DIA

Regulatory Submissions, Information, and Document Management Forum

Primer: February 4 | Forum: February 5-7

Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

PROGRAM CHAIRS

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Cyan Life Sciences

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CDER, FDA

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Peter Terbeek, MBA
Senior Director, Publishing, and Submission
Astellas

Overview

This Forum has experienced growth year after year in attendees, vendors, and presenters from industry and health authority representation, and 2018 is expected to continue this growth. Four tracks and daily health authority plenary sessions provide a comprehensive view of content and regulatory information management and submissions.

Highlights

- Four Tracks to choose from to tailor the meeting for you (See page 2 for more information on tracks)
- Two interactive "Ask the Regulator" sessions.
- Multiple general plenary sessions and four breakout tracks to tailor the forum to meet your needs
- Preconference short courses for even more learning
- Regulatory intelligence updates by health authority representatives from FDA, Health Canada, and other regions
- Dinner on the Town on Tuesday to get to network and engage with your peers over a meal

Who Should Attend?

Professionals involved in:

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

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Connect to the Complimentary Forum Wi-Fi

Network: **Marriott_Conference**

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Tracks

Track 1: RIM Business Track addresses processes for obtaining and managing regulatory information, organizational impact, and key issues shaping the global regulatory and business environments.

Track 2: RIM Technology Track focuses on standards related to submission of regulatory information, tools to effectively manage the information, implementation experiences and results, and implications for refinement.

Track 3: Electronic Document Management (EDM) Track examines the processes, systems, and best practices for content management across the product lifecycle, including alignment with the RIM system for optimal use of regulatory information.

Track 4: Electronic Regulatory Submissions (ERS) Track explores the submission process, regulatory requirements and new developments, best practices in regulatory submissions, and industry adoption techniques.

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Join Us Next Year!

February 11-13, 2019

Bethesda North Marriott Hotel and Conference Center

Registration Opens Monday, February 5. Lock in 2018 Rates before May 1!

DIAglobal.org/RSIDM19

Schedule At-A-Glance

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

PRIMER | SUNDAY, FEBRUARY 4		ROOM
9:30-10:30AM	Primer Registration	Forest Glen Foyer (Lower Level)
10:00AM-5:00PM	**Regulatory Content and Submissions Primer:** Tracking Content from Conception to Interment	Forest Glen
DAY ONE | MONDAY, FEBRUARY 5		**ROOM**
7:30AM-5:00PM	Registration	Ballroom Foyer (Upper Level)
8:30AM-12:00PM	**Short Course 1:** Global Identification of Medicinal Products (IDMP): Applied Principles and Practical Benefits from Compliance and Beyond	Brookside AB (Lower Level)
8:30AM-12:00PM	**Short Course 2:** Essentials for Compiling/Publishing Compliant Electronic Submissions (eCTDs)	Forest Glen
12:30-1:00PM	**DIA Global Mobile App Tutorial**	Ballroom E-H
1:00-1:30PM	**Welcoming Remarks and Presentation of the Volunteer Award**	Ballroom E-H
1:30-2:00PM	**Session 1:** Keynote Address: Introduction to Blockchain: Distributed Ledger Technology for Regulation and Supply Chain Security	Ballroom E-H
2:00-2:30PM	Refreshment Break in the Exhibit Hall	Ballroom A-D
2:30-3:45PM	**Session 2:** FDA Opening Plenary Panel: PDUFA VI Informatics	Ballroom E-H
3:45-5:00PM	**Session 3:** Other Regions Update	Ballroom E-H
5:00-6:00PM	Networking Reception in the Exhibit Hall	Ballroom A-D
DAY TWO | TUESDAY, FEBRUARY 6		**ROOM**
7:30AM-4:00PM	Registration	Ballroom Foyer
7:30-8:30AM	Networking Breakfast in the Exhibit Hall	Ballroom A-D
8:30-9:45AM	**Session 4:** New FDA Draft Guidance on Part 11 in Clinical Investigations and Mobile Technologies in Clinical Investigations	Ballroom E-H
9:45-10:30AM	**Session 5:** FDA Ask the Regulators: Part 1	Ballroom E-H
10:30-11:00AM	Refreshment Break in the Exhibit Hall	Ballroom A-D

