Regulatory Submissions, Information, and Document Management Forum

EDM, ERS & RIM

Tutorial: February 8 | Forum: February 8-10 | Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

PROGRAM CO-CHAIRS:

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

Betsy Fallen, RN
Consultant
BAFallen Consulting, LLC

Sarah Powell, RAC
President
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Accenture Accelerated R&D Services

Overview

In recent years, industry as a whole has been converging towards looking at regulatory as an end-to-end process. Document management, publishing, and technical regulatory requirements are all subsets of Regulatory Information Management (RIM) at its broadest definition. This course of managing documents starts at the creation of that document as part of the clinical trial.

The forum will provide you with opportunities to:

- Discuss emerging operational standards, best practices and the processes for submission creation, and maximum use of regulatory information.
- Explore information generated along the drug development continuum life cycle and alignment to ever evolving regulatory and electronic standards.
- Interact and share experiences related to processes for obtaining and managing regulatory information organizational impact as well as gain a greater understanding of key issues shaping the global regulatory environment.
- Focus on standards related to submission of regulatory information, the tools necessary to effectively manage the information, and associated implementation experiences and lessons learned.

Highlights

KEYNOTE SPEAKER:

Brad Wintermute
Deputy CIO - Director Office of Technology & Delivery
Office of Information Management
FDA

- Standards and necessary tools for effective management of regulatory information
- "Ask the Regulators" session with global regulators
- Exhibit Hall and numerous networking opportunities
- IDMP tutorial offering in the morning of Monday, February 8

Message from Program Co-Chairs

On behalf of the Program Committee and DIA Board of Directors, we are pleased to invite you to DIA's forum on Regulatory Submissions, Information, and Document Management 2016 (RSIDM). Last May for the first time, the EDM and ERS combined with RIM for the eRegulatory and Intelligence Annual Conference. Due to its success, we are pleased to offer this new combined forum of related topics moving forward. Increating this program, our goal has been to develop a comprehensive program that would inform and educate on the current hot issues and help identify the next ones to come. In response to the Call for Abstracts, we received a record number of proposals from which we selected the most exciting and invited the experts from regulatory authorities, sponsors, vendors, and standards organizations. This year, we're bringing back a keynote speaker and the geographical proximity to Washington, DC offers a unique opportunity for a FDA leader to present. Our keynote will share insights and updates on FDA's policy related to the forum topics of global submissions, IDMP implementation, cloud based EDMS and RIM, plus more. Additionally, we are offering a tutorial for the hot topic of IDMP as well as sessions covering a broad scope of information across the RIM, ERS, and EDM spaces from key experts in our industry today.

As technology has driven 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.

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Powell Regulatory Service

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Schedule At-A-Glance

Track 1 – RIM Business | Track 2 - ERS | Track 3 – EDM | Track 4 – RIM Technology

TUTORIAL AND DAY ONE | MONDAY, FEBRUARY 8

7:30 AM–5:15 PM	Registration
8:30 AM–12:00 PM	Tutorial – IDMP: "Start Early, Finish Strong"
1:00–1:10 PM	Welcome and Opening Remarks
1:10–1:45 PM	Keynote Address
1:45–3:15 PM	Plenary Session 1 – FDA Update
3:15–3:45 PM	Refreshment Break, Exhibits, and Networking
3:45–5:15 PM	Plenary Session 2 – Other Regions Update
5:15–6:15 PM	Networking Reception and Exhibits

DAY TWO | TUESDAY, FEBRUARY 9

7:30 AM–5:00 PM	Registration
7:30–8:30 AM	Continental Breakfast, Exhibits, and Networking
8:30–10:00 AM	Session 1 Track 1 – How Successful are RIM Solutions Anyway and how Does my Company Measure Up?
	Session 1 Track 2 – M1: Ad/Promo
	Session 1 Track 3 – Mission Possible: How TransCelerate is Improving the Protocol Template and Paving the way for the Digital Protocol
	Session 1 Track 4 – Is the Timing Right for RIM in the Cloud? Examining Capabilities and Where Industry is Headed
10:00–10:30 AM	Refreshment Break, Exhibits, and Networking
10:30 AM–12:00 PM	Session 2 Track 1 – Working With Affiliates
	Session 2 Track 2 – Optimizing Global Submissions
	Session 2 Track 3 – Cloud EDMS Selection, Implementation, and Use Interactive Discussion
	Session 2 Track 4 – The Strategic Challenges of Preparing for IDMP Implementation
12:00–1:30 PM	Luncheon, Exhibits, and Networking
1:30–3:00 PM	Session 3 Track 1 – Next Generation Regulatory Operations
	Session 3 Track 2 – ERS Diverse Processes
	Session 3 Track 3 – Update on Status of PhUSE – Inspection Site Selection Standard Data Elements Working Group
	Session 3 Track 4 – An Agile Approach Towards Implementing IDMP Technologies
3:00–3:30 PM	Refreshment Break, Exhibits, and Networking
3:30–5:00 PM	Session 4 Track 1 – DIA Regulatory Affairs Community Update
	Session 4 Track 2 – eCTD v4/RPS; Moving Towards Implementation
	Session 4 Track 3 – Technology Enablers to Optimize EDM
	Session 4 Track 4 – Structured Authoring – New Paradigm for Data Driven Authoring for Life Sciences

