Regulatory Submissions, Information, and Document Management Forum

Primer: February 5 | Short Courses: February 6 | Forum: February 6-8
Bethesda North Marriott Hotel and Conference Center| North Bethesda, MD

PROGRAM CO-CHAIRS

Michelle L. Charles, MPH
Manager, Regulatory Implementation
PAREXEL International

Virginia Hussong
Data Standards Program Manager, OD, BSS
CBER, FDA

Sarah Powell, RAC
President
Powell Regulatory Services

Jamie Marie Toth, MS
Director TMF Operations
Daiichi Sankyo, Inc.

PROGRAM COMMITTEE

V. "Bala" Balasubramanian, PhD, MBA
President and CEO
Cabeus. Inc.

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Michiel Stam
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Stacy Tegan
Manager, Regulatory Technology Consulting
Accenture Accelerated R&D Services

Overview

DIA is proud to present the *Regulatory Submissions, Information, and Document Management Forum.* This Forum was initially three separate DIA meetings: Electronic Document Management (EDM), Electronic Regulatory Submissions (ERS), and Regulatory Information Management (RIM), each with their own unique histories. In 2015, the three meetings were combined into one Forum in an effort to represent the end-to-end process of managing regulatory submissions and documents. The response to this approach has been incredibly positive with record attendance in 2016, as it serves as the premier place for the discussion of emerging operational standards, best practices, and the processes for the submission, creation, and maximum use of regulatory information. The Forum continues to explore information generated along the drug development continuum life cycle and alignment to ever evolving regulatory and electronic standards.

Highlights

Keynote Speaker
Theresa Mullin, PhD
Director, Office of Strategic Programs
CDER, FDA

- Exhibit Hall with numerous vendors
- Expert perspectives from industry, regulatory, and vendors worldwide
- *Wait, Wait, Don't Tell Me! Your Regulatory War Stories*
  Dinner on the Town | Tuesday, February 7 *(Dinner cost is on own)*
- **NEW:** FDA Track

Who Should Attend

Professionals involved in:

- Regulatory Affairs and Operations
- RIM
- Global Submission and Project Management
- Medical, Technical, and Regulatory Writing
- Data Management
- Information Technology and Support
- Document and eRecords Management
- Essential Document Process and Business System Owners
- Regulatory Standards Implementation Specialists
- Clinical Operations
- Quality Assurance and Compliance
- Contract Researchers and Service Support
- Emerging Pharmaceutical/ Biotech/Device
- Vendor Relationship Management

Message from Program Co-Chairs

On behalf of the Program Committee and DIA Board of Directors, we are pleased to welcome you to DIA's *Regulatory Submissions, Information, and Document Management* (RSIDM) Forum. The goal of this Forum has been to develop a comprehensive program that would inform and educate on the current hot issues and help identify topics that will impact the industry in the near future. In response to the Call for Abstracts, we received a record number of submissions this year, from which we selected the most exciting and relevant proposals and invited experts from regulatory authorities, sponsors, vendors, and standards organizations to share recent updates relevant to RSIDM. This year, with the same geographical proximity to Washington, DC, we have the opportunity to have an FDA leader to present the keynote address on PDUFA VI, as well as add a new FDA Track. Additionally, we are offering a full day short course, *Regulatory Content and Submissions Primer,* plus two half day short courses on IDMP and Outsourcing. As technology propels the end-to-end solutions to be increasingly interoperable, the forum's topics will also represent the experiences and informational material of all aspects from document creation to marketing application submission and life cycle. The sessions will represent points along the continuum where the interoperability is critical to consistency, compliance, and integrity of the final deliverables. The recognition, development, and adoption of regulations, standards, and best practices have facilitated the efforts of our speakers and they are preparing to share their experiences and knowledge with you.

Warm regards,

Michelle L. Charles, MPH
Manager, Regulatory Implementation
PAREXEL International

Virginia Hussong
Data Standards Program Manager, OD, BSS
CBER, FDA

Jamie Marie Toth, MS
Director TMF Operations
Daiichi Sankyo, Inc.

Sarah Powell, RAC
President
Powell Regulatory Services

Schedule At-A-Glance

Track 1: RIM Business **Track 2:** RIM Technology **Track 3:** EDM **Track 4:** ERS

