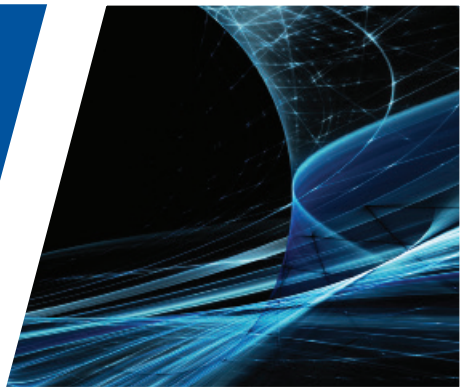
EDM and ERS/eCTD: The Content Continuum from Document Authoring through Submission Delivery

October 9-11 | Tutorials: October 8

Hilton Baltimore, Baltimore, MD



PROGRAM CO-CHAIRPERSONS:

Gary M. Gensinger
Deputy Director, Office of Business Informatics
CDER, FDA

Laura J. Sherman, MBA
Managing Partner
Distributed Compliance Solutions, LLC

Nancy Smerkanich
Vice President, Global Regulatory Affairs
Octagon Research Solutions, Inc.

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Bristol-Myers Squibb Company

Sarah Powell
Executive Director, Regulatory Affairs and Writing Services
Liquent, Inc.

This Conference has been developed with participation from members of the Document and Records Management and Electronic Regulatory Submissions SIACs (Special Interest Area Communities).

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Drug Information Association, Inc.
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GAIN PRACTICAL INSIGHTS INTO MANAGING CHANGE ACROSS THE CONTENT LIFE CYCLE

The EDM and ERS/eCTD conferences are back together again! This conference provides the perfect forum to offer practical insights on managing change, content life cycle and addressing hot topics. With ever evolving regulations, both industry and agencies must continually reassess standards, processes, and technology to be operationally positioned to meet emerging requirements. By focusing on the entire content continuum from authoring to submission delivery and maintenance, we'll look at approaches, impacts and challenges in implementing the necessary standards to ensure regulatory compliance. This year's conference will feature interactive working sessions which will give attendees the opportunity to interact with speakers, agency personnel and other participants in a dynamic and informative environment.

FEATURES

- Cross-functional sessions dedicated to the different areas of interest
- Presentation of best practices
- Interactive sessions to share and develop ideas and experience
- Excellent opportunity to network with colleagues from industry, regulatory and support organizations
- Exhibit hall with 30 exhibit booths

WHO SHOULD ATTEND

Professionals involved in:

- Regulatory Affairs and Operations
- Global Project Management
- Regulatory, Medical and Technical Writing
- Data Management
- Information Technology and Support
- Document and eRecords Management
- Standards Implementation
- Clinical Operations
- Quality Assurance and Compliance
- Contract Research and Service Support

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CONTINUING EDUCATION CREDITS

Drug Information Association has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102.

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer up to 2.1 CEUs for this program. Participants must attend the entire program (and/or tutorial if applicable) in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

LEARNING OBJECTIVES

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

- Describe global regulatory agency requirements, work in progress status and future initiatives
- Discuss organizational challenges when preparing to meet regional requirements
- Prepare for content lifecycle management in preparation of electronic submissions
- Examine process optimization when transitioning to an electronic environment
- Share best practices for creating guidance compliant submissions
- Recognize the importance of aligning standards and technology with the process
- Incorporate new processes, new standards and new technology for organizational change managements

CONTINUING EDUCATION CREDIT ALLOCATION

October 8, 2012 Tutorials	**October 9-11, 2012 Program**
Tutorial 1: .3 IACET CEUs	EDM and ERS/eCTD: The Content
Tutorial 2: .3 IACET CEUs	Continuum from Document
Tutorial 3: .3 IACET CEUs	Authoring through Submission
Tutorial 4: .3 IACET CEUs	Delivery: 1.5 IACET CEUs

If you would like to receive a statement of credit, you must attend the program and tutorial(s), if applicable, scan your name badge at each session you attend, and complete the on-line credit request process through DIA's My Transcript. To access My Transcript, please go to www.diahome.org, select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" to process your credit request. 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 Thursday, October 25, 2012.

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

- Regulatory Affairs Certificate Program: 10 Elective Units (for program participation only)

For more information go to www.diahome.org/certificateprograms

Disclosure Policy

It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

TUTORIAL DAY | **MONDAY, OCTOBER 8**

7:30 AM – 5:00 PM TUTORIAL REGISTRATION

8:30 AM – 12:00 PM CONCURRENT TUTORIALS – #1 AND #2

Tutorial #1 – eCSRs

Tutorial Instructors:

Nancy Smerkanich
Vice President, Global Regulatory Affairs
Octagon Research Solutions, Inc.

Vaishali Popat MD, MPH
Medical Officer, OND
CDER, FDA

This tutorial will examine the myriad of issues around the authoring and publishing of clinical study reports and their related components for electronic submissions. This includes but is not limited to granularity, hyperlinking and bookmarking best practices and the relationship between tables, figures and listings. A FDA medical reviewer will provide insight into how eCSRs are utilized by the agency during the course of application assessments.

