

# Electronic Document Management 2011

## The Intersection of Data, Documents, and Submissions

Preconference Workshop: February 14 | Conference: February 15-17, 2011

Gaylord National Resort & Convention Center  
National Harbor, MD



### PROGRAM CO-CHAIRPERSONS

#### Joseph A. Cipollina

Senior Director, Operational Excellence and Business Improvement, Worldwide Safety and Regulatory Operations, Pfizer Inc

#### Mark Gray

Director, Division of Regulated Review Support, Office of Business Informatics, CDER, FDA

#### Daniel F. Orfe, MS

President and CEO, Regulatory eSubmissions, LLC

### PROGRAM COMMITTEE

#### Gary Gensinger, MBA

Director (Acting), Office of Business Informatics, CDER, FDA

#### Stephanie Gleissner, MBA

Consultant, Lilly Research Laboratories, Operations, Eli Lilly and Company

#### Matthew Neal

Director, Global Regulatory Affairs and Safety, Amgen, Inc.

#### Shari Perlstein, MBA, PMP

Director, Global Records Management Program Office, Pfizer, Inc

#### Cynthia Piccirillo

Director, Global Dossier Management eStrategy  
Bristol-Myers Squibb Company

#### Laura J. Sherman, MBA

Managing Partner, Distributed Compliance Solutions, LLC

#### Kenneth VanLuvanee

Vice President, Global Professional Services, Image Solutions, Inc.

#### Virginia Ventura Hussong

Team Leader, eSST, Office of Business Informatics, CDER, FDA

### WHO SHOULD ATTEND

- Document and eRecords Managers
- Standards Implementation Specialists and Associates
- Regulatory Affairs Representatives
- Regulatory/Clinical Operations Representatives
- Quality Assurance and Compliance Professionals
- Medical & Technical Writers
- IT and Support Personnel
- Contract Researchers and Service Support Providers
- Academic Researchers
- Validation Professionals
- Pharmacovigilance Professionals
- Outcome Liaisons

#### Worldwide Headquarters

Drug Information Association, Inc.

800 Enterprise Road, Suite 200, Horsham, PA 19044, USA

#### Regional Offices

Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

Over the past 23 years, the DIA EDM Conference has served as a forum for the discussion of emerging standards and the processes for the creation, submission and retention of regulatory information. This year's program has been enhanced to provide a more comprehensive and interactive experience. The renewed approach affords opportunities to learn about and discuss the benefits and challenges of global standards development and implementation.

Additionally, the design and development of business processes to facilitate the conversion of data into document components resulting in high quality regulatory submissions will be examined. Managing information in a completely electronic environment and enabling the current and future electronic submission standards landscape are key focuses.

### MEETING HIGHLIGHTS

- Join industry, regulatory and support organization experts in discussions on the nexus of data, document management and submissions
- Excellent opportunity to network with colleagues from industry, regulatory and support organizations
- Exhibit hall with 30 exhibit booths

### KEYNOTE ADDRESS: Tuesday, February 15, 9:00-10:00 AM



**David Miller**  
Chief Security Officer  
Covisint

#### Document Access Management in a New Century: What the Pharmaceutical Industry Must Do to Avert Its Own WikiLeaks Disaster

In an age where organizations need to provide secure access to hundreds of thousands of sensitive documents, assigning access rights to various individuals is becoming more of an issue than controlling hackers. It's long been known in information security circles that most data breaches occur with individuals who abuse assigned access privileges for unintended purposes.

With the advent of cloud computing and counter movements such as WikiLeaks and OpenLeaks, the threats and risks associated with improper document access control have never been more apparent. In this keynote presentation, the unique challenges of industry-wide collaboration will be outlined, and necessary strategies for properly managing control in large complex ecosystems will be shared. Specific points of discussion include:

- Identifying access privileges for various types of users
- Monitoring usage and identifying individuals that are "abusing" privileges
- Applying techniques such as "white lists" and "black lists" in conjunction with traditional access control models
- Centralizing the access granting decisions across extended organizations
- Sharing of real world access control scenarios in Pharma, HealthCare and Manufacturing

This program has been developed by the  
**Document and Records Management  
and Electronic Regulatory Submissions  
SIACs (Special Interest Area Communities).**



## CONTINUING EDUCATION CREDITS



Drug Information Association has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102; (703) 506-3275. Drug Information Association is authorized by IACET to offer 2.1 CEUs for this program.

**CE Credit Allocation:** Conference: 1.5 CEUs

Tutorial 1: Optimizing Trial Master File Efficiency through Implementation of the Trial Master File Reference Model — .3 CEUs

Tutorial 2: Why Do We Need a Taxonomy — .3 CEUs

Tutorial 3: Guidance Compliant eCTDs — .3 CEUs

Tutorial 4: eCTD Onboarding — .3 CEUs

If you would like to receive a statement of credit, you must attend the program, and tutorial, if applicable, scan your name badge at each session you attend, and complete the on-line credit request process through My Transcript at [www.diahome.org](http://www.diahome.org). Participants will be able to download a statement of credit upon successful submission of the credit request.