PRIMER | SUNDAY, FEBRUARY 5	
10:00AM-5:00PM	**Regulatory Content and Submissions Primer:** Tracking Content from Conception to Interment
DAY ONE | MONDAY, FEBRUARY 6	
7:30AM-5:30PM	Registration
8:30AM-12:00PM	**Short Course 1:** Global Identification of Medicinal Products
8:30AM-12:00PM	**Short Course 2:** Achieving Regulatory Operations Excellence Through Outsourcing
1:00-1:25PM	**Welcome and Opening Remarks**
1:25-2:00PM	**Keynote Address:** Perspective on PDUFA VI and the Strategic Vision for CDER Going into the Next PDUFA Cycle
2:00-3:30PM	**Plenary Session 1:** FDA – PDUFA V Update
3:30-4:00PM	Refreshments, Exhibits, and Networking Break
4:00-5:30PM	**Plenary Session 2:** Other Regions Update
5:30-6:30PM	Networking Reception
DAY TWO | TUESDAY, FEBRUARY 7	
7:30AM-5:00PM	Registration
7:30-8:30AM	Continental Breakfast, Exhibits, and Networking Break
8:30-10:00AM	**Session 1:** FDA Data Standards and Regulatory Compliance Update
10:00-10:30AM	Refreshments, Exhibits, and Networking Break
10:30AM-12:00PM	**Session 2:** Breakout Sessions **Track 1:** Business Impacts to IDMP **Track 2:** Regulatory Analytics **Track 3:** EDMS in the 21st Century, Better, Broader, More Flexible **Track 4:** Ad/Promo
12:00-1:30PM	Luncheon, Networking, and Exhibits
1:30-3:00PM	**Session 3:** Breakout Sessions **Track 1:** What is RIM? **Track 2:** Master Data Management and Business - Where the Two Meet **Track 3:** eTMF Interchange: The Cross-Roads Between Sponsor, CRO, and Vendors **Track 4:** The Future of Electronic Submissions
3:00-3:30PM	Refreshments, Exhibits, and Networking Break
3:30-5:00PM	**Session 4:** Breakout Sessions **Track 1:** Regulatory Thought Leadership on the Industry-Wide Scale **Track 2:** Use of Regulatory Data **Track 3:** Digital Drivers: Reinventing and Accelerating Clinical Trials **Track 4:** Publishing Pet Peeves and Practical Pointers
5:30-7:30PM	**Dinner on the Town:** Wait, Wait, Don't Tell Me! Your Regulatory War Stories
DAY THREE | WEDNESDAY, FEBRUARY 8	
7:30AM-5:00PM	Registration
7:30-8:30AM	Continental Breakfast, Exhibits, and Networking Break
8:30-10:00AM	**Session 5:** Breakout Sessions **Track 1:** Registration Management **Track 2:** IDMP Technology Focus **Track 3:** Managing eTMF System Access: How SAFE-BioPharma Certified Credentials Enable Secure Identity Management **Track 4:** Following the Sun: Regulatory Ops in Global Organization
10:00-10:30AM	Refreshments, Exhibits, and Networking Break
10:30AM-12:00PM	**Session 6:** Breakout Sessions **Track 1:** Save $60 Million – The Easy Way **Track 2:** Structured Content Management **Track 3:** Leveraging Technology to Create a Seamless Process Between Collaboration and Official Repositories Such as ETMF, EDMS, and RIM **Track 4:** IND eCTDs: Transition from FDA Appreciating to Requiring eCTD INDs
12:00-1:30PM	Luncheon, Networking, and Exhibits
1:30-3:00PM	**Session 7:** FDA Electronic Submissions Update
3:00-3:15PM	Refreshments, Exhibits, and Networking Break
3:15-4:45PM	**Closing Plenary:** Ask the FDA
4:45-5:00PM	**Closing Remarks**

Learning objectives

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

- Describe organizational processes and governance to ensure integrity, quality, and security of records
- Discuss how to break down silos for end-to-end processing of regulatory information as it relates to EDM and ERS
- Envision the scope and future of IDMP with respect to systems, process, standards, and master data
- Discuss organizational implications related to increasing electronic interactions with stakeholders
- Explain ways to implement processes to improve communication of regulatory expectations and communications
- Interpret global health authority regulations and guidances for systems and processes
- Describe how to map eTMF capabilities to support clinical site inspections
- Identify techniques to create efficiencies in the overall end-to-end process of document and submission management

Continuing Education Credit

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As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer the up to 2.5 CEUs. Participants must attend the entire forum in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

Regulatory Content and Submissions Primer..... 0.6 CEUs
Short Course 1.....0.3 CEUs
Short Course 2 .....0.3 CEUs
Forum.....1.6 CEUs

If you would like to receive a statement of credit, you must attend the forum (Primer and/or Short Course(s), if applicable), complete the "Verification of Attendance" form located in your meeting folder, turn in your form to the registration desk at the conclusion of the forum, and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on **Wednesday, February 22, 2017.**

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SUNDAY, FEBRUARY 5

9:30-10:30AM — **Primer Registration**

10:00AM–5:00PM

Coffee break will be served.