Learning Objectives:

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

- Recognize and utilize granular CSRs for submissions
- Establish best practices for publishing standards for clinical reports
- Incorporate reviewer's needs into standards and processes for clinical submissions.

Target Audience:

Regulatory Affairs and Operations, Medical Writers and Project Managers who wish to gain a better understanding of the challenges of authoring and compiling clinical study reports and the supportive documentation and data that are used to evaluate them.

Tutorial #2 – Bringing eCTD Tools In-house: Vendor Selection and Request for Proposals (RFPs)

Tutorial Instructors:

Ronald Hernando MBA
Senior Manager, Regulatory Operations
MacroGenics, Inc.

Laura J. Sherman, MBA
Managing Partner
Distributed Compliance Solutions, LLC

This tutorial provides an overview for implementing e-submission publishing in-house. Topics include gathering user requirements, identifying stakeholders, Request for Proposals (RFPs), and the validation process.

We'll discuss the benefits of bringing e-submissions in-house vs outsourcing vs hybrid model, how to generate and evaluate RFPs, identify key components of RFPs and provide example templates for the vendor evaluation process.

We'll explain the validation process and how to generate an eCTD Demo and include FDA's eCTD Demo checklist and process. The goal is to ensure that the demos are acceptable in the first pass. This tutorial will provide tips as well to overcome challenges.

Learning Objectives:

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

- Identify steps to successfully implement e-submissions in-house
- Create efficient Request for Proposal to assist with vendor selection & evaluation
- Explain how to generate an eCTD demo

Target Audience:

This tutorial is designed for beginning/intermediate Regulatory Operations, Regulatory Affairs, Quality Assurance, IT and Project Management members involved with the assessment, selection and implementation to bring the eCTD submission publishing process in-house.

Please note that lunch is not served on tutorial day

1:30 – 5:00 PM CONCURRENT TUTORIALS – #3 AND #4

Tutorial #3 – Putting Regulations into Practice – Authoring for Module 3

Tutorial Instructors:

Deanna Murden-Beckett
President
ePharmaCMC, LLC

Norman R. Schmuff, Ph.D.
Associate Director for Pharmaceutical Quality
CDER/FDA

This half day tutorial will teach participants key elements of presenting a well written, concise CMC dossier in electronic format that is both easy to review and maintain throughout lifecycle. The tutorial will focus on practical elements of CMC dossier writing, review and lifecycle management in an electronic format based on many years of practical experience. Basic elements of submission planning and allowed flexibilities and strategies for lifecycle operations will be discussed. Participants will learn why CMC for a marketing application needs to be authored and presented differently than clinical trial applications, and how to use strategies that enhance, and not complicate the lifecycle process. A knowledge of CMC is not required to benefit from this course.

Learning Objectives:

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

- Describe how to plan and outline a thoughtful eCTD backbone for Module 3 that enables review
- Recognize how to write for eCTD vs. paper submissions
- Identify appropriate Module 3 elements to be included in a regulatory dossier
- Explain how to QC an eCTD backbone with Module 3 content

Target Audience:

Regulatory colleagues of all disciplines who have oversight of CMC data and dossiers. Including Directors and Associates of Regulatory Affairs, Regulatory Operations, Medical Writing, Technical Writing.

1:30 – 5:00 PM CONCURRENT TUTORIALS – #3 AND #4 (CONTINUED)

Tutorial #4 – EVMPD

Tutorial Instructors:

Susan Metz
Liquent, Inc.

Hans Van Bruggen
eCTDconsultancy B.V.

This tutorial provides an overview of XEVMPD implementation and industry's experience with the new standard. The XEVMPD concerns the identification of medicinal products to be referenced when attributing adverse events to a drug. Though Pharmacovigilance groups are responsible for the safety evaluation, regulatory affairs maintains all details about the package insert and quantitative and qualitative documentation of drug. A third group involved in this area concerns Regulatory Operations, that is likely in charge of compiling the actual electronic submissions supporting the XEVMPD. Topics include understanding why XEVMPD was implemented, industry experiences and challenges with gathering, submitting, and managing the required information. The session will also address the transition to IDMP and the additional impacts to industry.

Learning Objectives:

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

- Explain the objective of XEVMPD and impacts to industry
- Discuss and share practical experiences regarding collection, submission, and lifecycle management of the required data for XEVMPD
- Evaluate the organizational impact of the transition to IDMP
- Formulate a plan for successfully transitioning the organization to IDMP

Target Audience:

Regulatory Operations Professionals, Regulatory Affairs Managers (Local affiliates as well as headquarters), CMC Technical writers, Pharmacovigilance Professionals.

