describing content not as flat text, but as intelligent "containers" defined by their relationships, rules, and metadata. We will explore how UCML acts as an exchange standard to bridge disparate business units and demonstrate how enriching content with metadata supports digitization standards (CDISC DDF, PQ-CMC, IDMP). Crucially, we will show how this structure provides the "grounding" LLMs require to generate high-quality, traceable outputs across content lifecycles (e.g. Protocol-CSR-Clinical Summaries).

Finally, we will discuss the practical application of UCML, moving from abstract models to federated ecosystem architectures. We will examine how to balance the needs of different functional areas while maintaining a unified language for automation. Participants will leave with a roadmap for implementing a content-as-data strategy, understanding that the path to true AI scalability requires not just new tools, but a fundamental reimagining of how we model the narratives that define our science.

Chris Dowdall, Roche

Pavan Mummareddi, MS, Senior Technology Leader & Architect, Deloitte

Learning Objective :

- 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 Regulatory Information Management systems, 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

Pavan Mummareddi, MS

Senior Technology Leader & Architect
Deloitte, United States

Pavan Mummareddi is a Senior Technology Leader and Architect in Deloitte's Life Sciences practice, partnering with top biopharma clients to modernize regulatory and digital capabilities. He works on the ground with business and technology teams to streamline regulatory submissions by connecting data, content, and workflows across systems - improving speed, quality, and compliance - enabled by modern architecture, full-stack development, and AI/GenAI. He also leads enterprise architecture for an innovation portfolio of pharma drug development solutions across Clinical, Regulatory, and Safety.

9:10 AM — 10:25 AM Brookside AB (Lower Level)

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.

Enabled Regulatory Authoring of Quality Sections via Structured Content Management
Matthew Metzger, Merck

Global Regulatory Momentum and Implementation of Electronic Labeling (e-Labeling)
Eric Randel, Astellas Pharmaceuticals

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 provides ad hoc Regulatory consulting 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 and her global experience with various pharmaceutical clients.

Speaker(s)

Enabled Regulatory Authoring of Quality Sections via Structured Content Management

Matt Metzger, PHD

Principal Scientist
Merck & Co, Inc, United States

Matt Metzger is a Principal Scientist in Digital CMC at Merck, leading a data-centric regulatory authoring initiative connecting analytical and process development, Regulatory CMC, and IT. He is the business owner for Merck's structured content authoring capability, enabling accurate, reusable Quality data for regulatory submissions. His work draws on standards such as ISO IDMP, PQ/CMC, PQI, and ontology efforts from NIIMBL, Pistoia, and Allotrope. He previously spent over a decade in small-molecule development, focusing on control strategies and tech transfer. Matt holds a PhD from Rutgers and a BS from Lafayette College.

Global Regulatory Momentum and Implementation of Electronic Labeling (e-Labeling)

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 Ballroom F-H

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.

Enabling Efficient Regulatory Submissions: A Cloud-Based Approach to Structured CMC Dossiers
Ciby Joseph Abraham, AstraZeneca

Vada Perkins, Boehringer Ingelheim

Omar Serang, DNAnexus

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)

J Paul Kirwan, PHD, MSC

Senior Manager, Regulatory Affairs
Amgen, United States

J. Paul Kirwan is a Senior Manager, Regulatory Affairs, with Amgen. He currently leads reliance activities associated with cloud-based regulatory submissions and manages the initial filing content for module 3 authoring in collaboration with RA CMC and Process Development. Paul has been a member of the advocacy and external engagement team with Amgen and is active with ISPE, IQ Consortium, CASSS, and BioPhorum. He previously served as a Global CMC Regulatory Lead and is also a former FDA product quality reviewer (CDER, Office of Biotechnology Products) and FDA Commissioner's Fellow. Paul holds a PhD in Biochemistry from the University of Colorado Anschutz Medical Campus.

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

Rune Bergendorff, MSC

Partner, International Life Sciences
Implement Consulting Group, Denmark

Rune Bergendorff, Partner at Implement Consulting, boasts two decades of consultancy experience spanning Europe and the US. Educated in IT and business, his focus is centered on delivering sustainable digital transformations that drive business impact and value. Over the past 15 years, he has honed his expertise within Life Sciences, initially in RA and Quality, then expanding into Clinical and Safety. Rune has spearheaded initiatives such as digitalizing regulatory product submissions and implementing AI in safety and clinical data intake. He actively contributed to industry standards, including development of IDMP with ISO and as member of the EMA SPOR task force. Committed to community advancement, he champions improved digital workflows

Speaker

Omar Serang

Chief Cloud Officer
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 Brookside C (Lower Level)

Session 9, Track 4: Cross-Functional Collaboration for Regulatory Excellence: Integrations, Digital Innovation, and Inspection Readiness

As regulatory expectations evolve, seamless collaboration across regulatory, technical, and operational teams has become essential to sustaining compliance and driving innovation. This session brings together insights from integration initiatives and inspection-readiness strategies to illustrate how cross-functional partnerships can accelerate digital transformation, strengthen cloud-based review capabilities, and support regulatory rigor. Through real-world examples and practical frameworks, speakers will explore how unified planning, shared understanding, and intentional team design enhance both integration programs and hybrid/remote inspection activities. Attendees will gain actionable approaches to building connected, inspection-ready organizations that can scale with emerging regulatory interfaces, digital tools, and cloud-enabled review models.