***Please note: Lunch is not provided by DIA.*

Regulatory Content and Submissions Primer

Tracking Content from Conception to Interment

Instructors

Betsy Fallen, RN
Consultant
BAFallen Consulting LLC

Dan Orfe, MS
President and CEO
Regulatory eSubmissions, LLC

This activity is designed to meet the needs of individuals who are either new to biopharmaceutical-based document management, information management, and regulatory submission publishing for authorities, or already experienced in one area, looking to gain a broader understanding of the full spectrum of the regulatory submission, information, and document management arena. Understanding the various steps throughout the life of document components from their conception, publishing into a submission, delivery to regulatory agencies, and ultimate company archival, will yield "aha" moments for the attendees of this offering from all functions along the life-span of content.

Learning Objectives

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

- Describe the benefits of understanding the complete life phases of regulatory content and the impact that decisions in one place along the life path will have at other stages of the process
- Identify key drivers within each of the life phases and potential pros and cons associated with solution choices
- Recognize the needs of the other organizations involved within the life span of the regulatory content and fairly assess their concerns in process and procedure decision-making
- Comprehend the newly released regulations, guidelines, and industry best practices and gain an awareness of their impact

Note: At the conclusion of each section the attendees will be provided a list of the sessions at the forum, which can provide additional depth for that specific topic. Relevant DIA Communities will be identified at the conclusion of each session of the offering.

MONDAY, FEBRUARY 6

7:30AM-5:30PM — **Registration**

8:30AM-12:00PM

Coffee break will be served.

***Please note: Lunch is not provided by DIA.*

Short Course 1

Global Identification of Medicinal Products (IDMP): Applied Principles for Practical Implementation to Support Regulatory Compliance and Alignment with Existing Business Processes

Instructors

Vada A. Perkins, BSN, MS, MSc, RN
Founder and Managing Principal
IDENTIFICA, LLC

Michiel Stam
Regulatory Information Scientist
eCTDconsultancy B.V.,
Netherlands

Rebecca Freeman
Operating Platforms, Regulatory Affairs
Astellas

Brooke Casselberry, MS, RAC
Director
Paragon Solutions

This short course is aimed at providing stakeholders with a foundational knowledge of IDMP to support practical implementation within their organizations. More specifically, the course will demonstrate applied strategies and technologies used for the implementation, address practical issues within the regulatory landscape, and show relationships with established processes such as eCTD, XEVMPD, and SPL.

Learning Objectives

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

- Provide an introduction and overview on ISO IDMP
- Review the ongoing international standardization work on IDMP
- Recognize the main features of the five IDMP standards and corresponding technical specifications
- Prepare all relevant stakeholders for the implementation of the new IDMP standards with respect to their business requirements and RIM systems
- Define the relationships and dependencies between IDMP and existing processes like eCTD, XEVMPD, and SPL
- Share best practices for information management
- Review state-of-the-art technologies to support information management

MONDAY, FEBRUARY 6

8:30AM-12:00PM

Coffee break will be served.

***Please note: Lunch is not provided by DIA.*

Short Course 2

Achieving Regulatory Operations Excellence Through Outsourcing

Instructors

Steven Clark
Director
Amgen

Meghan Mendoza, MBA, RAC
Senior Manager, Regulatory Operations
Amgen Inc.

Hermineh Aghanian
Senior Manager, Regulatory Operations
Amgen Inc

Led by pharmaceutical industry regulatory operations staff, the course will take you through a journey to an optimized outsourcing model in Regulatory Operations and will cover outsourcing opportunities in both publishing and regulatory information management.

We will review case studies and industry experience on what a successful outsourcing project may look like, including transparency into what has worked well and potential hurdles.

Learning Objectives

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

- Describe industry standards for determination of business need and subsequent requirements for sourcing (i.e. short term contracting, external service provider, etc.)
- Explain Mechanisms for determination of process maturity for outsourcing
- Discuss industry trends on scope of Regulatory Operations outsourced processes
- Describe decision criteria for outsourcing partner
- Outline baseline governance and communication processes
- Discuss the criticality of quality and performance metrics

1:00-1:25PM

Welcome, Opening Remarks, and Volunteer Award

Session Co-Chairs

Sudip Parikh, PhD
Senior Vice President and Managing Director
DIA Americas

Sarah Powell, RAC
President
Powell Regulatory Services

Jamie Marie Toth, MS
Director TMF Operations
Daiichi Sankyo, Inc.