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 (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

**LEARNING OBJECTIVES** At the conclusion of this meeting, participants should be able to:

- Recognize the challenges and complexities of globally managing information
- Explain the importance of aligning standards, technology and leveraging interoperability
- Recognize the vital role of metadata in the intelligent management of data, documents and submissions
- Identify trends and standards in electronic records
- Describe global approaches to regulatory submissions
- Discuss current and future regulatory agency initiatives

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

## TUTORIAL DAY | MONDAY, FEBRUARY 14

8:30 AM-12:00 PM CONCURRENT MORNING TUTORIALS

### TUTORIAL #1

#### Optimizing Trial Master File Efficiency through Implementation of the Trial Master File Reference Model

TUTORIAL CO-INSTRUCTORS:

**Lisa Mulcahy**

TMF Management Consultant, Mulcahy Consulting, LLC

**Maryanne Quinn**

Founder, Integrated Submission Strategies, LLC

**Karen Redding**

Global Business Development Director, Pflexglobal

Creating, collecting, managing, and storing documents that are contained in the Trial Master File (TMF) is mandated by regulatory requirements. As a result, all entities conducting clinical studies are required to maintain the documentation for every clinical trial. The Trial Master File Reference Model (TMF RM) provides a clear definition of what documentation should be retained in the TMF and this tutorial will provide you with guidance on the following:

- Regulatory requirements
- Overview of the TMF structure
  - Artifacts
  - Zones
  - Sections
  - Metadata
- Establishing SOPs and training materials
- Defining TMF roles and responsibilities
- On-going assessment of inspection readiness
- Collaboration within and beyond the firewall
- Developing TMF metrics and assessing process efficiency
- Building a foundation for transition to an electronic TMF

**Learning Objectives:**

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

- Identify TMF content and requirements
- Implement practical planning for standardizing TMF processes such as establishing SOP's, training, defining roles, document capture, etc.

- Recognize the impact the TMF Reference Model can have on trial-related processes
- Assess and evaluate TMF process efficiencies
- Develop a business case, including user requirements, for implementing a consistent TMF process based on the adoption or adaption of the TMF RM
- Demonstrate requirements for transitioning to an e-TMF

**Level: Beginner**

### TUTORIAL # 2

#### Why Do We Need a Taxonomy?: EDMS and Metadata

TUTORIAL CO-INSTRUCTORS:

**Donald G. Palmer**

Associate Director, Regulatory Systems, MedImmune

**James Averback**

President, Life Science Integration Partners

The tutorial will start with a comparison of metadata models and their benefits for EDM systems, submission applications, and knowledge management. It will continue by addressing the use of metadata by computer systems and for human 'findability' and the need for metadata standards. The discussion will include a look at where the industry stands today with standards for metadata models and terminology. It will move into 'findability' methods (e.g. navigation, search) and the need to organize information according to standard structures, including taxonomies.

**Learning Objectives:**

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

- Discuss the importance of Metadata and the Metadata standards
- Describe two major 'findability' techniques
- Explain what Taxonomies are and how they make managing metadata easier

**Target Audience:**

- Submission Users with or considering EDMS
  - Authors
  - Regulatory Affairs
  - Regulatory Operations
- People defining Processes for EDMS Users

**Level: Beginners**

12:00-1:30 PM TUTORIAL REGISTRATION

1:30-5:00 PM CONCURRENT AFTERNOON TUTORIALS

### TUTORIAL #3

#### Guidance-compliant eCTDs

Co-INSTRUCTORS:

**Gary M. Gensinger, MBA**

Director (Acting), Office of Business Process Support  
CDER, FDA

**Virginia Ventura Hussong**

Team Leader, eSST, Office of Business Informatics, CDER, FDA

This half day tutorial will provide an overview of FDA's eCTD Guidance and a practical discussion on developing a guidance-compliant format for an eCTD submission

**Learning Objectives:**

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

- Explain the basic elements of eCTD Guidance Documents
- Discuss the content requirements for an eCTD
- Summarize how to develop an eCTD that facilitates review

**Target Audience:**

This tutorial is designed for regulatory affairs personnel, submission content contributors and project managers.

**Level: Beginner**

### TUTORIAL #4

#### eCTD Onboarding

Co-INSTRUCTORS

**Laura Sherman**

Managing Partner, Distributed Compliance Solutions, Inc.

**Matthew Neal**

Director, Global Regulatory Affairs and Safety, Amgen, Inc.

Accelerate start into eCTDs... This tutorial provides an introduction to the practical application of moving from the world of paper submissions to electronic submissions in eCTD format. This session is an ideal starting point for individuals and companies who need to understand the basics, background and practical application and challenges for submitting and maintaining eCTD submissions.

**Learning Objectives:**

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

- Explain eCTD concepts
- Define key acronyms associated with eCTD
- Identify organization changes in planning and preparing electronic submissions
- Summarize document lifecycle and granularity implications
- Discuss global process opportunities in the transition to eCTD

**Target Audience:**

This tutorial is designed for functional areas contributing content to submissions and those responsible for publishing and managing eCTDs.

**Level: Introductory**

12:00-5:00 PM EXHIBITOR REGISTRATION AND SET UP

4:00-6:00 PM ATTENDEE AND SPEAKER REGISTRATION

## CONFERENCE DAY 1 | TUESDAY, FEBRUARY 15

7:30-8:45 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:45-9:00 AM WELCOME AND OPENING REMARKS – Paul Pomerantz, MBA, CAE, Worldwide Executive Director, Drug Information Association, USA

9:00-10:00 AM KEYNOTE ADDRESS *See cover for details.*

10:00-10:30 AM REFRESHMENT BREAK IN THE EXHIBIT HALL (HALL OPENS AT 9:30 AM)

### 10:30 AM-12:00 PM PARALLEL TRACKS

#### Track A – Structured Authoring

SESSION CHAIR:

**Michael Brennan**

Director, Informatics Johnson & Johnson

This session will address the applicability of the DITA model for regulatory information authoring and management. The shift to topic-based authoring provides a critical means of unlocking the potential for re-purposing and retrieving information.