Schedule At-A-Glance

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

DAY TWO | TUESDAY, FEBRUARY 6		ROOM
11:00AM-12:15PM	**Session 6:** Breakout Sessions	
	Track 1: HeRO Forum Benchmarking: Global Regulatory Sourcing Strategies for Evolving Regulatory and Industry Solution	Ballroom FGH
	Track 2: The Increasingly Critical Roles of RIM Systems and Their Expanding Number of Use Cases Beyond Regulatory Affairs	White Oak (Lower Level)
	Track 3: Strategies for Ensuring Part 11/Annex 11 Compliance of eTMFs at Research Sites	White Flint (Lower Level)
	Track 4: eCTD AdPromo Panel Discussion	Brookside (Lower Level)
12:15-1:45PM	Networking Luncheon in the Exhibit Hall	Ballroom A-D
1:45-3:00PM	**Session 7:** Breakout Sessions	
	Track 1: Paradigm Shift in Data Management and How to Enrich Business Intelligence to Benefit the Industry	Ballroom FGH
	Track 2: How to Compete in the Data-Driven Digital Transformation in the Pharmaceutical Industry?	White Oak (Lower Level)
	Track 3: Understanding ICH E6 R2 and the Impact to Clinical Trial Documentation and the Trial Master File	White Flint (Lower Level)
	Track 4: Keeping up with Trends in eCTD: Submitting in US Module 1 Specification	Brookside (Lower Level)
3:00-3:30PM	Refreshment Break in the Exhibit Hall	Ballroom A-D
3:30-4:45PM	**Session 8:** Breakout Sessions	
	Track 1: Processes - Don't Make Them an Afterthought	Ballroom FGH
	Track 2: Transforming Regulatory Information Management Through Innovation	White Oak (Lower Level)
	Track 3: Creating and Streamlining Regulatory Dossier Management	White Flint (Lower Level)
	Track 4: Using Submission Management to Enable Streamlined Regulatory Planning	Brookside (Lower Level)
5:30PM	Dinner on the Town	

DAY THREE | WEDNESDAY, FEBRUARY 7		ROOM
7:30AM-2:00PM	Registration	Ballroom Foyer
7:30-8:30AM	Networking Breakfast in the Exhibit Hall	Ballroom A-D
8:30-9:45AM	**Session 9:** Breakout Sessions	
	Track 1: Critical Success Factors for Implementation of Regulatory Information Management Capabilities	Ballroom FGH
	Track 2: Driving Innovation in Regulatory Technology within Life Sciences	White Oak (Lower Level
	Track 3: How to Utilize Systems and Technology as Document Enablers	White Flint (Lower Level)
	Track 4: Regulatory Sourcing: Regulatory Sourcing - Who is Doing What and Some Real-World Industry Experiences	Brookside (Lower Level)
9:45-10:15AM	Refreshment Break in the Exhibit Hall	Ballroom A-D
10:15-11:30AM	**Session 10:** Breakout Sessions	
	Track 1: RIM 2020: Connecting to Other Functional Processest	Ballroom FGH
	Track 2: Artificial Intelligence (AI): The Next Frontier	White Oak (Lower Level)
	Track 3: Panel Discussion: Managing Partnerships	White Flint (Lower Level)
	Track 4: TransCelerate, FDA, and NIH: The Evolution of a Common Protocol Template	Brookside (Lower Level)
11:30AM-1:00PM	Networking Luncheon in the Exhibit Hall	Ballroom A-E
1:00-1:45PM	**Session 11:** FDA Ask the Regulators: Part II	Ballroom E-H
1:45-2:00PM	**Closing Remarks**	Ballroom E-H
2:00PM	**Forum Adjourns**	

Learning objectives

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

- Explain the regulatory electronic submission process from the completion of its upload to the Electronic System Gateway (ESG) through the time the submission is made available to the review team
- Discuss the agency target time frames for the 1) expected submission upload duration(s) and 2) timeframe between key milestones and notifications
- Describe the current required data standards for regulatory submissions and the status of ongoing data standards initiatives
- Describe organizational processes and governance to ensure integrity, quality, and security of regulatory information (data, documents, records)
- Estimate the scope and future of data standards, including IDMP, with respect to systems, processes, and master data
- Discuss ways data can be harmonized, integrated, and viewed to provide an end-to-end view of the regulatory information value chain
- Discuss organizational implications related to increasing electronic interactions with stakeholders and health authorities
- Explain ways to improve processes and communication of regulatory activities including communications, end-to-end processes, and integration of systems for document, submission, and records management
- Interpret global health authority regulations and guidances for systems and business processes
- Identify ways in which the integration of data, documents, and knowledge can be leveraged to develop insights and enable better business decisions
- Identify changes in submission-related regulations impacting RIM business processes

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Short Course 1: 0.3 CEUs
Short Course 2: 0.3 CEUs
Forum: 1.2 CEUs

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PRIMER COURSE | FEBRUARY 4

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

10:00AM-5:00PM

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 "ah-ha" moments for the attendees of this offering form all functions along the life-span of content.

