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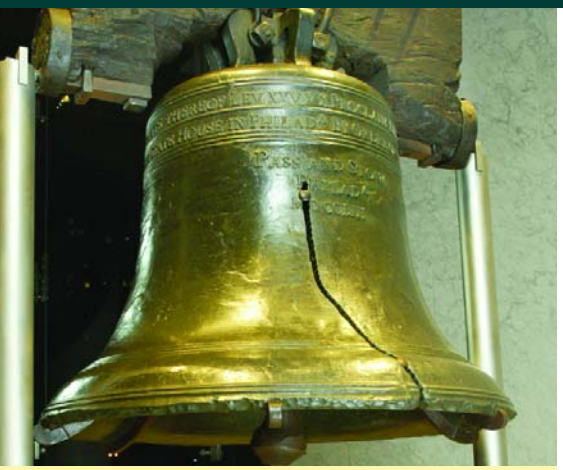
21st Annual DIA Conference for Electronic Document Management

DRUG INFORMATION ASSOCIATION

Managing Documents and Records— The Never-ending Process

February 5-8, 2008 | The Philadelphia Marriott Downtown, Philadelphia, PA



PROGRAM CO-CHAIRS

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Director, Regulatory Review Support Staff, CDER, FDA

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Managing Director, West Coast Operations, Octagon Research

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VIRGINIA VENTURA
Regulatory Information Specialist, CDER, FDA

STEPHEN E. WILSON, DRPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

In the past, DIA's EDM programs have focused on the Life Science Industry's move toward electronic information exchange and the wave of standards and initiatives to support this transformation. This year's focus will be "getting back to grass roots" and will include the basics and best practices of document and records management. We will provide a retrospective review of the processes upstream and downstream of the regulatory submission. This is inclusive of content management from creation to archival, and also examines the broader vision for electronic document management. A look across this landscape affords the opportunity to interact with and learn from experts representing industry and the vendor community, as well as regulatory authorities. Optimizing, repurposing and channeling information across the enterprise with final destinations to worldwide health authorities necessitates the need to get back to the fundamentals and strategically align the content with the process. Our newly organized interactive Regulatory Day will focus on the need to produce regulatory-compliant electronic submissions.

RECEPTION

Wine Tasting for Dummies Thursday, February 7, 6:30 - 8:30 pm – details on page 2.

LEARNING OBJECTIVES

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

- Recognize the challenges within document management, its implications across the enterprise and its impact on the organization
- Identify the challenges associated with managing information in a global environment
- Recognize the importance of aligning standards and technology with the process and interoperability implications
- Define multiple levels of lifecycle management within the drug development process
- Share best practices in streamlining and mapping the process and flow of information (both documents and data) within your organization
- Review the current initiatives and future vision of FDA and other regulatory authorities
- Identify challenges associated with maintaining national and regional regulatory compliance
- Appreciate the vital role of good document management in the overall process of preparing documents and regulatory submissions
- Evaluate the significance of good content management practices in the lifecycle of regulatory documents from creation to archival status

WHO SHOULD ATTEND

This meeting will benefit those who are engaged in EDM and looking for improvement and efficiency as well as those just beginning the journey. Sessions will include introductory through advanced topics, technical and business, large pharma and small pharma, US and global focus, agency and industry.

CONTACT INFORMATION

Conference: Joanne Wallace, Program Manager, +1-215-442-6180/email Joanne.Wallace@diahome.org
Exhibits: Erin Gilliland, Exhibits Associate, +1-215-442-6149/email Erin.Gilliland@diahome.org

SIAC THIS PROGRAM WAS DEVELOPED BY THE DOCUMENT AND RECORDS MANAGEMENT; ELECTRONIC REGULATORY SUBMISSIONS AND MEDICAL WRITING SPECIAL INTEREST AREA COMMUNITIES

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

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EDM
21ST ANNUAL DIA
ELECTRONIC DOCUMENT MANAGEMENT

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 information, in any type of media, is prohibited at all DIA events without prior written consent from DIA.

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 2.3 continuing education units (CEUs) to participants who successfully complete this program and tutorial(s).

To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities 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.

Continuing Education Credit Allocation

(*IACET CEUs are not available for the plenary sessions or the post-conference workshops)

Total Credits for Conference and Tutorials: 2.3 IACET CEUs
Full-day Tutorial: .7 IACET CEUs **Half-day Tutorials:** .3 IACET CEUs
Conference: 1.6 IACET CEUs

Wine Tasting for Dummies — Thursday, February 7, 6:30 - 8:30 pm

Crossing Vineyards and winery

Come learn about wine and have fun! Crossing Vineyards and Winery located in Bucks County, PA has been listed as one of the top 5 wineries located in the Atlantic Northeast Region by Tom Stevenson's Wine Report 2008. This will be a treat and a very enjoyable evening.