DAY THREE | WEDNESDAY, FEBRUARY 10

7:30 AM–5:15 PM	Registration
7:30–8:30 AM	Continental Breakfast, Exhibits, and Networking
8:30–10:00 AM	Session 5 Track 1 – Current Trends and Approaches to Managing Labeling Globally
	Session 5 Track 2 – Submission Production Potpourri
	Session 5 Track 3 – Connection With CROs
	Session 5 Track 4 – The Technical Challenges and Opportunities of Implementing IDMP Solutions
10:00–10:30 AM	Refreshment Break, Exhibits, and Networking
10:30 AM–12:00 PM	Session 6 Track 1 – RIM Working Group: Thought Leadership on a Complex Issue
	Session 6 Track 2 – Reg Ops Optimization/Lessons Learned
	Session 6 Track 3 – Trial Master File 2.0…What's Next?
	Session 6 Track 4 – Technology Considerations for Next Generation RIM Solutions
12:00–1:30 PM	Luncheon, Exhibits, and Networking
1:30–3:00 PM	Session 7 Track 1 – Regulatory Intelligence and Social Environments — Where the Two Collide
	Session 7 Track 2 – Touchdown! or Fumble? The Medical Writing-to-Publishing Handoff
	Session 7 Track 3 – Using the New DIA GMP Quality Systems and Labeling Reference Model
	Session 7 Track 4 – Trends and Opportunities for Master Data Management
3:00–3:30 PM	Refreshment Break and Networking
3:30–5:00 PM	Closing Plenary – "Ask The Regulators" Session
5:00–5:15 PM	Closing Remarks

Learning Objectives

At the conclusion of this forum, attendees will 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 reporting of regulatory expectations and communications
- Interpret global health authority regulations and guidance's 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

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Continuing Education Credit Allocation

Tutorial: "Start Early, Finish Strong": IACET: .3 CEUs
Forum: IACET: 1.6 CEUs

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This program is part of DIA's Certificate Program and is awarded the following:

- Regulatory Affairs Certificate Program: 8 Elective Units

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MONDAY, FEBRUARY 8

7:30 AM–5:15 PM Registration

8:30AM–12:00 PM

Tutorial – IDMP: "Start Early, Finish Strong"

Instructors:

Hans van Bruggen, MSc
eCTDconsultancy B.V.

Peter Terbeek
Director, Regulatory Affairs
Astellas

Jan Voskuil
CEO
Taxonic

This tutorial will cover the practical aspects of Identification of Medicinal Products (IDMP) implementation and the impact on the business processes and software tools. It is designed to be an educational environment where content focuses on actively engaging the topics presented.

The EU will apply a staged approach for IDMP implementation. Do not interpret this as postponed activity, but rather as an extension of the implementation time required. The impact of IDMP will be significant; as will the gain in efficiency, transparency, and ability to identify corrective and preventive actions (CAPAs). This tutorial will cover the practical aspects of cross-disciplinary IDMP implementation; the data sources and quality; business processes for IDMP baseline and maintenance; and need for software tools and infrastructure.

Learning Objectives:

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

- Discuss various ways to approach IDMP implementation
- Describe the opportunities and challenges in submitting data to ensure compliance with the global standards
- Examine tools, common terminology, and impact the new standards will have for pharmaceutical companies

1:00–1:10 PM

Welcome and Opening Remarks

Barbara Lopez Kunz
Global Chief Executive
DIA

Program Co-Chairs:

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

Betsy Fallen, RN
Consultant
BAFallen Consulting, LLC

Sarah Powell, RAC
President
Powell Regulatory Service

1:10–1:45 PM

Keynote Address

Brad Wintermute
Deputy CIO - Director Office of Technology & Delivery
Office of Information Management
FDA

1:45–3:15 PM

Plenary Session 1 – FDA Update

Session Chair:

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

Panelists:

Virginia Hussong
Acting Director
Division of Data Management Services & Solutions
OBI, OSP
CDER, FDA

Jonathan J. Resnick
Project Management Officer
OBI/OSP
CDER, FDA

Vada A. Perkins
Deputy Associate Director for Review Management (Acting)
CBER, FDA

La Misha Fields
IT Program Manager
Electronic Submissions Gateway (ESG)
Enterprise Applications Branch
Division of Application Services
Office of Information Management
FDA

3:15–3:45 PM Refreshment Break, Exhibits, and Networking

3:45–5:15 PM

Plenary Session 2 – Other Regions Update

Session Chair:

Michiel Stam
Regulatory Operations Consultant
eCTDconsultancy B.V.

An Essential Update on European Developments

Pieter Vankeerberghen
Coordinator
FAGG AFMPS
Brussels, Belgium

Other Regions

Hans van Bruggen, MSc
eCTDconsultancy B.V.

