Bethesda North Marriott Hotel and Conference Center

Feb 03, 2025 7:45 AM - Feb 05, 2025 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 03, 2025

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

Forum Registration

11:30 AM — 12:30 PM — Ballroom A-E

Networking Luncheon in the Exhibit Hall

12:30 PM — 12:55 PM — Ballroom E-H

Welcoming Remarks and Presentation of the Excellence in Service Award

12:55 PM — 1:40 PM Ballroom E-H

Session 1: Opening Plenary - Managing Change in a Time of Regulatory Transformation

The regulatory function is evolving in roles, structure, and priorities across three dimensions: Targeted regulatory strategy, globalization in submissions, and data / digital. The outcomes of this result in upskilling staff, preparing leaders for new responsibility and how to effectively capitalize on capabilities. Through a panel of VP level leaders in regulatory, an interactive fireside chat will reveal their perspectives on organizational preparedness, change management and approaches to positively prepare their organizations for future readiness, covering a range of topics.

Navigating Regulatory Shifts: Discuss strategies for effectively managing changes within regulatory, including best practices for communicating changes, training staff, and maintaining compliance during transitions.
Building Resilience: Explore how to foster a culture of adaptability and resilience among regulatory teams to better handle the dynamic nature of the regulatory landscape.
Streamlining Regulatory Processes: Share insights on implementing process improvements to enhance productivity and reduce compliance risks.
Enhancing Cross-Functional Collaboration: Highlight the importance of collaboration between regulatory, IT, and other departments to ensure seamless integration of digital solutions and technology.
Adopting Cutting-Edge Technologies: Explore the latest digital tools and technologies that can transform regulatory operations, such as AI, machine learning, and blockchain, and discuss how to effectively implement them.

Andrew Robertson, Takeda

Martine Zimmermann, Ipsen

Isolde Puschmann, Bristol Myers Squibb

Paul Nitschmann, Intercept Pharmaceuticals

Learning Objective :

- Identify key changes influencing regulatory roles and priorities organizations are taking across targeted regulatory strategy, globalization in submissions and data/digital dimensions
- Describe how key changes necessitate upskilling staff and preparing leaders for new responsibilities
- Apply strategies to foster organizational preparedness, adaptability, and resilience, enabling preparation for future regulatory challenges and opportunities

Track: General Session

Session Chair(s)

Sandra Krogulski, MA

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

Sandy Krogulski is an experienced and solution oriented individual with over 10 years of submission 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.

Vladimir Penkrat, MBA

Associate Vice President of 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)

Speaker

Andrew Robertson, JD, PhD

Vice President, Head of Global Regulatory Policy and Innovation
Takeda, United States

Andrew Robertson is the Vice President and Head of Global Regulatory Policy and Innovation at Takeda. With over twenty years of experience, Andrew has leveraged his expertise in science, law, and policy to advance global healthcare innovation and improve patient access to medicines. In his current role, Andrew oversees Takeda R&D's global regulatory policy and external engagement activities, affecting pre-clinical and clinical development, regulatory approval, and post-market strategy. Andrew has also spearheaded multiple strategic initiatives within Takeda combining digital, AI, and data-driven approaches within regulatory contexts.

Speaker

Martine Zimmermann, PharmD

Senior Vice President, Head of Global Regulatory Affairs
Ipsen , France

Martine Zimmermann is Senior Vice President, Head of Global Regulatory Affairs at Ipsen since January 2023. Dr Zimmermann has over 25 years of combined R&D and global regulatory strategy experience. She joined Alexion Pharmaceuticals (part of AstraZeneca since 2021) in 2009 and has since then been dedicated to the registration of several orphan medicinal products across the globe, as well as to the shaping of the regulatory environment for medicines under development for rare diseases. Prior to Alexion Pharmaceuticals, Dr Zimmermann held numerous

R&D and regulatory roles in companies such as Aventis (now Sanofi), Servier and H. Lundbeck A/S. Dr Zimmermann also serves currently as a Director in the Board of Inventiva Pharma.

Speaker

Isolde Puschmann, PhD, MPharm

VP, Global Regulatory Strategic Operations
Bristol Myers Squibb, United States

Currently the Vice President of Global Regulatory Strategic Operations, Isolde started her 30-year career at BMS as a Country Regulatory Manager in Austria. Self-motivated, Isolde rose through the ranks in various regulatory roles: Group Director of Global Regulatory Strategy Management, Group Director Regulatory Operations and Strategy Planning, Executive Director of Global Labeling & Mature Products when in 2020, she was promoted to Vice President. Isolde is passionate about helping her team find their voice, celebrate their accomplishment and overcome their own hurdles to create the career that matters to them. One of her favorite quotes is “A person who never makes a mistake never tried anything new. ”

Speaker

Paul Nitschmann, MD

SVP Regulatory Affairs
Intercept Pharmaceuticals, United States

Paul is SVP, Head of Regulatory Affairs at Intercept Pharmaceuticals, a wholly owned subsidiary of Alfasigma S.p.A., and has more than 30 years of experience in small, mid-size and large Pharma in various regulatory strategy roles. The last 10 years, he has expanded his responsibilities to leading regulatory operations, labeling and medical writing departments.

1:45 PM — 3:00 PM Ballroom E-H

Session 2: Global IDMP Implementation – Getting Closer to the Goal

The Identification of Medicinal Products (IDMP) offers a global framework for unique identification and consistent documentation of medicinal products, facilitating information exchange among regulators, manufacturers, suppliers, and distributors.

This session will present an overview of the testing results for the Global Pharmaceutical Product Identification (PhPID) Service operating model, which generates global PhPIDs for marketed medicinal products. The model's readiness for deployment, including its software functionality, interoperability, processes, and business rules will be discussed.

Malin Fladvad, Uppsala Monitoring Centre

Isabel Chicharo, European Medicines Agency

Flávia Moreira Cruz, ANVISA

Philipp Weyermann, Swissmedic

Vada Perkins, Boehringer Ingelheim

Karin Hay, Health Canada

Learning Objective :

- Describe the significance of IDMP
- Identify the current state of IDMP implementation
- Evaluate the challenges and benefits of IDMP adoption
- Assess the readiness of regulatory bodies for IDMP
- Discuss global collaboration on IDMP implementation
- Explore practical implications of IDMP for industry

Track: General Session

Session Chair(s)

Nimesh Patel

Director of Global Regulatory Systems
Eisai Pharmaceuticals, United States

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

Speaker(s)

Speaker

Isabel Chicharo, MPharm

Head of Regulatory Data Management
European Medicines Agency, Netherlands

I am responsible for Regulatory Master Data Management Services, currently on Substances, Products, Organisations and Referential data (also known as SPOR). I also coordinate the implementation of ISO IDMP in EU. I over 20 years of data management experience in the field of Medicines. My past experience covers clinical/hospital pharmacy, a medical dictionary company, the Portuguese medicines authority (INFARMED) and EMA.

Speaker

Philipp Weyermann, DrSc, MSc

Head of Unit Regulatory Assessment 2
Swissmedic, Switzerland

Dr. Philipp Weyermann is a team leader in the Regulatory Assessment division at Swissmedic, the Swiss therapeutic products agency. His role includes responsibility for substance management and the substance database. Philipp is a long time member in several international standardisation bodies, including the Global Identification of Medicinal Products (IDMP) Working Group (GIDWG) and the IDMP Working Group under the International Pharmaceutical Regulators Programme (IPRF). He is a chemist by training with a MSc from the University of Berne and a DrSc from ETH Zurich as well as a Postdoc at Caltech. Before joining Swissmedic in 2010, he worked in the pharmaceutical industry as a medicinal chemist and project leader for several years.

Speaker

Karin Hay

Senior Policy Analyst
Health Canada, Canada

Speaker

Flávia Moreira Cruz, PharmD

Specialist at Pharmacovigilance Officer (GFARM)
ANVISA, Brazil

As Pharmacist and Specialist in Health Surveillance and Regulation, I'm working at Anvisa since 2005. I had expertise in some medicine areas, like market authorization, traceability and authenticity, regulation of inserts and labels, etc. In 2016, I began work with Pharmacovigilance in activities related to the ICSRs management system, including the implantation of VigiFlow in Brazil with the partner of Uppsala Monitoring Centre (UMC), and the uses of PV databases. I'm representing Anvisa in the following Working Groups: ICH WG E2B (R3), ICH WG E2D(R1), and CIOMS WG XI on Artificial Intelligence in Pharmacovigilance.

Speaker

Malin Fladvad, PhD, MSc

Portfolio Officer
Uppsala Monitoring Centre, Sweden

Malin Fladvad is a Portfolio officer at Uppsala Monitoring Centre (UMC). In this position she is responsible for the WHODrug Product Portfolio which dictionaries and applications are used in clinical trials and safety monitoring worldwide. Malin is also engaged in various efforts for global implementation of the ISO standard for Medicinal Product Information (IDMP) such as ISO TC 215 WG6 and co-chair the Global IDMP Working Group (GIDWG). She has a master's in Molecular Biotechnology Engineering and a PhD in Medical Biophysics from Karolinska Institute, Sweden.

Speaker

Vada Perkins, DrSc, MSc

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

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

3:00 PM — 3:45 PM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

3:05 PM — 3:35 PM Forest Glen (Lower Level)

Hosted Session/Non-CE: Case Study Sponsored by DNAnexus

The complexity of managing dynamic regulatory submissions is driving the need for cloud-based digitalization, harmonization, and normalization of regulatory information. This session explores how leveraging global standards and Standards Development Organizations (SDOs) can enhance efficiency, interoperability, and AI-driven analysis of regulatory data. Key topics include the adoption of structured data and eCTD 4.0, AI integration to automate compliance workflows, and addressing jurisdictional challenges. By fostering trusted regulatory spaces, life sciences organizations can collaborate effectively while ensuring security and privacy. Attendees will gain actionable strategies to leverage regulatory cloud platforms for streamlined submissions and global compliance.