**Industry's Experience in Implementing Topic-based Structured Content**

**A. Brooke Hinkson**

Associate Director, Program Management,  
Global Biomedical Informatics  
Genzyme

**Implementing Topic-based Structured Content in Clinical Documentation**

**James Averback**

President  
Life Science Integration Partners

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#### Track B - DDMAC – Processes and Submissions

SESSION CHAIR:

**Laura Sherman**

Managing Partner  
Distributed Compliance Solutions, Inc.

This session will focus on promotional materials and explore the challenges and extent of impacts over the years for advocating electronic submissions. Successes and complexities will be highlighted in transitioning from traditional paper to advancements in electronic submissions by industry and the EASE group. A case study will provide an example of outsourcing as a means for expected cost savings, increased efficiencies and process improvements and unexpected gains along with updates from FDA.

**EASE Group and Advancing Electronic Submissions: The Future State of e-Promotional and Advertising Submissions**

**Daniel Clark**

Senior Manager, Strategic Regulatory  
Innovation, Novo Nordisk, Inc. *continued*

#### Track C – Sharepoint

SESSION CHAIR:

**Matthew Neal**

Director, Global Regulatory Affairs and  
Safety  
Amgen, Inc.

This session will focus on the emerging use of SharePoint for collaboration and other purposes where longstanding habits, technologies and strategies are evolving.

**Understanding Key Steps to Establish a Risk-based Strategy to Validate SharePoint for Regulated Uses**

**Cary Smithson**

Solution Partner, EMC Corporation

**Migration of Controlled Documents into Compliant SharePoint Document Management Systems**

**Joe Lucadamo**

Senior Consultant, Focused Consulting,  
Inc. *continued*

## 10:30 AM-12:00 PM PARALLEL TRACKS (CONTINUED)

<p><b>Is It Time to Consider the Adoption of an Information Tagging Standard for the Authoring of Regulatory Information?</b>  <b>Michael Brennan</b>          Director, Informatics          Johnson &amp; Johnson</p> <p>DISCUSSANT:</p> <p><b>In Search of Intelligent Content</b>  <b>Gabor Fari</b>          Director, Life Sciences Solutions          Microsoft Corporation</p>	<p><b>Use of Outsourced Review Committee Process Administration to Improve Processes, Increase Efficiency and Reduce Costs</b>  <b>Christi Bruce</b>          Project Supervisor, Labeling and Technology, US Regulatory Affairs          Marketed Products, sanofi-aventis</p> <p><b>FDA Perspective</b>  <b>Marci Kiester</b>          Leader, DTC Review Group, DDMAC          CDER, FDA</p>	<p><b>Embedding Compliance in Your SharePoint Platform</b>  <b>David Gwyn</b>          Vice President, R&amp;D and Collaboration          HighPoint Solutions</p>
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## 12:00-1:30 PM LUNCHEON IN THE EXHIBIT HALL

## 1:30-3:00 PM PARALLEL TRACKS

<p><b>Track A – Leveraging Standards and Technology to Streamline Content Authoring and Reuse</b></p> <p>SESSION CHAIR:  <b>Laura Sherman</b>          Managing Partner          Distributed Compliance Solutions, Inc.</p> <p>This session will explore drivers for applying information standards, technology advances and business processes to gain efficiencies throughout the drug development continuum. Challenges associated with electronic content management and complexities of today's environment combined with current constraints and global operations need to be addressed in order to reduce documentation preparation and review timelines without compromising submission timelines. Case studies will highlight the sharing of best practices from document authoring to facilitate submission-ready documents, content management and repurposing of information to clinical xml authoring.</p> <p><b>Bridging the Gap between Research Reporting and Regulatory Submission</b>  <b>Sunshine Bruce</b>          Regulatory Consultant          Image Solutions, Inc.</p> <p><b>Building a Model for Structured Authoring of the Clinical Protocol</b>  <b>Elaine Lowell</b>          Senior Business Analyst          Paragon Solutions</p> <p><b>Exploration of Efficiencies Gained from Innovative Business Solutions</b>  <b>Andrea S. Kozak</b>          Director, Regulatory Affairs Operations (RAO)          Business Solution Innovation (BSI)          Baxter Healthcare Corporation</p>	<p><b>Track B - A Construct for Successfully Managing Transformational Change of Regulatory Submission Processes and Technical Solutions</b></p> <p>SESSION CHAIR:  <b>Cynthia F. Piccirillo</b>          Director, Global Dossier Management eStrategy          Bristol-Myers Squibb Company</p> <p>Considerations for a comprehensive approach to planning for and managing transformational change in the complex document management and submission preparation environment will be presented based on the speakers' experiences.</p> <p><b>Begin with Strategic Alignment</b>  <b>Cynthia F. Piccirillo</b>          Director, Global Dossier Management e-Strategy          Bristol-Myers Squibb Company</p> <p><b>Define Requirements and Success</b>  <b>Geoff Colgan</b>          Managing Partner Attadale Partners</p> <p><b>Making It Happen</b>  <b>Edward S. Tripp</b>          President          Edward S. Tripp and Associates, Inc.</p>	<p><b>Track C – Migration of Regulated Data and Records</b></p> <p>SESSION CHAIR:  <b>Shari Perlstein</b>          Director, Global Records Management Program Office, Pfizer, Inc.</p> <p>Migration of data and content from one system to another poses a challenge under any circumstance. When regulated data or records are migrated the risks and complexity are even greater. Through real-life case studies, this session will outline the challenges associated with controlled data and content migration in multiple scenarios including new system deployment and integration following a merger or acquisition. Strategies for maintaining the integrity of migrated data and processes for successful migration and risk mitigation will be discussed.</p> <p><b>Records Management Integration after Mergers and Acquisitions</b>  <b>Jimmy Chen</b>          Vice President          DoubleBridge Technologies, Inc.</p> <p><b>Migration of Controlled Documents into Compliant Document Management Systems</b>  <b>Jane Tadlock</b>          Vice President          Focused Consulting</p> <p><b>How to Identify and Mitigate Risks When Migrating GxP Data</b>  <b>David Katzoff</b>          Managing Director          Valiance Partners, Inc.</p>
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## 3:00-3:30 PM REFRESHMENT BREAK IN THE EXHIBIT HALL

