Bethesda North Marriott Hotel and Conference Center

Feb 12, 2024 8:00 AM - Feb 14, 2024 2:30 PM

5701 Marinelli Road, , North Bethesda, MD 20852 , USA

Regulatory Submissions, Information, and Document Management Forum

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

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Print Agenda

Day 1 Feb 06, 2024

9:00 AM — 1:00 PM

Short Course: Driving IDMP Readiness and Compliance: Impact, Business Benefits, Strategies, and Application of AI

Session Chair(s)

Alison Buno, MBA

Senior Director, Regulatory Submissions
AbbVie, Inc., United States

Alison is Sr. Director, Regulatory Affairs Submissions at AbbVie Inc. She has many years of experience in all aspects of regulatory operations including global submissions management and

publishing, data and document management systems, quality assurance, regulatory information management and system support.

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.

Day 2 Feb 08, 2024

10:00 AM — 2:00 PM

Short Course: Mapping Common Regulatory Data Standards to FHIR

Day 3 Feb 12, 2024

11:30 AM — 5:00 PM

Ballroom Foyer (Upper Level)

Forum Registration

1:00 PM — 1:25 PM

Ballroom E-H

Welcoming Remarks and Presentation of the Excellence in Service Award

Welcoming Remarks and Presentation of the Excellence in Service Award

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)

Speaker

Rob Labriola, MS

Exec. Director, Regulatory Operations
Garuda Therapeutics, United States

Rob is a seasoned Regulatory Affairs Operations professional with over 30 years of experience. He was an early planner and adopter for the electronic Common Technical Document (eCTD), previously serving on Bio and PhRMA working groups for eCTD and electronic submissions. Rob has served as a leader of dynamic Regulatory Operations teams of all sizes, including past roles at Janssen, Millennium, Sunovion, and Alexion. His submission expertise includes global investigational and marketing applications. Rob has a demonstrated ability to drive and deliver operational strategies and an in-depth understanding of all facets of Regulatory Operations, including publishing, submission management, document management, and regulatory systems and tools.

Speaker

Alison Buno, MBA

Senior Director, Regulatory Submissions
AbbVie, Inc., United States

Alison is Sr. Director, Regulatory Affairs Submissions at AbbVie Inc. She has many years of experience in all aspects of regulatory operations including global submissions management and publishing, data and document management systems, quality assurance, regulatory information management and system support.

Speaker

Sandra Krogulski, MA

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

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Speaker

Jo English

VP and General Manager, Enterprise Technology
Calyx, United Kingdom

An established Regulatory Information Management expert with extensive skills and experience in life sciences. As the VP and GM of Enterprise Technology at Calyx Jo is responsible for the Commercial and SME functions. Our expert team are responsible for strategic consultancy and delivery of services and solutions to facilitate our clients' business using the Calyx RIM, Calyx CTMS and Calyx EDC technologies. With a remit to ensure that the our suite of technologies aligns with the changing regulatory landscape and client needs and to provide strategic regulatory input into the software development lifecycle, Jo is responsible for the overall budget to align with Calyx fiscal requirements.

Congratulations to our 2024 Excellence in Service Awardee!

Jake Doran

Head of Digital
Lykos Therapeutics, United States

Jake Doran is currently the Head of Digital @ MAPS Public Benefit Corporation. In this role, Jake is responsible for overseeing the development and implementation of the digital and IT strategy as the MPBC organization transitions from a clinical research startup to a commercial entity and industry pioneer. Prior to joining MPBC, Jake was the Head of Global R&D IT at Bausch Health. Jake prides himself in being a biologist by study and a technologist by trade and throughout his career has positioned himself at the intersection of science and technology. Earlier in his career, Jake held positions of increasing responsibility at Genpact, Janssen Pharmaceuticals and Schering Plough.

1:25 PM — 2:00 PM Ballroom E-H

Session 1: Keynote Address : Fostering Trustworthy and Responsible AI

With the increasingly widespread use of powerful data technologies, the importance of responsible innovation has never been greater. New and emerging technologies like AI have undeniably proven their potential in optimizing processes, improving decision-making, and enhancing the collection and management of data across the lifecycle. However, adoption may lead to several concerns such as transparency, unintended bias, and the need to stay compliant with new legal requirements. Reggie Townsend, VP of Data Ethics Practice at SAS, will share insights on how AI and other emerging

technologies can be responsibly leveraged in regulatory affairs and operations. You'll gain practical advice on how to join in on the responsible innovation movement and how your organization can maximize the rewards that you get from these technologies.

Track: General session

Session Chair(s)

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DIA, United States

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Speaker(s)

Keynote

Reggie Townsend

Vice President, Data Ethics
SAS, United States

As Vice President of the SAS Data Ethics Practice, Reggie Townsend leads a globally coordinated effort to empower employees and customers to deploy data-driven systems that promote human well-being, agency and equity. The US Department of Commerce has named Townsend to the National Artificial Intelligence Advisory Committee (NAIAC). The NAIAC will advise the president and the National AI Initiative Office on a range of issues related to AI. Townsend also sits on the board of EqualAI, a nonprofit organization focused on reducing unconscious bias in the development and use of AI. Townsend has more than 20 years of experience in strategic planning, program management, consulting and business development.

2:00 PM — 2:45 PM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

2:10 PM — 2:40 PM Forest Glen (Lower Level)

Hosted Session: Case Study Spotlight hosted by Yseop: 3 Use Cases: GenAI for Medical Writing

As the medical and scientific writing community manage unprecedented levels of new drug development, what role will generative AI (GenAI) play moving forward? Increasingly, BioPharma companies have turned to AI to augment their workforces, make teams more efficient, and accelerate submission timelines.

This session will look at how Yseop has partnered with some of the top pharmaceutical companies in the world to address their unique content automation requirements. Speakers will review three common use cases for GenAI and the dramatic results pharma companies have seen across preclinical and clinical document production.

Featured Topics

- How is GenAI impacting medical writers and the new drug development process?
- What are the unique requirements in life sciences for AI implementations compared to other, less regulated industries?
- What results can pharma companies anticipate? Dramatic improvements in quality and speed including hundreds of thousands of hours saved in writing time and more than 50% reduction in review time.

Track: Exhibitor Case Studies

Session Chair(s)

Representative Invited

United States

Speaker(s)

Nouri Chibane

Chief Revenue Officer
Yseop, United States

Camille Sauder

Solution Engineer
Yseop, United States

2:45 PM — 3:30 PM

Ballroom E-H

Session 2: FDA Plenary: Data and Technology Strategy

During this session presenters will cover a variety of topics about the FDA Data and Technology Strategy. Topics will include Next Generation of the Electronic Submissions Gateway, data quality challenges in regulatory submissions, and CBER updates.

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

- Discuss current FDA data quality challenges in regulatory submissions and identify areas of improvement to submit better quality data for FDA review
- Describe the details that encompass the next generation of the electronic submissions gateway in the cloud
- List and explain selected key data standards initiatives in CDER and CBER

Track: General session

Session Chair(s)

Ethan Chen, MBA, MS, PMP

Director, Division of Data Management Services and Solutions, OBI, OSP, CDER
FDA, United States

Ethan Chen provides overall leadership to CDER in streamlining electronic and traditional submissions and delivering solutions to enable rapid adoption of emerging electronic data standards. Since joining the FDA in 2012, Mr. Chen has led several critical initiatives as the CDER Informatics Architect, including Data Management, Analytics and Business Intelligence, Electronic Submission and Portal Collaboration programs. Ethan has over 20-years' experience in Data Management, Enterprise Architecture, Solution Development and System Integration.

Speaker(s)

Data Quality Challenges in Regulatory Submissions and Their Impact

Sri Mantha, MBA, MS

Director, Office of Strategic Programs, CDER
FDA, United States

Sridhar (Sri) Mantha is currently Director of the Office of Business Informatics (OBI) at the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration. As the Director of OBI, Sri is charged with leading informatics development to modernize CDER's drug regulatory operations. Prior to joining CDER in Dec 2020, Sri spent 25 years in the Lifesciences industry spanning Drugs, Biologics and Medical Device products. Sri held operational and leadership roles across Clinical Regulatory Informatics, Drug Safety, Quality and Information technology functions. Sri has master's degrees in engineering, Business Administration and Data Science.

Electronic Submission Gateway Next Generation (ESG NextGen)

Jessica Bernhardt, MS

ESG Program Manager
FDA, United States

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

CBER Updates

Ginny Hussong

Branch Chief, Data Standards, CBER
FDA, United States

Ginny serves as Chief of CBER's Data Standards Program, where she leads a multidisciplinary team that advances standards such as eCTD, SDTM, ADaM, SEND, ICSR, IDMP, SPL and related terminologies. In addition, the team leads reviewer training and support related to the review of study data. She serves as co-Chair of the FDA Data Standards Advisory Board and is FDA Topic Lead for the ICH M2 Electronic Standards EWG. Ginny has worked in informatics at FDA since 2004, previously serving as Director, Data Management Services and Solutions in OBI/CDER. She developed CDER's electronic submissions and reviewer training program, encompassing eCTD and CDISC Standards and well as contributing to the 745A binding guidances.

3:30 PM — 4:15 PM

Ballroom E-H

Session 3: FDA Plenary: ICH M11 Protocol Template: A Global Solution for Global Drug Development

The pandemic has taught us that clinical trials need to happen quickly and involve many regulators, pharma companies, investigators and clinical sites all over the world. One common necessary tool to conduct a trial is the clinical protocol. The protocol is a document that provides the roadmap how the trial will be conducted (the purpose, objectives, endpoints, estimands, methodology, and statistical considerations). For decades we have had a harmonized the electronic common technical document format for submission of marketing application, as well as a format and content for clinical study report. However, we have not, until now, had a globally harmonized clinical protocol. The lack of a common protocol template for global clinical trials contributes to inefficiencies and difficulties in the conduct of the study, as well as in the regulatory review, and assessment of the protocol content. The use of an electronic protocol that is standardized in its structure will improve access to consistent and searchable information (e.g., schedule of assessments, objectives, adverse event information) across sponsors, regulators and clinical sites.

This session will provide an overview and the latest developments of the ICH M11 Clinical Protocol Template: 1) Guideline, 2) Protocol template, and 3) Technical specification and how these documents will facilitate more efficient and effective conduct of global trials for global drug development.

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

- Describe the M11 ICH deliverables and the latest developments on ICH M11 guideline, protocol template and technical specification
- Describe the types of trials and phase that the template encompasses
- Understand the technical specification as a technical represenation of the template to facilitate electronic exchange

Track: General session

Session Chair(s)

Ron Fitzmartin, PhD, MBA

Senior Informatics Advisor, Office of Regulatory Operations, CBER
FDA, United States

Ron Fitzmartin is Senior Informatics Advisor, Office of Regulatory Operations, Center for Biologics Evaluation and Research, Food and Drug Administration. In this role Ron provides policy and strategy consultation and support on a wide range of topics focused on electronic regulatory submissions and standardized data. Some of Ron's activities include: chair of the PDUFA VI information technology committee, Regulatory Chair of the ICH M11 Expert Working Group on the standardized clinical protocol template, and chair of the IDMP Working Group under the International Pharmaceutical Regulators Programme. Ron received a PhD in statistics from the University of Maryland and MBA from University of New Haven.