Learning Objective :

- Addressing the cloud adoption gap for global regulatory stakeholder interaction
- Accelerating digitalization, harmonization, and normalization of regulatory information through sponsor, agency, and standards organization collaboration in the cloud
- Democratizing access to knowledge and tools for global health authorities to support eCTD 4.0 transition, post-approval changes to CMC, and AI-based submission validation

Track: Exhibitor Event

Session Chair(s)

Sponsored Sessions

United States

Speaker(s)

Fostering Dynamic Submission Management (DSM) Innovation through Trusted Regulatory Spaces (TRS)

Brooke Casselberry, MS, RAC

Vice President, Advisory and Delivery
Epista Life Sciences, 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.

Fostering Dynamic Submission Management (DSM) Innovation through Trusted Regulatory Spaces (TRS)

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.

Fostering Dynamic Submission Management (DSM) Innovation through Trusted Regulatory Spaces (TRS)

Akira Yamaguchi, MBA

Chief Technical Officer
LORENZ Life Sciences Group, United States

After an international career in management consulting and information technology at Software AG and Comshare, Akira Yamaguchi joined LORENZ Life Sciences in 1995. His initial role was software development in the field of electronic submissions, achieved in 2001 with the release of docuBridge as a major company milestone. In 2003, Mr. Yamaguchi became responsible for LORENZ' overall software product development. In his Project SME role, Mr. Yamaguchi advises larger customer implementation projects. His current task is to develop the strategic directions of LORENZ' software portfolio.

3:45 PM — 4:45 PM Ballroom E-H

Session 3: A Year in Review: FDA Updates

Over the past year, the U.S. Food and Drug Administration (FDA) has continued its modernization efforts, implementing significant changes in regulatory processes and technological advancements to enhance efficiency, transparency, and compliance in regulatory submissions. This session will provide a comprehensive review of key FDA updates and notable FDA guidance documents issued over the past year. Additionally, emerging trends, regulatory shifts, and insights that have shaped the FDA's approach to regulatory submissions and information management will be discussed.

Learning Objective :

- Describe the latest advancements, key developments and major changes within the FDA as it relates to regulatory submissions and information management

Track: General Session

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
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)

4:45 PM — 5:45 PM Ballroom A-D

Networking Reception in the Exhibit Hall

Day 2 Feb 04, 2025

7:45 AM — 8:15 AM Ballroom A-D

Networking Breakfast in the Exhibit Hall

7:45 AM — 4:30 PM

Ballroom Foyer (Upper Level)

Registration

8:15 AM — 8:30 AM

Ballroom E-H

Welcome to Day Two and DIA Community Update

Welcome to Day Two and DIA Community Update

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
DIA, United States

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Speaker(s)

Fostering Dynamic Submission Management (DSM) Innovation through Trusted Regulatory Spaces (TRS)

Brooke Casselberry, MS, RAC

Vice President, Advisory and Delivery
Epista Life Sciences, 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.

8:30 AM — 9:45 AM Ballroom E-H

Session 4: eCTD 3.2.2 & 4.0: EMA Updates & Industry Insights on Global Regulatory Efforts

This session will provide an in-depth overview of the latest developments in global electronic submissions, with a primary focus on regulatory agency perspectives on eCTD 3.2.2 and eCTD 4.0. Attendees will gain insights into ongoing global regulatory efforts and specific agency initiatives, such as the EMA's technical pilot of eCTD 4.0. This discussion will bring together key perspectives from regulatory authorities and industry representatives to outline the evolving regulatory landscape and expectations for future electronic submissions.

Handsome Ji, Pfizer

Lael McCune, EXTEDO

Kristiina Puusaari, European Medicines Agency

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

- Understand the current regulatory landscape for eCTD 3.2.2 and eCTD 4.0
- Gain insights on the EMA's pilot program for eCTD 4.0

Track: General Session

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
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)

Overview of Global Regulatory eCTD 4.0 Efforts

Lael McCune

Pre-Sales Manager

EXTEDO, United States

Lael is a key player in Extedo's presales efforts. She is responsible for presenting demonstrations of Extedo's RIM solution, assisting prospects with aligning their publishing efforts to industry best practices, and serving as a point of contact for publishing expertise. She began her career as a publisher at a CRO and moved on to manage a team of publishers before transitioning her career to the vendor side of regulatory operations. Lael holds a MS in Regulatory Science.

Update on eCTD v3.2.2 Submissions

Shenqi (Handsome) Ji

Regional Publishing Lead, Asia, Global Regulatory Operations
Pfizer, China

Handsome Ji is highly driven and experienced, with 18 years regulatory operational, project and change management experience within multi-cultured global environments. Handsome was invited as guest speaker in DIA China 7th, 10th and 11th Annual Meeting, served as host and Speaker for CMWC (China Medical Writing Community) forum in 2015 and 2016 and Program lead for DIA China M4/M8 Workshop(2020-2023), Handsome holds a seat for DIA China YMAC(2018-2019) and was nominated as Taskforce co-Lead for DIA China RA Community since 2019. Besides, Handsome is co-lead of RDPAC 'Regulatory Requirement' Workstream, including eCTD, Filling Review & ICH Harmonization for Registration, e.t.c.

eCTD v4.0 EU Implementation

Kristiina Puusaari, MBA, PMP

eSubmission Programme Management, Human Medicines Evaluation
European Medicines Agency, Netherlands

Kristiina Puusaari is an eSubmission coordinator at the European Medicines Agency (EMA) working on Programme and Project Management for electronic submission systems and projects, such as eCTD, EMA eSubmission Gateway, electronic Application Form (eAF), Common Repository, PSUR Repository and the Single Submission Portal. Kristiina is the business domain expert for the EMA eSubmission systems as well as the Chair of the eSubmission Change Management Board. Kristiina also represents EMA in the ICH M8 IGW/EGW.

9:45 AM — 10:45 AM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

10:05 AM — 10:35 AM Forest Glen (Lower Level)

Hosted Session/Non-CE: Case Study Sponsored by Weave AI

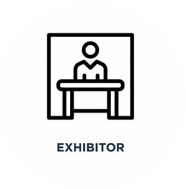
This talk explores the potential of generative AI to revolutionize regulatory writing, focusing on the comparative advantages of AI-assisted versus human-created content. By examining historical data and industry practices, we will discuss how AI tools can enhance the drafting process in regulatory submissions. The conversation will highlight the potential for improving efficiency and maintaining quality standards, offering a practical perspective on the role of AI in shaping the future of regulatory writing.

Learning Objective :

- Exploring Human and AI Drafting Approaches
- Overview of an Objective Assessment Framework
- Insights into Enhancing Efficiency and Quality

Track: Exhibitor Event

Session Chair(s)



Sponsored Sessions

United States

Speaker(s)

Evaluating Time Savings in Regulatory Writing: A Scientific Comparison of Human and AI Approaches

Lindsay Mateo

CCO

Weave, United States

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

Session 5, Track 1: A Framework for Decision-making for Regulatory Information Management and Operations Leaders

Through a panel of Regulatory Information Management (RIM) and Regulatory Operation (RO) leaders, this session will share insights on how to connect health authority and/or industry initiatives to your departmental or company objectives while balancing internal and external pressures. Gain insights on how to align data and technology initiatives to support the development and registration of your products while assessing and managing risk. Additionally, attendees will leave with key takeaways on communicating effectively with senior leaders and decision-makers regarding strategy and resource requirements while building regulatory organizations, processes, and systems.

Scott Cleve, Daiichi Sankyo

Matt Neal, Atara Biotherapuetics

Frits Stulp, Deloitte, Netherlands

Learning Objective : At the conclusion of this activity, participants should be able to:

- Identify internal and external inputs to create a RIM and/or RO strategy
- Assess and manage risk when creating a RIM and/or RO strategy
- Communicate effectively with senior leaders and decision-makers regarding strategy and resource requirements

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)

Author

Scott Cleve

Vice President Regulatory Labeling, Operations and Writing
Daiichi Sankyo, United States

Scott Cleve is currently the Vice president of Global Regulatory Labeling, Operations and Writing at Daiichi Sankyo where he leads a global organization responsible for delivering compliant and timely regulatory data and information to global Health Authorities and building a regulatory information management framework that is fit-for-purpose. In his career he previously led Regulatory Operations teams at bluebird bio, Boehringer Ingelheim, AbbVie and Astellas. Scott's focus is on developing the people in his organization, investigating technology to improve process and compliance, and partnering within industry to improve standards, process and technology.

Speaker

Matt Neal, MA

Executive Director, Global Regulatory Operations Strategy & Innovation
BeiGene 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.

Speaker

Frits Stulp, MSc

Chairman of the Board
CTADHL, Netherlands

Frits Stulp is Chairman of the Board of CTADHL (Call to Action Delivering Health Literacy), a not for profit organization involved in Transatlantic adoption of IDMP and other interoperability standards in medicine and healthcare (www.ctadhl.org). On a daily basis Frits is Managing Director of Iperion, a Deloitte business, with over 20 years of industry and consultancy experience. In this role he leads a team of regulatory / IDMP experts active in various projects to deliver value to both pharmaceutical companies as well as regulators. Frits is the IDMP topic group lead for the IRISS Forum. Regarded as an SME on IDMP, he gladly shares his gained knowledge and experience in various occasions around the globe.

10:45 AM — 12:00 PM

Brookside AB (Lower Level)

Session 5, Track 2: Igniting Seamless Data Flow: Enhancing Business Processes and Governance with FHIR and ICH Innovations

This session will explore the transformative initiatives by the International Council for Harmonization (ICH) to enhance global regulatory collaboration through innovative information exchange standards. It will highlight ICH Expert Working Group initiatives focused on establishing electronic communication standards and evolving eCTD guidelines. The session will also discuss the optimistic impact of adopting HL7 Fast Healthcare Interoperability Resources (FHIR) for regulatory submissions, emphasizing improved data quality, governance, and operational efficiency in the pharmaceutical sector.

Is Your Data Flammable and Controlled? A Case for FHIR in Regulatory Affairs - Kåre Hyttel, NNIT Inc.