Exhibitor Information

Tuesday, February 5, 3:00 – 7:00pm Exhibitor Registration and Booth Set-up

Exhibit Hall Hours

Wednesday, February 6 9:30am - 6:30pm **Thursday, February 7 9:30am - 3:00pm**

Light refreshments will be served from 5:00 - 6:30pm

Exhibiting Companies as of January 9, 2008

Adlib Software
Applied Clinical Trials
Apyx, Inc.
CanReg, Inc.
Computer Sciences Corporation
Data Conversion Laboratory, Inc.
Datafarm, Inc.
Doublebridge Technologies
EMC
EXTEDO (IABG Life Sciences Solutions)
First Consulting Group
Glemser Technologies
Good Products
i4i, Inc.
Impact Systems
ISI
Jacquette Consulting, Inc.
LORENZ Life Sciences Group
MasterControl, Inc.
MEI
Microsoft Corporation
Microsystems
Mission3, Inc.
NextDocs Corporation
Octagon Research Solutions, Inc.
OnLine Business Applications, Inc.
Phlexglobal Limited
PleaseTech Ltd.
QUMAS Inc.
Reed Technology
SCHEMALOGIC
TAKE Solutions
Thomson Scientific
Tourtellotte Solutions
Valiance Partners, Inc.
Virtify, Inc.
Vital Path

Meeting Contact and Exhibit Information

Meeting attendees are welcome to visit the exhibits during the workshop and receptions. For meeting information, contact Joanne Wallace, Program Manager at the DIA office in Horsham, PA by telephone +1-215-442-6180, fax +1-215-442-6199 or email: Joanne.Wallace@diahome.org. For exhibit information, contact Erin Gilliland at +1-215-442-6149, fax +1-215-442-6199 or email: Erin.Gilliland@diahome.org.

Tuesday, February 5 (Tutorials Only)

7:00 - 9:00am Tutorial Registration

9:00am - 5:00pm Full-day Tutorial 1

#1 Electronic Odyssey

Level: Beginner/Intermediate (.7 IACET CEUs)

Instructors

John Aitken, PhD

Managing Director, West Coast Operations, Octagon Research Solutions, Inc.

Brad Goebel, MS

EDMS Project Lead, FDA Regulated Systems Architect, Management and Technology Solutions Inc

Electronic document management (EDM) and the eCTD are often treated as completely separate processes in their planning and execution. They are, however, highly interdependent stages of an integrated document lifecycle management process. The tutorial will provide a comprehensive grounding in all of the components and stages of this integrated process, including:

- Standardizing software
- Computer systems validation
- Document standards for authoring and granularity
- Electronic document management
- Document repository
- Taxonomy
- Metadata
- Version control
- Workflows
- Collaboration
- Introduction to the eCTD
- Integrating EDM and the eCTD
- Document publishing
- Preparing eSub-ready documents
- Preparing a sample eCTD
- Compiling and submitting the eCTD
- eCTD lifecycle management

Learning Objectives

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

- Appreciate the vital role of good document management in preparing documents for the eCTD
- Learn about authoring and publishing electronic documents for the eCTD
- Recognize the key components of the eCTD process and its lifecycle management

Target Audience

This tutorial is designed for regulatory operations, regulatory affairs, medical writing, IT, clinical, non-clinical, and CMC personnel.

8:30am - 12:00pm Concurrent Morning Tutorials

#2 eIND

Level: Intermediate (.3 IACET CEUs)

Instructor

Denise Kramer

Manager of Curriculum Development/Education Services, Image Solutions, Inc.

This session will focus on the industry changes in submitting INDs electronically. It will cover the span of how IND submissions have evolved over the past several years and how the eCTD revolutionized the way they are currently being prepared and submitted.

Learning Objectives

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

- Convert IND documents into the eCTD
- Describe the eCTD structure
- List the requirements for preparing INDs electronically
- Recognize the benefits of life cycle management

Target Audience

This tutorial is designed for managers and personnel in regulatory affairs, regulatory operations, IT support, document management, and medical writing.

8:30am - 12:00pm Concurrent Morning Tutorials (continued)

#3 Practical Management of eCTD Lifecycle

Level: Intermediate (.3 IACET CEUs)

Instructor

Kenneth VanLuvanee
President and CEO, Apyx, Inc.

The eCTD lifecycle specification changes how we view submissions. This tutorial will discuss the practical challenges of submitting and maintaining an eCTD submission, including strengths and weaknesses of the model. Specific issues to be discussed will include a discussion of the eCTD lifecycle model itself, challenges and opportunities posed by the model, and options for specific solutions that can be applied to managing the inherently dynamic lifecycle of an eCTD.

Learning Objectives

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

- Describe the eCTD lifecycle model starting from initial submission
- Explain what the lifecycle model can and cannot do
- Summarize the issues surrounding eCTD lifecycle management from a records management perspective

Target Audience

This tutorial is designed for regulatory publishers, publishing managers, and archive managers responsible for publishing and managing eCTD submissions and components.

#4 Compliance: Avoiding Costly Submission Errors

Level: Beginner (.3 IACET CEUs)

Instructors

Guy Pawson, PhD
Manager, Electronic Submissions, Genentech, Inc.
Jacques Mourrain, PhD
Director, Computer Systems Compliance, Genentech, Inc.