5:15–6:15 PM Networking Reception and Exhibits

TUESDAY, FEBRUARY 9

7:30–8:30 AM Continental Breakfast, Exhibits, and Networking

8:30–10:00 AM **Session 1**

Track 1 – RIM Business

How Successful are RIM Solutions Anyway and how Does my Company Measure Up?

Session Chair:

Brooke Casselberry, MSRA
Associate Director
Paragon Solutions

Examine industry positions with regard to implementing, evaluating, and assesing RIM activities. Presentations will focus on real industry data related to RIM solutions.

Measuring and Achieving World Class RIM

Steve Gens, MS
Managing Partner
Gens and Associates Inc.

Regulatory Event Management: An Assessment of Common Processes and Best Practices

Jim Reilly
Director, RIM Strategy
Veeva Systems

Track 2 - ERS

M1: Ad/Promo

Session Chair:

Thomas Noto, MS
Senior Director
Regulatory Operations
Lexicon Pharmaceuticals

Explore the new specifications for submitting advertising and promotional materials, based on over 6 months of industry use. Topics will include an industry perspective on transitioning Ad Promo submissions from paper to eCTD, as well as best practices for implementing and using the latest Module 1. An overview of FDA interactions on this topic will also be highlighted.

Advertising and Promotion Submissions Using US Module 1 v3.3: A Year in the Life — Questions Asked and Lessons Learned

Sandra A. Krogulski
Regulatory Operations Manager
Accenture Accelerated R&D Services

Buying Into Promotional and Advertising Submissions in eCTD

Ian Oldham
Senior Manager, Regulatory Submissions Management
Teva Pharmaceuticals

What We've Learned About the FDA's New Module 1

Robert Connelly, MBA
Product Manager
GlobalSubmit

Track 3 – EDM

Mission Possible: How TransCelerate is Improving the Protocol Template and Paving the way for the Digital Protocol

Session Chair:

Stacy J. Tegan
Manager, Regulatory Technology Consulting
Accenture Accelerated R&D

TransCelerate BioPharma, a non-profit consortium of over 20 sponsor companies, is tackling some of the biggest challenges in the clinical development process. The Common Protocol Template, an implementation communications toolset, is now available to anyone via the TransCelerate website. Learn how this protocol template brings value today and sets the stage for enabling trial registry disclosure, downstream automation, and end-to-end traceability.

FDA Perspective of the Protocol Template

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

The Common Protocol Template: Common Structure, Common Language, Uncommon Benefits to End Users

Robert DiCicco, PharmD
Vice President, Clinical Innovation & Digital Platforms
GlaxoSmithKline

The Common Protocol Template: Foundation for the Future

Robert Ferendo, RPh
Process & Technology, Clinical Development Information & Optimization
Eli Lilly and Company

Track 4 – RIM Technology

Is the Timing Right for RIM in the Cloud? Examining Capabilities and Where Industry is Headed

Session Chair:

Michiel Stam
Regulatory Operations Consultant
eCTDconsultancy B.V.

Examine how industry is using the cloud for RIM solutions currently and visions for the future.

RIM in the Cloud: Clearing the Fog!

Shylendra Kumar, MA, MPH
President/CEO
ACUTA LLC

Implementing and Validating a Cloud Based RIMS

Charles E. Deeck
Senior Project Manager
Ariad Pharmaceutical, Inc.

RIM in the Cloud: Practical Considerations

Susan Metz
Principal Consultant IDMP
PAREXEL International
Integrated Product Development

10:00–10:30 AM Refreshment Break, Exhibits, and Networking

10:30AM–12:00 PM **Session 2**

Track 1 – RIM Business

Working With Affiliates

Session Chair:

Sarah Powell, RAC
President
Powell Regulatory Service

Most RIM solutions are developed and implemented with a focus on the needs of headquaters. However, the problems arise with infrequent users and affiliate offices. See how companies are rethinking their approach by keeping affiliates in mind.

Anchoring Yourself in a Vision to Help to Deliver the Reality of RIM and Enable a Move From Islands to Continents

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

René Kasan, MBA, MS
Senior Life Sciences Management Consultant, Compliance Subject Matter Expert
NNIT Switzerland AG

Considering the Affiliate User Experience When Implementing RIM Solutions

Justin Wear
Lead Consultant
Electronic Ink

Track 2 - ERS

Optimizing Global Submissions

Session Chair:

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

As the global business environment becomes increasingly competitive and complex, regulatory teams are increasingly challenged to contribute to the acceleration of the drug approval and maintenance process. It is critical that companies ensure an uninterrupted and "first time right" flow of regulatory information that starts from submission document creation. We will discuss lean critical thinking needed to optimize an end-to-end process for global filing strategies based on lessons learned; including a growing trend to implement core regulatory dossiers for use by affiliates to create local submissions.