Enhancing Global Regulatory Collaboration through ICH's Information Exchange Innovations - Rodrigo Palacios, F. Hoffmann-La Roche

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

- Comprehend ICH initiatives' role in global regulatory collaboration and reliance
- Evaluate electronic submission standards' impact on regulatory efficiency
- Explore FHIR's implications for regulatory data and its use within pharmaceutical organizations

Track: Optimizing Processes and Proceduress

Session Chair(s)

Maria Sagoua, MHA

Director of Regulatory Innovation
Accumulus Synergy, United States

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

Speaker(s)

Is Your Data Flammable and Controlled? A Case for FHIR in Regulatory Affairs

Kåre Hyttel, MSc

Principal Consultant
NNIT Inc., Denmark

Kåre is an IT consultant at NNIT with 3 years of experience and a 7-year entrepreneurial background. Specializing in pharmaceutical and regulatory data standards, he is passionate about leveraging FHIR to enhance operational efficiency, streamline data workflows, and enable real-time data exchange with regulatory authorities. Kåre has a proven track record of developing innovative solutions that bridge business needs and technology, from optimizing data integrations to crafting strategic roadmaps. In addition: his expertise includes establishing robust data governance frameworks, ensuring GxP compliance, and architecting scalable data solutions tailored to the life sciences industry.

Enhancing Global Regulatory Collaboration through ICH's Information Exchange Innovations

Rodrigo Palacios, MBA

Senior Director, Technical Regulatory Policy
F. Hoffmann-La Roche, Switzerland

Rodrigo Palacios is an Executive Director in Regulatory Policy at Roche. He is responsible for advancing global policy on data and technology in the regulatory domain. These topics include Cloud Submissions, Data Standardisation (e.g. IDMP), structured data submissions, eCTD and Regulatory Information Management. Rodrigo represents Roche in EFPIA and PhRMA Regulatory Technology expert groups and acts as PhRMA's deputy topic lead in the ICH M4Q R2 Expert Working Group. He has over 25 years of experience in data and technology strategy, Information Technology management, software development and consulting.

10:45 AM — 12:00 PM Ballroom F-G

Session 5, Track 3: How to Avoid AI Overload: Navigating Impactful Applications Today and Tomorrow

This session is tailored to inspire and equip you with the insights needed to navigate the evolving landscape of AI in Regulatory Affairs. Through diverse presentations, explore how companies are leveraging AI to automate tedious tasks, achieve digital transformation, and realize tangible returns on investment. Discover actionable use cases, hyperautomation strategies, and generative AI applications that optimize regulatory operations and set the stage for future advancements.

AI with ROI - Michelle Wu, NyquistAI

Integrated Hyperautomation in Regulatory Affairs - Abigail Peterson, Merck

Unlocking the Potential of Generative AI to Accelerate Innovation - Madhavi Gidh-Jain, Sanofi

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

- Identify real-world AI use cases for automating regulatory tasks
- Compare different AI applications and the human effort needed to operationalize them

Track: Adopting Innovative Technologies

Session Chair(s)

Aliza Nathoo

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

Aliza began her career supporting 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 with ROI

Michelle Wu, MBA

Co-founder & CEO
NyquistAI, United States

Michelle Wu is the cofounder and CEO of NyquistAI, with over a decade of experience in pharmaceuticals, medical technology, and digital innovation. She has been featured by Forbes and has spoken at various conferences on AI in life science. Before founding NyquistAI, she was the youngest global strategy manager at Novartis, where she played a pivotal role in the industry's first and only asset swap deal between Novartis, Eli Lilly, and GSK. This experience highlighted the challenges of manual data research, sparking her vision to create NyquistAI. Before Novartis, she worked for BCG, advising major pharma and Medtech companies on their global product development and emerging market strategies. She holds an MBA from Stanford University.

Integrated Hyperautomation in Regulatory Affairs

Abigail Peterson, MPA

Associate Director, Regulatory Affairs
Merck, United States

Abby Peterson is an Associate Director, Research Innovation and Information Management at Merck, within Global Regulatory Affairs and Clinical Safety. Her diverse career has spanned banking and finance, telecommunications, nonprofit and government sectors. As a former Captain in in the United States Marine Corps, she served six years as a Public Affairs Officer, refining her information management expertise. Based in Rahway, NJ, Abby leads her department's Hyperautomation Service, bringing together AI, Robotic Process Automation, and Power Platform services to expand on a "citizen developer" ethos, alleviating strain on enterprise IT while optimizing the workdays of her colleagues. She holds her MPA from Rutgers University.

Unlocking the potential of generative AI to accelerate innovation

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.

10:45 AM — 12:00 PM

Brookside C (Lower Level)

Session 5, Track 4: Enhancing Regulatory Submissions and Interactive Communication: Insights from PRISM

Dive into PRISM, a cutting-edge collaboration between the FDA and industry, leveraging FDA's cloud platform, PrecisionFDA. Explore real-world use cases that address today's regulatory challenges and pave the way for future advancements.

Vada Perkins, DrSc, Boehringer Ingelheim

Omar Serang, DNAnexus

Brooke Casselberry, Epista Life Sciences

Akira Yamaguchi, LORENZ Life Sciences Group

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

- Recognize how cloud-based technologies can enhance data exchange and regulatory collaboration
- Develop an understanding of PRISM use cases and their potential to inform solutions for transforming regulatory submissions

Track: Achieving Regulatory Excellence

Level: Intermediate

Session Chair(s)

Dominik Gigli

Management Consultant & Regulatory Consulting Lead
Main5 GmbH & Co. KGaA, Germany

Dominik Gigli is a senior expert in Regulatory Information Management and IDMP with 10+ years in the pharmaceutical industry driving the digital transformation in Regulatory Affairs. With his strengths drawing the big picture and vision towards data driven regulatory submissions and particular understanding of the steps and obstacles how to get there, Dominik is helping Life Science transform their organization to a digital future. Before joining MAIN5 in 2022, Dominik was working in several leading positions in Regulatory Operations focusing on RIM, IDMP, Data Management, Data Governance Data Quality, Reporting and Analytics in Merck Healthcare and Fresenius Kabi.

Speaker(s)

PROJECT PRISM

Vada Perkins, DrSc, MSc

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

Vada A. Perkins is Vice President. Global Head of Regulatory Policy & Intelligence for Boehringer Ingelheim. He is a former FDA Senior Advisor for Regulatory Science with international regulatory policy and strategy expertise in

promoting convergence for the assessment of medicinal products worldwide. He received his degrees from Johns Hopkins University, University of Southern California, and the University of Maryland.

From COTS to Cloud

Akira Yamaguchi, MBA

Chief Technical Officer
LORENZ Life Sciences Group, United States

After an international career in management consulting and information technology at Software AG and Comshare, Akira Yamaguchi joined LORENZ Life Sciences in 1995. His initial role was software development in the field of electronic submissions, achieved in 2001 with the release of docuBridge as a major company milestone. In 2003, Mr. Yamaguchi became responsible for LORENZ′ overall software product development. In his Project SME role, Mr. Yamaguchi advises larger customer implementation projects. His current task is to develop the strategic directions of LORENZ′ software portfolio.

Ten Years of Evolution of a Regulatory Cloud

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.

TRS Business Use Cases

Brooke Casselberry, MS, RAC

Vice President, Advisory and Delivery
Epista Life Sciences, 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.

12:00 PM — 1:15 PM

Networking Luncheon in the Exhibit Hall

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

Session 6, Track 1: DIA RIM Reference Model V2.0 Catches FHIR!

In this session, we will provide an overview of the updates to the RIM Reference Model in 2024. We will discuss physical implementation specifications for data requirements for organizations considering a RIM initiative and explain how to create a physical model to support migration activities between RIM systems and also real time integrations between RIM and other regulatory systems.

Overview and Highlights of RIM Reference Model V2.0 - Venkatraman Balasubramanian, VB Insights, LLC

RIM Reference Model V2.0: Deep Dive - John Jones, MBA, EntiTech Solutions

Leveraging the RIM Reference Model in a Small Company Setting - Vahe Ghahraman, Apellis Pharmaceuticals, Inc.

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

- Gain understanding of updates to DIA RIM Reference Model (V2.0)
- Understand use of the model as data requirements specification for an organization considering a RIM initiative and/or a regulatory data hub
- Explore how the model could be utilized as a data migration map between different RIM systems and/or in an merger and acquisition scenario

Track: Building and Sustaining Successful RSIDM Foundations

Level: Basic

Session Chair(s)

Jennifer Dames

Director, RA Submission Management
AbbVie, United States

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

Speaker(s)

Overview and Highlights of RIM Reference Model V2.0

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.

RIM Reference Model V2.0: Deep Dive

John Jones, MBA

Chief Executive Officer
Entitech Solutions, United States

John Jones is the Founder and CEO of Entitech Solutions, a system integrator focused on developing innovative technology solutions for unmet business needs in Life Sciences. John has more than 25 years experience in developing and delivering IT Solutions for various companies, and has extensive experience in the clinical, regulatory, and commercial areas. His technical specialties include: enterprise architecture planning and definition, long-term technology strategy development, knowledge and content management, information architecture and metadata definition, structured component authoring and data integration/business intelligence platform implementation

Leveraging the RIM Reference Model in a Small Company Setting

Vahe Ghahraman, PhD

Senior Director, Global Regulatory Operations Head
Apellis Pharmaceuticals, Inc. , United States

Vahé has over 24 years of global regulatory operations, project management and regulatory technology experience, with special focus on regulatory information management, data governance, business process optimization, regulatory intelligence, medical imaging, publishing and global submissions strategy. Vahé has had various leading roles at Alexion, Takeda, Dyax, Millennium, Parexel, and Datafarm, and has also been involved in consulting activities. He is currently heading the Global Regulatory Operation at Apellis. Vahé is an active member of the DIA-RIMWG sub-team on RIM Reference Model.