Learning Objectives

At the conclusion of this short course, 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

DAY ONE | MONDAY, FEBRUARY 5

7:30AM-5:00PM — **Registration**

8:30AM-12:00PM

Short Course 1

Global Identification of Medicinal Products (IDMP): Applied Principles and Practical Benefits from Compliance and Beyond

Session Chair

Vada Perkins, MSc, MS
Founder and Managing Principal
Identifica, LLC

Instructors

Michiel Stam
Regulatory Information Scientist

Andrew Marr
Managing Director
Marr Consultancy, Ltd

Frits Stulp, MSc
Managing Director
Iperion Life Sciences Consultancy, The Netherlands

In December 2010, new pharmacovigilance legislation was adopted by the European Parliament and European Council to require the use of common standards, formats and terminologies in the EU for the identification and exchange of information on medicines. Specific reference is made to the ISO Identification of Medicinal Product (IDMP) standards that were finalized in 2017 and the corresponding technical specifications developed with international standards development organizations (i.e., ISO and HL7). IDMP is a significant undertaking, but it also presents opportunities in terms of how Regulators and Industry manage and share data, both internally and externally, to support global product lifecycle data management.

This Short Course is aimed at providing stakeholders with a foundational knowledge of IDMP to support practical implementation within their organizations. More specifically, the tutorial will address issues within the regulatory landscape and demonstrate applied strategies for the implementation of the ISO IDMP to support global medicinal product identification. Topics to be addressed include a background of the IDMP standards and legislation, and an overview of the overall structure, content, and technical requirements of IDMP. More importantly, this tutorial will present practical examples and offer a demonstration of applied IDMP concepts to directly address regulatory initiatives and requirements. This session is applicable to entry and intermediate level stakeholders.

Learning Objectives

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

- Recognize the main features of the IDMP standards and corresponding technical specifications
- Understand the content and message exchange requirements for the submission of medicinal product information by relevant stakeholders
- Demonstrate applied strategies for the implementation of ISO IDMP beyond compliance (true benefit across the value chain within an organization)
- Understand and apply IDMP concepts regulatory and other business needs

DAY ONE | MONDAY, FEBRUARY 5

8:30AM-12:00PM

Short Course 2

Essentials for Compiling/Publishing Compliant Electronic Submissions (eCTDs)

Instructors

Jillian Carinci, MS
Associate Director, Regulatory Operations
Accenture Regulatory

Dan Orfe, MS
President and CEO
Regulatory eSubmissions, LLC

Whether you've submitted 100 initial filings, or are preparing for your first one, getting your team ready for that initial submission is always important. Dotting all the i's and crossing all the t's can lead to a successful submission and make you better prepared for the rapid responses during agency information requests. This short course will walk through the important regulatory and clinical guidance documents, connecting them specifically to submission needs. It will break down specific requirements by Module, including specific points on SPL creation and data packages, while noting best practices to avoid the dreaded RTF.

Learning Objectives

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

- Understand best practices for US eCTD Submissions
- Recognize how clinical data packages impact the regulatory world
- Implement best practices for managing an application's lifecycle

12:30-1:00PM

DIA Global Mobile App Tutorial

1:00-1:30PM

Welcoming Remarks and Presentation of the Volunteer Award

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

RSIDM Track Chairs

1:30-2:00PM

Session 1

Keynote Address: Introduction to Blockchain: Distributed Ledger Technology for Regulation and Supply Chain Security

Keynote Speaker

Jim St. Clair
Founder
Institute for Healthcare Financial Technology

First made popular by Bitcoin and other digital currencies, Blockchain represents a new distributed ledger system that is being applied across multiple industries. Blockchain is being considered in multiple use cases in healthcare product management, supply chain security, and regulatory information. This presentation will provide a high-level overview of Blockchain-distributed ledge technology and its uses and pilot efforts in healthcare products.

2:00-2:30PM

Refreshment Break in the Exhibit Hall

2:30-3:45PM

Session 2

FDA Opening Plenary Panel: PDUFA VI Informatics

Session Chair

Ron Fitzmartin, DIA Fellow, MBA, PhD
Senior Advisor, Data Standards Program, Office of Strategic Programs
CDER, FDA

This session will provide an overview of the FDA electronic submission systems and data standards that impact sponsors applications from time of submission at the ESG through the time the submission is made available to the review team. In addition, receive an update on the CBER-CDER Joint Data Standards Strategy and Action Plan, and the Public Meeting scheduled for March 2018.