Cross-Functional Collaboration for Regulatory Excellence: Integrations, Digital Innovation, and Inspection Readiness
Dominique Lagrave, Accumulus Technologies

Inspection-Ready by Design: Digital Strategies to Support Hybrid and Remote Regulatory Inspections
Andrea Bastek, Florence Healthcare

Matt Neal, BeOne

Learning Objective :

- Identify how regulatory, operational, and technology teams can jointly scope, plan, and execute integration initiatives aligned to real regulatory use cases
- Apply collaborative strategies and digital design principles that enhance inspection readiness—especially for hybrid and remote regulatory inspections
- Evaluate common cross-functional pitfalls and implement practices that strengthen regulatory excellence across the product lifecycle

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)

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.

Cross-Functional Collaboration for Regulatory Excellence: Integrations, Digital Innovation, and Inspection Readiness

Dominique Lagrave, PHARMD

Chief Regulatory Officer
Accumulus Technologies, United States

Dominique has over 25 years of International Regulatory Affairs experience with the last 20 years spent in Global Regulatory Operations leadership role. Past experiences include work at Galderma, Novo Nordisk, Liquent-Parexel and Dendreon. Dominique joined Accumulus as SVP of Regulatory Innovation in early 2022 coming from Amgen where he was heading Global Regulatory Operations. As part of his role at Accumulus, Dominique is supporting global Accumulus platform adoption from Health Authorities and Biopharmaceutical organizations. Dominique is also a Board Member of IRISS Forum since 2021. Dominique holds a Pharm D and a master's in International Regulatory Affairs from the University of Paris.

Speaker

Matt Neal, MA

Executive Director, Global Regulatory Operations Strategy & Innovation
BeOne Medicines USA, Inc., United States

Matt Neal is an author and frequent keynote speaker. He joined Atara Biotherapeutics in 2019 as the Head of Regulatory Operations. Prior to that, Matt was the Head of Product Management for the InSight Suite of Regulatory Information Management Solutions at Parexel, Inc. and partnered with Microsoft. Before joining PAREXEL, Matt was a Director of Regulatory & Safety Operations at Amgen, Inc. (2003-2016) and was one of the pioneering members of the Regulatory Submissions Department for GlaxoSmithKline (1996-2003). Matt has been publishing and submitting electronic dossiers to the FDA since 1996, and submitted the very first fully electronic NDA for GSK in 1999.

10:25 AM — 11:10 AM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

10:30 AM — 11:00 AM Swarthmore AB

Case Study Sponsored by GlobalVision: Your Competitive Edge: The AI Readiness Roadmap for Regulatory Labeling

The shift to AI is imperative, yet many life science companies lack a strategic roadmap to move from aspiration to confident adoption. This session, led by GlobalVision, provides an AI Readiness Roadmap designed to benchmark your current operational readiness and define your next steps. Learn how to cultivate the organizational confidence required to secure a competitive edge while ensuring unassailable quality and compliance. Join us to move beyond debate and start strategically building your AI future.

Following this session, you will be able to:

- Benchmark your company's current position within our AI Readiness Index
- Successfully transition existing processes to reliable AI systems
- Eliminate labeling errors using AI as a copilot, while keeping your people in charge
- Keep up with the AI imperative and create a tangible competitive edge over your competitors

Track: Exhibitor Event

Session Chair(s)

Arpad Lehoczki

Sales Director
Global Vision, Canada

Speaker(s)

11:10 AM — 12:30 PM Ballroom E-H

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.

Kristiina Puusaari, European Medicines Agency

Update on eCTD v3.2.2 & v4.0 in APAC Region

Handsome Ji, Pfizer

Key Updates Shaping the Future of Regulation

Andrea Johnson, Medicines and Healthcare products Regulatory Agency (MHRA)

Learning Objective :

- Discuss how regulatory agencies are transforming their operating models to adapt to emerging industry needs
- Explain modernization efforts within regulatory infrastructure, focusing on how digital tools, data capabilities, and streamlined processes support more efficient review and submission management
- Recognize the importance of governance and patient centric principles in shaping the next phase of regulatory review

Track: General Session

Session Chair(s)

Lindsay Fitzgerald

Delivery Manager
Astrix, United States

Experienced Regulatory Affairs Delivery Manager & Business Solutions Expert with a strong background in project management, advisory services, business analysis, and departmental support within the pharmaceutical industry. Certified Veeva Vault Platform Associate Administrator and recognized Regulatory Operations Subject Matter Expert (SME). Skilled in managing and optimizing multiple electronic document management systems (eDMS), with a focus on business administration, cross-functional alignment, and industry best practices. Adept at stakeholder engagement across all organizational levels, consistently maintaining a a customer-centric approach and high attention to detail.

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.

Key Updates Shaping the Future of Regulation

Andrea Johnson

Deputy Director of Future System 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 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.

Update on eCTD v3.2.2 & v4.0 in APAC Region

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.

12:30 PM — 12:45 PM

Closing Remarks and Forum Adjourned