CONFERENCE DAY 1 | **OCTOBER 9**

7:30 – 8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 – 8:45 AM WELCOME AND OPENING REMARKS

Program Chairpersons

Gary M. Gensinger
Deputy Director, Office of Business Informatics
CDER, FDA

Laura J. Sherman, MBA
Managing Partner
Distributed Compliance Solutions, LLC

Nancy Smerkanich
Vice President, Global Regulatory Affairs
Octagon Research Solutions, Inc.

8:45 – 10:15 AM PLENARY SESSION 1

FDA Update/eCTD Progress Report

Session Chair

Gary Gensinger
Deputy Director, Office of Business Informatics
CDER, FDA

Module 1 Update

Mark Gray
Director, Division of Data Management Services and Solutions, Office of Business Informatics
CDER, FDA

PDUFA V eSubmissions

Hilmar Hamann, PhD
Director, Office of Business Informatics
CDER, FDA

PDUFA V eData Standards

Mary Ann Slack
Deputy Director, Office of Planning and Informatics
CDER, FDA

10:15 – 10:45 AM REFRESHMENT BREAK

10:45 AM – 12:00 PM PLENARY SESSION 2

Other Regions Update

Session Chair

Cynthia Piccirillo
Director, Global Dossier Management
Bristol-Myers Squibb

Health Canada Update

Irena Pastorekova
Regulatory Affairs Supervisor
Health Products and Food Branch (HPFB), Therapeutic Drug Directorate (TPD), Submission and Information Policy Division (SIPD)
Health Canada

EU Update

Hans Van Bruggen
eCTDconsultancy B.V.

Saudi Food and Drug Authority Update

Mohammed Jobran, MSc.
Chief Pharmacist, Regulatory Affairs Administration
Licensing Executive Administration, Drug Sector
Saudi Food and Drug Authority

12:00 – 1:30 PM LUNCH

1:30 – 3:00 PM SESSION 1

TRACK 1

Authoring Considerations

Session Chairperson

Sarah Powell
Executive Director, Regulatory Affairs and Writing
Services
Liquent, Inc.

This session will revisit content re-use paradigm shift and discuss the benefits of using XML editors. Regulatory submissions are slowly moving from handling information at the Document level to handling information at the Content level. This shift especially impacts the authors and authoring process of documents. Business drivers needing the additional capabilities will be presented, the challenges, lessons learned, and next steps to avoid a 'big bang' approach to content management.

Moving to Content Management & Authoring: Steps for Change

Donald G. Palmer
Associate Director, Regulatory Knowledge & Information Management (R-KIM)
Medimmune, LLC

Breaking the Document Boundary- Is the Content Re-Use Paradigm Shift Approaching the Tipping Point?

Sheila Jewels, MBA
Strategy Consultant
Virtify, Inc

An Agile Approach to Implementing Structured Content Authoring System for Clinical Documentation

Bhanu Bahl, MA
Senior Manager, Technology Information Management (TIM)
sanofi

Mitzi Allred, PhDEE
Assistant Director, Sanofi R&D Technical Information Management Clinical Sciences Operations

TRACK 2

TMF 1 - TMF Model and Implications

Session Chairperson

Stephanie Gleissner, MBA
Advisor – R&D IT
Eli Lilly and Company

The TMF Reference Model is now in its third year of existence and the scope of the model has broadened beyond the traditional clinical trial. The latest revision in June 2012 included investigator site files, device studies, investigator initiated studies and process-based metadata. By expanding scope, the TMF Reference Model has significantly widened applicability. This session will review how to eliminate duplication of the DIA EDM and TMF Reference Models while discussing the pros and cons of implementing both reference models simultaneously versus incrementally. Provide the survey results from mid-2012 will be included as well as introduce version 1.0 of the Framework for the Destruction of Paper, released in June 2012. The 6 process flow diagrams supporting the framework's recommendations will be reviewed as well as a brief theoretical / actual case study.

Expanding the scope of the TMF Reference Model

Karen Jane Redding, MPharm
Director, Global Business Development
Phlexglobal Limited

Destroy that Paper!! Introduction of the Framework for the Destruction of Paper

Lisa D. Mulcahy
TMF Content Management Consultant
Mulcahy Consulting, LLC

Reconciling the overlap between the EDM and TMF Reference Models

Patricia Santos-Serrao
Senior Product Manager
MasterControl, Inc.

TRACK 3

Standards RPS eCTD v4

Session Chairperson

Mark Gray
Director, Division of Data Management Services and Solutions
Office of Business Informatics
CDER, FDA

eCTD v4, based on the Health Level Seven (HL7) Regulated Product Submission (RPS) exchange message, is a paradigm shift with new organizational challenges, compared to eCTD v3.2.2. RPS is more than just a different backbone. RPS includes more submission metadata, addresses context-of-use and document lifecycle, file reuse, and support for the exchange of information between regulatory authorities and sponsors. This session will cover the message functionality, technical aspects of the message, and organizational challenges in implementing eCTD v4, including having systematic tracking of complete submission content and activities This session will enable attendees to understand the impact of the new standard, provide an update on the testing and implementation process, and prepare for the transition to RPS.