3:30-5:00 PM PARALLEL TRACKS

### Track A – Fill It to the RIM: Regulatory Information Management

SESSION CHAIR:

**Donald G. Palmer**Associate Director, Regulatory Systems  
MedImmune

Metadata is gaining an increasingly important role for Life Sciences and, in particular, for Submission related Document Management Systems. This shift is generating the need for Regulatory Information Management to control the use of metadata present at every step of the submission process. The simple use of documents in a submission is no longer sufficient today. We need to search and find documents, re-use documents and content, and track where documents are used. To gain efficiencies, we need to gather metrics on how and when documents are used and re-used. All this requires the management of metadata and regulatory information.

**RIM to RIM: The Grand Canyon of Submission Information****Joel Finkle**Director, Regulatory Informatics  
Image Solutions, Inc.**Fill It to the RIM: Regulatory Information Management****Donald G. Palmer**Associate Director, Regulatory Systems  
MedImmune**Metadata – Curse or Salvation?****Antoinette Azevedo**President & CEO  
e-Submissions.com

### Track B – Evolving Trends

SESSION CHAIR

**Stephanie Gleissner**Advisor, Lilly Research Laboratories  
IT Strategy  
Eli Lilly and Company

This session will explore three distinct but related areas of evolving trends in the regulated content environment. By exploring the shift toward increased global collaboration in the pharmaceutical industry, this session dives into new considerations and capabilities for third party access, security, and what new tools are available for use. Presentations will cover topics ranging from changes in the traditional business model of accomplishing work, new technologies such as portals and cloud computing, and the potential of social media and Web 2.0 in the regulated content environment. Through general technology overviews, case study examples, risk analysis and considerations specific to regulated environment, the audience will be better positioned to consider how these trends may impact and/or can be applied in their business.

**Into the Clouds: Understanding How Cloud Computing Will Affect the Future of Regulated Content Management****Jennifer Goldsmith**Vice President, Strategy  
Veeva Systems**Opening Pandora's Box – A Discussion on Opening Your Regulated Systems to the Outside World****Franciska Darmer**EMA Life Science Solution Specialist  
CSC Life Sciences, UK**Enter the Blogosphere: How Web 2.0 Will Impact Global Content and Records Management****Edsel David**Director, Project Management – Head  
Knowledge Management Technology  
Fannie Mae

### Track C – Records and eArchive

SESSION CHAIR:

**Shari Perlstein**Director, Global Records Management  
Program Office, Pfizer, Inc.

In a regulated environment, the need to develop new or enhance existing strategies to efficiently manage electronic data throughout its lifecycle has become increasingly important. This session will present case studies focusing on strategies for effective use of metadata and approaches for storage across multiple repositories. Policy, process and technology challenges that need to be considered in order to ensure that sound records management, legal and regulatory requirements are met will be presented.

**A Case Study for a Global Submission Archiving System****Mauricha Marcussen**Project Manager  
Edward S. Tripp and Associates, Inc.**Archive Implementation****Steven Becker**Director - Global Head of Records Management  
AstraZeneca**Implementing a Global Electronic Archive Solution – A Case Study****Jennifer Learned**eArchive Service Team Program Lead,  
eRIM, Legal  
Pfizer, Inc.

5:00-6:30 PM RECEPTION IN THE EXHIBIT HALL

## CONFERENCE DAY 2 | WEDNESDAY, FEBRUARY 16

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

8:30–10:00 AM PARALLEL TRACKS

### Track A – Getting the Most from Your Document Management System

SESSION CHAIR:

#### Ed Tripp

President

Edward S. Tripp Associates Inc.

This session covers several approaches and strategies to leveraging the most from your document management systems. Presentations address lower cost approaches to validation, the optimization of workflows and meeting the challenges of globalization. The presentations will address the challenges, gathering and analysis of requirements, as well as present successful approaches in each of the three topic areas.

#### Risk-based Approach to Electronic Document Management System (EDMS) Validation

##### Michael Zwetkow

Pharmaceutical IT Consultant  
Montrium Inc., Canada

#### Optimizing Workflows in a Document Management System

##### Ed Tripp

President

Edward S. Tripp Associates Inc.