Speaker(s)

Speaker

Y. Veronica Pei, MD, MEd, MPH

Acting Associate Director, Biomedical Informatics and Regulatory Review Science
FDA, United States

Dr. Veronica Pei is a board-certified emergency physician and a commissioned officer in the U.S. Public Health Service currently serving as Associate Director (Acting) of Biomedical Informatics and Regulatory Review Science team in the Office of New Drugs (OND), FDA. In this role, Dr. Pei is involved in development, implementation, and support of bioinformatics initiatives within OND. She is the current FDA topic lead for ICH M11 expert working group on the Structure and Content of Clinical Protocols. Dr. Pei is also the current lead for Standard Tables and Figures and Technical Specifications for Submitting Clinical Trial Data Sets for Treatment of NASH guidance.

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.

4:20 PM — 5:10 PM Ballroom E-H

Session 4: FDA: Ask the Regulators – Part 1

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

Please note: *due to the high volume of questions, not all will be answered live at the forum. We encourage participants to consider the regulators' backgrounds and expertise when directing their questions to ensure a more tailored and focused discussion.*

Track: General session

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FDA, United States

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FDA, United States

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Speaker

Ron Fitzmartin, PhD, MBA

Senior Informatics Advisor, Office of Regulatory Operations, CBER
FDA, United States

Ron Fitzmartin is Senior Informatics Advisor, Office of Regulatory Operations, Center for Biologics Evaluation and Research, Food and Drug Administration. In this role Ron provides policy and strategy consultation and support on a wide range of topics focused on electronic regulatory submissions and standardized data. Some of Ron's activities include: chair of the PDUFA VI information technology committee, Regulatory Chair of the ICH M11 Expert Working Group on the standardized clinical protocol template, and chair of the IDMP Working Group under the International Pharmaceutical Regulators Programme. Ron received a PhD in statistics from the University of Maryland and MBA from University of New Haven.

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5:10 PM — 6:10 PM Ballroom A-D

Networking Reception in the Exhibit Hall

Day 4 Feb 13, 2024

7:45 AM — 8:15 AM Ballroom A-D

Networking Breakfast in the Exhibit Hall

7:45 AM — 5:00 PM Ballroom Foyer (Upper Level)

Registration

8:15 AM — 8:30 PM Ballroom E-H

Welcome to Day Two and DIA Community Update

Welcome to Day Two and DIA Community Update

Track: General session

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
DIA, United States

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Speaker(s)

Speakers

Brooke Casselberry, MS, RAC

Vice President, Consulting Services
Epista Life Sciences, United States

Brooke Casselberry is a leading Life Sciences consultant working with Life Sciences Organizations and Health Authorities to educate, develop, and deploy technologies as accelerators to regulatory initiatives. She has been awarded PharmaVoice top 100 of the most inspiring people, DIA's Excellence in Service award, and she has published a number of articles and public presentations on regulatory operations topics. Brooke is a programming chair for DIA Global Annual Meeting with the Data and Technology track and as well as the co-chair of the DIA Regulatory Affairs Community.

8:30 AM — 9:45 AM

Ballroom E-H

Session 5: FDA Plenary: Electronic Submissions Update

This session will provide information related to electronic submissions. Topics include an update on FDA's implementation of eCTD v4.0, eCTD validations, PQ/CMC standardization, recent updates to CDER's NextGen portal, and information about how to submit premarket safety reporting to FAERS using ICH E2B R3 standards. FDA will provide details such as metrics, timelines, and where to find more information.

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

- Prepare for eCTD v4.0
- Develop understanding to publish premarket safety reports using ICH E2B R3 and submitting to FAERS
- Identify content that may be submitted via CDER's NextGen Portal
- Describe benefits of PQ/CMC submission data standardization
- Identify the most common types of validation failures related to eCTD submissions

Track: General session

Session Chair(s)

Jonathan Resnick, PMP

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

Jonathan Resnick is a member of CDER's Division of Data Management Services and Solutions, with a focus on eCTD and has been with FDA for 13 years. Prior to joining FDA, Jonathan spent 18 years working in IT project management supporting federal and private sector clients.

Speaker(s)

eCTD Submissions Update

Heather Crandall, MA

Business Informatics Specialist, OBI, OSP, CDER
FDA, United States

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

CDER NextGen Portal: One Stop Shop for the Purpose of Non-eCTD Submission, Collaboration, and Reporting

Seyoum Senay, MS

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

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

PQ/CMC and KASA

Zhouxi Wang, PhD

Senior Biologist, OPQ, CDER
FDA, United States

Zhouxi Wang joined CDER FDA in 2017, where she has been conducting quality assessments for a diverse array of applications, covering original and supplemental ANDAs/NDAs and inspections. She actively contributes to several working groups and initiatives, including Knowledge-aided Assessment and Structured Application (KASA), Pharmaceutical Quality/Chemistry, Manufacturing & Controls (PQ/CMC), and guidance drafting. She brings her

expertise to support various projects, specializing in quantitative analysis, facilitating software development, and optimizing databases.

PreMarket Safety Reporting to FAERS Using ICH E2B R3 Standards

Suranjan De, MBA, MS

Deputy Director, Regulatory Science, OSE, CDER
FDA, United States

Mr. De is the Deputy Director of CDER's Office of Surveillance and Epidemiology, Regulatory Science Staff at FDA. He provides expert advice and technical direction on regulatory science for developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products. He has over twenty years of experience with the FDA, the NIH & in the pharmaceutical industry. His work includes compounding reporting guidance, data management of FAERS system, Safety Reporting Portal for mandatory post-marketing electronic submissions and the FAERS Public Dashboard.

9:55 AM — 10:40 AM Ballroom E-H

Session 6: Ask the Regulators – Part 2

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

Please note: *due to the high volume of questions, not all will be answered live at the forum. We encourage participants to consider the regulators' backgrounds and expertise when directing their questions to ensure a more tailored and focused discussion.*

Track: General session

Session Chair(s)

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FDA, United States

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Speaker(s)

Speaker

Heather Crandall, MA

Business Informatics Specialist, OBI, OSP, CDER
FDA, United States

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

Speaker

Suranjan De, MBA, MS

Deputy Director, Regulatory Science, OSE, CDER
FDA, United States

Mr. De is the Deputy Director of CDER's Office of Surveillance and Epidemiology, Regulatory Science Staff at FDA. He provides expert advice and technical direction on regulatory science for developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products. He has over twenty years of experience with the FDA, the NIH & in the pharmaceutical industry. His work includes compounding reporting guidance, data management of FAERS system, Safety Reporting Portal for mandatory post-marketing electronic submissions and the FAERS Public Dashboard.

Speaker

Seyoum Senay, MS

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

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Speaker

Norman Schmuff, PhD

Associate Director for Science, OPMA, OPQ
FDA, United States

Norman R. Schmuff joined the FDA in 1990. For more than 20 years, he has participated in ICH as a member of several Expert Working Groups. He was the Rapporteur for the M4 CTD (eCTD) – Quality Implementation Working Group. He is involved in many FDA electronic submission initiatives, including the Pharmaceutical Quality/Chemistry, Manufacturing, and Controls structured data project. He is also serves as a delegate to the International Organization for Standardization's (ISO) Technical Committee (TC 215) on health informatics which deals with the IDMP standards. Currently he is Associate Director in FDA's Office of Process and Facilities in CDER. He has never served time in prison.

Speaker

Zhouxi Wang, PhD

Senior Biologist, OPQ, CDER
FDA, United States

Zhouxi Wang joined CDER FDA in 2017, where she has been conducting quality assessments for a diverse array of applications, covering original and supplemental ANDAs/NDAs and inspections. She actively contributes to several working groups and initiatives, including Knowledge-aided Assessment and Structured Application (KASA), Pharmaceutical Quality/Chemistry, Manufacturing & Controls (PQ/CMC), and guidance drafting. She brings her expertise to support various projects, specializing in quantitative analysis, facilitating software development, and optimizing databases.

10:40 AM — 11:15 AM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

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

Hosted Session: Case Study Spotlight hosted by Glemser: How Automation Optimizes Quality and Time for ePI Conversions

Discover how Artificial Intelligence (AI), through Natural Language Processing and Machine Learning, streamlines content extraction and conversion processes, improving accuracy and efficiency. Learn how advanced algorithms automate labor-intensive tasks, accelerating Electronic Product Information (ePI) conversions. Use automated Structured Content Authoring to facilitate ePI generation in various formats like FHIR and SPL with enhanced consistency and adaptability.

Featured Topics:

- ePI conversions
- e-labeling
- Structured content authoring
- Artificial intelligence

Learning Objective : Featured Topics:

- ePI conversions
- e-labeling
- Structured content authoring
- Artificial intelligence

Track: Exhibitor Case Studies

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Pawan Gandhi, MSc

Director, R&D
Glemser Technologies Corp, United States

Bryan Reynolds

Founder & CEO
Docxonomy, United States

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

11:15 AM — 12:30 PM

Brookside (Lower Level)

Session 7 Track 1: eCTD 4.0 - Paving the Path for Streamlined Global Drug Submissions

As eCTD 4.0 becomes a reality, the entire industry eagerly anticipates the advantages this standard can bring to streamline global regulatory submissions and facilitate a smooth transition towards data-driven processes. This session will carefully examine the implementation of eCTD 4.0 in regions that are newly adopting the standard. We will draw valuable insights from these experiences and shed light on the best practices, challenges and opportunities involved in embracing eCTD 4.0.

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

- Describe the current implementation status of eCTD 4.0 across different regions
- Discuss the impact of the shift to the new standard on current business processes
- Identify best practices for implementing eCTD 4.0 in their global submission process

Track: Track 1: Building and Sustaining Successful RSIDM Foundations

Level: Intermediate

Session Chair(s)

Daniel Offringa

Principal Consultant
eSub Solutions, United States

Dan Offringa has 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, including guidance promulgation, standards and process development, and system 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)

eCTD 4.0 - Path to Streamline Global Submission

Wilesha Wright

Associate Director, Regulatory Operations
MacroGenics, Inc., United States

Wilesha Wright is a gamechanger, leader, Regulatory Operations expert and professional with 16+ successful years of experience. She is the Associate Director of Regulatory Operations at MacroGenics, Inc. in Rockville, Maryland where she leads and manages the company's Regulatory Operations group as a people manager and oversees all programs which include electronic platform management, publishing of regulatory eCTD submissions to FDA, and administrator of Veeva RIM (Regulatory Information Management) Vault, Veeva PromoMats Vault, and IQVIA's RIM Smart publishing tool. Her experience spans the gamut with her experience at CROs (PPD & IQVIA) as Regulatory Affairs Manager and Officer, as well as completion of tenure as CMC Specialist at GSK.

eCTD 4.0 - Path to Streamline Global Submission

Sadia Ahmed

Associate Director Product Management, Regulatory Technology
IQVIA, United States

Sadia leads the team responsible for RIM Smart Submission Management at IQVIA. She has over 20 years of experience in IT and Life Sciences Industry working globally for consulting and technology solution companies. Sadia has comprehensive knowledge of global electronic submissions publishing, business process optimization, document management, systems integrations, and regulatory information management.