RPS/eCTD v4.0 - Regional Information and Functionality

Mark Gray
Director, Division of Data Management Services and Solutions
Office of Business Informatics
CDER, FDA

Understanding eCTD v4.0 – Changes and Challenges for Industry

Joseph A. Cipollina, MS
Director, Global Dossier Management
eStrategy & ICH M8 Co-rapporteur
Bristol-Myers Squibb Company

Implication of RPS/eCTD v4 Implementation to Processes and Validation

Akira Yamaguchi MBA
Vice President, Product Development
Lorenz International LLC

3:00 – 3:30 PM BREAK

3:30 – 5:00 PM SESSION 2

TRACK 1

The BMS Regulatory Submissions Optimization Program

Session Chairperson

Cynthia F. Piccirillo
Director, Global Dossier Management eStrategy
Bristol-Myers Squibb Company

Case study on considerations for a comprehensive approach to planning for and managing transformational change in the complex document management and submissions preparation environment. The presenters will share their perspectives on this collaborative effort.

The BMS Vision for Improving Regulatory Submissions Capabilities

Tobias Massa, PhD
Vice President, Global Regulatory Operations and Mature Products
Bristol-Myers Squibb

How BMS Approached Implementation of a Transformational Program to Improve its Regulatory Submissions Capabilities

Marc Gabriel, BS
Global Regulatory Practice Lead, Accenture

How BMS is Improving its Authoring Capability Through Process, Technology, Standards and Role Ehancements

Lisa A. Miller, BA
Senior Consultant
Octagon Research Solutions

TRACK 2

TMF 2 - TMF Practical Applications

Session Chairperson

Stephanie Gleissner, MBA
Advisor - R&D IT
Eli Lilly and Company

This session will review the TMF Reference Model and how it can be used to improve clinical trial management via use of an EDMS. Best practices and lessons learned related to eTMF transition will be discussed, including considerations when moving from paper to eTMFs and potentially eCRFs. A deeper dive on the CRF archiving process will demonstrate how errors can be significantly reduced by adopting scanning and semi-automatic indexation with ongoing metrics capture and analyses.

eDMS Configurations & TMF

Andrew MacKelfresh
Clinical Data Systems Analyst
Duke Clinical Research Institute

How to optimise electronic archiving of Case Report Forms (CRFs)

Nikolaj Brasen
Principal Architect
NNIT A/S

Real World eTMF Implementation - A Case Study

Adair Turner MSc,RAC
Regulatory Affairs Manager
Mission3 Inc.

TRACK 3

The "Cloud" for the benefit of the Content Continuum from Document Authoring through Submission Delivery. How *is* that done anyhow?

Session Chairperson

Daniel F. Orfe
Associate Director, Global Regulatory Operations – Technology, Standards & Vendor Management
Teva Pharmaceuticals

This will be a highly interactive session. Industry experts will provide highlights on how the cloud is being leveraged to support the Content Continuum from Document Authoring through Submission Delivery.

Topics the session will look to address include:

The opportunities and challenges of cloud based solutions in regulated environments.

Identification of emerging and continuing trends in content management and how the cloud is being leveraged by both large and small life sciences companies for content management needs.

Regulatory information safety, security, IP, compliance and data integrity in the cloud.

The use of cloud based systems to enable globally distributed staff to acquire, create, and manage content that is universally accessible, reportable, and is extensible to meet the needs of current and emerging standards.

A significant portion of the session will involve questions from the audience for our panel of experts.

The Life Science Cloud Acceptance Curve From 2007 To 2013: What It Took to Come From Skepticism To Acceptance

Dirk Karsten Beth
President and CEO
Mission3 Inc.

Regulated Content in the Cloud: The Future of Global Collaboration and Content Creation

Bryan Ennis
Director, Enterprise Program Management
NextDocs Corporation

Regulatory Compliant Cloud Computing 101

Paul Fenton, MBA
President and CEO
Montrium Inc.

Don't Wait: Innovate! Leveraging the Cloud to Support Rapid Business Change

Matt Wallach
Chief Strategy Officer and Co-Founder, Veeva Systems

5:00 – 6:00 PM NETWORKING RECEPTION

CONFERENCE DAY 2 | **OCTOBER 10**

7:30 – 8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 – 10:00 AM SESSION 3

TRACK 1

CDISC SEND: Implementing Standardized Non-clinical Data in Submissions

Session Chairperson

Lou Ann Kramer
Consultant
Eli Lilly and Company

CDISC SEND datasets are soon to be required in regulatory submissions. This session will prepare you to assess your organization's readiness to implement CDISC SEND datasets for Non-clinical data.

FDA Perspective

Timothy Kropp, PhD
Toxicologist, Office of Oncology Drug Products
CDER, FDA

A Sponsor's Perspective from SEND Pilot Participation

William Houser
Capability Manager
Bristol-Myers Squibb

A Non-clinical Service Provider's Perspective

Peggy Zorn, MBA, MS
Senior IT Consultant
Integrated Nonclinical Development Solutions, Inc.