Michelle L. Charles, MPH
Manager, Regulatory Implementation
PAREXEL International

Virginia Hussong
Data Standards Program Manager, OD, BSS
CBER, FDA

1:25-2:00PM

Keynote Presentation

Perspective on PDUFA VI and the Strategic Vision for CDER Going into the Next PDUFA Cycle

Keynote Speaker

Theresa Mullin, PhD
Director, Office of Strategic Programs
CDER, FDA

MONDAY, FEBRUARY 6

2:00-3:30PM

Plenary Session 1
FDA – PDUFA V Update

Session Chair
Ronald Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program,
Office of Strategic Programs
CDER, FDA

REMS
Adam Kroetsch
Operations Research Analyst,
OMPT, OSP, OPSA, ES
CDER, FDA

Biomarkers and Adaptive Trial Design
Aloka Chakravarty, PhD
Director, Division of Biometrics VII, Office of
Biostatistics, Office of Translational Science
CDER, FDA

Sentinel
Aaron Niman, MPH
Research Officer, Office of Surveillance
and Epidemiology, OMPT, RSS
CDER, FDA

PDUFA VI Informatics Preview
Virginia Hussong
Data Standards Program Manager, OD, BSS
CBER, FDA

3:30-4:00PM

Refreshments, Exhibits, and Networking Break

4:00-5:30PM

Plenary Session 2
Other Regions Update

Session Chair
Michiel Stam
Regulatory Information Scientist
eCTDconsultancy B.V., Netherlands

Comparison of eSubmissions by Regions, Updates, and Future Outlook
Akira Yamaguchi, MBA
Vice President Product Development
LORENZ Life Sciences Group

Heath Products and Food Branch (HPFB) IT Plan – Regional Update
Vikesh Srivastava, MS, MSc
Associate Director, Business
Informatics Division
Health Canada

5:30-6:30PM

Networking Reception and Exhibits

TUESDAY, FEBRUARY 7

7:30AM-5:00PM	**Registration**
7:30-8:30AM	**Continental Breakfast, Exhibits, and Networking Break**
8:30-10:00AM	**Session 1** FDA Data Standards and Regulatory Compliance Update **Session Chair** **Ronald Fitzmartin, PhD, MBA** Senior Advisor, Data Standards Program, Office of Strategic Programs CDER, FDA **Data Standards** **Mary Ann Slack** Deputy Director, Office of Strategic Programs CDER, FDA **Compliance- CDER** **Jean Mulinde, MD** Senior Policy Advisor, Office of Scientific Investigations OC, OSI, DCCE CDER, FDA **Compliance- CBER** **Bhanumathi Kannan, MSc** Consumer Safety Officer, Office of Compliance and Biologics Quality CBER, FDA
10:00-10:30AM	**Refreshments, Exhibits, and Networking Break**

TUESDAY, FEBRUARY 7

10:30AM-12:00PM | **Session 2:** Breakout Sessions

Track 1: RIM Business

Business Impacts to IDMP

Session Chair
Vada A. Perkins, BSN, MS, MSc, RN
Founder and Managing Principal
IDENTIFICA, LLC

Explore some of the opportunities and challenges of addressing IDMP integration within the pharmaceutical environment. Discussion topics include collaborative processes and principles for successful assessment and implementation of an IDMP program, along with a case-study from a company perspective to provide lessons learned in their approach to IDMP to deliver business improvements.

Collaborative Processes for a Successful IDMP Program

Susan Metz
Principal Consultant
PAREXEL International

IDMP Readiness – Status Based on Pharmaceutical Company Assessments in Europe

Thomas Hornbaek Svendsen, MS
Principal Consultant
NNIT A/S, Denmark

Sponsor Perspective Case Study

Christian A. Buckley, MBA, RAC
Associate Director, Regulatory Affairs
Astellas

Track 2: RIM Technology

Regulatory Analytics

Session Chair
V. "Bala" Balasubramanian, PhD, MBA
President and CEO
Cabeus. Inc.

During this session, we will introduce the topic of Regulatory Analytics and explore how rich strategic insights are possible with the vast amounts of data being collected as part of RIM and IDMP initiatives. With a panel of three speakers from the industry and vendors, we will have a rich discussion with case studies on how organizations can leverage RIM and IDMP data to go beyond compliance and achieve operational excellence and strategic advantage.

Regulatory Analytics: Strategic Insights Beyond Compliance and Efficiency

V. "Bala" Balasubramanian, PhD, MBA
President and CEO
Cabeus. Inc.

Gaining Intelligence from Regulatory Information Management via Utilizing Medicinal Product Analytics

Olaf Schoepke, PhD
Director of Strategic Development
Samarind Limited, United Kingdom

Regulatory Analytics: Asking the Right Questions to Yield Real and Sustainable Business Value

Thomas Denaro
Director, Regulatory Global Systems
BD Biosciences

Track 3: EDM

EDMS in the 21st Century, Better, Broader, More Flexible

Session Chair
Dimitri Stamadtiadis, PhD, MBA
Founder and CEO
MAIA Consulting, Switzerland

Those from smaller pharma companies, consultants, and vendors will get direct benefit from learning about this free-to-use packaged EDMS implementation protocol developed as a DIA initiative "by the industry, for the industry."

Pocket EDMS a DIA Initiative for Small and Medium Pharma and Biotech

Dimitri Stamadtiadis, PhD, MBA
Founder and CEO
MAIA Consulting, Switzerland

The Future of DMS Design and User Experience

Richard London
Project Manager
GlobalSubmit

Bringing TMF and eCTD Together: Is Your TMF Submission Ready?