Industry Readiness: Learnings from Pilot Submissions

Olga Alfieri, MBA, MSc, RAC

Senior Director, Global Submission Management & Operations
Eisai Pharmaceuticals, United States

Olga Alfieri is the Director of Global Submissions Management at Eisai with over 25 years of Global Regulatory Operations and Submission Management professional experience. She operates as a global strategic partner and subject matter expert for the Global Submissions team (US, Europe, Asia and Emerging Markets). She is key contributor for supporting global implementation for Regulatory Systems (RIM, Document Management, Submission Management Applications, and other systems.

11:15 AM — 12:30 PM White Oak (Lower Level)

Session 7 Track 2: Optimizing Affiliate Engagement: Learnings from a Landmark Affiliate Study

A comprehensive survey was conducted across over 300 affiliate offices (aka country offices/LOCs) during June-August 2023. Participants responded to questions covering the use of systems across nine individual RIM areas including submission forecast and planning, product registration management, health authority (HA) commitment management, HA interactions, local label management, submission content management, submission archiving, regulatory intelligence, and promotional materials. The session will have three presentations, each by a member of the survey's core research team covering aspects of the study results to share the specific needs and challenges of affiliate offices and how to better address country-level challenges in RIM programs and in ongoing operations.

Learning Objective :

- Understand the affiliates' perspective on how they can be better supported within their functions
- Identify key barriers for collaboration and engagement with headquarters
- Identify opportunities to improve process and system efficiencies

Track: Track 2: Optimizing Processes and Procedures

Level: Intermediate

Session Chair(s)

Alison Buno, MBA

Senior Director, Regulatory Submissions
AbbVie, Inc., United States

Alison is Sr. Director, Regulatory Affairs Submissions at AbbVie Inc. She has many years of experience in all aspects of regulatory operations including global submissions management and publishing, data and document management systems, quality assurance, regulatory information management and system support.

Speaker(s)

Overview of the Gens & Associates Landmark Study: Optimizing Affiliate Engagement

Katherine Yang-Iott, MS

Consultant
Gens and Associates, United States

Katherine Yang-Iott is a core member of the Gens & Associates team with 20 years of experience in the healthcare and pharmaceutical industry, leading and managing complex interdisciplinary projects. Her earlier career was spent working in R&D as a research scientist in industry, academia, and healthcare at companies including Regeneron Pharmaceuticals and the Children's Hospital of Philadelphia before transitioning to organizational consulting work. As a change practitioner and thought leader, her expertise is in strategy development and change management in evolving organizations. Katherine has a Master of Science in Organizational Dynamics from the University of Pennsylvania and a Bachelor of Science in Biochemistry from Virginia Tech.

Think Globally, Act Locally: Why Affiliate Use of RIM Tools Should be Optimized

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.

We're in This Together: Partnering with Affiliates to Optimize Global RIM Performance

Kelly Hnat

Principal
K2 Consulting/Gens & Associates, United States

Kelly is a recognized industry leader in RIM and IDMP with 30 years in the pharma industry, the last 17 focused on Regulatory Affairs. She currently heads K2 Consulting, a specialty firm focused on Regulatory Affairs, has previously held leadership positions in IT and Regulatory Operations/RIM at Wyeth, Pfizer, Shire and Teva. Kelly is part of the Gens & Associates World Class RIM core reasearch team, has been actively involved in the EU implementation of IDMP as a member of the SPOR Task Force and its PMS subteam, and currently the President of IRISS Forum.

11:15 AM — 12:30 PM Ballroom FGH

Session 7 Track 3: The Future of Regulatory Submissions: Innovation of the Possible using a Non-disruptive Framework

Innovative advances for automating and exchanging submission data content within a recognized regulatory framework referencing M4Q-R2, SPQS, and PQ-CMC advances relative to eCTD v4.0. Collaboration, and transformation envelops eCTD v4.0 and its far-reaching implications. Technology may be disruptive and revolutionary but must be introduced in a non-disruptive way to a highly regulated environment. Innovation within the CTD / eCTD v4.0 framework including cloud computing provides exactly this vehicle for change.

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

- Identify eCTD 4.0 as a non-disruptive solution to data exchange
- Evaluate updates about M4Q R2 and its relationship to eCTD 4.0 and plans for SPQS
- Prepare for PQ-CMC and recognize its relevance to eCTD 4.0

Track: Track 3: Adopting Innovative Technologies

Level: Intermediate

Session Chair(s)

Jared Lantzy, PMP

Executive Director, Global Regulatory Operations
Novavax, Inc., United States

Speaker(s)

The Future of Regulatory Submissions Using eCTD 4.0 as a Non-disruptive Framework for Data Exchange

David Sidney Ross, MBA, MSc, PMP, RAC

Senior Director, Regulatory Data and Submissions
AstraZeneca, United States

David Ross has led enterprise projects at AstraZeneca and Abbott Labs. He implemented enterprise solutions at AZ for cross-functional CSR Initiative, led the PQ/CMC pilot for AZ, developed roles for Early Clinical Authoring and leads Clinical Study Start up improvements in alignment with EU CTR 2022. He has delivered strategic and process improvements in labelling, CMC and Non-Clinical. He led the first eCTD Implementation in AZ. He is AZ representative of the PhRMA Regulatory IT Knowledge Group. He leads the GSO IRISS IRISS Forum, and is the AZ

PhRMA IT group representative. He holds a B.SC in Biochemistry and a BASc. in Chemical Engineering. His graduate degrees include an MBA and Engineering Management from University of Ottawa.

The Future of CMC Submissions with ICH eCTD, M4Q R2, and SPQS

Rodrigo Palacios, MBA

Regulatory Policy Lead
F. Hoffmann-La Roche, Switzerland

Rodrigo Palacios is an Associate 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. He has over 25 years of experience in data and technology strategy, Information Technology management, software development and consulting.

Balancing Structured Data and Narrative for CMC

Sarah Pope Miksinski, PhD

Executive Director, CMC Regulatory Affairs
Gilead Sciences, United States

Sarah Pope Miksinski has been with Gilead since July 2023 and is currently an Executive Director in CMC Regulatory Affairs. She represents Gilead in various external capacities In 2021, she was appointed as the PhRMA Topic Lead for ICH M4Q(R2) and was appointed to the ISPE Board of Directors in 2022. She concurrently serves as the Rapporteur of the ICH Quality Discussion Group (QDG). Previously, Sarah served at AstraZeneca for over 5 years, holding roles in the CMC Regulatory Affairs space. Prior to that, she held a lengthy tenure at FDA, lasting from 2002-2018.

11:15 AM — 12:30 PM White Flint Ampitheater

Session 7 Track 4: Achieving Operational Excellence through Master Data and Optimizing Digital Processes

In today's current state, data and many procedures are bound by functional silos, and while the data collected and the existing processes might be considered optimized within their individual domains, to truly achieve breakthrough improvement, optimization of data and processes must be achieved across the enterprise and beyond these individual domains. Many of these business needs already exist, including the need to measure time from safety signal to implementation of an updated label, or having the ability to run reports specific to combining regulatory authorization and marketing information.

Key to solving these challenges is leveraging standards (like the RIM Reference Model, open APIs) that allow for more consistent and seamless flows of information in and around the 'regulatory Information' that sits at the middle of the

equation. That along with being able to define business processes and & information capture needs in a repeatable, consistent and automated fashion will support operational excellence as well as greater information traceability.

Working to break down silos and having data flow across many domains will lead to business value including seeing measurable improvement across the end-to-end submission process, implementation of manufacturing improvements by implementing changes closer to the time of health authority (HA) approval, and drive efficiency with release of product to patients. In this session, we will discuss how establishing a road map for creating rules for master data, empowering Business Process Owners to work cross-functionally and connecting authoritative sources for information across the enterprise will eliminate unnecessary hand-offs, will reduce cycle times, and will improve compliance to regulations.

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

- Identify inputs to building a vision for stitching data together across domains at their respective company
- Illustrate how requirements like IDMP can set the foundation to working smarter internally
- Explain how, with cross-functional data better connected, driving measurable improvement within end-to-end processes specific to compliance, cycle times, and all with fewer hand offs is possible

Track: Track 4: Achieving Regulatory Excellence

Level: Intermediate

Session Chair(s)

Dominik Gigli

Management Consultant
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)

Measurable Improvement with Integrated Information

Eric Cardwell, MBA

Director, Regulatory Information Management
AbbVie, United States

Eric Cardwell is the Director of Regulatory Information Management at AbbVie. Prior to joining AbbVie in 2014, he was the Director of Quality and Regulatory Affairs for Cardinal Health with oversight of three manufacturing sites. Eric has held several positions at Hospira, including Sr. Manager Commercial Quality and Device On-Market Support. Before Hospira, Eric was the Continuous Improvement Lead for the medical device division of Rexam. Eric earned his MBA from Roosevelt University and graduated University of Illinois at Chicago with bachelor's in Biology. Eric holds professional certifications including two Six Sigma certifications (ASQ & TQM), his Six Sigma Master Black Belt (Stat-A-Matrix) and his Certified Quality Engineer (ASQ).

Importance of Leveraging Data Standards, RIM Reference Models, and Open APIs

James Nichols

Chief Product Officer
Phlexglobal - Now Cencora Pharmalex, United States

Jim has nearly 30 years of experience with compliant software solutions for regulated processes in both the insurance and life sciences industries. He has held senior management positions at Intracorp (a CIGNA company), Liquent, Thomson Reuters, ePharmaSolutions, DitaExchange and Cunesoft. Following the merger of Cunesoft into Phlexglobal, Jim is now the Chief Product Officer at Phlexglobal. Phlexglobal is now part of Cencora PharmaLex. Jim holds a Bachelor of Science in Mathematics from The Pennsylvania State University.

Stitching Data Together, What Does that Look Like?

Vanni Carapetian, MPH

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

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

12:30 PM — 1:45 PM Ballroom A-D

Networking Luncheon in the Exhibit Hall

1:45 PM — 3:00 PM Brookside (Lower Level)

Session 8 Track 1: Submission Standards and Efficiencies

This session will explore three different models of submission standards and efficiencies:

- A comprehensive overview of the WHO's eCTD implementation, highlighting its benefits, challenges, and impact on the global regulatory landscape.
- How a well-designed Regulatory Information Management (RIM) System is critical to support effective document management processes and the streamlined compilation of regulatory submissions through dispatch.