LEAN Dossier and Submission Management: Approaches to Process Optimization

Timm Pauli, MSc
Head of Regulatory Operations
PharmaLex GmbH

Achieving Operational Excellence in the Global Regulatory Simultaneous Submissions Process

Olga Alfieri, MBA, RAC
Associate Director
Eisai Product Creation Systems

Managing Global Submissions – From Identifying Core Content to What is Actually Submitted

Mary Gallagher, MS
Principal Consultant
EMC Corporation

Track 3 – EDM

Cloud EDMS Selection, Implementation, and Use Interactive Discussion

Session Chair:

Daniel F. Orfe, MS
President & CEO Regulatory eSubmissions, LLC

Cloud based EDMS systems are becoming a key driver in the Pharma-Biotech industry. These systems are being used to meet regulatory requirements and provide for organizational efficiency.

The participants from emerging Pharma-Biotech companies and the session chair will relate three significant benefits and three major considerations (hurtles - errors), based upon each of their organizations experiences.

The session will cover the selection process, implementation efforts, and ongoing use of the cloud based EDMS system. Once background has been provided by the panelists, you will be engaged to participate in a highly interactive session.

A Service Provider's Experience with Cloud EDMS

Marc C. Gabriel
Global Head of Regulatory Operations and Information Management Advisory Services
Kinapse Inc.

18 Months (and Counting) of Agony Fixed in 7 Weeks: Implementing a Cloud-Based EDMS

Ronald Hernando, MBA
Associate Director, Regulatory Operations
Macrogenics Inc.

Cloud Based EDMS: Three Pros and Three Cons

Samuel Collier
Product Integration and Deployment Coordinator
Montrium, Inc.

Track 4 – RIM Technology

The Strategic Challenges of Preparing for IDMP Implementation

Session Chair:

Andrew P. Marr, PhD
Managing Director
Marr Consultancy Ltd

With the upcoming deadlines in Europe of the implementation of IDMP, regulators and industry are gearing themselves up in readiness. This session will address the latest status of regulators plans and how industry can address the challenges and opportunities of defining and moving programs forward.

FDA: Preparing for IDMP Implementation

Vada A. Perkins, MSc
Deputy Associate Director for Review Management (Acting)
CBER, FDA

IDMP: A Compliance Project or a New Way of Conducting Business?

Rune Bergendorff, MSc
Managing Consultant
NNIT A/S

Strategies for Ensuring the Quality of the Data Needed to Support IDMP Compliance

William Mandarino, MSc
Associate Director, Product License Knowledge Management
UCB, Inc.

12:00–1:30 PM Luncheon, Exhibits, and Networking

1:30–3:00 PM **Session 3**

Track 1 – RIM Business

Next Generation Regulatory Operations

Session Chair:

Sarah Powell, RAC
President
Powell Regulatory Service

Many Regualtory Operations organizations suffer from the same set of problems. Learn how Regulatory Operations organizations are looking to transform themselves and become more strategic partners within their organizations.

Quality by Design and the Strategic Transformation of Regulatory Operations

Joe Shepley, PhD, MA
Vice President and Practice Leader
Doculabs

Christopher Hanna, PhD, MBB
Principal
Kattner-Thalmann Partners

The Future Regulatory Operations Organization

Beth Turek
Senior Director, Global Regulatory Operations
Johnson & Johnson

Track 2 - ERS

ERS Diverse Processes

Session Chair:

Thomas Noto, MS
Senior Director
Regulatory Operations
Lexicon Pharmaceuticals

Focus on a broad spectrum of environments where eCTD is being implemented. First, we will explore the challenges of submitting eCTDs in the high-pressure world of generic drugs. Second, we will identify barriers and potential tools to accelerate adoption of eCTD in academia. Finally, we will discuss processes to increase the performance of CMC-driven variations through automated content creation processes.

A Race to Submit: An Overview of Submitting First-To-File ANDAs

Ryan Hernandez
Manager, Global Regulatory Operations
Teva Pharmaceuticals

FDA eSubmissions for Non-Commercial Research INDs – Tools, Problems, and Promise to Reduce the Paper Burden

Mitchell Seymour, PhD, RAC
Principal/Founder; Lead, Regulatory Operations
R&D Advisors, LLC

Integral Submission Life Cycle – A Holistic Approach to Comprehensively Manage CMC Submission Documents and Processes Globally

Romuald Braun, MSc
Managing Director
uanotau gmbh

Track 3 – EDM

Update on Status of PhUSE – Inspection Site Selection Standard Data Elements Working Group

Session Chair:

Betsy Fallen, RN
Consultant
BAFallen Consulting, LLC

In order to verify the integrity of data submitted to the FDA, CDER has developed a risk-based inspection site selection tool that combines data from both sponsor and FDA databases to evaluate clinical site level data for selection of clinical sites for inspection. FDA published a Draft Guidance in 2012 and is working on an update. A voluntary working group, the Inspection Site Selection Standard Data Elements Working Group, is currently evaluating how to incorporate site selection data set variables into existing standards (CDISC). The group will provide an update on their efforts, which include a gap analysis to compare FDA requirements and CDISC standards.