#### Implementing Sound Document Management in Regulatory Submission Documents for Global Applications

##### Patricia Santos-Serrano

Manager, Global Regulatory Solutions  
QUMAS

### Track B – Submissions and Business Technology: A Case Study on Achieving Submission Readiness Through Innovative Technology and Standards

SESSION CHAIR:

#### Joseph Cipollina

Senior Director, Worldwide Safety and Regulatory Operations  
Pfizer, Inc.

This case study will identify some of the business process benefits realized through a combination of technology and applying an enterprise taxonomy (based on the TMF/EDM reference model) to automate document life cycle processes and improve submission readiness through process reengineering and training. The case study will also demonstrate best practices and challenges that had to be overcome during the passage from a manual paper based environment to an automated electronic environment.

#### The Foundation - Developing a Roadmap for Superior Document Management

##### Helen Teichman

President

Chestnut Solutions, Inc.

#### The Deconstructed Workflow – Providing Flexibility to the Document Life Cycle Process

##### Tevin Pathareddy

CTO

Montrium, Inc., Canada

#### Hope on the Horizon – Using Metadata and Automation to Organize Submission Preparation

##### John Fedirka

Director, Regulatory Operations

Ironwood Pharmaceuticals

### Track C – Regulatory Submission Strategy for Global Regulated Products - Business Intelligence, Regulatory Information Management and Content Reuse

SESSION CHAIR:

#### Cynthia Piccirillo

Director, Global Dossier Management  
eStrategy

Bristol-Myers Squibb Company

This session covers the lay-of-the-land as it relates to global product marketing and approval approach through the development of a global submission strategy. Presentations will address the sponsors' internal planning, business intelligence gathering and regulatory information management. They will also discuss global interactions with agencies and local company affiliates and how to approach submission strategy development for ICH and non-ICH countries. Furthermore, they will examine the specific case studies of reusing content and cloning as it applies to MAAs for EU and Swiss submissions.

#### Global Submission Strategies: Management of Product Registrations in a Global Regulatory Environment

##### Dirk Beth

President and Founder  
Mission 3

#### Non-ICH Regions Regulatory Filing Requirements and Updates

##### Brooke Casselberry

Senior Manager, Regulatory Affairs and Writing Services  
Liquent

#### Producing MAAs in 24h' – Maximizing Cloning and Content Reuse

##### Joerg Schnitzler

Associate Director, Regulatory Operations,  
Astellas Pharma Europe R&D, Netherlands

10:00–10:30 AM REFRESHMENT BREAK IN THE EXHIBIT HALL

10:30- AM-12:00 PM

## PARALLEL TRACKS

**Track A – Paper to Electronic**

SESSION CHAIR:

**Kay Bross**

CEO

Interop.K.Bross Consulting, LLC

This session will focus on issues of significant consideration when moving from managing documents in a paper paradigm to managing them in an electronic paradigm. What are the issues? How should they be resolved to allow for today's needs as well as long term archiving needs? What resources are available to answer these and other questions?

**Transition from Paper Data Management Binder to Electronic Data Management File**  
**Nancy Wakeley**

Clinical Data Integration, Program Manager  
 Duke Clinical Research Institute

**Managing Electronic Records in the Modern Pharma Archive**

**Steve Columbus**

Director, Records Information Center  
 Abbott Pharmaceuticals, Inc.

**Electronic Documents: How Can Digital Signatures Secure Them?**

**Kay Bross**

CEO

Interop.K.Bross Consulting, LLC

**Track B - Leveraging standards and technology to improve business process definition and execution**

SESSION CHAIR:

**Joseph Cipollina**

Senior Director, Worldwide Safety and Regulatory Operations, Pfizer, Inc

Business Process Management (BPM) is both practice and technology that has been embraced by leading life sciences organizations because it is able to better accommodate and support process change by combining process design, modeling, execution, monitoring and optimization. Many companies are looking toward BPM to bridge gaps in areas such as Clinical, Regulatory Compliance, Manufacturing and Sales & Marketing. These organizations are leveraging BPM to provide the IT linkages across functional areas to allow a broad array of improvements ranging from pre-clinical study design and drug procedures to grants management and post-approval safety reporting. This session will provide an overview of Business Process Management and how it can be applied in Life Sciences to enable business & IT to directly capture and execute predictive models and break down silos between existing systems such as CTMS, Safety, EDM, ERP and CRM to fill execution gaps and eliminate redundancies.

**Leveraging a Business Process Management Approach to Optimizing Product Development Efficiency**

**Melonie Warfel**

Director, Life Sciences  
 Pegasystems, Inc.

**Leveraging Documentation Management Standards for Continuous Clinical Trial Process Improvement**

**Paul Fenton**

Vice President, Pharmaceutical Processes and Technology  
 Montrium, Inc. Canada

**Leaner and More Efficient Business Processes**

**Mary McKenna**

Associate Director US and Frankfurt  
 Regional Head - Clinical Electronic Document Management  
 sanofi-aventis

**Track C Compliance and Information Management**

SESSION CHAIR:

**Matthew Neal**

Director, Global Regulatory Affairs and Safety  
 Amgen, Inc.

This session will explore global information management and the robust business process needed to maintain the big picture.