- Building a single sequence that can distribute documents to several different applications simultaneously in the US via Grouped Submissions utilizing Ad Promo as an example.

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

- Recognize common challenges face during eCTD adoption and react to WHO eCTD requirements
- Practice effective and streamlined document management and apply fundamental principles of submission management to end-to-end process
- Identify strategies and publishing approaches for preparing a promotional submission

Track: Track 1: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Jillian E. Carinci, MS

Senior Director, Head of Submission Sciences
Biogen, United States

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

Speaker(s)

Enhancing Global Regulatory Collaboration: Implementing eCTD for WHO Submissions

Frank Dickert

Senior Business Consultant
EXTEDO Gmbh, Germany

Frank Dickert started with an apprenticeship in the pharmaceutical industry and afterwards studied biochemistry with a focus on bioinformatics and structural biochemistry. In 2011 he took an opportunity as a Regulatory Affairs Specialist at a pharmaceutical company and was responsible for centralized, DCP/MRP and national procedures. In 2017 Frank joined EXTEDO's Regulatory Competence Center and since then, he is consulting pharmaceutical companies in regulatory business and eCTD submissions and IDMP worldwide. Furthermore, he is analyzing and optimizing regulatory business processes and document lifecycles with or without software, resolving customer support issues with different eSubmission tools, and offers regulatory consulting with

Streamlined End-to-End Submission Management Using a State-of-the-Art Regulatory Information

Management System

Wim Dhaeze, PhD

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

Wim DHaeze 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 the Registrations, Submissions, and Submissions Archive and collaborates cross-functionally to implement complex changes and keep RIMS/DMS in a validated state. Most recently, together with the Regulatory CMC, QA, and IT teams, he participated in a successful implementation of the Connector between Vault eQMS and Vault RIMS/DMS. The eQMS-RIMS/DMS Connector streamlines business processes supporting Change Controls with Regulatory Impact.

Utilizing Grouped Submissions for Ad Promo

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.

1:45 PM — 3:00 PM White Oak (Lower Level)

Session 8 Track 2: The Value of Reference Models and Data Governance for RIM

As Regulatory Information Management (RIM) evolves and matures, the value of standardization and data governance shifts from desirable to critical to the success of the program. In this session we will review the progress of the RIM Reference Model team, presenting results of initial test drives of the model, plus updates that have been incorporated into the model in 2023. Coupled with that, we will understand how data governance enhances data quality, consistency, and compliance while supporting decision-making processes.

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

- Understand the value of the DIA RIM Reference Model
- Understand how data governance enhances data quality, consistency, and compliance while supporting decision-making processes
- Gain insights into best practices of data governance for RIM, including data classification, ownership, privacy, and security measures, enabling participants to establish robust and compliant data management frameworks

Track: Track 2: Optimizing Processes and Procedures

Session Chair(s)

Jamie O'Keefe

Head, Clinical & Regulatory Consulting
Astrix, United States

Mr. O'Keefe has over 18 years of R&D management and IT consulting expertise, working with both top tier pharmaceutical firms, and early stage biotechs. Prior to joining Astrix, he led Business & Technology Consulting at Just in Time GCP; he established and led the R&D Consulting Solutions practice for Paragon Solutions/CGI Life Sciences, where he focused on helping drive adoption of business capabilities such as: submissions management and archiving; IDMP; electronic management of Trial Master Files and investigator interactions; and defining and implementing risk-based monitoring programs. He has over 20 years of business and IT consulting experience, with the past 15 years focused in life sciences clinical and R&D.

Speaker(s)

Test Driving the DIA RIM Reference Model

D. Vanessa Brewer-Yizar

Manager, Global Regulatory Affairs
Gan & Lee Pharmaceuticals Corp. US, United States

For over 15 years' I have been in Regulatory Affairs for large and small Pharmaceutical and Medical Device companies. I am currently Senior Regulatory Affairs Manager of Global Regulatory Affairs for Gan & Lee Pharmaceutical US Corporation. During my years in the industry, I have contributed to the production, manufacturing, registration, and marketing of medicinal products, that include biopharmaceuticals, Oligonucleotides, and orphan-drugs designated for specified rare diseases or conditions.

Speaker

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

Value of and approach to Data Governance for RIM

Michael Smart, MBA

Sr. Director Customer Success
Astrix Technology Group LLC, United States

1:45 PM — 3:00 PM

Ballroom FGH

Session 8 Track 3: Modern Applications of Innovative Technologies in Regulatory Processes

This session will focus on real life examples of artificial intelligence (AI), robotic process automation (RPA), and large language model (LLM) applications in regulatory functions. From RPA bots to AI-driven solutions, technological advancements in the industry are aiding organizations to streamline their day-to-day operations. Companies can leverage technology to complete mundane tasks allowing resources to focus on more strategic work. However, applying advanced technology can inherit risk to an organization and must be used with caution to avoid misinterpretation and data invalidity.

Learning Objective :

- Describe AI, RPA and LLM applications in Regulatory and analyze the efficiencies to be gained in organizational processes while ensuring compliance
- Employ best practices for adopting advanced technology in your Regulatory function to ensure outputs are compliant with industry standards
- Hypothesize the validity of data output from modern technologies in Regulatory use cases and discuss the risks and limitations of leveraging technological advancements

Track: Track 3: Adopting Innovative Technologies

Session Chair(s)

Neel Patel, MS

Principal Consultant
Red Nucleus, United States

Neel Patel is a Principal Consultant at Red Nucleus with many years of experience in spearheading digital transformation initiatives within the Life Science industry. As a strategic, operations, and advisory consultant, Neel excels in digital innovation, technology transformation, business process optimization and software product development, showcasing a results-oriented approach and a track record of successfully executing complex business and technology programs. Neel is recognized for building and leading high-performing teams and cultivating key customer relationships across Clinical, Pharmacovigilance, Regulatory, and IT functions in pharmaceutical organizations.

Speaker(s)

Case Study: Using Robotic Process Automation to optimize the process of compiling Clinical Study Reports

Kavya Chowdary Chowdary Konka, MS

Sr Manager Medical Writing Operations
Abbvie, United States

Kavya Konka is the Senior Manager of Medical Writing Operations at AbbVie. She has over a decade of experience in Medical Writing Operations and Trial Disclosure areas, and some of her key competencies include project management, business process analysis, process optimization, gap analysis, and system design and implementation. In her current role, she manages a team of Medical Writing Coordinators, Documentation Specialists and Report Publishers who assist the Clinical Medical Writing team.

Leveraging modern technologies for resolving complexities in Health Authority Query Response generation and tracking

Vladimir Penkrat, MBA

Associate Vice President, Global Head of Safety and 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 R&D functional areas including clinical development, biometrics, biostatistics, medical writing, pharmacovigilance, and regulatory affairs. Over the past three decades Vladimir has experience in top pharmaceutical, biotech startups, CROs, and consulting firms. Vladimir's leadership has enabled clients' businesses to prepared and adapt to the evolving digital landscape and prepare for changes. As a business leader he has scaled business operations greater than 500 FTE in size globally to deliver services across the R&D landscape.

Generative AI for Regulatory Intelligence – More Questions than Answers?

Venkatraman Balasubramanian, PhD, MBA

SVP and Global Head, Industry Solutions - Healthcare and Life Sciences
Orion Innovation, United States

V. "Bala" Balasubramanian is Senior Vice President and Global Head, Industry Solutions Group for Healthcare and Life Sciences at Orion, a global digital transformation products, solutions and services firm. Bala has over three decades of IT and digital transformation experience. Prior to Orion, Bala was the President and CEO of Cabeus, a niche Life Sciences services firm where he was also responsible for vision and strategy for a cloud platform called ReALM® to transform the regulatory value chain for Life Sciences. Bala developed IT strategies and capabilities for Bristol-Myers Squibb, Roche, Aventis, Merrill Lynch, AT&T, Bell Atlantic and IBM. Bala has his PhD and MBA from Rutgers University and MS in Computer Science from NJIT.

1:45 PM — 3:00 PM White Flint Ampitheater

Session 8 Track 4: Achieving a Global Dossier: How Can Industry Encourage Convergence and Collaboration to Revolutionize Regulatory Review?

This session will focus on the vision for a global dossier and how reliance principles reduce review timelines by encouraging collaboration across regulatory authorities and reducing duplicate effort and complexity of questions. Two industry case studies will be presented. Speakers will highlight the strategic approach for convergence, practical considerations, and success metrics for global and regional reviews.

Learning Objective :

- Understand how industry can successfully execute “one dossier” initiatives
- Understand Reliance principles and how this impacts regulatory strategy and operations
- Define practical use cases that can have immediate impact towards the long term vision of a global dossier
- Assess industry's role in accelerating convergence and collaboration across regulatory agencies

Track: Track 4: Achieving Regulatory Excellence

Level: Advanced

Session Chair(s)

Katherine Novak, MS

Principal Product Manager
Accumulus Synergy, United States

Katherine Novak provides experience as a Business Analyst across the full drug product lifecycle, including Clinical Research, Regulatory Operations, Regulatory Information Management, Pharmacovigilance, and large-scale Manufacturing. She obtained her MS degree from Georgetown University in Clinical and Translational Research, where she focused on large-scale meta-analyses as a basis for clinical trials. With over four years of experience in the life science industry, Katherine supports clients in system implementation, process development, and data quality. Her passion is in data standard harmonization, specifically Regulatory data and optimization for Regulatory decision-making.

Speaker(s)

Ignite the Future - Our Exciting PAC Reliance Journey with 48 NRAs

Francesca Mangia, PhD

Regulatory Affairs International Operations Manager
F. Hoffmann-La Roche Ltd, Switzerland

Francesca Mangia joined the Regulatory Affairs department at F. Hoffmann-La Roche after completing her Doctoral Degree in Structural Biology and Biophysics at the University of Basel. She works in the CMC Regulatory

International Operation & Policy group at F. Hoffmann-La Roche where she drives filings strategy in International Markets integrating Reliance approaches and advocating for convergence and harmonization.

Establishing a Core Dossier for Multiple Regulatory Submissions: A Case Study in the Latin America Region

Omar Ruiz

Sr. Director Regulatory Affairs
Pfizer, United States

Bachelor in Pharmacy and Biochemistry with 27 years of practice in the Pharmaceutical industry. Developed his career holding responsibilities in Quality Assurance, Clinical Trial and Regulatory Affairs. Former Regulatory head of Eli Lilly and Pfizer Peruvian subsidiaries. Worked as Regulatory Strategist for the Emerging Markets at Pfizer Inc. New York Head Quarters. Current in a transition role from Head of the Latin American regulatory hub team managing new product applications and the product lifecycle in the Pfizer Global Regulatory Science group.