Office of Scientific Investigations - Bioresearch Monitoring (BIMO) Selection of Clinical Sites for Inspection - Sponsor Perspective

Colleen Davenport, PhD
Executive Director Regulatory Affairs and Pharmacovigilance
AnGes, Inc.

CDISC Perspective

Nate Freimark
Vice President - Clinical Programming and Data Standards Company
The Griesser Group

FDA Update on CDER's Clinical Investigator Site Selection Tool

Jean Mulinde, MD
Senior Policy Advisor
Division Clinical Compliance Evaluation Office of Scientific Investigations Office of Compliance, CDER, FDA

Track 4 – RIM Technology

An Agile Approach Towards Implementing IDMP Technologies

Session Chair:

Michiel Stam
Regulatory Operations Consultant
eCTDconsultancy B.V.

Documents containing IDMP information exist of natural language and allow for semantic differences. In practice this results in inconsistent and/or out-of-sync information across data containers, disciplines, regions, and products. The general belief is that managing information in a structured format should tackle these challenges and offer new opportunities to reuse data without rework. One of the hallmarks of IDMP will be moving product information from unstructured, document-bound information to more structured environments, enabling structured content management. This session will focus on extracting text from unstructured sources, as well as planning for never having to do that again using structured document authoring. Furthermore, it discusses how information stored in a huge amount of documents can be analysed and normalised according to a common terminology.

Global IDMP Journey - Alignment of Structured and Unstructured Data Provide Opportunities to Drive Value Beyond Compliance

Marcel Lissinna
Specialist Leader
Deloitte

From Documents to Data: Extraction and Transformation to Standard Terminology

Michiel Stam
Regulatory Operations Consultant
eCTDconsultancy B.V.

Building the IDMP-Agile Enterprise

Joel Finkle
Solution Lead, IDMP
CSC Life Sciences

3:00–3:30 PM Refreshment Break, Exhibits, and Networking

3:30–5:00 PM **Session 4**

Track 1 – RIM Business

DIA Regulatory Affairs Community Update

Session Chair:

Brooke Casselberry, MSRA
Associate Director
Paragon Solutions

The DIA Regualtory Affairs Community is one of the most active communities within DIA. Come learn from the community leadership what the regulatory intelligence, labeling, and advertising and promotional working groups have been doing in 2015.

Panelists:

Kimberly Belsky, MS
Executive Director
OneSource Regulatory

Emily Huddle
Regulatory Intelligence Executive
GlaxoSmithKline

Su-Yueh Lin, RPh, MS
Sr. Director, Head of Regulatory Labeling
Regeneron Pharmaceuticals Inc

Track 2 - ERS

eCTD v4/RPS; Moving Towards Implementation

Session Chair:

Mark Gray
Senior Project Manager
BSS
CBER, FDA

Now that the Regulated Product Submission (RPS) Release 2 is a normative standard and the International Council for Harmonisation (ICH) is finalizing the eCTD v4 implementation package, the focus is now on preparing for the implementation of eCTD v4. Based on the Health Level Seven (HL7) RPS exchange message, eCTD v4 is more than just a different backbone. eCTD v4 includes more submission metadata, new life cycle functionality, document reuse, and support for the exchange of information between regulatory authorities and sponsors. This session will provide information on the development and benefits of eCTD v4 but will also address the impact of the new standard and provide an update on the implementation process to prepare for the transition to eCTD v4.

eCTD v4.0: The Path to Implementation

Jared Lantzy, PMP
Manager, Global Regulatory Agencies and Processes
LORENZ International LLC

eCTD 4 is Sneaking Into Your Submissions Processes

Joel Finkle
Advisor
Emerging Practices
CSC Life Sciences BPS

What is the Impact to the Current Regulatory Information System

Hitoshi Matsui
Executive Officer
CAC EXICARE Corporation

Track 3 – EDM

Technology Enablers to Optimize EDM

Session Chair:

Michelle Charles, MPH, CPM
Manager, Regulatory Implementation
PAREXEL International

Advances in technology have enabled the industry to continuously innovate in the creation, management, and integrity of data and documents. This session will present a variety of technology developments and offer the impact and benefit of each advance. Beginning with electronic and digital signatures incorporated into document approvals and workflows, the session builds with sharing the advances needed to enable the collaborative processes between consortiums, business partners, and sponsors with disparate systems. The final presentation will bring it all together with an overview on the impact and benefit of the adoption of an eTMF on a Clinical Data Management group.

Get insight on how implementing cutting edge technology along with adopting efficient technology enablers into business processes can to lead to improved resource utilization, efficient business processes, enhanced integrity, and compliance.

Managing Trust, Identity, and Security in Digital Transactions

Ellen Reilly, MBA
VP, Life Science and HealthcareDocuSign

Facilitating Collaborations Through Technology

Elisa Cascade
President
DrugDev Data Solutions

eTMF for Clinical Data Management

Ajitha Gadangi
Associate Director
Merck & Co., Inc.