Electronic Submissions Gateway Update

La Misha Fields
IT Program Manager, Electronic Submissions Gateway, OIMT, OC
FDA

Data Standards Strategy and Action Plan Update

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

Electronic Submissions Update

Ethan Chen, MSE, MBA
Director, Division of Data Management Services and Solutions, OBI, OSP
CDER, FDA

DAY ONE | MONDAY, FEBRUARY 5

3:45-5:00PM

Session 3
Other Regions Update

Session Chair
Michiel Stam
Regulatory Operations Consultant
eCTDconsultancy B.V., The Netherlands

Receive updates about developments in other regions including Canada, European Union, and Japan. Hear agency and industry representatives speak about electronic submissions, development of new data standards, local implementation plans, and Health Authority IT strategies.

Vikesh Srivastava
Associate Director, Business Informatics Division, HPFB
Health Canada

Mickel Hedemand, MSc
Special Advisor, Medicines Licensing, Workflow
Danish Medicines Agency, Denmark

Harv Martens
Technical Expert for JPMA on ICH M2 and M8 Expert Working Groups

5:00-6:00PM

Networking Reception in the Exhibit Hall

DAY TWO | TUESDAY, FEBRUARY 6

7:30AM-4:00PM

Registration

7:30-8:30AM

Networking Breakfast in the Exhibit Hall

8:30AM-12:00PM

Session 4
New FDA Draft Guidance on Part 11 in Clinical Investigations and Mobile Technologies in Clinical Investigations

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

During this session, you will review the new 2017 FDA Guidance on 21 CFR Part 11 in Clinical Investigations and the public comments, discuss next steps, and hear from the audience on the topics presented.

Part 11 Guidance
Cheryl Grandinetti, PharmD
Health Scientist, Policy Analyst
FDA

Regulatory Considerations in the Use of Mobile Technology in Clinical Investigations
Leonard Sacks, MD
Associate Director for Clinical Methodology, Office of Medical Policy
CDER, FDA

9:45-10:30AM

Session 5
FDA Ask the Regulators: Part 1

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

Speakers

Ethan Chen, MSE, MBA
Acting Director, Division of Data Management Services and Solutions, OS
CDER, FDA

Ron Fitzmartin, DIA Fellow, MBA, PhD
Senior Advisor, Data Standards Program, Office of Strategic Programs
CDER, FDA

La Misha Fields
IT Program Manager, Electronic Submissions Gateway, OIMT, OC
FDA

Cheryl A. Grandinetti, PharmD
Health Scientist, Policy Analyst
FDA

Mark Gray
Senior Project Manager, BSS
CBER, FDA

Jean M. Mulinde, MD
Senior Policy Advisor, Office of Scientific Investigations, OC
CDER, FDA

Leonard Sacks, MD
Associate Director for Clinical Methodology, Office of Medical Policy
CDER, FDA

10:30-11:00AM

Refreshment Break in the Exhibit Hall

11:00AM-12:15PM

Session 6
Breakout Sessions

TRACK 1
HeRO Forum Benchmarking: Global Regulatory Sourcing Strategies for Evolving Regulatory and Industry Solution

Session Chair
Jake Doran
Chief Technology Officer
Genpact Pharmalink

In this session, Mike Keech (Vice President, Head of US Advisory Services at Kinapse) will coordinate the presentations from the Heads of Regulatory Operations at three pharmaceutical companies. These leaders will share their organizational approaches to building a regulatory function in 2018. They will share their challenges, successes, and thoughts of where Regulatory is headed in the future and how you can prepare for the upcoming changes within your own organization.

Michael Keech
Vice President, Advisory
Kinapse

Karen Towns
Vice President, Publishing, and Product License Support
Pfizer, Inc

Eckart Schwarz
Senior Vice President, Global Quality and Compliance
GlaxoSmithKline

David Berglund
Global Head of Regulatory Operations
AstraZeneca

TRACK 2
The Increasingly Critical Roles of RIM Systems and Their Expanding Number of Use Cases Beyond Regulatory Affairs

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

RIM systems play an increasingly critical role in our organizations and their scope and use cases extend further beyond the Regulatory Affairs department. This session will focus on strategies and best practices for redefining and implementing RIM systems within today's organization to successfully support a wide range of applications.