Speaker

Nélio Cézar de Aquino, MSc

General Manager of Medicines
ANVISA, Brazil

Nélio Cézar de Aquino is the General Manager of Medicines at the Brazilian Health Regulatory Agency (Anvisa). He has held various positions at Anvisa, including General Manager of Information Technology, Ports, Airports, Borders, and Customs Warehouses, Public Quality Control Laboratories, Food Registration, and GMP Inspection. He started his career at Anvisa in 2007 as an Inspector of Good Manufacturing Practices. Aquino holds a Bachelor's degree in Pharmacy and Biochemistry and a Master's degree in Pharmaceutical Sciences from the University of São Paulo. He also has specializations in Health Surveillance from the Oswaldo Cruz Foundation and in Micropolitics of Management and Work in Health from the Federal University of Fluminense.

3:00 PM — 3:45 PM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

3:10 PM — 3:40 PM Forest Glen (Lower Level)

Hosted Session: Case Study Spotlight hosted by Astrix: Evolving a Sponsor RIM Organization – Supporting Regulatory Excellence leveraging COEs and centralized capabilities

As Sponsors continue to evolve and modernize their Regulatory Information Management (RIM) capabilities, it requires an evolution of the supporting business organization to exploit the value of modern RIM.

This session will explore the current state of RIM in the market, what business capabilities are required to support the modern RIM technology and broader Regulatory organizations' use of it, as well as the business processes and governance required to "feed the beast."

We will present different business models for RIM, and outline the pros and cons of each.

Featured Topics:

- Understand how organizations are evolving and maturing in the strive for world-class RIM capabilities
- What business capabilities are required to support the broader Regulatory organization?
- What operating models make the most sense: COE, full centralized capability, or a mix?

Track: Exhibitor Case Studies

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Speakers

Lindsey Fitzgerald

Senior Consultant
Astrix, United States

Regulatory Affairs Business Solution expert with proven industry experience in project management, advisory services, business analysis and business support of the Department. With her 10 years' experience at AstraZeneca leading Regulatory IT projects, spanning business/technology analysis, project management, validation/testing, business training development and delivery she has credibility speaking with both IT and Regulatory business stakeholders. As an end-to-end RIM process data and system expert with 7 years' experience in Regulatory consulting for top pharma clients she has led business process optimization, RFP and vendor selection, implementation, and migration projects.

Speakers

Kristen Sauter, MBA

Senior Director, Head, Global RIM, Analytics & Digital Innovation
Takeda Pharmaceuticals, United States

Kristen has 20 years of experience helping life sciences clients create modern and innovative regulatory practices and processes that leverage cutting-edge technology to satisfy both FDA requirements and their bottom line. She has built and led global regulatory operations and project management teams for top industry organizations using forward-facing strategy and business systems. Her experience includes comprehensive knowledge of electronic submissions requirements, connections into e-subs group, strong experience in pharmaceutical process and submission preparation through pre-market and NDA stages of development, and strong exposure and awareness of post-marketing and international filings.

3:45 PM — 5:00 PM

Brookside (Lower Level)

Session 9 Track 1: Shaping and Overseeing Regulatory Strategy, Operations, and Vendor Relationships

This session will explore best practices that enable high-quality relationships between clients and vendors in the regulatory submissions space. We will delve into the ever-growing number of acquisitions and mergers/partnerships as it relates to strategy and execution in submissions operations. An examination into successfully shifting from a vendor-based RIM model to an in-house operation will be discussed.

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

- Define and explain operational performance with metrics and KPIs
- Analyze the scope and appraise the process for execution
- Identify tools, processes, and personnel necessary for success
- Employ different governance processes to create and maintain high-quality vendor relationships

Track: Track 1: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Rob Labriola, MS

Exec. Director, Regulatory Operations
Garuda Therapeutics, United States

Rob is a seasoned Regulatory Affairs Operations professional with over 30 years of experience. He was an early planner and adopter for the electronic Common Technical Document (eCTD), previously serving on Bio and PhRMA working groups for eCTD and electronic submissions. Rob has served as a leader of dynamic Regulatory Operations teams of all sizes, including past roles at Janssen, Millennium, Sunovion, and Alexion. His submission expertise includes global investigational and marketing applications. Rob has a demonstrated ability to drive and deliver operational strategies and an in-depth understanding of all facets of

Regulatory Operations, including publishing, submission management, document management, and regulatory systems and tools.

Speaker(s)

Excellence in Vendor Management

Amanda Lewis

Senior Manager, Regulatory Outsourcing Management
Bristol Myers Squibb, United States

Amanda Lewis is an experienced outsourcing manager with over 8 years of experience in the global regulatory space. In her current role, Amanda is responsible for partnering with internal and external stakeholders to ensure successful, high-quality vendor relationships. Amanda oversees contract execution, accurate financial deliverables, and a detailed KPI/metrics system. She also drives supplier relationship management and governance efforts for strategic vendors in regulatory submissions and labeling operations for BMS.

Shifting from a vendor-based RIM model to a full-service in-house Function

Richard Fredericks, MBA

Senior Director, Regulatory Operations and Technology
Mersana Therapeutics, United States

I have been in the life sciences industry for over fifteen years functioning entirely in the Regulatory Operations space. My career began in regulatory publishing and over the past decade has gravitated towards the technology and process side of the business. I currently lead the RIM group at Mersana Therapeutics where I am responsible for the creation and evolution of the Regulatory Information Management business unit; RIM ecosystem, publishing and associated operating procedures. Prior to Mersana I have worked at several other pharmaceutical/biotech companies including Black Diamond Therapeutics, GSK/Tesaro, Shire, Sunovion, Ariad, Ironwood, Pfizer, Regeneron, Ipsen and Genzyme.

Grappling with Asset Transfers – Regulatory Strategy, Execution, and Considerations

Rohan Mammen, MS

Manager Regulatory Submission Planning
BIOGEN, Canada

3:45 PM — 5:00 PM

White Oak (Lower Level)

Session 9 Track 2: Developing and Implementing the International CMC Data Standards to Improve the Post-Approval Change Process

CMC data is a critical piece of product assessment. Yet, no international data standard existed...until now. Learn how the DX-PQ Implementation Guide, FHIR, and technology can accelerate global regulatory activities like post-approval changes.

Learning Objective :

- Define the current state of CMC data standardization
- Describe framework and elements of the forthcoming DX-PQ implementation guide
- Demonstrate how adopting data standards, reliance practices, and innovative solutions can improve regulatory processes like, CMC-related post-approval changes

Track: Track 2: Optimizing Processes and Procedures

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)

Driving Efficiency in Post-Approval CMC Change Management with Structured, Standardized Data

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.

Lessons Learned from a Completed CMC Post Approval Change Reliance Project Pilot

Cynthia Ban

Global Head, Regulatory Affairs CMC, Vaccines
Sanofi, Canada

Cynthia Ban is the Global Head Regulatory CMC & Devices for Vaccines at Sanofi. Senior Global Leader in the pharmaceutical industry specializing in Regulatory Affairs. Worked for small biotech and large multinational companies. Led and developed teams across multiple geographies and a wide range of therapeutic areas including, Vaccines, Oncology, HIV, Specialty Care, Rare diseases and established brands. Highly adaptable with extensive experience in new and rapidly changing environments such as pandemics. A strategic thinker who likes to disrupt the status quo.

3:45 PM — 5:00 PM Ballroom FGH

Session 9 Track 3: Taking Advantage of Generative AI to Optimize Regulatory & Medical Writing – Uses, Benefits and Risk Management

With the advent of ChatGPT and other large language model (LLM) solutions, regulatory, medical writing and other R&D organizations have been exploring how LLMs can be used to save time and resources, improve speed to market, and enhance regulatory compliance. In this session, we will share the work that sponsors and other companies are doing to take advantage of LLM technology, the approaches they are taking, and where they are having successes or dealing with challenges. We will discuss the kinds of regulatory problems or use cases that these solutions can potentially solve as well as inherent functionality gaps and risks to avoid when using LLM tools. For example, LLMs can have challenges providing references for summary text and can even “make up” information to fill a gap (aka, hallucination). Given the popularity of LLMs and widespread adoption by the public, we will also talk about how to govern the use of such technologies, especially to support regulated business processes. Lastly, we will address how LLMs change our ways of working, the potential new roles these automations will introduce, and skill sets we may need to add to our Regulatory teams. This session includes case studies, experiments and information gathered from sponsor firms, the DIA RIM Intelligent Automation Team, consultancies and software vendors.

Speakers share what they are doing with generative AI to enable efficiencies across regulatory and medical writing, approaches for managing the risk of such tools and governing their application, and how LLMs change how we work.

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

- Provide an overview of Generative AI

- Identify how sponsor companies are exploring the use of Generative AI in Regulatory and Medical Writing and how that may change ways of working
- Discuss approaches for governing Generative AI technologies and managing risks and limitations

Track: Track 3: Adopting Innovative Technologies

Session Chair(s)

Kristen Sauter, MBA

Senior Director, Head, Global RIM, Analytics & Digital Innovation
Takeda Pharmaceuticals, United States

Kristen has 20 years of experience helping life sciences clients create modern and innovative regulatory practices and processes that leverage cutting-edge technology to satisfy both FDA requirements and their bottom line. She has built and led global regulatory operations and project management teams for top industry organizations using forward-facing strategy and business systems. Her experience includes comprehensive knowledge of electronic submissions requirements, connections into e-subs group, strong experience in pharmaceutical process and submission preparation through pre-market and NDA stages of development, and strong exposure and awareness of post-marketing and international filings.

Speaker(s)

Taking Advantage of Generative AI

Cary Smithson, MBA

Senior Director, Business Transformation & Systems Management
Cencora Pharmalex, United States

Cary Smithson is the Senior Director, Business Transformation and Systems Management at PharmaLex and has over 30 years of experience helping life science Regulatory, Clinical and Quality organizations drive increased productivity, streamline information management and enhance regulatory compliance. Her areas of expertise include regulated content and information management, regulatory information management, eTMF, GxP quality / compliance, IT strategy, business process optimization, Agile and project / program management. Cary co-leads the DIA RIM Working Group, leads the DIA RIM Intelligent Automation Topic Team, contributes to the RIM and EDM Reference Models and led the development of the DIA GMP Quality Systems Reference Model.

Speaker

Bikalpa Bikash Neupane, PhD

Head of AI and NLP
Takeda, United States

Dr Neupane is the head of AI and NLP at Takeda Pharmaceuticals. His group provides ‘AI-ML-NLP as a service’ and ‘Experimentation-as a Service’ which includes design and development of POCs/MVPs within Clinical, Non-Clinical, Med Affairs, Document Processing, and lately Gen AI capabilities etc. to several Takeda business units and business functions such as R&D, Digital data and Technology, Data Science Institute to name a few. Dr Neupane teaches graduate level courses in Natural Language Processing, Text Mining, Predictive Analytics, and Data Science.