Patricia Santos-Serrao, RAC
Director of Clinical and Regulatory Solutions for Life Sciences
MasterControl, Inc.

Track 4: ERS

Ad/Promo

Session Chair
Thomas J. Noto
Senior Director, Regulatory Operations
Lexicon Pharmaceuticals

This session will focus on the changes to the eCTD that come with the new U.S. Module 1 specification (DTD v.3.3) and key considerations for establishing an end-to-end process for ad promo eCTD submissions. The session will also highlight real-world tips and tricks for transitioning to an efficient electronic 2253 submission workflow.

Submitting Ad Promo in eCTD: Tips and Tricks

Sandra A. Krogulski
Regulatory Operations Manager
Accenture Accelerated

Lessons Learned for First Time OPDP Submissions, Promotional Material, and Labeling

Thomas Christensen, RAC
Senior Regulatory Affairs Manager
SynteractHCR

Transitioning to eCTD for Ad Promo Submissions

William P. Liston
Regulatory Associate, Submissions Specialist
Pfizer Inc.

Key Considerations for Establishing an End-to-End Process for FDA M1 AdPromo eCTD Submissions Process Prior to Implementation

Olga Alfieri, MBA, RAC
Director
Eisai Product Creation Systems

12:00-1:30PM | **Luncheon, Networking, and Exhibits**

TUESDAY, FEBRUARY 7

1:30–3:00PM | **Session 3:** Breakout Sessions

Track 1: RIM Business

What is RIM?

Session Chair
Sarah Powell, RAC
President
Powell Regulatory Services

RIM can mean different things in different organizations. This session will explore the results of a recent industry survey regarding RIM and how to increase the value of the program within your company.

Good Regulatory Information Management Practices

Patti Palm-Principe, MS
Director of Client Services
Cabeus, Inc

Benefits and Challenges of a Global RIM Organization

Angela Shain
Manager, Regulatory Operations
Amgen

Increasing the Business Value of Your RIM Program: Strategy, Measures, and Practices

Steve Gens, MS
Managing Partner
Gens and Associates Inc.

Track 2: RIM Technology

Master Data Management and Business - Where the Two Meet

Session Chair
Brooke Casselberry MS, RAC
Director
Paragon Solutions

Hear approaches, strategies, and effects of utilizing Master Data Management (driven by IDMP), to improve product master management, life cycle management, and the business impacts from these changes. Listen to the case studies on how a top five pharmaceutical organization has approached master data management, IDMP, and the business impacts these initiatives have had across the functional areas.

Master Data Management: Leveraging Commercial Best Practices in a Regulatory Landscape

Kevin Remphrey
Director, Information Technology
Merck & Co, Inc.

Data Governance, Entity Extraction, and Structured Authoring: The Triple Core of IDMP Readiness

Jan Voskuil
CEO
Taxonic, Netherlands

MDM and Business Readiness - Preparing Your Business for Transformational Change

Donna Yosua
Director, Regulatory Affairs, Master Data Management and Information Governance
Merck

Track 3: EDM

eTMF Interchange: The Cross-Roads Between Sponsor, CRO, and Vendors

Session Chair
Jamie Marie Toth, MS
Director TMF Operations
Daiichi Sankyo, Inc.

This session is aimed at discussing:
- Hot topics in TMF for 2017
- Inclusivity: TMF requirements and challenges faced in Sponsor, CRO, and Vendor partnerships
- Flexibility: When and if interchange is necessary
- Case Study: Experience highlighting interoperability

There will also be a interactive discussion on the day-to-day challenges of managing multiple eTMF platforms.

TMF Topics – What's HOT This Year and Why YOU Should Care!

Lisa D. Mulcahy
Owner, Principal Consultant
Mulcahy Consulting, LLC.

Sponsor/CRO Case Study on Working Together and Overcoming Challenges

Jamie Marie Toth, MS
Head of TMF Operations
Daiichi Sankyo

Gareth Sully, PhD
Vice President, Site Startup and Regulatory
Inc Research, Inc., United Kingdom

Interoperability Case Study

Paul Fenton, MBA, MS
President and CEO
Montrium, Canada

Track 4: ERS

The Future of Electronic Submissions

Session Chair
Michelle L. Charles, MPH
Manager, Regulatory Implementation
PAREXEL International

This session will cover some of the future changes in electronic submissions including RPS, eCTD 4.0, and the future use of metadata associated with electronic regulatory submissions.