**Managing Regulatory Information – Remaining Compliant in a Global Marketplace**

**Sarah Powell**

Executive Director, Regulatory Strategies  
 Liquent

**Global Submission Management: Improving efficiencies working with Non-ICH regions - A Case Study**

**Dominique Lagrave**

Senior Director, Regulatory Operations and Innovation  
 Novo Nordisk, Inc.

12:00-1:30 PM

LUNCHEON IN THE EXHIBIT HALL

1:30-3:00 PM

## Regulatory Update Session 1

SESSION CHAIR:

### Gary Gensinger

Director (Acting) Office of Business Informatics  
CDER, FDA

This first session presented by FDA staff focuses on issues of immediate impact to the pharmaceutical industry concerning electronic submission format. Experts will discuss changes to eCTD Module 1, validation codes and DDMAC's plan to receive electronic submissions of promotional and advertising material in eCTD format.

#### RPS and Module 1

##### Mark Gray

Director, Division of Regulated Review Support, Office of Business Informatics  
CDER, FDA

#### eCTD Validation Update

##### Jared Lantzy

Regulatory Information Specialist  
CDER, FDA

#### DDMAC Electronic Submissions: What's Ahead

##### Marci Kiester

Leader, DTC Review Group, DDMAC  
CDER, FDA

3:00-3:30 PM

REFRESHMENT BREAK IN THE EXHIBIT HALL (HALL CLOSES AT 3:45 PM)

3:30-5:00 PM

## Regulatory Update Session 2

SESSION CHAIR:

### Mark Gray

Director, Division of Regulated Review Support, Office of Business Informatics  
CDER, FDA

This FDA session provides a discussion of standards for the submission of data and their implementation within CDER and CDRH. Officials working on implementation of these standards will provide an update on both the current status of implementation and what the Centers are planning in the future.

#### CDRH: Current and Future Uses of Data Standards in eSubmissions

##### Terrie L. Reed

Associate Director for Informatics  
CDRH FDA

#### Data Standards Plan

##### Catherine Jansto

CDER, FDA

#### The Changing Landscape for Nonclinical Data Management and Submission

##### Timothy Kropp

Toxicologist, Office of Oncology Drug Products  
CDER, FDA

5:00-5:30 PM

## FDA Town Hall

**Ask the Regulator!** This Regulatory FDA Town Hall session is one of the more popular features of our annual document management meeting. A panel of agency representatives will be available to answer questions and share dialogue. This is a unique opportunity to learn about the latest FDA initiatives and to obtain current and practical advice from key agency personnel that are responsible for electronic submission standards and reviews.

If you have specific questions that you would like to ask the panelists regarding FDA submission standards, processes, regulations, guidance, or initiatives, please send them to [Joanne.Wallace@diahome.org](mailto:Joanne.Wallace@diahome.org) (subject: "Questions for the FDA")

**Please note that not all questions may be answered due to time limitations.**

5:30 PM

END OF DAY 2

## CONFERENCE DAY 3 | THURSDAY, FEBRUARY 17

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

8:30-10:00 AM PARALLEL TRACKS

### Track A – Document Granularity: Breaking up is NOT hard to do!

SESSION CHAIR:

**Cynthia F. Piccirillo, Director**

Global Dossier Management e-Strategy  
Bristol-Myers Squibb Company

Preparing documents in a granular format allows additional gains in life cycle efficiencies of documents and applications afforded by the construct of the electronic Common Technical Document. This session will provide details about the business case and benefits to make this transition as well as insight on how others have successfully managed the change.

**The Writer's Perspective – Managing the Granularity Puzzle**

**Sherry Hickman**

Senior Regulatory Specialist, Central Regulatory Operations, Eli Lilly and Company

**The Publisher's Perspective - Managing the Granularity Puzzle**

**Scott Cleve**

Associate Director, Regulatory Affairs  
Astellas Pharma Global Development, Inc

**Lifecycle and Change - Managing the Granularity Puzzle**

**Nancy Smerkanich**

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

### Track B – The Trial Master File Reference Model and Industry Interpretations

SESSION CHAIR:

**Daniel F. Orfe**

President and CEO  
Regulatory eSubmissions, LLC

The launch of the DIA TMF Reference Model in June 2010 is indicative of the evolving drive for consistency in Trial Master Files across the industry. This taxonomy and metadata reference model, a comprehensive review of content generated during clinical trials across functional disciplines, was developed by industry representatives. The model goes far beyond the minimum requirements specified in ICH E6. Any company can use the model as a starting point for enhancement of their current TMF processes or technology.

This session will review the features of the newest version 1.1 of the TMF Reference Model, plus provide real industry experiences using or adapting the model as a basis for the pursuit for process optimization around the implementation and use of an electronic TMF.

**The Trial Master File Reference Model**

**Lisa Mulcahy**

TMF Management Consultant  
Mulcahy Consulting, LLC

**Applying the TMF Reference Model**

**Fran Ross**

TMF Process Owner  
Senior Analyst  
Genzyme Corporation

**The TMF Reference Model - Leveraging for Success**

**Karen Redding**

Global Business Development Director  
Phlexglobal, UK

### Track C - IRISS Forum and eCTD Interoperability

SESSION CHAIR:

**Deanna Murden**

CEO, ePharmaCMC

Crowd sourcing has become popular in recent years as a mechanism to leverage mass collaboration to solve problems and achieve business goals. Implementation of Regulatory Information Submission Standards (IRISS) was formed under this same premise as a global, open, multidisciplinary non-profit organization. IRISS serves to harness the universal industry desires for a smooth and successful adoption of a paperless regulatory environment around the world through inviting open participation, capturing the diversity and expertise of the masses to understand problems and freely share collective knowledge with everyone. This session will present a selection of topics currently being studied under the IRISS organization, challenges, progress and considerations.