Track 4 – RIM Technology

Structured Authoring – New Paradigm for Data Driven Authoring for Life Sciences

Session Chair:

Jake Doran
Managing Director
List Innovations LLC

Structured authoring isn't something new, but is the life sciences industry now ready to adopt the concept and implement the vision to realize the strategic advantage? Examine compelling information around the concept of structured authoring, how structured authoring has developed over the years, and how a comprehensive enterprise approach to Structured Content Management (SCM) can be leveraged by your organization to streamline the process of developing submission information. Learn how SCM can be utilized to facilitate information and document re-use and ensure accuracy of information throughout the life cycle of product development. Hear from subject matter experts on the concept and from an industry representative on the journey one organization is taking to realizing the future of document authoring.

Structured Authoring - New Paradigm for Data Driven Authoring for Life Sciences?

Romuald Braun, MSc
Managing Director
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An Information Architecture Designed for Reusability: Avoiding Tiny Topic Syndrome

James Nichols
Vice president
Life Sciences & US Operations
DitaExchange Inc.
President & CEO
IRISS Forum

Building the Business Case for Adopting a Structured Authoring Toolkit: What Does it Take and Why is the Process so Painful?

Frank J. Meloni, MSc
Director
Janssen Research and Development, LLC

5:30 PM **Networking Dinners**

Make plans to form new connections, network with peers, and dine with colleagues! DIA has secured a limited number of seats at local restaurants for attendees to meet, eat, and network. (Sign-up sheets will be available onsite at the DIA registration; dinner cost is on your own.)

WEDNESDAY, FEBRUARY 10

7:30–8:30 AM Continental Breakfast, Exhibits, and Networking

8:30–10:00 AM **Session 5**

Track 1 – RIM Business

Current Trends and Approaches to Managing Labeling Globally

Session Chair:

Sarah Powell, RAC
President
Powell Regulatory Service

Examine current trends within the Labeling organizations and how organizations are better positioning themselves to control and ensure proper and timely implementation of changes throughout global labeling.

Global Labeling Alignment Trends and Best Practices

Mauricha F. Marcussen, MBA
Founder
Auditgraph

Global Labeling Management: Global Labeling – Collaborating With the Affiliates on Local Labeling

Abhishek Harde, MBA, MPharm, RAC
Regulatory Business Consultant
Cognizant Technology

CCDS Process/Tracking

Gerrit jan-Nijveldt, MSc
Senior Director of Labeling
Sanofi

Track 2 - ERS

Submission Production Potpourri

Session Chair:

Daniel F. Orfe, MS
President & CEO Regulatory
eSubmissions, LLC

This session will cover a range of submission production topics spanning blinded study IND eCTD submissions, outsourcing strategies, and dealing with major versus daily submission activities.

1) Best practices and scenarios supporting eCTD INDs during blinded study trials. Information security, contingency planning, application maintenance, PV - Regulatory transitions, and meeting safety reporting deadlines will be covered.

2) Insight and challenges associated with simultaneous management of major and routine submissions will be reviewed. Emphasizing the criticality to maximize resourcing for quality, time effectiveness, and workload distribution.

3) How internal submission capabilities should frame your core operational strategy will be outlined. Best practices for selecting the best vendor for your organization's needs based on your internal structure, technology, and support.

Challenges Encountered Supporting Both Brands and Generics – A Publishing Point of View

Kristin Wehr
Publishing Associate
Teva Pharmaceuticals

eCTD IND Submission Support for Blinded Trials – Successful Options and Best Practices Considered

Meghan Alice Demollari
Submission Project Manager
Accenture

Determining Core Operational Strategy Using Internal Capabilities

Heather McIntosh
Regulatory Operations Manager
BTG International Inc.

Track 3 – EDM

Connection with CROs

Session Chair:

Michelle L. Charles
Manager, Regulatory Implementation
PAREXEL International

More often than not, sponsors are working with CROs to execute programs, trials, or functional tasks. This session will bring varied scenarios of CRO responsibilities and technology interaction.

Data and documentation at clinical sites has long been a collection of paper, electronic, and portable digital mediums. Ensuring the completeness and quality of the site records has traditionally involved on-site monitoring model, but the size, complexity, and number of clinical trials mean that complete on-site monitoring is becoming an ineffective, expensive and inefficient process. Alternate methods for remote monitoring will be explored. In addition, how can essential document management be utilized to enable CRO accountability and what are the best options to ensure compliance. Is there a benefit to both a sponsor and a CRO maintaining separate eTMFs? Is it too much of a good thing? What are industry and compliance driven best practices for a dual system model.

Implementing Risk Based Monitoring Approach to Clinical Trials

Ashok Ghone, PhD
VP-Clinical Operations
MakroCare

Essential Document Management - Using Metrics to Drive Compliance and Provide Oversight

Kelley Robinson
TMF/Registry Process Analyst
Pfizer

eTMF – Options for the Sponsor When Working With A CRO

Paul Nalepa, CCRP
Associate Manager
Information Governance & Compliance
Global Quality and Compliance
PPD

Track 4 – RIM Technology

The Technical Challenges and Opportunities of Implementing IDMP Solutions

Session Chair:

Andrew P. Marr, PhD
Managing Director
Marr Consultancy Ltd

IDMP will require data from many parts of the organization which may have different structures and uses for the data that for those intended specifically for regulatory submission. This session will address the challenges and opportunities for the handling of data within organizations.