Global Use Cases and Practical Challenges of Managing Regulatory Information from a Single Source of Truth
Michiel Stam
Regulatory Information Scientist
eCTDconsultancy B.V., The Netherlands

Foundational RIM Strategy for a Small- to Medium-Size Enterprise
Vahe Ghahraman, PhD
Senior Director
Alexion Pharma

Manage Change…Don't Let Change Manage You
Sue Metz
Vice President, Technical
PAREXEL International

TRACK 3
Strategies for Ensuring Part 11/Annex 11 Compliance of eTMFs at Research Sites

Session Chair
James Riddle, MCSE, CIP, CPIA
Vice President of Client Services
Kinetiq, a Division of Quorum IRB

Don't be caught off guard with a preventable compliance finding. Building a risk-based Part 11/Annex 11 compliance program at research sites is easier than most think. FDA has made it clear in recent draft guidance that electronic regulatory master files and other 'e' systems are subject to Part 11 regulations. All parties need to understand the requirements and develop strategies for compliance.

James Riddle, MCSE, CIP, CPIA
Vice President of Client Services
Kinetiq, a Division of Quorum IRB

Darren Lacey
Chief Information Security Officer
Johns Hopkins University

Lawrence Rich
Partner
Gxp Authority

TRACK 4
eCTD AdPromo Panel Discussion

Session Chair
Thomas Noto
Senior Director, Regulatory Operations
Lexicon Pharmaceuticals

Although the eCTD AdPromo Guidance from the FDA has been out for more than two years, the majority of companies haven't switched this process to eCTD. Commonly heard excuses are that it is complicated, expensive, and just too hard to change a process that entails hundreds of submissions a year per marketed product. This session will be an informative and fun panel discussion with seasoned experts who have made the switch to submitting AdPromo materials in eCTD format within their own companies, and lived to tell about it.

Josephine Secnik, MS, MBA
Director, Ad/Promo Regulatory Affairs
Eli Lilly and Company

Thomas Noto
Senior Director, Regulatory Operations
Lexicon Pharmaceuticals

Thomas Christensen, RAC
Senior Regulatory Affairs Manager
SynteractHCR

12:15-1:45PM

Networking Luncheon in the Exhibit Hall

DAY TWO | TUESDAY, FEBRUARY 6

1:45-3:00PM

Session 7
Breakout Sessions

TRACK 1
Paradigm Shift in Data Management and How to Enrich Business Intelligence to Benefit the Industry

Session Chair
Brooke Casselberry, MSRA, RAC
Owner
Cyan Life Sciences

This session covers case studies from three top biopharmaceutical companies and how they are changing the way they use data in their organizations. You will learn how organizations are using data and standards in more expansive ways. You will hear directly from peers on the steps taken to change the current thinking in their organizations on data, RIM, IDMP, and overall standards.

Case Study – Implementing a Paradigm Shift in RIM Data Management: From Administrative Afterthought to Strategic Asset
Kelly Hnat
Principal
K2 Consulting

Case Study – Improvement of Collaboration Across Industries
Andrea Herrmann, PhD
Director, Strategy Implementation Leader
Merck KGaA, Germany

Case Study – Enhanced Planning for Due Diligence and M&A Using the ISO IDMP Data Model
John Stanek
Senior Associate, Global Regulatory Affairs
Johnson & Johnson Group of Consumer Companies

TRACK 2
How to Compete in the Data-Driven Digital Transformation in the Pharmaceutical Industry?

Session Chair
Jake Doran
Chief Technology Officer
Genpact Pharmalink

The introduction of the digital transformation across life sciences in now in full swing. Being successful in the digital age requires a different approach than what has been done in the past. Pharmaceutical companies have often felt that their products were their biggest asset, however, it is becoming abundantly clear the most important asset of any company is the data. In this session, we will look at various elements of the technology ecosystem being forged across the industry and what is required in order to manage and succeed in this new world.

How to Compete in the Data Driven Digital Transformation in the Pharmaceutical Industry?
Morten Lindaa, MSc
Consuting Director, Life Sciences
NNIT, Denmark

Achieving Digital Transformation in Regulatory
Cary Smithson, MBA
Principal Consultant
OpenText Corporation

Case Studies in Digital Transformation Across Life Sciences
Jake Doran
Chief Technology Officer
Genpact Pharmalink

TRACK 3
Understanding ICH E6 R2 and the Impact to Clinical Trial Documentation and the Trial Master File

Session Chair
Joanne Malia, MSc
Associate Director, Clinical Documentation Management
Regeneron Pharmaceuticals

ICH E6 R2 was released in November 2016 and has outlined new expectations for all stakeholders of clinical trials. Additionally, the EMA released its draft guidance on the Trial Master File (TMF). This session will discuss the resulting expectations impacting clinical trial documentation and the TMF. The impact and response from different stakeholders such as vendors, sponsors, and regulators will be presented and discussed.