TRACK 2

Opportunity Knocking - AdPromo eCTD submissions in 2013? 3-way perspective from FDA, Industry & Vendor

Session Chairperson

Dan P. Clark
Senior Manager, Strategic Regulatory Innovation
Novo Nordisk

Current regulations and a newly adopted FDA eCTD Module 1 have specific impact on promotional materials for prescription drugs. This session will explore the Office of Prescription Drug Promotion requirements, discuss how to manage, review, approve and submit promotional materials as well as describe what and how to provide to the OPDP while maximizing efficiency and ensuring maximum compliance.

How to Prepare for AdPromo eCTD's at Your Company

Dan P. Clark
Senior Manager, Strategic Regulatory Innovation
Novo Nordisk

End-to-end Promotional Materials Management for Biotech and Pharmaceutical Companies

Dirk Beth
President and CEO
Mission3

"What the Future Holds" Implementing Process & Technology to be ready to Electronically Submit Advertising & Promotional Material

Rob Labriola
Director, Regulatory Operations
Sunovion Pharmaceuticals Inc.

Preparing for the Submission of Advertising and Promotional Labeling in eCTD: OPDP Update

Marci Kiester, PharmD
Associate Director, Office of Prescription Drug Promotion
CDER, FDA

TRACK 3

eCTD special topics; Unique Situations

Session Chairperson

Gary M. Gensinger
Deputy Director, Office of Business Informatics
CDER, FDA

FDA may request, for various reasons, the administrative split of an IND application.

Case studies will focus on the impact on eCTD-format INDs. Best practices for the initial split, cross-referencing, as well as considerations for life-cycle management of split applications.

Managing Administrative Split of eCTD IND due to Office of Hematology and Oncology Products (OHOP) Request

Rachel Harrington
Associate Regulatory Submissions Manager
Astellas Pharma Global Development, Inc

Impact of FDA OHOP reorganization on Dossier Management and Publishing; Organization and Lifecycle of the Compound

Sharon R. Camerato
Manager
Bristol-Myers Squibb

FDA Office of Hematology and Oncology Products (OHOP) Reorganization and Administrative split of INDs

Tamy Kim, PharmD
Associate Director of Regulatory Affairs, Office of Hematology Products
CDER, FDA

10:00 – 10:30 AM BREAK

10:30 AM – 12:00 PM SESSION 4

TRACK 1

Clinical Standards Draft Guidance on Data Standarization Planning (CBER/CDER/CDRH)

SESSION CHAIRPERSON

Nancy Smerkanich
Vice President, Global Regulatory Affairs
Octagon Research Solutions, Inc.

With the publication of the draft guidance on Data Standardization Planning FDA Centers for Drugs, Biologics and Medical Devices is clearly signaling their commitment to the use of data standards throughout the development process. As part of this session participants will hear from the regulators the backround to this guidance and it's intended use and audience and highlight where in the product lifecycle sponsors will need to define and defend their implementation plans.

Introduction to CDISC and Data Standards

Nancy Smerkanich
Vice President, Global Regulatory Affairs
Octagon Research Solutions, Inc.

Data Standardization Planning Across FDA Centers for CBER

Amy Malla
Consumer Safety Officer,
Review Management
Office of the Director, CBER/FDA

Data Standardization Planning Across FDA Centers for CDER

Ron Fitzmartin, MBA, PhD
Senior Advisor,
Office of Planning and Informatics
CDER, FDA

TRACK 2

Collaborative Opportunities

SESSION CHAIRPERSON

Cynthia Piccirillo
Director, Global Dossier Management
Bristol-Myers Squibb

There are many different forums utilized to accomplish the work around standards development and implementation. This session will provide insight on the activities going on in several working groups that the health authorities, vendors and industry are all utilizing to collaborate in order to achieve successful outcomes for standardization of content and format for regulatory submissions.

Speakers Invited

Working Together on the Implementation of Regulatory Information Submission Standards (IRISS)

Lenore Palma
Regulatory Software Product Unit Manager, ArisGlobal LLC

IRISS IDMP Topic Group

Andrew P. Marr, PhD
Managing Director,
Marr Consultancy Ltd, UK

The FDA/PhUSE CSS Initiative: An Overview the Initiative Goals and Update on Working Group Objectives

Chris Decker, MS
Vice President, Life Sciences Practice
d-Wise Technologies

Standards Collaboration: HL7 Regulated Clinical Research Information Management (RCRIM)

Edward Tripp
President, Edward S. Tripp and Associates
Vice President, IRISS Forum

TRACK 3

eCTD Special Topics: FDA BIMO and PhUSE

SESSION CHAIRPERSON

Betsy Fallen
Lead, Global Essential Document and Supply Chain Management Global Clinical Trial Operations
Merck & Co., Inc.

The Office of Scientific Investigations may request information to be submitted in an original NDA. This session will focus on the Best Practices for organization of the information within the eCTD, as well as, subsequent site specific information requested to facilitate site inspection. The regulators perspective in the use of the information will be discussed followed by one company's experience from the request to the submission of the information in the eCTD NDA. An assessment of the information as it is related to data standards both current and future will also be presented.