IDMP a Successful Relationship

Anjana Pindoria
Product Strategy Manager
EXTEDO GmbH

MDM Facilitating IDMP Compliance While Aligning With Corporate Data Integration Strategies

Lior Keet, MBA
Vice President
Life Sciences R&D Practice
HighPoint Solutions

The Technical Challenges and Opportunities With Implementing an IDMP Solution – An Industry Perspective

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

10:00–10:30 AM Refreshment Break, Exhibits, and Networking

10:30 AM–12:00 PM **Session 6**

Track 1 – RIM Business

RIM Working Group: Thought Leadership on a Complex Issue

Session Chair:

Sheila Mahoney-Jewels, MBA
Principal Consultant
smjStrategies, Inc.

This session will be an introduction to the newly formed RIM Working Group, which seeks to collectively explore emerging disparate RIM issues, such as widely varying terminology, non-harmonized definitions of "Core RIM", and high caliber, realistic metrics.

While not a "reference model" as yet, the RIM Working Group seeks to follow the same methodology so successfully employed by the EDM and TMF Reference Model. The goal is to harmonize across three key areas: Core RIM, terminology, and metrics.

From Compliance Burden to Competitive Advantage: RIM KPIs and Metrics

Steve Gens, MS
Managing Partner
Gens and Associates Inc.

What is RIM Exactly?

Bernie Coney, MA
Group Lead Technologies & Information Management, Global Regulatory Operations
Shire

From Entropy to Order: RIM Terminology

Peter Terbeek
Director, Regulatory Affairs
Astellas

Track 2 - ERS

Reg Ops Optimization/ Lessons Learned

Session Chair:

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

Outline and explore practical advice and tools to help plan, prepare, and manage global regulatory submissions. Seasoned professionals will share their experience from both the sponsor side as well as the vendor side so that participants can avoid pitfalls and make better decisions in the regulatory operations space. Specifically, we will discuss the implications for granularity, life cycle, and attribute decisions. We will outline how to prepare for new business processes and leverage technology in a global submission management group. You are encouraged to ask questions and share their experience for an interactive discussion.

Lessons Learned: A Vendor's Perspective on Regulatory Submissions

Adair Turner, MSc, RAC
Director of Clinical and Regulatory Operations
Arivis

If I Knew Then What I Know Now – Lessons Learned From a Decade of Global Submissions

Carrie A. Mazzrillo
Submissions Manager
Global Regulatory Affairs
Eisai Inc.

Matt Millstein
Senior Manager, Regulatory Affairs
Stealth BioTherapeutics

Track 3 – EDM

Trial Master File 2.0.... What's Next?

Session Chair:

Betsy Fallen, RN
Consultant
BAFallen Consulting, LLC

The efficiency and importance of the eTMF is being driven by influences such as the implementation of the TMF Reference Model and guidance from regulatory agencies on their expectations for inspections. What is next for the eTMF?

Digitizing, storing, and archiving clinical site documents is the next horizon. The intersection of digital documents and technology solutions is expected to enhance compliance, inspection readiness, and patient safety. The anticipated benefits and challenges of the eISF will be presented by three stakeholders as an eConsent form will be tracked from creation through review and upload to an inspectable repository.

Trial Master File 2.0 – What's Next? The Sponsor Perspective

Joanne Malia, MS
Director, Medical Research Process Management
Purdue Pharma LP

View from an eICF

Eric Delente, MA
Managing Director
Enforme Interactive

Essential Document Integration: IRB and Site Perspective

Adam Roth
Director of Operations
Schulman IRB

Track 4 – RIM Technology

Technology Considerations for Next Generation RIM Solutions

Session Chair:

Jake Doran
Managing Director
List Innovations LLC

Technology innovation in the RIM space has not been as transformational over the years as what we have seen in other areas, i.e. Clinical, Safety, etc. Is this paradigm about to change? What is industry doing to address the current needs around information and what are the strategic decisions that come from having a clear vision into RIM data?

We will take an in-depth look at the value of regulatory data and how it is now being viewed as a strategic corporate asset. We will transition in to a discussion around disruptive technologies and how technology has driven the transformation in other verticals and then finally take an in-depth look at the current state of the technology available in the RIM space and evaluate what is needed in order to be successful in the future. Are we on the cusp of the next generation of RIM tools?

Regulatory Information: (Un)necessary Evil or Corporate Asset?

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

Digital Health Impact on Regulatory and RIM

Michael Sauter, MD
Independent

Achieving a Future State RIM Solution

John Jones
Independent IT Subject Matter Expert

12:00–1:30 PM Luncheon, Exhibits, and Networking

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1:30–3:00 PM **Session 7**

Track 1 – RIM Business

Regulatory Intelligence and Social Environments – Where the Two Collide

Session Chair:

Brooke Casselberry, MSRA
Associate Director
Paragon Solutions

This session will address important considerations that should be taken into account as the world of regulatory intelligence intersects with social environments.