1:15 PM — 2:30 PM

Brookside AB (Lower Level)

Session 6, Track 2: Driving Value from Regulatory Intelligence – A Multi-disciplinary Approach

The session will include successful regulatory intelligence case studies that add value from precedent insights that add value beyond regulatory requirements. Specific examples include:

Aggregating data across company source intelligence to drive effective regulatory filing or clinical strategy
Precedent insights from Health Authority Communications to improve actions
Example metrics and KPIs both at the operational level and strategic level from legacy data to drive effectiveness
Defining the business case for Regulatory Intelligence projects (quality, speed and efficiency outcomes and expectations)

Driving Value from Regulatory Intelligence - Patterson Shafer, FTI Consulting, Inc.

Leveraging Regulatory Affairs Metrics to Drive Continuous Improvement - Eric Cardwell, MBA, AbbVie

Knowledge Management - Steve Hamby, Vitality TechNet

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

- Leverage the knowledge embodied within their company's regulatory systems to better understand health authority expectations and achieve right-first-time results
- Develop a business case for enabling a regulatory knowledge management capability
- Identify analytical capabilities within RIM systems to drive operational performance

Track: Optimizing Processes and Proceduress

Level: Intermediate

Session Chair(s)

Vladimir Penkrat, MBA

Associate Vice President of 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)

Driving Value from Regulatory Intelligence

Patterson Shafer

Managing Director

FTI Consulting, Inc., United States

Pat Shafer is a Managing Director at FTI Consulting. He is responsible for delivering services, solutions and thought leadership for pharmaceutical, biotech and medical device clients. He has over 30 years of experience solving complex global challenges and helping clients achieve their strategic and operational objectives in the areas of regulatory affairs and operations, quality, compliance, clinical operations, safety and surveillance, manufacturing, supply chain, medical affairs and commercial compliance. He currently leads the development of the RIM Whitepaper 3.0 as part of the RIM Working Group, and leads the Culture of Quality initiative as part of the FDA/MDIC Case for Quality.

Leveraging Regulatory Affairs Metrics to Drive Continuous Improvement

Eric Cardwell, MBA

Director, Regulatory Information Management
AbbVie, United States

Eric Cardwell is the Director of Regulatory Information Management and Life Cycle Management at AbbVie. Eric has a proven history of leading a Regulatory Information Management (RIM) team, successfully implemented a RIM system thus optimizing the end-to-end submission process and manages a team responsible for structured data submissions including xEVMPD. Eric has over 20 years of experience in life sciences with domain depth in Quality, Regulatory Affairs, Manufacturing, Product Development and Continuous Improvement.

Knowledge Management

Steve Hamby, MBA

Senior Semantic Engineer
Vitality TechNet, United States

Steve Hamby is a semi-retired Senior Semantic Engineer for Vitality TechNet, Inc. where he assists customers in integrating semantic systems to solve business problems. Mr. Hamby brings 35+ years of experience in the information technology industry with a focus on knowledge integration and management. Mr. Hamby is widely regarded as an industry leader in the field of semantic technologies and has authored / co-authored numerous technical and business papers on the subject area. His technical leadership in this field has led to being a past award winner of the American Business Awards™ Technology Executive of the Year, Silver Award; the InfoWorld Technology Leadership Award; and the SmartCXO, CIO/CTO Award for the Mid-Atlantic Region.

1:15 PM — 2:30 PM Ballroom F-G

Session 6, Track 3: How to Make the Most of an Evolving Tech Landscape Crowded with Competing Solutions:

Survival of the Fittest vs Symbiosis?

This session will describe, differentiate and discuss the distinct approaches life sciences regulatory organizations have taken in acquiring, combining, and eliminating new innovative capabilities to optimize their digitalization journey. This session will include use cases from three different Life Sciences Companies of various sizes and illustrate their decision-making processes in evaluating, deploying, and managing digital capabilities. They will share their business needs, technical and process issues, design and decision-making frameworks, results, and key learnings.

A Tale of Two Use Cases: Lessons Learned and Way Forward in Combining Digital Capabilities Effectively - Salim Saglam, Genentech, Inc.

Digital Navigation: Selecting the Optimal Solution for Business Success - Jason Moyer, Gilead

Smart Choices: Decision-Making Frameworks for Digital Capability Integration - Jessica Romero, Sarepta Therapeutics

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

- Differentiate and assess strategic approaches for digitalization in life sciences
- Apply decision-making frameworks to tech evaluation
- Address challenges in digital adoption with limited resources

Track: Adopting Innovative Technologies

Level: Intermediate

Session Chair(s)

Matthias Sijtstra

Senior Consultant
Main5 GmbH & Co. KGaA, Netherlands

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

Speaker(s)

Digital Navigation: Selecting the Optimal Solution for Business Success

Jason Moyer, MBA

Executive Director Reg Affairs Innovation, Digital & External Partnerships
Gilead, United States

Jason has over 25 years of life sciences experience and has held positions of increasing responsibilities in information technology, business consulting, finance, clinical operations, medical affairs operations, and regulatory affairs

operations. Currently, Jason is leading the Innovation, Digital, and External Partnerships organization for regulatory affairs within Gilead. In this role he is establishing a digital strategy and engaging with external partners to drive transformative change for regulatory affairs. Jason holds a BS in computer science from Ursinus College and holds an MBA with a focus in management from Saint Joseph's University. He is a certified six sigma green belt and a certified project manager.

A Tale of Two Use Cases: Lessons Learned and Way Forward in Combining Digital Capabilities Effectively

Salim Saglam, MBA

Director & Business Transformation Lead, Product Development
Genentech, Inc., United States

Salim Saglam is a Director and Business Transformation Lead at Roche / Genentech Product Development. He brings >10 years of industry and consulting experience across the Life Sciences value chain. Areas of past work include tech ops, product transfers, business development, and operating model (re)design. For the past five years he has been working on digital transformation and implementation and scaling of innovative solutions in Life Sciences. More recently he has been focusing on establishment and operationalization of structured content management and automation capabilities across and beyond the submission documentation landscape within Roche Product Development organization.

Smart Choices: Decision-Making Frameworks for Digital Capability Integration

Jessica Romero

Director, Global Regulatory Operations, Global Regulatory Affairs
Sarepta Therapeutics, United States

With 20 years of experience in Regulatory Operations as a dedicated leader in submission management, archiving and employee development. I strive for creating efficiencies, fostering a culture of collaboration, and a growth mindset within my team. I have technical experience using a variety of document management systems, publishing tools, and project tracking tools. I am excited to be a part of the conference as a speaker this year and look forward to connecting with new and seasoned attendees.

1:15 PM — 2:30 PM

Brookside C (Lower Level)

Session 6, Track 4: Is a Single Dossier Really Possible? Attainable Technological and Regulatory Advancements Toward Global Dossier Harmonization

This session will describe how a global dossier approach, digital technologies such as, structured data, and AI methodologies, and reliance practices could enhance authoring and regulatory submissions. It will weave together diverse perspectives for an interactive learning session with polling and a panel discussion to explore how stakeholders have leveraged momentum and adapted current ways of working to accelerate regulatory review of critical therapies worldwide. Presenters will convey findings from new research and pilot projects to illuminate opportunities for further drive consensus and harmonization on the global dossier; apply technology solutions to solve regulatory strategy and submission challenges; and standardize global reliance best practices within regulatory authorities to democratize and accelerate access to therapies for all patients.

Shaping global Regulatory Innovation with Learnings from the Financial Sector - Craig Anderson, Pfizer Inc

Leveraging Digital Transformation to Streamline Regulatory Authoring and Global Harmonization - Rita Algorri, Amgen

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

- Identify possibilities for harmonized submission authoring using contemporary technologies
- Discuss industry and agency perspectives on standardizing global reliance best practices for a global dossier
- Prepare for global initiatives that offer opportunities for consensus and harmonization on the global dossier

Track: Achieving Regulatory Excellence

Level: Intermediate

Session Chair(s)

Maria Sagoua, MHA

Director of Regulatory Innovation
Accumulus Synergy, United States

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

Speaker(s)

Shaping Global Regulatory Innovation with Learnings from the Financial Sector

Craig Anderson

Director, R&D Labeling Lead, International Labeling
Pfizer Inc , Canada

As Director, R&D Lead at Pfizer, Craig Anderson is responsible for research, development, business and process-related functions across the International Labeling organisation. This includes topics such as electronic labelling,

medicinal product information, digital health, and data standards. Craig is also Co-lead of HL7's Vulcan accelerator project for electronic Product Information (ePI) and co-lead for HL7's Pharmaceutical Quality (Industry) project.

Leveraging Digital Transformation to Streamline Regulatory Authoring and Global Harmonization

Rita Algorri, PhD, MS

Senior Manager, Global Regulatory Affairs (CMC)
Amgen, United States

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

2:30 PM — 3:15 PM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

2:35 PM — 3:05 PM Forest Glen (Lower Level)

Hosted Session/Non-CE: Case Study Sponsored by InteliNotion

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 hallucinations, navigating the evolving regulatory landscape, ensuring compliance and governance, managing the proliferation of diverse language models, maintaining human oversight and intervention. This comprehensive case study chronicles the journey of a leading global biopharmaceutical company as it leverages the synergistic potential of Structured Content Authoring and GenAI, addressing the complexities and opportunities in medical writing, and pioneering a path to streamlined, AI-driven content creation.

Learning Objective :

- Content Structuring: Enhance content quality through effective organization and architecture
- Content Governance: Ensure regulatory compliance through robust governance policies and procedures
- Precision Prompting: How to craft targeted prompts to drive accuracy in generated content
- Agent-Driven Approach: Leverage agent-driven technology for precise and reliable content generation

Track: Exhibitor Event

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Harnessing GenAI in a Global Biopharmaceuticals Company

Matthew Renda, PhD, MS

Senior Director Medical Writing Operations
Alexion, Astrazeneca Rare Disease, United States

Matt Renda has 13 years of academic research experience focused on gene therapy and 17 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 Gold accreditation for completing the AstraZeneca Generative AI Accreditation Programme. Matt holds a PhD in Biochemistry and MS in Microbiology & Immunology from the University of Rochester and conducted postdoctoral research at the Yale Stem Cell Center.