Previously, he was a member of Natural Language Processing group at IBM Watson and Microsoft Operating Systems group in engineering disciplines.

Can we Teach Language Models to Learn Facts?

Ari Caroline, MA, MBA

CEO and Co-Founder
Weave, United States

Ari is CEO and Co-Founder of Weave Bio, a generative AI startup helping biopharma companies to "weave' together regulatory documentation directly from the source studies. Weave's first product, AutoIND is currently in beta with a commercial release planned for March 2024. Previously, Ari was the first Chief Analytics Officer at Memorial Sloan Kettering (MSK) where he drove pioneering efforts using clinical data to analyze patient outcomes. Ari's team at MSK developed the first operational AI model to match patients to clinical trials. While at MSK, Ari also played a role catalyzing startups like Flatiron Health and Paige AI. In 2019, Ari cofounded Daat.AI which was acquired by Tempus Labs, where Ari served as SVP of RWD.

3:45 PM — 5:00 PM White Flint Ampitheater

Session 9 Track 4: The Transformational Impact of FHIR on Regulatory Affairs Now and in the Future

Modernizing information exchange between sponsors and regulators will unlock efficiencies, accelerate decision making, and provide a springboard for innovation. This session will provide a non-technical overview of how the exchange standard commonly used in the healthcare industry is being leveraged to transform exchange of regulatory information. HL7® FHIR® (Health Level 7 International's Fast Healthcare Interoperability Resources standard) is a next-generation interoperability standard that can be used to exchange structured data and unstructured information. This session will focus on examining specific real-world implementation examples for using FHIR to support exchange of labeling, protocols, and CMC information across the biopharmaceutical industry. Speakers will present an overview of and demonstrate a modern method for exchanging and processing real-time medicinal product information using Health Level 7 International's (HL7) Fast Healthcare Interoperability Resources (FHIR®) standard, application programming interfaces (API), and artificial intelligence (AI). Once in place, this new method of data exchange is expected to (1) improve efficiency by reducing the time and effort needed to manage regulatory information; (2) accelerate decision making; and (3) encourage innovation. Currently, the end-to-end timescale for the pharmaceutical regulatory workflow is measured in months and years. This new paradigm will use FHIR APIs and other supporting technologies to reduce the potential time for data exchange from months to days, hours, minutes, and eventually sub-seconds. With such drastic improvements in speed provided by digitization, automation, and interoperability, the biopharmaceutical industry can reach more patients, more quickly than at any time in the industry's history. This session will focus on examining specific real-world implementation examples for using FHIR to support exchange of ePI and CMC information within and across the biopharmaceutical industry.

Learning Objective :

- Describe HL7 FHIR in lay language, including commonalities and differences from other standards
- Explain ways that FHIR is being used to advance the exchange of regulatory information

- Access resources to further learn about this topic

Track: Track 4: Achieving Regulatory Excellence

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)

What is HL7 FHIR and what does it have to do with Regulatory Information?

Stacy Tegan

Program Director
Transcelerate Biopharma, Inc., United States

Stacy Tegan is a Program Director at TransCelerate Biopharma, Inc., a non-profit organization with a mission to collaborate across the biopharmaceutical R&D community. In her current role she oversees projects to enable information sharing and harmonization across the clinical development process. She has expertise in Regulatory Operations, Clinical Development processes, and Project Management gain through 20+ years of experience working for sponsor, consulting, technology, and nonprofit organizations in the pharmaceutical industry.

Preparing for a paradigm shift: The impact of FHIR, Real-time Data Exchange, and AI on labelling and CMC regulatory data

Craig Anderson

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

Craig is responsible for leading regulatory informatics projects like the implementation of the Structured Product Labeling (SPL) standard; development of health informatics policy and IT modernization.

Future Benefits of Using FHIR for FDA Data Exchange

G. Scott Gordon, PhD

Senior Health Informatics Officer, OSP, CDER
FDA, United States

Since 2016, Dr. Gordon has been a lead for data standardization efforts including those for pharmaceutical quality, manufacturing, and labelling, as well as real-world data derived from health information technology for use in clinical research and pharmacovigilance. Before arriving at FDA, Dr. Gordon received his core scientific training with a Ph.D. in Molecular Microbiology from Tufts University Medical School, entered the public health domain in 2005 working on public health emergency preparedness and from 2011 with a focus on public health informatics.

5:00 PM — 5:30 PM Forest Glen Foyer (Lower Level

RIM Working Group Open House and Team Meeting

Hear what the RIM Working Group is all about and meet with existing members as the team discusses hot topics and plans for the year ahead. New and prospective members are encouraged to join us to help shape the future of the group.

Session Chair(s)

Cary Smithson, MBA

Senior Director, Business Transformation & Systems Management
Cencora Pharmalex, United States

Cary Smithson is the Senior Director, Business Transformation and Systems Management at PharmaLex and has over 30 years of experience helping life science Regulatory, Clinical and Quality organizations drive increased productivity, streamline information management and enhance regulatory compliance. Her areas of expertise include regulated content and information management, regulatory information management, eTMF, GxP quality / compliance, IT strategy, business process optimization, Agile and project / program management. Cary co-leads the DIA RIM Working Group, leads the DIA RIM Intelligent Automation Topic Team, contributes to the RIM and EDM Reference Models and led the development of the DIA GMP Quality Systems Reference Model.

Day 5 Feb 14, 2024

8:00 AM — 8:30 AM Ballroom A-D

Networking Breakfast in the Exhibit Hall

8:00 AM — 2:30 PM Ballroom Foyer (Upper Level)

Registration

8:30 AM — 9:45 AM Brookside (Lower Level)

Session 10 Track 1: Leveraging Structured Content Authoring in Regulatory Submissions: Real-World Experience, Industry Insights and Tools

This session is a unique opportunity focused on the application of structured content authoring in the Life Sciences regulatory submissions. This presentation will highlight the latest EDM Structured Reference Model team developments, showcasing how their work influences industry-wide adoption. Gain valuable perspectives from two respected industry leaders who have successfully implemented this approach in their companies' regulatory processes. They will share their experiences, outline the challenges encountered, and discuss the practical benefits of structured content authoring.

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

- Analyze Implementation Case Studies: Review real-life examples from industry leaders on integrating structured content authoring
- Explore Benefits and Outcomes: Investigate the advantages and efficiencies achieved through structured content authoring
- Apply Insights to Practice: Develop strategies to implement structured content authoring in your organization's regulatory submission workflow

Track: Track 1: Building and Sustaining Successful RSIDM Foundations

Level: Basic

Session Chair(s)

Nimesh Patel

Director of Global Regulatory Systems & Operations
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)

DIA EDM Structured Reference Model: Empowering the Life Sciences Industry

David Gwyn, MBA

VP, Business Consulting Services
fme US, United States

With more than 25 years of experience in the Life Sciences industry, David is a seasoned executive with extensive experience delivering solutions to customers, with a particular focus in the areas of regulatory information management (RIM), content management and collaboration. His main focus is aligning customer needs with the capabilities of the company's Life Sciences Suite and ensure that the solution meets the needs of the customer. David also leads the DIA EDM Submission Reference Model team that developed a document architecture for use when designing and building content management solutions.

Harnessing the Power of Structured Content Authoring in your Submission

Bettsy Mayes

Product Manager - Document & Content Management
Roche - Genentech, United States

Bettsy Mayes is a seasoned professional in the field of Informatics, currently serving as a Product Manager with a focus on Document and Structured Content Management for the past three years. Prior to her current role, she held the position of Program Director and Business Technology Lead in Regulatory for several years, where she played a pivotal role in managing diverse programs related to document management, Clinical Trial Regulation (CTR), and eSubmissions. Her extensive experience in Informatics includes a previous role as a Delivery Service Manager, where she led a large global operational group that provided critical support to over 8,000 users.

If Data-Centricity is the Answer to the Intelligent Submissions of the Future, Why is it so Hard to Achieve?

Gerald Kukko

Information architect
Janssen, Canada

8:30 AM — 9:45 AM White Oak (Lower Level)

Session 10 Track 2: Complying with EU CTR: Managing Business Change and Submissions in CTIS

In this session, panelists will discuss sponsor approaches to comply with the EU Clinical Trial Regulations (CTR), the importance of managing business process changes, and the challenges they dealt with along the way. We will explain the mandatory use of EMA's Clinical Trial Information System (CTIS), the redaction requirements, and the impact to sponsor business processes. We will also share anonymized screenshots of CTIS, how sponsors have used automation technologies to streamline CTIS data entry, address the dynamics between MSCs (Member State Countries), their Health Authorities and Ethics Committees.

Learning Objective :

- Explain EU CTR, requirements for CTIS data / content entry, and redaction
- Discuss how sponsors have prepared their companies to comply with the regulation
- Describe how complying with EU CTR requirements impacted sponsor business processes, system use and data as well as potential challenges and ways to overcome them

Track: Track 2: Optimizing Processes and Procedures

Session Chair(s)

Cary Smithson, MBA

Senior Director, Business Transformation & Systems Management
Cencora Pharmalex, United States

Cary Smithson is the Senior Director, Business Transformation and Systems Management at PharmaLex and has over 30 years of experience helping life science Regulatory, Clinical and Quality organizations drive increased productivity, streamline information management and enhance regulatory compliance. Her areas of expertise include regulated content and information management, regulatory information management, eTMF, GxP quality / compliance, IT strategy, business process optimization, Agile and project / program management. Cary co-leads the DIA RIM Working Group, leads the DIA RIM Intelligent Automation Topic Team, contributes to the RIM and EDM Reference Models and led the development of the DIA GMP Quality Systems Reference Model.

Speaker(s)

Clinical Trials Information System

Hans van Bruggen, MSc

CSO
Qdossier, a Celegence Company, Netherlands

Hans van Bruggen has been involved in the transition form paper to digitalized paper to data exchange to data sharing. Key areas of expertise: lean regulatory documents, data capture right-first-time, and reuse rather then recreate or copy. Hans has an MSc in Pharmaceutical Medicine from the University of Surrey and has worked within, or for, the pharmaceutical industry for more than 30 years in Global or European Headquarters. Using that scientific background he brings together people, processes and tools, leading to lean interdisciplinary and international processes.

Commercially Confidential Information (CCI) & Protected Personal Data (PPD) Management in EU CTR

Richard Durrance

Clinical Trial Transparency & Disclosure Manager
Pfizer, United Kingdom

Richard has 20+ years of pharmaceutical industry experience. He started his career at GSK in the Clinical Document Management group, finally managing the UK team before becoming more engaged in technological process & system development and implementation. For the last 7-8 years he has been involved in clinical transparency activities, including managing document anonymisation for GSK pharma, disclosing European Medicines Agency Policy 0070, Health Canada Public Release of Clinical Information, as well as in support of voluntary disclosures and local transparency requirements; he now focuses on supporting disclosure at Pfizer.