Fran Ross
Associate Director, Clinical and Regulatory Optimization
Paragon Solutions

Joanne Malia, MSc
Associate Director, Clinical Documentation Management
Regeneron Pharmaceuticals

Ann McCabe
Director, Process Excellence and Risk Management
Daiichi Sankyo, Inc.

TRACK 4
Keeping up with Trends in eCTD: Submitting in US Module 1 Specification

Session Chair
Peter Terbeek, MBA
Senior Director, Publishing, and Submission
Astellas

This session will explore the good, the bad, and the ugly of transitioning to the new US Module 1 Specification. We will examine considerations and obstacles for converting and hear from a vendor on how to support a mixed portfolio. We will cover software and validation considerations, training to understand the regulatory changes, and US M1 metadata and new document fields. This session will encourage your participation by asking questions and polling your experiences.

Transitioning to ECTD, a Small Company Perspective
Greg May
Associate Director, Regulatory Affairs
Nabriva Therapuetics

Managing a Global Portfolio, a Large Company Perspective
Jennifer Moore
Manager, GRAAS Ops Publishing
Amgen, Inc.

Supporting Multiple Specifications Simultaneously, a Vendor Perspective
Sandra Krogulski, MA
Regulatory Operations Submission Manager
Accenture Regulatory

3:00-3:30PM

Refreshment Break in the Exhibit Hall

DAY TWO | TUESDAY, FEBRUARY 6

3:30-4:45PM

Session 8
Breakout Sessions

TRACK 1
Processes - Don't Make Them an Afterthought

Session Chair
Sarah Powell, RAC, FRAPS
President
Powel Regulatory Services

Organizations often ignore one of the most critical success factors when implementing new technology – process definition. Learn how other organizations have approached process definition as an aid to successful implementations and change management.

Successful Process Definition Methodology
Sarah Powell, RAC, FRAPS
President
Powell Regulatory Services

Importance of Well-Defined and Documented Processes to Your RIM Program
Elizabeth Turek
Head, Knowledge Management
Johnson & Johnson

TRACK 2
Transforming Regulatory Information Management Through Innovation

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

How can data-intensive regulatory business processes be supported by rich information management applications where expectations of ubiquity and better user experience are of utmost importance? What can enterprise implementations of systems learn from consumer applications such as Amazon? What is the industry doing about taking an end-to-end view of regulatory information management (RIM)? This session will have a reputed panel of experts sharing their views on how the industry must innovate and transform to the next generation of capabilities.

Information and Connection
Matt Neal, MA
Senior Director, Product Management
PARAXEL International

Eliminating White Space in Managing Marketing Products
Peter Lassoff, PharmD
Vice President and Head, Global Regulatory Affairs
IQVIA

DIA's RIM Working Group: Its Mission, Vision, and Value to Industry
Jim Nichols
Executive Director, Life Sciences
Cunesoft, Inc.

TRACK 3
Creating and Streamlining Regulatory Dossier Management

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

This session will provide tried-and-tested methods for creating and streamlining regulatory dossier management. This includes a deep dive into the implementation of a cloud-based EDMS at a small biotech and how it established a 'one stop shop' for regulatory content reporting and tracking. Also, learn leading practices for expanding regulatory initiatives across the globe by taking a single-dossier approach to product registrations.

Designing and Implementing an Integrated Regulatory Experience
Richard Fredericks, MBA
Associate Director, Regulatory Systems and Information Management
Tesaro

Take a Global Approach to Regulatory Dossier Management
Alex Butler, MBA
Product Marketing Manager
MasterControl

Lillian Erickson, MCP
QA/RA Director, Gas Sending, Analysis, and Delivery
Maxtec, LLC

TRACK 4
Using Submission Management to Enable Streamlined Regulatory Planning

Session Chair
Michelle Charles, MPH
Director, Regulatory Affairs
Gene Therapy Program and Orphan Disease Center
University of Pennsylvania, Perelman School of Medicine

This session will focus on how you can work business efficiency and project management into all aspects of regulatory submissions. We will begin with a presentation focused on the implementation of a global submission planning tool to enable portfolio management, then move to a presentation optimizing submission resources, and end with how to efficiently manage a submission lifecycle.