3:15 PM — 4:30 PM

White Oak (Lower Level)

Session 7, Track 1: Common Pain Points Surrounding Regulatory Submissions

For decades, our industry has communicated key regulatory data in documents, first in physical documents, and later in electronic documents. Over time, standards have evolved to govern how different categories of data are presented in these documents. This session will explore issues that cause frustration, complexity and increased cost to be added to the regulatory submission process, as well as approaches to dealing with those problems.

Common Pain Points with Regulatory Submissions - Samuel Thompson, NNIT

Ineffective Submission Processes: What Does it Mean to your Business? - Sarah Powell, Powell Regulatory Services

Improving Data Related Outcomes in Submissions - David Ortiz, Accumulus Synergy

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

- Recognize the common pain points in the regulatory submission process
- Identify new ways to mitigate these problems
- Distinguish which techniques best solve each type of problem

Track: Building and Sustaining Successful RSIDM Foundations

Level: Advanced

Session Chair(s)

Daniel Offringa

Principal Consultant
eSub Solutions, United States

Dan Offringa has a regulatory career spanning over thirty years. For the past 20+ years he has worked in the electronic submissions field for both the FDA and industry, with responsibilities including guidance promulgation, standards and process development, and systems implementation. He is the owner of eSub Solutions, an electronic publishing consultancy, and has been responsible for thousands of submissions to multiple regulatory authorities. Dan holds a bachelor of science degree from Duke University.

Speaker(s)

Common Pain Points with Regulatory Submissions

Samuel Thompson

Managing Consultant
N/A, United States

Sam Thompson is an information technology professional with 35 years of experience in data management, of which 25 are the life sciences industry. He focuses on the applied use of data technology for clinical, regulatory and safety applications. Specific experience includes the design and implementation of lakes/warehouses, implementing regulatory compliant data management solutions and compliance with data standards, including FHIR, IDMP, CDISC and PQ/CMC. In his spare time, Sam enjoys mountain biking, officiating field hockey and is a volunteer firefighter.

Ineffective Submission Processes: What Does it Mean to your Business?

Sarah Powell, RAC

President
Powell Regulatory Services, United States

Sarah Powell is the President of Powell regulatory Services. Sarah has over 35 years of experience in pharmaceutical and related regulated industries. Sarah has worked as an independent consultant assisting clients with projects related to process improvements, standards development, and implementation of new technology. While in industry, Sarah performed roles within the Clinical, Quality, Regulatory Affairs and Regulatory Operations groups. Sarah has extensive experience with preparing regulatory submissions for biologic products for submission in the US and EU. She also has detailed knowledge on the requirements for the regulatory information systems.

Improving Data Related Outcomes in Submissions

David Ortiz

Principal Data Architect
Accumulus Synergy, United States

David Ortiz is the Principal Data Architect at Accumulus Synergy. He is responsible for managing the data engineering team and helping to ensure the Accumulus platform is well architected, with his focus being on reporting and external integrations. David brings a strong background in data lake architecture, and data pipelines; honed from years in the advertising and defense industries. At Accumulus, David has been responsible for leading technical efforts to integrate with the Pharmaceutical Quality Industry specification, as well as providing oversight over several efforts around data modeling, and integration with external systems.

3:15 PM — 4:30 PM Brookside AB (Lower Level)

Session 7, Track 2: Towards Instantaneous Approvals in 5 Years: What Would it Take to Get There?

Human biology is almost hopelessly intricate, making it almost miraculous that we have efficacious treatments. In contrast, the framework we use to accept evidence of safety and efficacy needs not be this complex. We believe it offers a practical and surmountable challenge to speeding up patients' access to life saving treatment by combining better technology, and ethical and more courageous risk management. The output of this hands-on workshop will be consolidated in a multi-stakeholder framework publication.

Tony Fantana, Eli Lilly

Peter Caetano, Ipsen

Dominique Lagrave, Accumulus Synergy

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

- Discuss current submission and approval process
- Brainstorm opportunities to significantly shorten submissions and approval timelines
- Formulate and execute a high-level plan with interim goals that will get us closer to an 'instantaneous approval' in the appropriate circumstances

Track: Optimizing Processes and Proceduress

Level: Intermediate

Session Chair(s)

Cary Smithson, MBA

Managing Partner
LeapAhead Solutions, Inc., United States

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

Speaker(s)

Author

Tony Fantana, PhD

Sr. Dir
Eli Lilly, United States

Tony Fantana is the Global Regulatory Affairs Innovation and Technology Lead at Eli Lilly. He is passionate about creatively solving unmet medical needs through innovative technology solutions. Trained at Harvard Medical School, Tony held roles of increasing responsibility driving innovation and organizational change. At Lilly, he started Digital Health and patient-centric blood sampling, and won twice the Top 100 Innovator Award. Tony leads an Innovative Health Initiative consortium and works with regulators in the US and EU. Recognized as an expert in digital health and enabling better data at lower patient burden, he served as a Visiting Professor at Massachusetts General Hospital and Brown University, and as a healthcare startup CEO.

Speaker

Peter Pedro Caetano, PharmD, PhD, MBA, MPH

Global Regulatory Affairs – Senior Director
Ipsen, United States

Peter Caetano is a Senior Director, Global Regulatory Affairs, and Global Regulatory Lead at Ipsen in Cambridge, MA, US. He had previous regulatory roles at Allergan-AbbVie, UK, Genzyme-Sanofi, MA, and P&G, Ohio. He has FDA, EMA, PMDA, NMPA CDE, ANVISA, etc. regulatory strategy expertise throughout product life cycle, including development strategy, submissions, and postmarketing commitments, in neurology, oncology, rare diseases, etc. Dr. Caetano has a PhD in Pharmaceutics, where at the University of Michigan he collaborated with FDA, USP, Viatris (formerly Mylan, UpJohn), BMS, and Merck. Peter completed a PharmD at Ohio State, an MPH at Harvard, an MBA at ESSEC-Mannheim, and postgraduate diplomas at Oxford, Hertfordshire, and London.

Speaker

Dominique Lagrave, PharmD

Senior Vice President of Regulatory Innovation
Accumulus Synergy, 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.

3:15 PM — 4:30 PM Ballroom F-G

Session 7, Track 3: ICH PQKM Task Force to Enable Regulatory Collaboration on Post Approval CMC Through Technology Approaches

The ICH Pharmaceutical Quality Knowledge Management (PQKM) Technology Task Force was initiated in March 2024 to support emerging needs for the establishment and operation of a secure technology platform to enable collaborative review across regulators, with initial focus on CMC Prior Approval Supplement Submissions (major changes).

The ICMRA (International Coalition of Medicines Regulatory Authorities) Pilots were the first instance when multiple regulators interacted for simultaneous approvals of PQKM submissions. Challenges identified during these pilots, included collaboration, transparency, and project management among multiple regulators and sponsors. Drawing from insights gained during the ICRMA PQKM Pilots, the task force organized focus groups on Governance and Operating Model, Policy and Regulatory Alignment, and Journey Map (end-to-end business and operational flows).

This session will summarize the conclusions and outline next steps based on combined analysis from the focus groups named above; including recommendations to ensure consistency with international policy, regulatory, and legal guidelines.

David Sidney Ross, AstraZeneca

Hilmar Hamann Management, European Medicines Agency

Learning Objective :

- Explain the ICH PQ KM Task Force purpose, progress, methodology and initial recommendations
- Describe approaches for data and technology capabilities to support the collaborative assessment process based on ICMRA Pilot Feedback
- Apply recommendations for governance of 3rd-party provisioning services, aligning with legal, regulatory and privacy policies for a secure technology interactive platform

Track: Adopting Innovative Technologies

Level: Intermediate

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)

Author

David Sidney Ross, MBA, MSc, PMP, RAC

Senior Director, Regulatory Data and Submissions
AstraZeneca, United States

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

Speaker

Hilmar Hamann, PhD

Head of Information Management
European Medicines Agency, Netherlands

Dr Hilmar Hamann is the Head of Information Management at the European Medicines Agency (EMA), where he leads the transformation of technological capabilities within the EU Regulatory Medicines Agencies Network to enable an all-digital, efficient, and data-driven operations framework. Previously, he served as the Director for Business Informatics at the FDA's Center for Drug Evaluation and Research from 2011 to 2020, leading advancements in regulatory data management, data analytics, and the modernization of the regulatory review platforms.

3:15 PM — 4:30 PM

Brookside C (Lower Level)

Session 7, Track 4: The Next Frontier in Regulatory Submissions: Powering Industry Growth with Structured

Data to Deliver Value Through Connected Global Use Cases

The session explores real-world examples of how structured data, GenAI, and semantic data standards can address regulatory challenges and prepare the industry for advanced submission strategies. Speakers will discuss advancements from regulators in digital and collaborative review initiatives and give insights on how the industry can prepare their data and processes to benefit from these advancements.

Key Players to Enable the Future of Regulatory Submissions - Katherine Novak, Epista Inc.

Future of Regulatory Submissions - Sridevi Nagarajan. DIA Communities Lead for AI in Healthcare

Advancing Regulatory Submissions with Standardized Semantic Structured Data - Heiner Oberkampf, ACCURIDS

Learning Objective :

- Explain how structured data, GenAI, and semantic data standards can address regulatory challenges and prepare the industry for advanced digital submission strategies
- Examine the role of digital tools in the shift towards data-driven product authorizations
- Outline solutions to prepare structured data in order to benefit from global collaboration and cloud-based review to accelerate approval

Track: Achieving Regulatory Excellence

Level: Advanced

Session Chair(s)

Cindy Chiu

Senior Director, Regulatory Affairs Operations and Quality Management
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)

Key Players to Enable the Future of Regulatory Submissions

Katherine Novak, MS

Principal Consultant
Epista Inc., 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.