8:30 AM — 9:45 AM

Ballroom FGH

Session 10 Track 3: So, You Think Technology Solutions are Failing your Content Transformation? Did You Set Them up for Success?

Many companies are investing heavily in software to digitize and automate their regulatory content operations with varying success. The most successful intelligent automation implementation teams think content before software: a software-agnostic mindset is key to success. Building, adopting, and sustaining software-agnostic content standards help organizations put the needs of people and processes before technology selection. Our goal is to demonstrate how applying a software-agnostic content standards methodology can break the ground and pave the way for effective content transformation across people, processes, technology, and data/content.

Learning Objective :

- Discuss the importance of software-agnostic content standards and how they can be a foundation for content analysis
- Demonstrate how the outputs from business content analysis can be applied to technology solution requirements and design to meet content needs; propose and discuss best practices and pitfalls
- Prepare for software-agnostic content standards to help drive holistic transformation

Track: Track 3: Adopting Innovative Technologies

Level: Intermediate

Session Chair(s)

Matthias Sijtstra

Senior Data Management Specialist
Qdossier, A Celegence Company, Netherlands

Matthias works as a Senior Data Management Specialist for Qdossier, a Celegence company. 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/DADI). 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. Additionally, Matthias has experience in software development and validation in a highly regulated environment.

Speaker(s)

A Tale of Two Use Cases: The cautionary tale - When the document creeps in

Aliza Nathoo

Senior Business Transformation Leader
F. Hoffmann-La Roche Ltd., Canada

Aliza has over 20 years of experience in the biopharmaceutical industry. She is an expert in structured content authoring, component content management, and content reuse. Over the last several years, she has used her extensive and varied expertise to evolve a theoretical enterprise content strategy into sustainable content operations for the Roche pharma organization. She collaborates with various organizational units to standardize content practices, implement structured content management technology solutions, and drive results that align with future work paradigms.

Software-Neutral Content Standards Overview

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.

A Tale of Two Use Cases: The happy path - When the content leads (vs. technology)

Salim Saglam, MBA

Business Transformation Lead
Genentech, Inc., United States

Salim Saglam is a Business Transformation Lead, Principal Product Leader 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 ~5 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.

8:30 AM — 9:45 AM White Flint (Lower Level)

Session 10 Track 4: Electronic Product Information (ePI): A Digital Passport for Therapeutic Product Information

This session will provide a holistic view of electronic Product Information (ePI), emphasizing its significance in delivering timely drug information to patients and healthcare providers. You'll gain insights into the current status of ePI adoption and discover the essential factors needed for its global implementation.

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

- Understand the purpose of ePI & how it fits within regulatory ecosystem
- Highlight the current state of ePI adoption globally
- Describe the benefits of adopting ePI, best practices for implementation, and barriers to adoption
- Explain how ePI interacts with global data standard initiatives & Why it matters

Track: Track 4: Achieving Regulatory Excellence

Level: Intermediate

Session Chair(s)

Jo English

VP and General Manager, Enterprise Technology
Calyx, United Kingdom

An established Regulatory Information Management expert with extensive skills and experience in life sciences. As the VP and GM of Enterprise Technology at Calyx Jo is responsible for the Commercial and SME functions. Our expert team are responsible for strategic consultancy and delivery of services and solutions to facilitate our clients' business using the Calyx RIM, Calyx CTMS and Calyx EDC technologies. With a remit to ensure that the our suite of technologies aligns with the changing regulatory landscape and client needs and to provide strategic regulatory input into the software development lifecycle, Jo is responsible for the overall budget to align with Calyx fiscal requirements.

Speaker(s)

Electronic Product Information (ePI): A Digital Passport for Therapeutic Product Information; case study : "Unlocking ePI: A Possible Solution to Drug Shortage Management"

Katja Pecjak, MPharm

Director BD, Sales and Marketing
Billev Pharma East Ltd., Slovenia

Katja has a Master's in Pharmacy and has been in Pharmaceutical Industry for 20 years. Her journey in Billev Pharma East Ltd. started in September 2008, as a Director of Regulatory Affairs and EU QPPV. Presently, she is responsible for the business development within the company and empowering the team with a profound understanding of intricate pharmaceutical business processes. Her expertise has been sought when she was called upon to assume the role of Subject Matter Expert in the EMA ePI Pilot Project, representing the Pharmaceutical Industry perspective since July 2022. She is a member of Medicines for Europe working groups (RSAC, Telematics), TOPRA and an ePI Topic Group Lead in IRISS Forum.

Electronic Product Information (ePI): A Digital Passport for Therapeutic Product Information

G. Scott Gordon, PhD

Senior Health Informatics Officer, OSP, CDER
FDA, United States

Since 2016, Dr. Gordon has been a lead for data standardization efforts including those for pharmaceutical quality, manufacturing, and labelling, as well as real-world data derived from health information technology for use in clinical research and pharmacovigilance. Before arriving at FDA, Dr. Gordon received his core scientific training with a Ph.D. in Molecular Microbiology from Tufts University Medical School, entered the public health domain in 2005 working on public health emergency preparedness and from 2011 with a focus on public health informatics.

Speaker

Cesar Vinces

EU Interim and International Policy Lead
Accumulus Synergy, United States

Cesar serves as Interim EU & International Policy Lead at Accumulus Synergy within Regulatory Innovation. He engages with industry experts, national regulators, and global organizations to foster policy changes and develop strategies that enhance regulatory frameworks, promoting industry collaboration through a cloud-based data exchange model. Cesar supports efforts that permit the adoption of the Accumulus platform by both sponsors and regulators. Additionally, he leads a Topic Group Digitalization in Regulatory for IRISS, pushing forward industry-wide digital advancements. Cesar has over two decades of experience, the last 12 years he spent in Submissions Management leadership roles within Regulatory Operations at Pfizer.

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 where he focuses on transforming technology capabilities for the Network of Regulatory Agencies in the EU and its stakeholders to become an all-digital, efficient and data-driven Network of the future. Prior to joining EMA, from 2011 to 2020, he served as the Director for Business Informatics at the U.S. Food and Drug Administration leading the transformation of medicines regulatory data, advancing data analytics, and modernizing the scientific computational and collaboration platforms that underpin operations.

Speaker

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.

9:45 AM — 10:30 AM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

9:55 AM — 10:25 AM Forest Glen (Lower Level)

Hosted Session: Case Study Spotlight hosted by Genpact: AI was Meant to Have all the Answers. But is Regulatory Asking the Right Questions?

Companies are expecting AI to solve every business problem, but without a thorough understanding of Regulatory's specific needs, your AI investments won't progress beyond experiments.

We have a different, more human-centered approach. By working with regulatory professionals to dive into the questions and frustrations you face every day, we've crafted a suite of solutions that your business can embed and scale. With AI at

your side, your business will make smarter more efficient decisions, accelerate submissions, and improve user experiences. Join this session to learn how you too can build an AI-first regulatory team.

Featured Topics:

- AI for regulatory professionals
- AI with regulatory expertise
- Generative Artificial Intelligence, Gen AI
- Human, persona based design
- Helping Regulatory Affairs embrace and thrive through AI
- Change Management

Session Chair(s)

Representative Invited

United States

Speaker(s)

Robert Baldry

Digital and Data Lead, Regulatory Affairs
Genpact, United States

Robert Baldry leads Genpact's Data and RIM migration practice focused on projects to improve regulatory data management through better technology, process and governance. Robert has over 15 years of experience implementing new technologies to the pharmaceutical industry. Projects include xEVMPD and IDMP migration projects. Enterprise wide multi-source legacy RIM to cloud based RIM system implmentations. Global data remediation and migration programs as well as paper to digital transformation projects. Robert studied business and technology at the University of Wolverhampton, United Kingdom and InHolland University of Applied Sciences, the Netherlands

10:30 AM — 11:45 AM Brookside (Lower Level)

Session 11 Track 1: Improving Regulatory Processes Through Data-Driven Metrics, Generative AI, and Effective Change Management

This is an introductory session focused on how data-driven processes and generative AI can be implemented to improve efficiency in regulatory operations. The session will also highlight the importance of change management and effective change management strategies. The topics include a case study for improving data quality to enhance regulatory metrics,

use cases for generative AI to improve accuracy and efficiency in regulatory operations, and how change management is essential for implementing these changes in an organization.

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

- Discuss how to collaboratively define a metrics roadmap focused on a regulatory organization
- Understand how generative AI can improve efficiency by automating manual and repetitive tasks
- Gain insight into the benefits of using generative AI in regulatory operations
- Develop effective change management strategies and communication

Track: Track 1: Building and Sustaining Successful RSIDM Foundations

Session Chair(s)

Katherine Novak, MS

Principal Product Manager
Accumulus Synergy, United States

Katherine Novak provides experience as a Business Analyst across the full drug product lifecycle, including Clinical Research, Regulatory Operations, Regulatory Information Management, Pharmacovigilance, and large-scale Manufacturing. She obtained her MS degree from Georgetown University in Clinical and Translational Research, where she focused on large-scale meta-analyses as a basis for clinical trials. With over four years of experience in the life science industry, Katherine supports clients in system implementation, process development, and data quality. Her passion is in data standard harmonization, specifically Regulatory data and optimization for Regulatory decision-making.

Speaker(s)

Our Journey to Improve Data Reliability and Establish Regulatory Metrics

Noelia Plaza

Director of Process Excellence & Analytics
Daiichi Sankyo, United States

Generative AI Across Regulatory Operations

Leslie Kitchen, BSN, RN

Senior Director Regulatory Innovation and Information Management
Merck & Co., United States, United States

Leslie Kitchen is a Senior Director in the Regulatory Innovation & Information Management organization at Merck. She joined Merck in 2007 after a successful career as a cardiac nurse. She served in various roles across Safety and Regulatory Affairs including Global Safety Operations, Process and Portfolio Management, and Business Development, Sourcing, and Alliance Management. In her current role at Merck, she leads a Regulatory Information & Communication Management group focusing on developing and supporting innovative digital solutions to manage information across Global Regulatory Affairs. Leslie is also pursuing a Master's degree in Information Technology Management through Georgetown University.

Criticality of Change Management during a global RIM implementation

Kevin M. Costello

Senior Consultant, Clinical and Regulatory Consulting
Astrix Inc., United States

Kevin has worked as an implementation and strategy consultant for over 13 years, in financial services, technology solutions, and life sciences. With a background in organizational behavior and business strategy, he has lead business process transformations that helped redesign Wall Street back office operations and changed how patient service organizations connect with those undergoing treatment. Currently, Kevin works with Astrix to support the clinical and regulatory strategy and operations of top-10 pharmaceutical clients from submissions and regulatory information management, to data integrity in the manufacturing and quality space.