FDA Office of Scientific Investigations: Organization of Information in the eCTD NDA

Paul Okwesili, MEng
Operations Research Analyst, Office of Scientific Investigations, Office of Compliance
CDER, FDA

Jean Mulinde, MD
Medical Officer, Office of Scientific Investigations
CDER, FDA

A Case Study: Bioresearch Monitoring (BIMO) Clinical Information in the eCTD NDA

Melinee Wilson
Regulatory Submissions Associate Manager
Astellas Pharma Global Development, Inc.

FDA BIMO Data from a CDISC Standards Perspective – What is There (and Where) and What is Yet To Come

Nate Freimark
Senior Director, Biometrics Operating Standards Group
Theorem Clinical Research

12:00 – 1:30 PM LUNCH

1:30 – 2:30 PM SESSION 5: COLLABORATIVE SESSIONS

This year, we will offer multiple breakout sessions hosted by knowledgeable facilitators and FDA and EU representatives, who will lead each session where common challenges and solutions will be exchanged. For Session 1, the topics will include Module 1 for US and, running concurrently a session on the common pain points in eRecords and Archiving. Afterwards, Session 2 will present M1 for EU and Rest of World (RoW), simultaneous with a session on Standards. Audience participation is not just strongly recommended, it is vital to the success of these sessions, so come prepared to question and share!

Collaborative Session Break-Out 1: US Module 1

FACILITATOR:

Gary M. Gensinger
Deputy Director, Office of Business Informatics
CDER, FDA

PANELISTS:

Mark Gray
Director, Division of Data Management Services and Solutions
CDER, FDA

Constance Robinson
Regulatory Information Specialist, eDMST, DDMSS, OBI, OPI
CDER, FDA

Marci Kiester, PharmD
Associate Director, Office of Prescription Drug Promotion
CDER, FDA

Nancy Smerkanich
Vice President, Global Regulatory Affairs
Octagon Research Solutions, Inc.

TOPICS:

- Follow up questions from the FDA Update plenary
- Update on Validation criteria

Collaborative Session Break-Out 2: eRecords and Archiving – Pain Points

FACILITATOR:

Shari Perlstein, MBA, PMP
Director, Enterprise Records & Information Management
Pfizer Inc.

PANELISTS:

Robert Barber, MS, PhD
Director of Validation Services
JPC Partners LLC

Betsy Fallen
Lead, Global Essential Document and Supply Chain Management
Global Clinical Trial Operations
Merck & Co., Inc.

Lisa D. Mulcahy
TMF Content Management Consultant
Mulcahy Consulting, LLC

Laura J. Sherman, MBA
Managing Partner
Distributed Compliance Solutions, LLC

TOPICS:

- Current status
- Challenges

2:30 – 3:00 PM BREAK

3:00 - 4:30 PM SESSION 6: COLLABORATIVE SESSIONS CONT

Collaborative Session Break-Out 3: EU and RoW Module 1

FACILITATOR:

Hans Van Bruggen
eCTDconsultancy B.V.

PANELISTS:

Irena Pastorekova
Health Canada

Andrew P. Marr, PhD
Managing Director
Marr Consultancy Ltd.

Cynthia F. Piccirillo, BS
Director, Global Dossier Management
Bristol-Myers Squibb

TOPICS:

- Challenges of Module 1

Collaborative Session Break-Out 4: Standards – Data and Document Challenges

FACILITATOR:

Nancy Smerkanich
Vice President, Global Regulatory Affairs
Octagon Research Solutions, Inc.

PANELISTS:

Gary M. Gensinger
Deputy Director, Office of Business Informatics
CDER, FDA

Douglas Warfield, Ph.D.
Interdisciplinary Scientist
Division of Data Management Services & Solutions
Office of Business Informatics
CDER, FDA

FDA Panelists Invited

TOPICS:

- Use of vendors
- FDA Training on Standards
- Standards Governance

CONFERENCE DAY 3 | **OCTOBER 11**

7:30 – 8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 – 10:00 AM SESSION 7

TRACK 1

Internal Standardization Adoption

Session Chairperson

Sarah Powell
Executive Director, Regulatory Affairs and Writing
Services
Liquent, Inc.

As companies globalize, it is critical to ensure efficient regulatory information access as well as product information consistency across all regions. The need to manage regulatory approvals and manufacturing changes is a constant challenge and great effort to standardize. This session will explore case studies on the cross functional alliance between company stakeholders in EU, Japan and the US to achieve common goals for submission and management of regulatory information.

Importance of Regulatory Standards

Sarah Powell, RAC
Executive Director, Regulatory Affairs and Writing Services
Liquent

Leveraging Regulatory Information and Global Process Standards

Christian A. Buckley, MBA
Associate Director, Regulatory Operations
Astellas Pharma Global

TRACK 2

Successful Practices for Sponsor Collaborations

Session Chairperson

Betsy Fallen
Lead, Global Essential Document and Supply Chain Management Global Clinical Trial Operations
Merck & Co., Inc.