Future of Regulatory Submissions

Sridevi Nagarajan, PhD, MS, MSc

DIA Communities Lead for AI in Healthcare
Independent, United Kingdom

An influential and data-driven executive professional with a robust background in the Pharmaceutical and Public Health sectors, bringing a unique blend of expertise in leading digital transformation initiatives and leveraging data to guide corporations through complex business changes. Recognized as a thought leader/industry expert in the data, digital health, and AI ecosystem, excelling at understanding industry trends and developing strategic perspectives to guide digital health and AI partnerships and investments. High-level analytical skills and deep expertise in drug development, clinical, safety and regulatory processes, data management, digital innovation, and governance.

Advancing Regulatory Submissions with Standardized Semantic Structured Data

Heiner Oberkampf, PhD

CEO
ACCURIDS, Germany

Heiner Oberkampf is the CEO and Co-founder of ACCURIDS, providing a software for data standardization, helping large pharma, e.g., in the implementation of IDMP standards through a federated product data graph. With a group of pharma companies, Heiner has initiated the IDMP Ontology project under the umbrella of the Pistoia Alliance to promote a universal implementation of the IDMP standards in a collaborative manner in alignment with health authorities.

Day 3 Feb 05, 2025

7:30 AM — 8:00 AM — Ballroom A-E

Networking Breakfast in the Exhibit Hall

7:30 AM — 12:45 PM — Ballroom Foyer (Upper Level)

Registration

8:00 AM — 9:15 AM White Oak (Lower Level)

Session 8, Track 1: Regulatory Submission Revolution: Insights into eCTD 4.0, Agile Governance and AI-Driven Document Migration

This session will delve into key technological advancements in regulatory submissions and document management. It will explore the technical refinements of eCTD 4.0, offering clarity on specialized outputs for successful submissions. Explaining the impact of artificial intelligence (AI) and machine learning (ML) in automating legacy migration from documents to data components. Furthermore, the session will emphasize the importance of an agile governance structure across systems, ensuring accurate data transfer to RIM systems and streamlined processes for effective submission management.

Diving into eCTD v4.0: Examination of the Technical Changes to the eCTD Structure - Rachel Bombara, Certara

Governance, a Potent Tool to Sync Data and Processes Across Systems for Effective End-to-End Submission Management - Wim Dhaeze, Sarepta Therapeutics, Inc

Turn Documents into Data and Future-Proof Your Information - Ryan Adamson, Glemser Technologies

Learning Objective :

- Identify key differences between eCTD 4.0 and 3.2.2, focusing on file/folder structure and XML review
- Share how data governance enables seamless data transfer between RIM systems and other systems, ensuring that data is consistent, accurate, and accessible across all systems
- Explain the benefits and cost savings of natural language processing (NLP) and AI-driven data parsing for document conversion

Track: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Shenqi (Handsome) Ji

Regional Publishing Lead, Asia, Global Regulatory Operations
Pfizer, China

Handsome Ji is highly driven and experienced, with 18 years regulatory operational, project and change management experience within multi-cultured global environments. Handsome was invited as guest speaker in DIA China 7th, 10th and 11th Annual Meeting, served as host and Speaker for CMWC (China Medical Writing Community) forum in 2015 and 2016 and Program lead for DIA China M4/M8 Workshop(2020-2023), Handsome holds a seat for DIA China YMAC(2018-2019) and was nominated as Taskforce co-Lead for DIA China RA

Community since 2019. Besides, Handsome is co-lead of RDPAC 'Regulatory Requirement' Workstream, including eCTD, Filling Review & ICH Harmonization for Registration, e.t.c.

Speaker(s)

Diving into eCTD v4.0: Examination of the Technical Changes to the eCTD Structure

Rachel Bombara

Sr. Regulatory Services Manager
Certara, United States

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

Governance, a Potent Tool to Sync Data and Processes Across Systems for Effective End-to-End Submission Management

Wim Dhaeze, PhD

Senior Director, Regulatory Operations, RIMS/DMS Lead
Sarepta Therapeutics, Inc., United States

Wim DHaeze, PhD, ELS, has been the Regulatory Information and Document Management System (RIMS/DMS) Lead at Sarepta Therapeutics since June 2021. He is responsible for access to and training on Registrations, Submissions, and Submissions Archive and collaborates cross-functionally to implement complex changes and to keep RIMS/DMS in a validated state. He played a key role in the successful implementation of the connector between Vault eQMS and Vault RIMS/DMS and is currently working cross-functionally to initiate the implementation of the connectors between the PromoMats and Clinical Vaults and Vault RIMS/DMS. Most recently, he kicked off the cross-vault governance Center of Excellence at Sarepta.

Turn Documents into Data and Future-Proof Your Information

E. Ryan Adamson

Director, Operations
Glemser Technologies, United States

Ryan is experienced in directing global delivery teams that solve complex industry and regulatory challenges in life sciences. Through proven implementation processes and innovative software solutions, Ryan and his team provide

the highest level of service to ensure every client meets its business, quality and compliance, and return on investment goals.

8:00 AM — 9:15 AM Brookside AB (Lower Level)

Session 8, Track 2: Automated Authoring: The Perfect Harmony of SCA and Gen AI

Preparing sections of regulatory dossier, such as Module 3 CMC documentation, typically takes more than 8 months for a new drug application, once all the data is available. With some foundational elements, creative solution design and enabling technologies, we can reduce that time to 8 weeks. In this session, presenters will share their journiesey in acceleratinge submissions, lessons learned, and what success could look like.

Automated Authoring: The Perfect Harmony of SCA and Gen AI - Vaibhav Shinde, Deloitte

The Future of Regulatory Filings: A Digital Transformation - Mike Abernathy, Amgen Inc.

Automated Authoring: The Perfect Harmony of SCA and Gen AI - Matthew Birmingham, Workiva

Learning Objective :

- Demonstrate how authoring solutions can be used to author regulatory documents more efficiently
- Differentiate the benefits and uses of structured content authoring in parallel with supporting technologies (AI, Scripting, Gen AI)
- Share lessons learned with their own organizations to start or continue their own authoring automation journey

Track: Optimizing Processes and Proceduress

Level: Intermediate

Session Chair(s)

Theresa Pinnell, MLS

Director of Regulatory Solutions
Kivo, United States

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

Speaker(s)

Automated Authoring: The Perfect Harmony of SCA and Gen AI

Vaibhav Shinde

Consulting Managing Director
Deloitte Consutling, United States

Vaibhav Shinde is a Managing Director with Deloitte Consulting and an information/content management strategist. He specializes in complex technology transformations, including the implementation of enterprise solutions for document and content management in highly regulated industries. Over the past 6-8 years, Vaibhav has worked with multiple clients to automate the end-to-end document generation process for regulatory submissions, utilizing a range of reporting, data management, and, most recently, AI/GenAI technologies.

The Future of Regulatory Filings: A Digital Transformation

Michael Abernathy, MS, RAC

Executive Director, Global Regulatory Affairs
Amgen Inc., United States

Michael Abernathy, Executive Director, leads Amgen's Global RA Chemistry, Manufacturing and Controls (CMC) function. The extent of Michael's product oversight and responsibilities traverse molecular discovery, early and late-stage clinical development and approved life-cycle programs. He also founded Amgen's RA CMC External Engagement function targeting activities that comprise a CMC focus, promoting company and industry initiatives, engaging with Health Authorities around the world and contributing to industry organizations. He is currently leading Amgen's regulatory digitalization initiative, and he is also co-developer of HL7 FHIR Product Quality International Standard (UV-pharm-quality https://build.fhir.org/ig/HL7/uv-dx-pq/).

Automated Authoring: The Perfect Harmony of SCA and Gen AI

Matthew Birmingham, MS

Manager of Solution Development
Workiva, United States

Matthew is a seasoned leader and solution strategist, serving as the Manager of Solution Development at Workiva. With a focus on uniting data, processes, and people, Matthew drives the creation of innovative solutions that help organizations meet complex regulatory requirements. Leveraging advanced technologies such as Generative AI, Centralized Content Management, Modular Workflows, and robust Audit Trails with Compliance Tracking, they enable businesses to reduce risk, enhance accuracy, and boost operational efficiency. Known for their strategic vision and technical expertise, Matthew plays a key role in helping Workiva deliver powerful, scalable solutions to empower organizations to meet evolving regulatory demands with confidence.

8:00 AM — 9:15 AM

Ballroom F-G

Session 8, Track 3: How to Be Data-Centric: A Practical Approach for Data-Driven Regulatory Authoring and Exchange

Biopharmaceutical organizations generate and consume large volumes of data throughout the drug development lifecycle. However, this data is often siloed across different systems, unstructured, and unstandardized, limiting its usability. In this session, attendees will learn how to modernize key regulatory business processes by enabling data centricity, interoperability, and data standardization. The session will include discussion of real-world examples of data marketplace implementation, FHIR-based data exchange, and an IDMP-coded structured labeling use case.

How an Enterprise Data Marketplace can Improve Decision-making and Create Measurable Benefits for your Organization - Donna Yosua, Merck & Co., Inc

FHIR and the Race to Reduce Time and Effort Needed to Achieve Global Regulatory Approvals - Sheetal Gaiki, Johnson & Johnson Innovative Medicines

Driving Value with IDMP-coded Structured Labeling Content - Niklas Jaenich, Boehringer Ingelheim

Learning Objective :

- Understand how a cohesive data management strategy can drive modernization of key business activities
- Describe how a data marketplace can work synergistically to support data standards implementation
- Recognize real-world implications and benefits of implementing a cohesive organizational data framework
- Evaluate the utility of interoperability and centralized data accessibility across domains

Track: Adopting Innovative Technologies

Session Chair(s)

Rita Algorri, PhD, MS

Senior Manager, Global Regulatory Affairs (CMC)
Amgen, United States

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

Speaker(s)

How an Enterprise Data Marketplace can Improve Decision-making and Create Measurable Benefits for your Organization

Donna Yosua

Director, Master Data Management & Data Governance
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.