Dale Cooke
Owner
PhillyCooke Consulting

Taming the Flood of Regulatory Information

Alexander Gaffney, RAC
Senior Manager
Health Research Institute at PwC

Track 2 - ERS

Touchdown! or Fumble? The Medical Writing-to-Publishing Handoff

Session Chair:

Stacy J. Tegan
Manager, Regulatory Technology Consulting
Accenture Accelerated R&D

Proper planning and communication between medical writing and publishing can facilitate a clean handoff and minimize threats to the submission timeline. The handoff from medical writing to the publishing team is critical and often occurs at the "11th hour" of the overall submission timelines. Often, medical writing deliverables are on the critical path and compete with publishing directives for the medical writers' attention. This session will detail common risks, risk mitigation, and establishing integrated workflows across functions. Presenters provide perspectives of a project manager, medical writer, and finally the publisher to cover the end-to-end process of submission documents.

Medical Writing Perspective

Natalie Herr, PhD
Medical Writer, Consultant
Whitsell Innovations, Inc.

Lead Writer Perspective

Dove Bunkin-Thomas
Senior Manager, Global Regulatory Writing
Amgen

Publisher Perspective

BJ Witkin
Senior Manager, Regulatory Operations
Impact Pharmaceutical Services

Track 3 – EDM

Using the New DIA GMP Quality Systems and Labeling Reference Model

Session Chair:

Betsy Fallen, RN
Consultant
BAFallen Consulting, LLC

Get information on the new DIA GMP Quality Systems and Labeling Reference Models that were developed by the Documents and Records Management Community. The session topics include an overview of the reference models and an interactive walk-through of the models, key considerations and best practices for adoption, and a case study to highlight the experiences from a major pharmaceutical firm implementing the new GMP model.

Using the New DIA GMP Quality Systems and Labeling Reference Models

Cary Smithson, MBA
Associate Director, Health Sciences Information Management
Paragon Solutions, Inc.

Piloting the DIA GMP Quality Systems Reference Model

Mary Emanoil, MS
MILS, Library and Info Science
Senior Director, Content Management and Authoring, Information Management
Pfizer

Labeling Reference Model: What's New and How to Implement

Karin Schneider, MS
Document Management Enablement Head
Janssen Research & Development

Track 4 – RIM Technology

Trends and Opportunities in Master Data Management

Session Chair:

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

Pharmaceutical companies have seen the increasing adoption of master data management around key corporate information such as product, customer, employee, etc. This session will start off with an overview of master data management (what and why), how master data is already used in industries such as retail, consumer goods etc., and highlight the importance of product master data in life sciences. It will be followed by a vendor perspective around master data management, especially in the light of ISO/EMA requirements around IDMP. We will also hear a sponsor's perspective and case study on how master data management has been implemented within their organization to address various business needs, highlighting some of their successes and challenges.

Master Data Management: Why Now?

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

Product Master: Drug Sponsor Case Study

Laurie Strehl
Associate Director, Product Data Management, Global Manufacturing Supply
Bristol-Myers Squibb

MDM Strategy for IDMP, RIM, and the Broader Business Value

Joe McLaughlin, MBA
Vice President Regulatory Information Management
Genpact Pharmalink

3:00–3:30 PM Refreshment Break and Networking

3:30–5:00 PM **Closing Plenary – "Ask The Regulators" Session**

Session Chair:

Mark A. Gray
Senior Project Manager
Bioinformatics Support Staff (BSS)
CBER, FDA

Panelists:

Virginia Hussong
Director
Division of Data Management Services & Solutions
OBI, OSP
CDER, FDA

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

Jonathan J. Resnick
Project Management Officer
OBI/OSP
CDER, FDA

Vada A. Perkins, MSc
Deputy Associate Director for Review Management (Acting)
CBER, FDA

La Misha Fields
IT Program Manager
Electronic Submissions Gateway (ESG)
Enterprise Applications Branch
Division of Application Services
Office of Information Management
FDA

5:00-5:15 PM **Closing Remarks**

Program Co-Chairs:

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

Betsy Fallen, RN
Consultant
BAFallen Consulting, LLC

Sarah Powell, RAC
President
Powell Regulatory Service

5:15 PM **Forum Adjourned**

Exhibiting Companies

As of February 1, 2016

- ACUTA
- AMPLEXOR
- arivis
- Cardinal Health
- CSC
- DIA
- DITA Exchange
- DLTA
- EMC Corporation
- EXTEDO GmbH
- Global Submit
- HighPoint Solutions
- i4i
- LORENZ Life Sciences Group
- MakroCare Ltd.
- Microsystems
- NNIT U.S.
- Paragon Solutions
- PAREXEL
- PleaseTech Ltd.
- RegCheck
- Schlafender Hase
- Schulman IRB
- Synchrogenix, A Certara Company
- Veeva Systems

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– Barbara Lopez Kunz, DIA Global Chief Executive

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