10:30 AM — 11:45 AM White Flint (Lower Level)

Session 11 Track 2: Optimizing Submission Filings: Understanding the Challenges and Developing Strategies Accelerating Submission Delivery to Health Authorities

Regulatory is on the critical path to launch and valuable time can be saved or lost during the final stage before handing the submission over to health authorities for review. This session provides insight regarding the accelerating of the submission timeline, proactive publishing strategies for mitigating document re-work, and management of label content. All efficiencies presented will focus on ensuring content consistency across the product lifecycle and different regions, maintaining submission compliance and quality, and preventing potential risks to patient safety.

Learning Objective :

- Identify a range of tools, for accelerating average submission times to get safe and effective medicines to the patient faster
- Describe real-world examples for mitigating publishing re-work and ways to increase efficiency
- Recognize the significant impact of a centralized digital label management platform on improving automatic tracking and managing of different label versions across different markets

Track: Track 2: Optimizing Processes and Procedures

Session Chair(s)

Teresa Martins

Senior Director, US Site Head Regulatory Submission Management
Bayer U.S. LLC, United States

Teresa joined Bayer in August 2009 and has held increasing levels of responsibility in Submission Management. Currently, as Senior Director, Teresa drives strategic technology initiatives, compliance and submission activities for the US region while operating within a global network. She began her career at Interleaf, Inc. building and supporting electronic document management and publishing systems. This experience developed into further opportunities to hold publishing responsibilities within Wyeth Consumer Health, Johnson & Johnson, Schering-Plough and other companies. Teresa brings over 30 years of publishing experience and has a Bachelor of Science in Computer Science from Muskingum University with specialization in Math and Chemistry.

Speaker(s)

A Multi-faceted Approach to Achieving Faster Filings

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.

Publishing with a Global Mindset: Do's & Don'ts of Re-using Documents across eCTD Applications

Rachel Bombara

Regulatory Services Manager
Certara, United States

Rachel Bombara is a Regulatory Services Manager at Certara with 12+ years of experience in Regulatory Operations and helping clients achieve their submission goals. She has managed the submissions 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 regulatory operations.

Optimizing Product Label Management: Enhancing Compliance and Efficiency

Priyanka Kumari, DMD

Senior Manager, Regulatory Affairs & Labeling
Indegene, India

Dr. Priyanka has over 19 years of experience in the clinical and pharma sector. A dental surgeon by profession and a postgraduate diploma in clinical research, Dr. Priyanka has around 7 years of experience in clinical practice and another 12+ years of experience in various facets of clinical research, including regulatory affairs, global/local labeling, and medical writing. Her core area of specialization involves delivering Regulatory Intelligence assistance, offering Strategic Consultation, HA interactions, formulating Labeling Strategies, and providing Regulatory Submission support to big and mid-sized pharmaceutical sponsors across geographies. She excels in managing health authority queries and crafting responses to questions (RTQs).

10:30 AM — 11:45 AM Ballroom FGH

Session 11 Track 3: Exploring Opportunities and Challenges of Cloud Technology for Industry and Regulators

Although cloud technology is not a new concept, it has recently gained significant attention in our industry due to the opportunities and efficiencies it offers. This session aims to provide an overview of the regulatory landscape of cloud-based technologies, highlighting the opportunities and challenges associated with implementing them for regulatory use. With examples, case studies, discussion and input from the FDA and EMA regulators, the panel will explore the practicalities of cloud technology and discuss how further advancements could enhance the submission landscape.

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

- Illustrate how cloud-based technologies can enhance data exchange and regulatory review
- Identify current challenges and potential solutions in implementing cloud-based technologies for regulatory use

Track: Track 3: 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)

Past, Present, and Future: Utilizing Cloud Technology for Regulatory Use

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.

FDA's Approach to Leveraging Cloud Technology

Helen Yejin Saccone, PharmD

Associate Director, Global Regulatory Policy, GO, OC
FDA, United States

CAPTAIN Helen Saccone serves as a Senior Advisor within CDER's Office of Strategic Programs (OSP). In this role, she manages the strategic development and implementation of CDER priorities including PDUFA VII technological commitments and CDER's Artificial Intelligence Steering Committee. CAPT Saccone was also a member of the inaugural team that initiated the US-EU Mutual Reliance Initiative in 2014, that led to the negotiations and implementation of an international trade agreement for the FDA.

Security, Privacy, Quality, and Compliance Requirements for a Cloud-based Regulatory Platform

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.

Exploring Cloud Technology: The Future of Regulatory Submission & Collaboration

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 where he focuses on transforming technology capabilities for the Network of Regulatory Agencies in the EU and its stakeholders to become an all-digital, efficient and data-driven Network of the future. Prior to joining EMA, from 2011 to 2020, he served as the Director for Business Informatics at the U.S. Food and Drug Administration leading the transformation

of medicines regulatory data, advancing data analytics, and modernizing the scientific computational and collaboration platforms that underpin operations.

An Introduction to PRISM (precisionFDA Regulatory Information Service Module)

Ginny Hussong

Branch Chief, Data Standards, CBER
FDA, United States

Ginny serves as Chief of CBER's Data Standards Program, where she leads a multidisciplinary team that advances standards such as eCTD, SDTM, ADaM, SEND, ICSR, IDMP, SPL and related terminologies. In addition, the team leads reviewer training and support related to the review of study data. She serves as co-Chair of the FDA Data Standards Advisory Board and is FDA Topic Lead for the ICH M2 Electronic Standards EWG. Ginny has worked in informatics at FDA since 2004, previously serving as Director, Data Management Services and Solutions in OBI/CDER. She developed CDER's electronic submissions and reviewer training program, encompassing eCTD and CDISC Standards and well as contributing to the 745A binding guidances.

10:30 AM — 11:45 AM White Flint Ampitheater

Session 11 Track 4: New Trends and Challenges in Combination Products, Companion Diagnostics, and Digital Health Technologies

This session focuses on challenges and opportunities related to the development and commercialization of combination products and companion diagnostics from both the regulatory and industry perspectives. It also covers the impact of the recent advancements in digital health technologies for improving healthcare outcomes and patient experiences. Furthermore, it offers considerations and ways to manage the complex challenges created by myriad of new regulatory policies and ensure compliance with safe and efficacious deployment of such technologies.

Learning Objective :

- Evaluate impacts of combination products on regulatory affairs' ways of working
- Share challenges in dealing with Health Authority regulatory processes and pathways related to development and commercialization of combination products and best practices to manage them
- Explore the considerations and challenges associated with operationalizing regulatory policy assessments for digital health

Track: Track 4: Achieving Regulatory Excellence

Session Chair(s)

Vahe Ghahraman, PhD

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

Vahé has over 20 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.

Speaker(s)

The Growing Impact of Combination Products and Companion Diagnostics – A Regulatory Perspective

Kavita A. Vyas

Review Chemist, OD, CBER
FDA, United States

Dr. Vyas is currently a Product Jurisdiction Office in CBER/Office of Director. Dr. Vyas has served in FDA for 15 years. She has worked on a broad range of matters covering quality assessment, policy, strategy and programmatic levels for drugs and biological products. Most notably, Kavita focused on scientific and policy questions to help implement certain key provisions related to biosimilars. In addition, she contributed to numerous Agency, Inter-Center initiatives and steering committees and external stakeholder engagements. Prior to joining FDA, she served as research faculty at the Johns Hopkins University and School of Medicine in basic biomedical sciences.

The Growing Impact of Combination Products and Companion Diagnostics – An Industry Perspective

Brian Williams

Advisory Managing Director, Life Sciences
KPMG, United States

Brian is a leader in KPMG's Life Sciences Consulting practice, with a focus on Regulatory Affairs. He has extensive experience helping clients improve efficiency and enable compliance by implementing process and technology changes. His experience includes leading programs related to global RIM deployments, RA operating model and process redesign, data cleansing/harmonization and adoption of emerging digital technologies.

Considerations and Challenges of Operationalizing Regulatory Policy Assessments for Digital Health

Stephen Philipp

Associate Director Regulatory Digital Health / Policy Execution

Merck, United States

Stephen Philipp has worked at Merck for more than 20 years supporting various aspects of the pharmaceutical industry including Operations, Technology and Engineering Initiatives and Regulatory Affairs. In 2014 he started supporting drug and diagnostic regulatory submissions. In his current role within Regulatory Digital Health, Stephen continues to provide project management expertise in support of EU Regulatory Submissions. Stephen currently leads a policy execution team in the assessment, implementation, and tracking of regulatory policies that impact multiple functional areas within Regulatory Affairs. Stephen holds a BS in Biology from Millersville University and is a certified Project Management Professional (PMP).

11:45 AM — 1:00 PM Ballroom A-D

Networking Luncheon in the Exhibit Hall

1:00 PM — 2:15 PM Ballroom E-H

Session 12: International Regulatory Updates and Insights

Receive the latest updates from international regulators and an industry representative on recent and future developments related to data standards, analytics, electronic submissions, and health authority IT programs. 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*

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)

Speaker

Mick Foy

Director of Delivery
Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Mick Foy has been with the MHRA for more than 35 years, he is a member of the MHRA's Executive Committee and has recently been appointed Director of Delivery . Amongst his responsibilities is to drive initiatives to introduce new and improved services to stakeholders. Mick is SRO for the SafetyConnect and RegulatoryConnect programmes. He also leads MHRA efforts to build PV capabilities in other countries particularly low and middle income countries as part of a global initiative with the Bill and Melinda Gates Foundation.

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 where he focuses on transforming technology capabilities for the Network of Regulatory Agencies in the EU and its stakeholders to become an all-digital, efficient and data-driven Network of the future. Prior to joining EMA, from 2011 to 2020, he served as the Director for Business Informatics at the U.S. Food and Drug Administration leading the transformation of medicines regulatory data, advancing data analytics, and modernizing the scientific computational and collaboration platforms that underpin operations.

Electric ERA (China eSubmission/eCTD): Revolution in Regulatory Affairs and Operations

Shenqi (Handsome) Ji

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

Handsome Ji has rich experience in sharing Electronic Common Technical Documents (eCTD) knowledge on many conferences of domestic and international. In 2016, Handsome was invited to China Regulatory Summit as an industry specialist and advisor for eCTD Symposium. In early 2018, Handsome was nominated to a consultant of Regulatory Affairs of Young Member of Advisory Committee (YMAC), DIA, as well as Taskforce co-Lead for DIA China RA Community. From 2015 to 2023, Handsome has chaired sub-forums of ICH Theme Day of DIA China Annual Meetings and DIA China M4/M8 Workshops and presented topics about Regulatory Operation.

An Update on Health Products Standards and Innovation at HPFB

Nick Karitsiotis

Director of Business Innovation
Health Canada, Canada

2:15 PM — 2:30 PM Ballroom E-H

Closing Remarks

2:30 PM — 2:30 PM

Forum Adjourns