FHIR and the Race to Reduce Time and Effort Needed to Achieve Global Regulatory Approvals

Sheetal Gaiki, MPharm

Senior Principal Scientist II, Dossier Development & Operations
Johnson & Johnson Innovative Medicines, United States

Sheetal Gaiki, Sr. Principal Scientist II, CMC Dossier Development & Operations, Johnson & Johnson Innovative Medicine, has 20+ years of industry experience in development of biologics, combination products and small molecules. In her current role, she is responsible for developing content strategy and delivering biologic and combination products dossiers for global submissions. She is involved in, and leading various internal and cross-industry efforts related to CMC data standardization, GenAI and use of emerging technologies for regulatory information management. To mention, developing a new FHIR PQ (Industry) IG and Controlled Terminologies for CMC data, automating regulatory dossier authoring through structured content and GenAI tools.

Driving Value with IDMP-coded Structured Labeling Content

Niklas Jaenich, PhD, RPh

Head of Global Labeling Operations and Digitization
Boehringer Ingelheim, Germany

Dr. Niklas Jänich is Head of Global Labeling Operations & Digitization at Boehringer Ingelheim. In this position Dr. Jänich is responsible for Labeling process, systems, compliance and digitization as well as for driving the implementation of structured content management in the GxP-regulated Labeling process. Dr. Jänich is a certified pharmacist and holds a PhD in medicinal chemistry and a Master of Drug Regulatory Affairs.

8:00 AM — 9:15 AM Brookside C (Lower Level)

Session, 8 Track 4: Future-proofing Regulatory Affairs: Redesigning Operational Models in a Transformative Era

Regulatory Affairs is undergoing a transformative shift necessitating a redesign in operating models. This session will convene leading experts from industry and regulatory agencies to explore critical considerations for designing optimal operational models. Together, we will establish guiding principles to future-proof regulatory groups and ensure they remain agile and effective in this evolving landscape. Effective upskilling strategies will be discussed, including training and development programs through in-house sessions, online courses, and partnerships with external providers.

Future-proofing Regulatory Affairs: Redesigning Operational Models in a Transformative Era - Helena Corte-Real Correia, F. Hoffmann-La Roche Ltd

BMS Case Study: Learning and Development as Catalysts for Regulatory Evolution - Sandra Krogulski, Bristol-Myers Squibb Company

Future-proofing Regulatory Affairs: Redesigning Operational Models in a Transformative Era - Hilmar Hamann, European Medicines Agency

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

- Understand the impact of technological and scientific advances on Regulatory Affairs
- Explore new forms of collaboration and partnerships emerging in Regulatory
- Identify key principles for future-proofing Regulatory groups
- Identify key areas where upskilling is essential along with best practices to achieve it

Track: Achieving Regulatory Excellence

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)

Future-proofing Regulatory Affairs: Redesigning Operational Models in a Transformative Era

Helena Corte-Real Correia, PhD

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

Helena Corte-Real Correia is the VP, Regulatory Portfolio 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 Portfolio Data and Content Leader.

BMS Case Study: Learning and Development as Catalysts for Regulatory Evolution

Sandra Krogulski, MA

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

Sandy Krogulski is an experienced and solution oriented individual with over 10 years of submission 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.

Future-proofing Regulatory Affairs: Redesigning Operational Models in a Transformative Era

Hilmar Hamann, PhD

Head of Information Management
European Medicines Agency, Netherlands

Dr Hilmar Hamann is the Head of Information Management at the European Medicines Agency (EMA), where he leads the transformation of technological capabilities within the EU Regulatory Medicines Agencies Network to enable an all-digital, efficient, and data-driven operations framework. Previously, he served as the Director for Business Informatics at the FDA's Center for Drug Evaluation and Research from 2011 to 2020, leading advancements in regulatory data management, data analytics, and the modernization of the regulatory review platforms.

9:25 AM — 10:40 AM White Oak (Lower Level)

Session 9, Track 1: Gaining Efficiency: Using Automation across Writing, Hyperlinking, and Rendering

In the ever-evolving regulatory landscape, gaining efficiency through automation is paramount. This session delves into transformative strategies and technologies to optimize critical processes such as content creation, hyperlinking, and rendering. With a focus on leveraging AI, automation, and advanced rendering, attendees will learn practical approaches to streamline submission workflows, reduce redundancy, and improve compliance.

From crafting AI-ready source content to automating document authoring and hyperlinking, and exploring process improvements in advanced rendering, this session offers actionable insights and best practices to enhance regulatory efficiency. Attendees will gain a comprehensive understanding of how these innovations can revolutionize their document management processes and drive industry progress.

Writing Quality Source Content for AI-Driven Regulatory Submissions - Regina Lynn Preciado, Content Rules, Inc.

Streamlining Submission Processing Through Automation of Document Authoring and Hyperlinking - Alishay Pringle, Biogen

Exploring Process Improvement in Document Management through Advanced Rendering - Paul Richard Ireland, DocShifter

Learning Objective : At the conclusion of this activity, participants should be able to:

- Evaluate and prepare regulatory submission content for AI-driven processes
- Integrate automated solutions to optimize submission timelines, reduce manual efforts, and ensure quality compliance
- Explore advanced rendering techniques to identify process improvements and enhance efficiency across document management lifecycles

Track: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Nimesh Patel

Director of Global Regulatory Systems
Eisai Pharmaceuticals, United States

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

Speaker(s)

Streamlining Submission Processing Through Automation of Document Authoring and Hyperlinking

Alishay Pringle, MS

Global Deliver Manager
Biogen, United States

Alishay Pringle is a seasoned regulatory professional with extensive expertise in project oversight, operational enhancements, and automation of regulatory submission processes. Alishay career spans over two decades of driving process efficiency, implementing system solutions, and managing vendor relations to enhance submission quality and compliance. In Alishay's current role as a Global Delivery Manager she oversees publishing deliverables

for assigned programs, enhancing process efficiency and regulatory compliance through innovative management and strategic partnerships.

Writing Quality Source Content for AI-Driven Regulatory Submissions

Regina Lynn Preciado

Senior Director of Content Strategy Solutions
Content Rules, Inc., United States

Regina Lynn Preciado is the Senior Director of Content Strategy Solutions at Content Rules. She leads content strategy teams to help pharma and biotech organizations adopt structured content successfully. She has 25+ years of experience in structured content strategy for pharma/biotech, med device, high tech, financial services, and manufacturing. Regina is an industry expert in structured content authoring, component content management, and content reuse and automation. She lives a dogspotting lifestyle.

Exploring Process Improvement in Document Management through Advanced Rendering

Paul Richard Ireland

VP Life Sciences
DocShifter, Belgium

Currently the VP of Life Sciences and Product Owner at DocShifter, Paul has over 20 years of experience in helping to provide regulatory software and service solutions to Life Sciences organisations globally. Paul has practical industry and commercial experience in delivering content authoring & rendering, Regulatory Information Management, submission and report-level publishing, and electronic Document Management solutions.

9:25 AM — 10:40 AM Brookside AB (Lower Level)

Session 9, Track 2: Optimizing Marketing Application Timelines: Insights and Strategies for Transitioning to eCTD 4.0

This session will explore the transition to eCTD 4.0 and its implications for marketing timelines. By examining the objectives of eCTD 4.0 and the challenges it presents for Regulatory Agencies and Industry, attendees will understand the importance of collaboration and be better equipped for its implementation. This session will help promote collaboration between industry and Health Authorities to streamline the transition to eCTD 4.0 and fully leverage its benefits.

eCTD 4.0 – THE Ambitious Attempt to Pull Together - Anjana Pindoria, EXTEDO GmbH

The Journey to eCTD 4.0: Test Driven Insights and Recommendations - Ankita Sunilkumar, Otsuka Pharmaceutical Development and Commercialization, Inc

Avoiding Common Roadblocks to Marketing Application Timelines - Allison Steffen, WAYS Pharmaceutical Services

Learning Objective :

- Understand the evolution and objectives of eCTD 4.0, identify regional challenges and divergences and evaluate the Impact of new submission formats and data standards
- Recognize the need for strong collaboration among Industry, Vendors, and Health Authorities for the global implementation of eCTD 4.0
- Avoid common roadblocks and identify best practices to streamline the submission review process and help prepare for eCTD 4.0

Track: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Lindsay Fitzgerald

Delivery Manager
Astrix Inc., United States

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

Speaker(s)

eCTD 4.0 – THE Ambitious Attempt to Pull Together

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.

The Journey to eCTD 4.0: Test Driven Insights and Recommendations

Ankita Sunilkumar, MS, RPh

Senior Manager
Otsuka Pharmaceutical Development & Commercialization, Inc., United States

Ankita Sunilkumar carries over a decade of experience in the pharmaceutical industry. She holds a Bachelor's degree in Pharmacy, along with Master's degrees in Regulatory Affairs, and Project Management. Currently, Ankita is a key player in the Global Regulatory Operations team at Otsuka Pharmaceutical Development and Commercialization Inc., where she focuses on ensuring system and tool readiness for various submissions and submission formats, across new and existing markets. Additionally, she identifies business needs that can benefit from Automation (RPA) and Artificial Intelligence (AI), driving innovation and efficiency within the organization.

Avoiding Common Roadblocks to Marketing Application Timelines

Allison Steffen

Submissions Lead, Regulatory Operations
WAYS Pharmaceutical Services, United States

Allison Steffen is currently the RO Submissions Lead at WAYS Pharmaceutical Services. With over 12 years in client services, she is well versed in the compilation and submission of eCTD applications. She has been the project lead on nearly 80 Initial Applications, as well as hundreds of lifecycle sequences for a wide range of products across multiple Global Health Authorities.