Next Stop - RPS (eCTD v4.0)

Robert Connelly, MBA
Product Manager
GlobalSubmit

eCTD v4.0: Field Testing the Implementation Guidelines

Jared Lantzy, PMP
Manager, Global Regulatory Agencies and Processes
LORENZ Life Sciences Group

See the Unseen: Across and Within Applications

Hans van Bruggen, MSc
Regulatory Affairs Scientist
eCTDconsultancy B.V., Netherlands

3:00-3:30PM | **Refreshments, Exhibits, and Refreshment Break**

TUESDAY, FEBRUARY 7

3:30–5:00PM | **Session 4:** Breakout Sessions

Track 1: RIM Business

Regulatory Thought Leadership on the Industry-Wide Scale: Outcomes, Updates, and Opportunities for Participation

Session Chair
Jake Doran
Founder, Managing Director
List Innovations, LLC

This session will explore a few of the industry groups that have been formed over the years to help us as an industry work together to solve common regulatory problems. Hear from the HeRO Forum, a consortium of Heads of RegOps from top 10 pharma; as well as the DIA RIM Working Group, a group of industry professionals working to identify common elements of RIM and define industry standards accordingly. We will also explore an update from the IRISS Forum.

Making Sense of RIM – Driving Consistent Understanding of Terms, Processes, and Metrics

Peter Terbeek
Senior Director, Publishing, and Submission
Astellas

Sheila Mahoney-Jewels, MBA
Business Development
CluePoints

Collaboration for Implementation of Standards: How the IRISS Forum Brings Value

Jim Nichols
President and CEO,
The IRISS Forum; Vice President Life Sciences North America;
Cunesoft

HeRO Forum – Industry Collaboration Addressing the Evolving Challenges of Regulatory Affairs Organizations

Bernie Coney, MA
Head of RIM Advisory Services
Kinapse Inc.

Track 2: RIM Technology

Use of Regulatory Data

Session Chair
Steven Clark
Director
Amgen

This session will provide three case studies to illustrate the efficiency benefits of linking RIM with submission documents. Case studies will include: managing health authority correspondence and commitments, submission planning, and product registration management.

Connecting Submission Documents and Regulatory Data to Bring True Efficiency to Regulatory Processess

Jim Reilly
Director, Vault RIM (Regulatory)
Veeva Systems

Unifying RIM: End-to-End Submission Development

Sandra Herder
Director, Regulatory Operations
The Medicines Company

Dear Excel, I met Someone Better to Manage my HA Interactions and Correspondences. We're Breaking Up! Best of Luck, Reg Ops

Ronald Hernando, MBA
Director, Regulatory Operations
MacroGenics, Inc.

Track 3: EDM

Digital Drivers: Reinventing and Accelerating Clinical Trials

Session Chair
Ellen Reilly, MBA
Vice President
DocuSign

This session will:
- Explore how technology has advanced to address critical problems in clinical trial site on-boarding and recruitment while meeting heightened expectations from an empowered patient population
- Discuss the challenges for using electronic signature for patient consent forms and clinical trials documentation
- Identify best practices around mobility, language, and governance around adoption of electronic signatures and clinical trials documentation in the cloud
- Explain the regulatory and audit requirements, record retention, and adoption issues globally in moving to fully digital solution

Digital Technology IT Compliance Considerations

Elizabeth McLellan
Global Projects Quality
Astra Zeneca

Signature Bottlenecks in Clinical Trials

Beth Robinson, RN, MSHS
Executive Director, Clinical Compliance and Operations
Horizon Pharma

Maximizing Clinical Trials Through e-Signatures

Jenny Lester, MPH, CCRP
Senior Research Project Advisor
Cedars-Sinai Women's Cancer Program

Track 4: ERS

Publishing Pet Peeves and Practical Pointers

Session Chair
Stacy Tegan
Manager, Regulatory Technology Consulting
Accenture Accelerated R&D Services

Electronic submissions have been standard practice for many years, but that does not mean submission preparation is standard! This will be an interactive, discussion-based session to go beyond slide presentations and into the nitty gritty, real-world challenges faced in publishing.

Hear from "been there done that" experts. Bring questions for our panelists representing big pharma, small biotech, and outsource publishing vendor experience.

Olga Alfieri, MBA, RAC
Director
Eisai Product Creation Systems

Successful Practices for Regulatory Collaborations

Jillian E. Carinci, MS
Submission Manager, Global Regulatory Services
Accenture Accelerated R&D Services

Nancy Pire-Smerkanich, DrSc, MS
Assistant Professor, Clinical Pharmacy, Educational Liaison, Instructor, ICRS
University of Southern California

5:30PM | **Dinner on the Town:** Wait, Wait, Don't Tell Me! Your Regulatory War Stories
(Dinner cost is on your own)

Moderated by Matt Neal and Sheila Mahoney-Jewels, hear individuals briefly share their regulatory war stories. Take a break from rigorous educational content while still ensuring time well spent. This night is designed to ensure that you leave in good humor, and feeling much better about your own regulatory histories.