**IRISS Overview & Interoperability Topics**

**Lenore Palma**

Director, Product Development  
Liquent, Inc.

**ETICS III eCTD Tool Interoperability and Compliance Study**

**Harv Martens**

Vice President of Operations North America and Japan, Extedo, Inc.

**eCTD Life Cycle Topic Group**

**Joseph Cipollina**

Senior Director, Worldwide Safety and Regulatory Operations, Pfizer, Inc

10:00-10:30 AM REFRESHMENT BREAK

10:30- AM-12:00 PM

PARALLEL TRACKS

**Track A – CDISC**

SESSION CHAIR

**Stephanie Gleissner**

Advisor, Lilly Research Laboratories, IT Strategy  
Eli Lilly and Company

This session will dive into details on what has been accomplished via the industry and FDA CDISC consortia. Specifically, presenters will target on the purpose of CDISC, specific details related to both SEND and SDTM data standards, technologies that exist to support SEND and SDTM, and the implications to data, document, and submission preparation. Additionally, the FDA will discuss the impact and implementation of CDISC from the agency's perspective.

**Specifying SDTM Datasets: Tools to Help in the Real World****Christie Wolf**

Project Director  
Axio Research, LLC

**STDM****Chuck Cooper**

Medical Officer, Office of Translational Sciences  
FDA

**SEND (Standard for Exchange of Non-clinical Data)****Lou Ann Kramer**

Eli Lilly and Company

**Track B – Implementation of the Trial Master File Reference Model – Opportunities for Achieving Process Efficiencies**

SESSION CHAIR:

**Daniel F. Orfe**

President and CEO  
Regulatory eSubmissions, LLC

A primary goal of the TMF RM is to provide a single, unified interpretation of current regulations via a standard listing of artifacts and related metadata which can be adopted or adapted by any life science company. The TMF RM provides a collaborative advantage to companies in creating and managing their TMF's and provides the industry with a mechanism to refine TMF processes based on input and consensus from the industry.

This session will provide you with an overview of the operational aspects of implementing the TMF RM in your organization, emphasizing the expected efficiencies and benefits.

**Trial Master File Reference Model: An Opportunity for Industry Standardization****Maryanne Quinn**

President  
Integrated Submissions Strategies

**Redefining the Trial Master File****Ivan Walrath**

Process Owner, Trial Master File  
Pfizer, Inc.

**Improving the Efficiency of Clinical Trial Start up through the use of Metadata-Driven Document Creation****Chet Shemanski**

Director of Product Management  
NextDocs

**Track C – eCTD Perspectives from Chemistry, Manufacturing and Controls – Templates, Authoring and Life Cycle**

SESSION CHAIR:

**Deanna Murden**

President  
ePharmaCMC, LLC

The session will describe the nuances and inside experiences of working with the eCTD format in Regulatory Chemistry, Manufacturing and Controls (CMC) (Module 3). There are many opportunities to leverage, and certainly challenges which span product life cycle management, quality compliance and global dossier management unique to CMC. Industry speakers will discuss (a) lessons learned from the sponsor side when transitioning from a paper based regulatory compliance and tracking system for product quality information to one which leverages the eCTD technology, (b) authoring considerations and implementation challenges within organizations where authoring templates that were in place for paper based Module 3 submissions, and how they have evolved with continual lessons learned and best practices to best integrate with an electronic common technical document, and (c) life cycle considerations that span different CMC content areas such as Drug Master Files, Quality Overall Summaries, ASMF and Biologics.

The session is intended for advanced audiences, and will not cover basic eCTD concepts and terminology. The session will focus on real world applications and case studies of points to consider and lessons learned around Chemistry, Manufacturing and Controls.