Enabling Global Regulatory Submission Project and Portfolio Management Via a Unified Submission Planning Toolset
Laura Shelley, RPh, PMP
GRACS – Regulatory Portfolio and Submission Management
Merck & Co., Inc.

Submission Lifecycle Management
Laurie Henricks
Director, Regulatory Submissions Operations
Cardinal Health Regulatory Sciences

Utilizing Submissions Management to Free up Resources in Regulatory Affairs
Stephanie Hughes
Regulatory Submissions Management Associate
Teva Pharmaceuticals Inc.

5:30-7:30PM

Dinner on the Town

Traveling on your own or looking to connect with fellow attendees? Visit the DIA Registration Desk to link up for dinner! Sign up sheets will be provided for various local restaurants. Cost of dinner is the responsibility of the individual attendee.

DAY THREE | WEDNESDAY, FEBRUARY 7

7:30AM-2:00PM — **Registration**

7:30-8:30AM — **Networking Breakfast in the Exhibit Hall**

8:30-9:45AM — **Session 9**
Breakout Sessions

TRACK 1
Critical Success Factors for Implementation of Regulatory Information Management Capabilities

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

As organizations embark on transformational changes to their RIM systems, they must begin with a thorough understanding of business processes and requirements and focus on critical success factors such as business process transformation, organizational design, and change management, in addition to innovative technologies. This session will have a reputed panel of experts sharing their views on how organizations must focus on critical success factors to transform the RIM landscape.

Actionable Regulatory Intelligence as a Service
V. "Bala" Balasubramanian, PhD, MBA
President and CEO
Cabeus, Inc.

Did the Emperor Forget His Clothes? Why Any Successful Technology or System Implementation Begins with Defining His Outfit
Kristen Sauter, MBA
Director, R&D Consulting, and Regulatory Practice Lead
Paragon Solutions

The Use of SPOR/IDMP and the Impact on Regulatory Affairs and RIM Solutions in the EU
Remco Munnik
Regulatory Information Director
Asphalion S.L., Spain

TRACK 2
Driving Innovation in Regulatory Technology within Life Sciences

Session Chair
Vikesh Srivastava
Associate Director, Business Informatics Division, HPFB
Health Canada

This session will cover digital innovation in regulatory information management technology, its impacts on the Life Sciences industry, and a perspective for the future. In addition, we will discuss how regulatory interactions are expected to change, particularly considering recent advances in analytics, real world evidence, machine learning, and mobile health, as well as the challenges this brings for both the industry and regulatory authorities. The discussion will speak to industry case studies.

Lifecycle Data Management: Practical Application of Data Standards, Innovation, and Technology for Global Regulatory Convergence
Vada Perkins, MSc, MS
Founder and Managing Principal
Identifica, LLC

Navigating the Regulatory Landscape of Innovation and Technology
Representative Invited
Deloitte LLP, United Kingdom

Q/A-Industry Perspective on Adoption of Data Standards and Technology
John Kiser, MSc
Principal
Kiser Regulatory Consulting Services

TRACK 3
How to Utilize Systems and Technology as Document Enablers

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

This session will focus on utilizing technology within the EDMS space and the importance of applying business process, utilizing system vendors as partners, and having technology be a differentiator and improve interoperability.

Successful Business Process Driven EMDS Implementation in Less Than Nine Months
Cheryl Ressland
Executive Director, Regulatory Operations
Daiichi Sankyo, Inc.

Dalia El-Sherif, DrSc, PhD
Partner
Pyxa Solutions

Structured Content Management: Auto-Population and Auto-Generation of Documents at Roche
Hans van Bruggen, MSc
Regulatory Affairs Scientist
eCTDconsultancy B.V., The Netherlands

eTMF Interoperability: The Move Towards Content Portability
Christina Mantzioros, MS
Clinical Solutions Specialist
Montrium, Inc., Canada

TRACK 4
Regulatory Sourcing: Regulatory Sourcing - Who is Doing What and Some Real-World Industry Experiences

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

Regulatory submission outsourcing has been a major component in submission publishing for the past decade. Changes in technology and real-world industry experiences have contributed to a reexamination of outsourcing. This session will provide benchmarking and trending information regarding the use of outsourcing looking back over the past 10 years of industry tracking. An exploration will be provided on outsourcing practices over time, activities being brought back in house, and which regions are becoming more active in leveraging outsourcing. Two industry organizations will provide insights into their own experiences with outsourcing touching on the pros, cons, beneficial strategies, and pitfalls to avoid.

Regulatory Sourcing - Who is Doing What?
Steve Gens, MS
Managing Partner
Gens and Associates, Inc.