Whether your organization is planning or in the midst of a co-development project, merger / acquisition, or just working with a number of third parties; this session will explore the challenges and opportunities that come with these types of transactions. Come hear from those who have developed processes leading to successful integration following mergers and acquisitions and learn what common practices and pitfalls your industry peers have experienced. The session will also present some of the latest benchmark data on these trends and practices and what to expect in the future. Our industry is changing rapidly and co-development and M&A have become common headlines; the experts will share their experiences and welcome questions.

Creating Integration Synergies: A Case Study of a Global Integration And Harmonization Effort At Teva Pharmaceuticals

Anne M. Marra
Head, Global Regulatory Operations
Teva Global Branded Products

Leveraging Submission Data Standards to Consolidate Repositories from Co-Development Partners

Cortney Gilbert, MBA, MS
Associate Director, Regulatory Affairs
Merck & Co., Inc.

Industry Benchmark: Collaboration, M&A, and Business Development Status/Trends

Steve Gens, MSOD
Managing Partner
Gens and Associates Inc.

TRACK 3

Managing Change: Strategies and Impacts to the Organization

Session Chairperson

Laura J. Sherman, MBA
Managing Partner
Distributed Compliance Solutions, LLC

No matter what type of initiative, whether it be systems/tools deployments/upgrades, new regulations, or mergers/reorganizations, how best to position an organization and targeted audiences for managing change is key to a practical implementation. Case studies will examine critical success factors and assess associated complexities: an EDMS system being deployed, process planning and how best to be prepared for go-live and future growth; positive drivers and influencing approaches to shift a global company from being paper-based to electronic and conclude with managing change across the industry, investigate current industry changes, internal upheavals, impacts to teams/functions/leadership and how to best to implement behavioral change adaptation.

Change Management

Dan Glass
Vice President of Content Management
Y-Prime, LLC

Influencing Change Across the Global Enterprise

Andrea S. Kozak
Global Regulatory Affairs
Regulatory Operations and Compliance
Director, Regulatory Information Management (RIM)
Baxter Healthcare Corporation

Coping in the Dynamic Change Climate in Biopharma Today

Karen Soskin, MLS
Principal Change Learning and Development Leader
Roche

10:00 – 10:30 AM BREAK

10:30 AM – 12:00 PM SESSION 8

TRACK 1

From Electronic Data Capture to Submission Lifecycle Management and Beyond: A True Partnership between Sponsor and Vendors

Session Chairperson

Cynthia F. Piccirillo, BS
Director, Global Dossier Management
eStrategy
Bristol-Myers Squibb Company

This case study will focus on the benefits of a true partnership between a sponsor company and their vendor when generating submission ready data across a broad project portfolio and submitting and maintaining several regulatory applications. The session will highlight the cost benefit and efficiency that comprehensive project management adds to development programs and submissions from both the sponsor and the partner's point of view. A focus on choosing the right electronic data capture technology to improve the handoff from data to submission lifecycle will be discussed. This point of view will contain a look at how choosing the right technology makes the process of moving from clinical research to regulatory submission more efficient and streamlined. The collaboration will be presented with a focus on both major and small submission types. We will review the importance of EDC systems in producing submission-ready deliverables and how they reduce the overall submission timeline and budget. The productivity and efficiency of a joint sponsor-vendor team will be compared to a model where the sponsor chooses multiple vendor relationships; best practices and lessons learned will be presented in both situations. This entire session is based on an ongoing case study of these roles and relationships.

Benefits of Producing Data Deliverables with the Regulatory Submission in Mind

Sailaja Bhaskar, RPh, PhD
Executive Director, Clinical Research
Noven Pharmaceuticals, Inc

Project Management: from Data Deliverables to Submission and Managing Multiple Vendors

Shawn E. Lucini, Pharm.D.
Senior Director, Regulatory Affairs
Noven Pharmaceuticals, Inc.

Productivity and Efficiency of a Joint Sponsor-Vendor Team

Meghan Demollari
Senior Specialist, Regulatory Operations
Octagon Research Solutions, Inc.

TRACK 2

eRecords/eArchive: Records Lifecycle Challenges along the Drug Development Continuum

Session Chairperson

Laura J. Sherman, MBA
Managing Partner
Distributed Compliance Solutions, LLC

This session will highlight 21 CFR Part 11 Compliance / validation requirements and the associated systems used to create, manage, archive and retrieve electronic records and eSignatures. Presenters will share case study challenges, best practices and strategic approaches for the practical implementation and management of electronic records and the development and implementation of an electronic archive.

Topics will include areas that your organization may also be confronting:

- Required Documentation
- Can you scan and destroy?
- What is required for preservation of digital assets?
- How do you manage high volumes of records being received indifferent formats at various time intervals?
- How do you classify large volumes of records according to a retention schedule?
- How do you know when retention requirements have been met and what can/cannot be disposed of?