WEDNESDAY, FEBRUARY 8

7:30AM-5:00PM	**Registration**
7:30-8:30AM	**Continental Breakfast, Exhibits, and Networking**
8:30-10:00AM	**Session 5:** Breakout Sessions

Track 1: RIM Business

Registration Management

Session Chair
Sarah Powell, RAC
President
Powell Regulatory Services

Registration Management in Medical Device organizations create challenges that are different that those in a traditional pharmaceutical company. This session will focus on these challenges and solutions that can be applied.

ID of Medical Devices in Registration Management Systems

Karin Sailor
Consultant
SRO, Inc.

Regulatory Information Management System A Strategic Asset

Lana Holder, MS
Senior Project Manager
Life Science Solutions Transperfect

Innovative Approach to Aligning Two Disparate Processes Within a Challenging Regulatory Framework

Kanchana Iyer, MS
Senior Regulatory Affairs Specialist
PENTAX Medical

Track 2: RIM Technology

IDMP Technology Focus

Session Chair
Captain Vada A. Perkins, BSN, MS, MSc, RN
Founder and Managing Principal
IDENTIFICA, LLC

Explore the alignment of IDMP and existing standards and processes within the regulatory landscape: (e) CTD maintenance, ICSR, and CDISC standards respectively. Discussion topics include how companies can leverage change control and regulatory impact analyses outcome for IDMP maintenance; the structure of the ISO/HL7 Individual Case Safety Report specification, how it supports multiple surveillance programs, improves data quality and reconciles pre- and post-market safety data; and the upcoming B2E project that will bring CDISC standards into compliance with IDMP, including protocol and results registration and how IDMP extends the substance and product information within the SEND and SDTM standards.

IDMP Driven Revisit of Change Control and Impact on EU Variation Classification Document

Michiel Stam
Regulatory Information Scientist
eCTDconsultancy B.V., Netherlands

A Case Study in ICSR and IDMP Integration: Electronic Adverse Event Reporting Systems

Lise Stevens
Prinicpal Owner
Saturn Services LLC

CDISC Beginning to End Standards Harmonized with IDMP and Extending CTR and Protocol

Paul Houston
CDISC Europe – Head of Operations
CDISC, France

Track 3: EDM

Managing eTMF System Access: How SAFE-BioPharma Certified Credentials Enable Secure Identity Management

Session Chair
Cindy Chiu
Director, Regulatory Affairs Operations and Quality Management
Merck & Co., Inc.

One of the largest pharmaceutical companies in the world has been a leader in the adoption and use of SAFE-BioPharma certified credentials for digital signing and identity management. After adopting a cloud-based eTMF, security and access through robust identity management was critical to maintaining protection of proprietary and sensitive documentation. The use of the existing credentials for company employees was an obvious transition to develop the use case for accessing the eTMF.

Overview of the Identity Authentication Credential: What Does it Mean for Security in the Cloud?

Betsy Fallen, RN
Consultant
BAFallen Consulting LLC

Process of Adopting the Use of SAFE-BioPharma Credentials and How the Management of Those Credentials is Executed to be Efficient, Compliant, and Timely

Cathy Carfagno
Associate Director Merck IT
Merck & Co, Inc.

eTMF Platform Identity Management

Todd Tullis
Director, Product Management
Veeva Systems

Track 4: ERS

Following the Sun: Regulatory Ops in Global Organizations

Session Chair
Christian A. Buckley, MBA, RAC
Associate Director, Regulatory Affairs
Astellas

This session aims to cover:
- Challenges for cooperation among a worldwide workforce
- Data quality framework and options to embed continuous data quality control
- Regulatory process owner – continuous improvement beyond compliance
- Submissions needing project leaders, not super heroes
- Off-shoring of regulatory operations as an effective solution to increasing operational demands

From Regulatory Operations to Integrated Regulatory Information and Submission Management

Timm Pauli
Senior Director, eSubmission Services, Head of Regulatory Operations
PharmaLex GmbH, Germany

Cross-Continent Competence: Successes and Struggles with Offshore Regulatory Operations Support

Mary Anne Potok
Technical Manager, Regulatory Operations
MMS Holdings, Inc.

Global Work Share – A Case-Study of Utilizing Workshare Between Groups to Balance Workload

Jennifer Costello
Manager, Global Regulatory Operations
Teva Pharmaceuticals

WEDNESDAY, FEBRUARY 8

10:00-10:30AM | **Refreshments, Exhibits, and Networking Break**

10:30AM-12:00PM | **Session 6:** Breakout Sessions

Track 1: RIM Business

Save $60 Million – The Easy Way

Session Chair
Brooke Casselberry, MS, RAC
Director
Paragon Solutions

During this session Matt, Karin, and Brooke will dive into the Procurement life cycle in a laugh-out-loud session identifying the weaknesses and ineffective manners in which RFP's have been adopted in our industry.