**Regulatory Quality Compliance and eCTD Dossiers****Kathy Lenz**

Abbott Laboratories

**Paper to eCTD, writing considerations for CMC Authors****Anita McClernon**

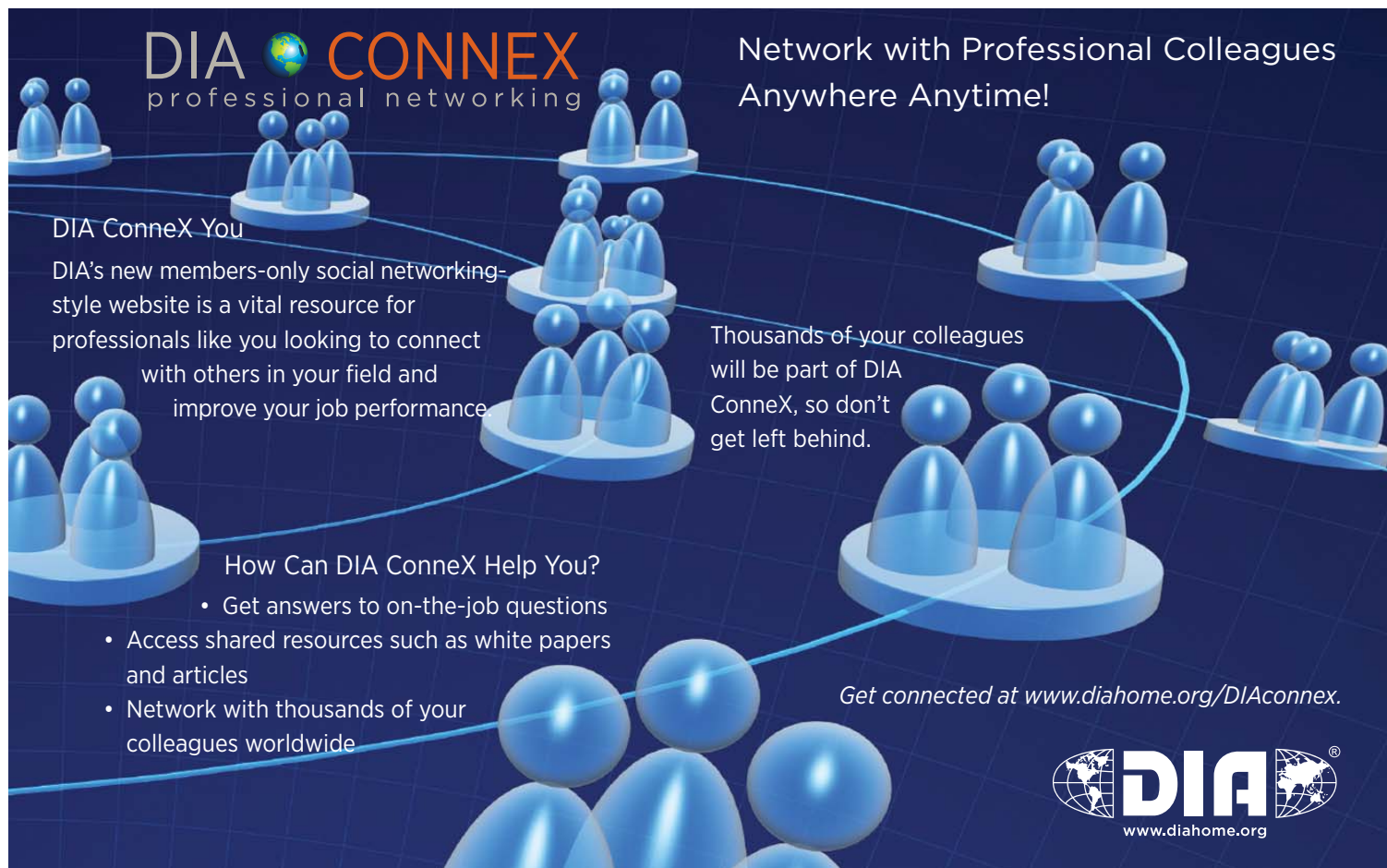
CMC Regulatory Project Manager  
GlaxoSmithKline

**Lessons Learned regarding eCTD Formats for CMC Applications****Colleen Godshall**

Senior Regulatory Scientist  
Merck & Co., Inc.

12:00 PM

CONFERENCE ADJOURNED



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**Art of Writing a Clinical Overview**  
February 14, 2011 Event ID 11401  
National Harbor, MD

**Development of a Clinical Study Report**  
February 14, 2011 Event ID 11405  
National Harbor, MD

#### Other courses of interest:

**Regulatory Affairs: Part I: The IND Phase and Part II: The NDA Phase**  
January 9-12, 2011 Event ID 11413  
University of Southern California, Irvine, CA

**European Regulatory Affairs**  
March 7-8, 2011 Event ID 11415  
DIA Headquarters, Horsham, PA

**Regulatory Affairs for Biologics**  
April 6-7, 2011 Event ID 11414  
DIA Headquarters, Horsham, PA

Register at [www.diahome.org/global2011](http://www.diahome.org/global2011) and enter the five-digit Event ID.

# REGISTRATION FORM

Register online or fax this page to +1.215.442.6199

## Electronic Document Management 2011 Event #11003

Preconference Workshop: February 14, 2011 • Conference: February 15-17, 2011  
Gaylord National Resort & Convention Center, National Harbor, 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	On or before JAN. 24, 2011	After JAN. 24, 2011
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**Nonmember Fee** US \$1680

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

Discount Fees	MEMBER	NONMEMBER
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Charitable Nonprofit/Academia (Full-time)	US \$770 <input type="checkbox"/>	US \$910 <input type="checkbox"/>

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### Preconference Workshops: February 14, 2011

#### Half Day Tutorial : 8:30 AM-12:00 PM

Tutorial #1 US \$405   
Tutorial #2 US \$405

#### Half Day Tutorial : 1:30-5:00 PM

Tutorial #3 US \$405   
Tutorial #4 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.

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**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 Ronald Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Gaylord National Hotel & Convention Center is holding a block of rooms at the reduced rate below until January 24, 2011 for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$189 / Double \$189

Attendees must make their own hotel reservations. Contact the Gaylord National Hotel & Convention Center by telephone at +1.301.965.2000 and mention the DIA event. The hotel is located at 201 Waterfront Street, National Harbor, MD 20745, USA.

### CANCELLATION POLICY: On or before FEBRUARY 7, 2011

**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:** DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office 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**

### EVENT INFORMATION

Contact **Joanne Wallace, Program Manager**, Phone **+1.215.442.6180**

Fax **+1.215.293.5931**, email **Joanne.Wallace@diahome.org**

### 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 \_\_\_\_\_

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Phone Number \_\_\_\_\_ Fax Number **Required for confirmation** \_\_\_\_\_