We'll explore a few essential elements of risk assessment, eRecords privacy protection and security, as well as planning for the unknown, e.g., global systems with local policies, when PDF is not the standard format anymore, and regulations that have not caught up for how we use current technology.

eRecords Validation, Compliance and the Associated Challenges

Robert Barber, MS, PhD
Director of Validation Services
JPC Partners LLC

eRecords, Considerations for Implementation of eRecords/ eArchive

Andrew Waite, MBA
Director, Records and Information Management
Global Regulatory Affairs & Safety
Amgen, Inc.

eArchive: Challenges of Implementation, A Case Study

Shari Perlstein, MBA, PMP
Director, Enterprise Records &
Information Management
Pfizer Inc.

TRACK 3

Portfolio and Submission Management Planning, Tracking and Metrics

Session Chairperson

Daniel F. Orfe
Associate Director, Global Regulatory Operations – Technology, Standards & Vendor Management
Teva Pharmaceuticals

This session will explore both submission management as well as the management of a portfolio of products and their associated submission production. The presenters will provide their first hand experiences with the methods and tools used for planning, tracking and metrics collection. The session will cover these activities from both the large and emerging pharmaceutical industry perspective.

Centralizing Management and Delivery of Agency Ready Submissions for All Countries – A Practical Experience

Karen Towns
Senior Director and Global Head, Publishing and Product License Support,
Pfizer

Making a List and Checking it Twice: Using Checklists for Submission Management

Ronald Hernando
Senior Manager, Regulatory Operations
MacroGenics, Inc.

"Planning to Plan" Approaching Submission Planning and Tracking for a Newly Global (and/or Merged) Organization

Joseph R. Baldari
Manager, Regulatory Publishing Systems
CSL Behring, Inc.

12:00 PM CONFERENCE ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

EDM and ERS/eCTD: The Content Continuum from Document Authoring through Submission Delivery Event #12003

Tutorials: October 8 | October 9-11
Hilton Baltimore, Baltimore, MD

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

Member Early-bird Opportunity Available on nondiscount member fee only	On or before SEPT. 17	After SEPT. 17
Member Fee	US $1390 ❑	US $1540 ❑

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	MEMBERSHIP
	US $175 ❑

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

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A one-year membership to DIA is available to those paying a nonmember registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discount Fees	MEMBER	NONMEMBER
Government (Full-time)	US $615 ❑	US $790 ❑
Charitable Nonprofit/Academia (Full-time)	US $770 ❑	US $945 ❑

**If paying a nonmember fee, please check one box above, indicating whether you want membership.*

TUTORIALS: MONDAY, October 8, 2012

Half-day Morning – 8:30 AM-12:00 PM

Tutorial #1 – eCSRs	US $405 ❑
Tutorial #2 - Bringing eCTD Tools In-house	US $405 ❑

Half-day Afternoon: 1:30-5:00 PM

Tutorial #3 – Putting Regulations into Practice	US $405 ❑
Tutorial #4 - EVMPD	US $405 ❑

TO RECEIVE AN EXHIBIT APPLICATION, PLEASE CHECK ❑

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

❑ **Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.**

1. _____

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3. _____

Payment options: Register online at www.diahome.org or check payment method.

❑ **CREDIT CARD** number may be faxed to: +1.215.442.6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX Exp Date_____

Card # _____

Name (printed) _____

Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

TRAVEL AND HOTEL The most convenient airport is Baltimore Washington International and attendees should make airline reservations as early as possible to ensure availability. **Hilton Baltimore is holding a block of rooms at the reduced rate below until September 17, 2012 for the DIA event attendees.** Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $199 / Double $199

Attendees must make their own hotel reservations. Contact the Hilton Baltimore by telephone at +1.800.HILTONS and mention the DIA event. The hotel is located at 401 West Pratt Street, Baltimore, MD 21201, USA.

CANCELLATION POLICY: On or before OCTOBER 1, 2012
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Preconference Workshop (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: Reasonable accommodations will be made available to persons with disabilities wo attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.

EXHIBIT INFORMATION

Attendees may visit the exhibits during the event and receptions.
Contact **Shannon Lewis, Exhibits Associate,** Phone **+1.215.442.6149**
Fax **+1.215.442.6199,** Email **Shannon.Lewis@diahome.org**

REGISTRATION INFORMATION

For registration questions, please contact **Marilyn Ginsberg** by phone at **+1.215.442.6135** or by Email **Marilyn.Ginsberg@diahome.org**.

EVENT INFORMATION

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Please check the applicable category:

❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student
(Call for registration information)

Last Name _____

First Name _____ M.I.

Degrees _____ ❑ Dr. ❑ Mr. ❑ Ms.

Job Title _____

Company _____

Address (As required for postal delivery to your location) _____ Mail Stop

City _____ State _____ Zip/Postal _____ Country

email **Required for confirmation** _____

Phone Number _____ Fax Number **Required for confirmation**