Matthew Neal, MA
Senior Director Product Management
PAREXEL

Brooke Casselberry, MS, RAC
Director
Paragon Solutions

Karin Schneider, MLIS, MS
Document Management Enablement Head
Janssen Pharmaceuticals, Inc.

Track 2: RIM Technology

Structured Content Management

Session Chair
Michiel Stam
Regulatory Information Scientist
eCTDconsultancy B.V., Netherlands

This session will focus on several business cases for structured contents management and the importance of standardized or structured processes, utilizing structured data.

Structured Information and Process Management Reduce Drug Development by $250 Million

Jack Yeager
CEO
Sylogent

DOCX; Ability to Channel Regulatory Information from Company Databases Through Documents to Agency Databases

Hans van Bruggen, MSc
Regulatory Affairs Scientist
eCTDconsultancy B.V., Netherlands

A Grand Design

Mark Cottingham
Senior Business Lead in Operational Business Excellence Group of Pharma Technical
F. Hoffmann-La Roche Ltd., Switzerland

Track 3: EDM

Leveraging Technology to Create a Seamless Process Between Collaboration and Official Repositories Such as ETMF, EDMS, and RIM

Session Chair
Ty Molchany
Principal Consultant
Paragon Solutions

The necessary value of official archives such as eTMF and RIM are recognized by all biopharma companies. However they all are faced with the challenge of how to transition from "unofficial" collaborative authoring and document sharing environments to the official systems, which end up being the system of record for a filing. This presentation attempts to present a unique approach that was applied successfully to connect these disparate systems, each with a different use case, but connected to support the drug development process.

Ty Molchany
Principal Consultant
Paragon Solutions

Lindsey Hart
Senior CMC Regulatory Sciences Specialist, CMC Regulatory and Process Sciences
Regeneron

Track 4: ERS

IND eCTDs: Transition from FDA Appreciating to Requiring eCTD INDs - Paper and Procrastination are No Longer Options

Session Chair
Dan Orfe, MS
President and CEO
Regulatory eSubmissions, LLC

This session will outline the various strategies that emerging Pharmaceutical and Biotechnology companies can employ for production and delivery of their IND eCTDs. The pros and cons associated with those strategies will be explored.

IND eCTDs Production and Delivery Strategies from a Low Volume Emerging Biotechnology Company

Emily Hall
Senior Manager Regulatory Operations
Acadia Pharmaceuticals

IND eCTDs Production and Delivery Strategies from a High Volume Organization

Kevin Tompkins, MBA
Director, Head of North America, Global Submissions Management
Teva Pharmaceuticals, Inc.

IND eCTDs Production and Delivery Strategies from aneCTD Publishing Services Provider

Dan Offringa
Senior Prinicipal Consultant
Pharmaceutical eConsulting

IND eCTDs Production and Delivery Strategies from an Integrated Regulatory Science and Solutions Provider

Gina Ross
Managing Director, Regulatory Submissions and Administrative Operations, Regulatory Sciences- Speciality Solutions
Cardinal Health

12:00-1:30PM | **Luncheon, Networking, and Exhibits**

WEDNESDAY, FEBRUARY 8

1:30-3:00PM

Session 7
FDA Electronic Submissions Update

Session Chair
Virginia Hussong
Data Standards Program Manager,
OD, BSS
CBER, FDA

General Updates

Jonathan Resnick
Project Management Officer, OMPT
CDER, FDA

eCTD 4 Update

Mark A. Gray
Senior Project Manager, BSS
CBER, FDA

Paper Submissions and Rejection

Mia Prather
Supervisory Program Analyst
CDER, FDA

3:00-3:15PM

Refreshments, Exhibits, and Networking

3:15 –4:45PM

Closing Plenary
Ask The FDA

Session Chair
Mark A. Gray
Senior Projct Manager, BSS
CBER, FDA

Panelists

Virginia Hussong
Data Standards Program Manager,
OD, BSS
CBER, FDA

Ronald Fitzmartin, PhD, MBA
Senior Advisor, Data Standards Program,
Office of Strategic Programs
CDER, FDA

Jonathan Resnick
Project Management Officer
CDER, FDA

Mia Prather
Supervisory Program Analyst
CDER, FDA

Mary Ann Slack
Deputy Director, Office of
Strategic Programs
CDER, FDA

Jean Mulinde, MD
Medical Officer,
OC, OSI, DCCE
CDER, FDA

4:45-5:00PM

Closing Remarks

Session Co-Chairs

Sarah Powell, RAC
President
Powell Regulatory Services

Jamie Marie Toth, MS
Director TMF Operations
Daiichi Sankyo, Inc.

Michelle L. Charles, MPH
Manager, Regulatory Implementation
PAREXEL International

Virginia Hussong
Data Standards Program Manager,
OD, BSS
CBER, FDA

5:00PM

Forum Adjourned