Sourcing Experiences and Insights – Pros, Cons, Beneficial Strategies, and Pitfalls
Heather Sinsel
Manager, Regulatory Operation and Submissions
Inovio Pharmaceuticals, Inc.

We Have How Many Submissions?!? Sourcing at a High-Volume Organization
Kevin Tompkins, MS, MBA
Director North America, Regulatory Submissions Management
Teva Pharmaceuticals

9:45-10:15AM — **Refreshment Break in the Exhibit Hall**

DAY THREE | WEDNESDAY, FEBRUARY 7

10:15-11:30AM

Session 10
Breakout Sessions

TRACK 1
RIM 2020: Connecting to Other Functional Processes

Session Chair
Sarah Powell, RAC, FRAPS
President
Powell Regulatory Services

This session will provide information on how other companies are thinking and connecting their RIM capabilities with other functional systems and processes. It will be a combination of industry presenters and the latest benchmarking research.

RIM 2020: Connecting to Other Functional Processes
Steve Gens, MS
Managing Partner
Gens and Associates, Inc.

RIM: Delivering Value for Regulatory and the Enterprise
James Hanly, MBA
Head IT Business Partner, Global Regulatory, Safety Biometrics
Bristol Myers Squibb

TRACK 2
Artificial Intelligence (AI): The Next Frontier

Session Chair
Brooke Casselberry, MSRA, RAC
Owner
Cyan Life Sciences

This session will provide an overview of Artificial Intelligence (AI) technologies such as robotic process automation (RPA), natural language processing (NLP), and machine learning, and offer insight into how these AI technologies are developed and applied to regulatory affairs. Speakers will share their recent experience with implementing AI projects, their decision processes, and lessons learned along the way.

Smart Regulatory Affairs: From Document Creation to Supported Decision-Making
Adair Turner, MSc, RAC
Principal Consultant, Director Regulatory Operations
PharmaLex GmbH

Using Artificial Intelligence to Augment Regulatory Affairs Knowledge
Nicholas Drago, RAC
Assistant Director, Regulatory Policy, and Intelligence
Bayer Pharmaceuticals

A Journey from Automation to AI within Regulatory Operations
Cesar Vinces
Director, Head of US and Canada Submissions Management, Regulatory Operations
Pfizer, Inc

TRACK 3
Panel Discussion: Managing Partnerships

Session Chair
Sholeh Ehdaivand
President and CEO
LMK Clinical Research Consulting

This panel-style presentation will detail examples of how partnerships with CROs and vendors can be properly managed for clinical trial success. The panel will discuss how metrics can help support measurable actions and mange CRO/vendor partnerships.

Sharon Scricca
Associate Director, Submission Services, GDM
Bristol-Myers Squibb

TRACK 4
TransCelerate, FDA, and NIH: The Evolution of a Common Protocol Template

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

The TransCelerate Common Protocol Template and the NIH-FDA Protocol Template are tools available to facilitate authoring of streamlined, harmonized protocols. Learn about the collaboration between these organizations. Hear from an FDA reviewer on the protocol review process and why this harmonization is critical to regulators. This session will include a demonstration of the electronic protocol tool which enables content reuse.

An FDA Reviewer's Perspective on the Common Protocol Template
Eileen Navarro Almario, MD, MS, FACP
Lead Medical Officer, OCS, OTS
CDER, FDA

Collaboration between NIH, FDA, and TransCelerate to Create Harmonized Protocol Templates
Respresentative Invited

TransCelerate's Technology Enabled Common Protocol Template
Mitzi Allred, PhD
Director, Clinical Trial Operations
Merck & Co., Inc.

11:30AM-1:00PM

Networking Luncheon in the Exhibit Hall

1:00-1:45PM

Session 11
FDA: Ask the Regulators: Part II

Session Chair
Mark Gray
Senior Project Manager, BSS
CBER, FDA

Speakers

Ethan Chen, MSE, MBA
Director, Division of Data Management Services and Solutions, OS
CDER, FDA

La Misha Fields
IT Program Manager, Electroic Submissions Gateway, OIMT, OC
FDA

Ron Fitzmartin, DIA Fellow, MBA, PhD
Senior Advisor, Data Standards Program, Office of Strategic Programs
CDER, FDA

Valerie Gooding
Regulatory Information Specialist, OBI, OSP
CDER, FDA

Jonathan Resnick
Project Management Officer, OBI, OSP
CDER, FDA

1:45-2:00PM

Closing Remarks
RSIDM Track Chairs

2:00PM

Forum Adjourns

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