9:25 AM — 10:40 AM Ballroom F-G

Session 9, Track 3: Strategic Innovation in Regulatory: Advancing Technology and Its Impact on Submissions

This session will be a comprehensive session on the future of Regulatory, where industry experts will analyze current readiness for AI and advanced technology & its projected impact over the next three years. We'll explore the technology initiatives noted within PDUFA VII, focusing on how these initiatives connect to submission review processes and cloud environments. The session will conclude with a sponsor's perspective on balancing projections with reality, offering practical advice on investment priorities and managing leadership expectations. Gain valuable insights to navigate the evolving landscape of regulatory effectively.

Will Advanced Technology Mature for Regulatory in the Next 3 Years? - Steve Gens, Gens & Associates Inc

Advancing New Approaches and Technologies for Submissions and Regulatory Review - Rebecca Nebel, PhRMA

Regulatory Technology: Bridging the Gap Between Expectations and Reality - Kevin Tompkins, Bristol Myers Squibb

Learning Objective :

- Gain an understanding of where the future of technology is headed in the Regulatory Space
- Develop a plan of action and digital strategy that incorporates internal business needs and external trends

- Assess regulatory technology trends and develop a plan to implement that does not overlook People and process

Track: Adopting Innovative Technologies

Session Chair(s)

Sandra Krogulski, MA

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

Sandy Krogulski is an experienced and solution oriented individual with over 10 years of submission 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(s)

Will Advanced Technology Mature for Regulatory in the Next 3 Years?

Greg Brolund, MS

Consultant
Chicopee Falls Consulting, United States

Greg Brolund is a management and technology consultant with experience with global pharmaceutical companies' regulatory information management business processes and supporting technology. He was at the FDA / CDER for over 25 years was the rapporteur of the ICH M2 group leading to the initial eCTD specification. After FDA, Mr. Brolund was the Chief Technology Officer for the US Department of Health and Human Services and has been a pharmaceutical industry consultant for the last 18 years.

Advancing New Approaches and Technologies for Submissions and Regulatory Review

Rebecca Nebel, PhD

Senior Director, Science and Regulatory Advocacy
PhRMA, United States

Rebecca Nebel, PhD, is a Senior Director of Science and Regulatory Advocacy at PhRMA. In this role, she leads advocacy efforts to advance FDA regulatory policy on key issues including digital health, regulatory information and technology, real-world evidence, and combination products. Prior to joining PhRMA, Dr. Nebel worked at the Society for Women's Health Research where she led scientific initiatives designed to improve research, diagnosis, treatment, and access to quality care for women, and at the National Institutes of Health where she managed and implemented strategic initiatives to improve operational processes. She was also a Christine Mirzayan Science & Technology Policy Graduate Fellow at the National Academies.

Regulatory Technology: Bridging the Gap Between Expectations and Reality

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.

9:25 AM — 10:40 AM

Brookside C (Lower Level)

Session 9, Track 4: Not Business as Usual: How to Modernize your Regulatory Operations for Today's Venture Capital and AI-fueled Pharma Market

Over 70% of clinical trials are now led by small, venture-funded teams. These teams are using agile strategies and novel operating models to accelerate pipelines, maximize productivity with limited headcount, and successfully meet aggressive regulatory milestones. This session will distill these market trends into actionable takeaways for emerging and leading pharmaceutical organizations alike. Featuring expert speakers from various perspectives including Investor, Partner, Technology, and Sponsor, sessions will outline how smaller organizations can build and run a nimble regulatory function.

How New Technology and Investment Models Have Transformed Work in Emerging Companies - Toban Zolman, Kivo Inc.

How to Nimbly Lead the Regulatory Affairs Function at an Emerging Company - Alissa Minkoff, Third Harmonic Bio

How Emerging Pharma Teams are Accelerating Pipelines and Achieving Big Milestones - Sara Chan, SSI Strategy

Learning Objective :

- Align their path-to-market strategy to today's investor priorities and market dynamics
- Develop and manage an agile operating model for their team and external partners
- Effectively utilizese of technology and automation to maximize bandwidth, without sacrificing compliance

Track: Achieving Regulatory Excellence

Level: Intermediate

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)

How New Technology and Investment Models Have Transformed Work in Emerging Companies

Toban Zolman, MA

CEO
Kivo Inc., United States

Toban has over 20 years of experience creating drug development software. He has consulted at 47 of the top 50 pharmaceutical companies and worked directly with over 200 companies to align with global regulatory submission standards. As CEO of Kivo, Toban combines his years of experience working with regulators, clinical, regulatory, and quality groups with enterprise process management best practices to bring regulatory software into the 21st century.

How Emerging Pharma Teams are Accelerating Pipelines and Achieving Big Milestones

Sara Chan

Vice President
SSI Strategy, United States

Sara is a VP at SSI Strategy and has more than 17 years of consulting experience focused on the acceleration of various parts of the R&D lifecycle. She has worked in biotechs, CROs, global BioPharma's of various sizes, the US Army Medical R&D Command and health tech startups. She has held lead roles within the medical office to lead strategic efforts and transformation programs to reduce cycle time and reduce spend. Her focus on cross functional strategic alignment early and often toward end goals is the secret to her success. She helps teams to apply agile methods and design thinking to improve asset decision making and collaboration across functions of the CMO to de-risk and drive aggressive asset development and launch plans.

How to Nimbly Lead the Regulatory Affairs Function at an Emerging Company

Alissa Minkoff, MS

Executive Director, Head of Regulatory Affairs
Third Harmonic Bio, United States

Alissa Minkoff is currently Executive Director, Head of Regulatory Affairs at Third Harmonic Bio. She has 15+ years of experience in the pharmaceutical and biotech industry and has served in several leadership roles across regulatory strategy, operations, and medical writing functions. Prior to Third Harmonic Bio, she oversaw regulatory affairs and medical writing at Ventus Therapeutics and Surface Oncology, and previously held regulatory roles at Deciphera Pharmaceuticals and Vertex Pharmaceuticals. Alissa holds a bachelor of science degree from Boston University and master of science degree from Northeastern.

10:40 AM — 11:20 AM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

10:45 AM — 11:15 AM Forest Glen (Lower Level)

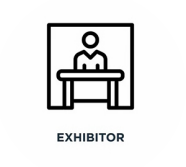
Hosted Session/Non-CE: Case Study Sponsored by Astrix

Effective change management is critical to the success of initiatives that span cross-functional teams, particularly in industries undergoing rapid transformation. This presentation will explore proven strategies for implementing change management and training programs that enhance workforce adaptability and skill development. Additionally, we will discuss practical methods to streamline cross-functional team collaboration, addressing common pain points such as communication gaps, conflicting priorities, and resource constraints. This session, centered on Automated Content Generation (ACG), will explore innovative approaches to streamlining the document creation and addressing the change across teams and the organization. Attendees will gain a comprehensive understanding of how to design and execute change initiatives that maximize efficiency, improve stakeholder satisfaction, and deliver measurable results for their organizations. This case study is ideal for professionals seeking to align people, processes, and technology to achieve sustainable success.

Learning Objective : Review different change management and training approaches How to obtain stakeholders buy-in and return on investment (ROI) Streamlining cross-functional team collaboration

Track: Exhibitor Event

Session Chair(s)



Sponsored Sessions

United States

Speaker(s)

Optimizing Change Management for Collaborative Success

Kruti Shah

Senior Consultant
Astrix, United States

11:20 AM — 12:35 PM

Ballroom E-H

Session 10: International Regulatory Authority Updates

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.

Kellen Cristina de Freitas Gissoni, ANVISA

Swissmedic Regulatory Update – DIA RSIDM Forum 2025 - Philipp Weyermann, Swissmedic

Karin Hay, Health Canada

International Regulatory Authority Update - Hilmar Hamann, European Medicines Agency

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

- Gain insights on recent updates and future developments from various global regulators

Track: General Session

Session Chair(s)

Lindsay Fitzgerald

Delivery Manager
Astrix Inc., United States

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

Tamei Elliott, MS

Associate Director, Scientific Programs
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

Kellen Christina de Freitas Gissoni, RPh

Health Regulation Specialist
ANVISA, Brazil

Kellen Gissoni is a pharmacist who joined ANVISA in 2014 as a Health Regulation Specialist. She has worked in the Office of Post-Approval Changes, responsible for the evaluation of changes in drug products and substances. Later, in the Clinical Trials Office, her work included assessing drug development dossiers with a focus on Chemistry, Manufacturing, and Controls (CMC), as well as overseeing the VigiFlow system for pharmacovigilance notifications. Currently, as an assessor in the General Management of Medicines (GGMED), she contributes to various activities and projects related to the offices under its purview.

Swissmedic Regulatory Update – DIA RSIDM Forum 2025

Philipp Weyermann, DrSc, MSc

Head of Unit Regulatory Assessment 2
Swissmedic, Switzerland

Dr. Philipp Weyermann is a team leader in the Regulatory Assessment division at Swissmedic, the Swiss therapeutic products agency. His role includes responsibility for substance management and the substance database. Philipp is a long time member in several international standardisation bodies, including the Global Identification of Medicinal Products (IDMP) Working Group (GIDWG) and the IDMP Working Group under the International Pharmaceutical Regulators Programme (IPRF). He is a chemist by training with a MSc from the University of Berne and a DrSc from ETH Zurich as well as a Postdoc at Caltech. Before joining Swissmedic in 2010, he worked in the pharmaceutical industry as a medicinal chemist and project leader for several years.

Health Canada Update

Karin Hay

Senior Policy Analyst
Health Canada, Canada

International Regulatory Authority Update – EMA

Hilmar Hamann, PhD

Head of Information Management
European Medicines Agency, Netherlands

Dr Hilmar Hamann is the Head of Information Management at the European Medicines Agency (EMA), where he leads the transformation of technological capabilities within the EU Regulatory Medicines Agencies Network to enable an all-digital, efficient, and data-driven operations framework. Previously, he served as the Director for Business Informatics at the FDA's Center for Drug Evaluation and Research from 2011 to 2020, leading advancements in regulatory data management, data analytics, and the modernization of the regulatory review platforms.

12:35 PM — 12:45 PM Ballroom E-H

Closing Remarks

Speaker(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
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.

12:45 PM — 12:45 PM

Forum Adjourns