This tutorial will focus on the practical steps necessary to ensure that submission documents are free of errors and function in the manner intended. The tutorial will provide a roadmap to developing a strategy for compliance for smaller companies approaching their first submission, and a checklist for others who may wish to refine their procedures for ensuring optimal document quality. The tutorial will address two approaches to compliance: that of the eSubmission filing team whose primary responsibility is publishing, and that of the compliance team itself. We will show how close integration of each group's role in the compliance process results in an effective model for ensuring the highest quality of submission deliverables.

Learning Objectives

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

- Identify the relevant FDA regulations and guidance that impact their electronic records, documents and submissions
- Discuss and analyze the current regulatory compliance expectations, including design and validation issues for electronic document and publishing systems
- Interpret the regulations and guidance to formulate realistic and justified plans and standards for their company's electronic records, documents, submissions, and related computerized systems

Target Audience

This tutorial is designed for managers and personnel in information technology and management, regulatory affairs, compliance, and submissions, as well as regulatory submission content contributors and project managers.

12:00 - 1:30pm Tutorial Registration

1:30 - 5:00pm Concurrent Afternoon Tutorials

#5 Guidance-compliant eCTDs

Level: Beginner (.3 IACET CEUs)

Instructors

Gary M. Gensinger, MBA
Director, Review Technology Staff, CDER, FDA
Bronwyn Collier
Associate Director, Regulatory Affairs, Office of Drug Evaluation III, CDER, FDA
Virginia R. Ventura
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA
Norman R. Schmuff, PhD
Deputy Director, Division of New Drug Chemistry III, 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.

#6 Authoring Medical Templates

Level: Beginner (.3 IACET CEUs)

Instructor

Marc J. Stern

Assistant Director, Document Formats and Standards, Forest Research Institute

Kenneth VanLuvanee

President and CEO, Apyx, Inc.

In the world of electronic submissions, regardless of the type of document management system, publishing system, or submission format that is used, the submission must be well written not only from the content perspective, but from its formatting as well. Authors involved in an electronic submission process need to be aware that every keystroke they use may impact the downstream publishing process.

Templates are the key to successful submissions. They help enforce content standards as well as laying the foundation to successful electronic submissions. But how are these templates created? Who programs them? How do you program them? How are they approved? How is training done? How do you ensure templates that are created in Clinical and templates created in CMC will work in the same publishing environment?

This hands-on tutorial will step through the process of how to create templates starting with the master template. The class will learn how to create and modify styles and see how styles are the key in creating successful electronic templates. After the styles are created, macros will be introduced. These macros will help with the standardization process (eg, ensuring all tables will look the same) and the tutorial will go over some rudimentary Visual Basic for Applications (VBA) language.

After the master template is created, a basic content template will be created. The class will learn about the relationship between the master and content template, including how making one change to the master template can impact all content templates.

Even after the templates are built, there are many other questions that the class will learn to answer: What is the best way to get your templates reviewed and approved? Should SOPs govern these processes? When should hands-on training be used versus classroom training? How do companies get groups to agree upon a set of standards? Are out-of-the-box templates better or worse than creating your own? How do you get CROs or partners to use them? Are there international issues?

It is evident that creating templates is not a simple, but rather complex process. Authors will be spending most of their time working in templates, thus it is important that they are set up, programmed, implemented, and trained upon carefully and correctly.

Learning Objectives

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

- Identify the technical and business processes involved to create, approve, and train the authoring community in templates
- Explain the impact of templates in the submission process.

Target Audience

Medical/scientific writers, regulatory affairs, IT, and publishing professionals who are responsible for creating or supporting an authoring system designed for electronic submissions.

#7 Validation of Computerized Systems for Regulated Electronic Records, Documents, and Submissions

Level: Beginner (.3 IACET CEUs)

Instructor

Kim W. Nitahara, MBA

Principal Consultant, META Solutions, Inc.

This tutorial will provide an overview of the primary FDA regulations and guidance regarding the validation of computerized systems that create, modify, maintain, archive, retrieve, and transmit regulated electronic records, documents, and submissions, including the submission management and publishing. The presented information will focus on the regulatory requirements, as well as the practical issues, problems, and concerns that affect computer systems design and validation. The presentation will include a review of the 21 CFR 11 "Electronic Signatures; Electronic Records" regulations, as well as the underlying "predicate" regulations that govern GxP and regulatory submissions to the FDA. The tutorial will include a review of current industry best-practices in computerized systems validation, and any updates on the changes to the 21 CFR 11 validation requirements. Practical information and approaches to meet the validation requirements will be presented and, if time permits, discussed with participants, using industry examples and actual FDA inspection results.

Learning Objectives

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

- Identify the relevant FDA regulations and guidance that impact their electronic records, documents, and submissions
- Discuss and analyze the current expectations for the design and validation of electronic document and submission publishing systems
- Interpret the regulations and guidance to formulate realistic and justified validation plans and standards for their company's electronic records, documents, submissions, and related computerized systems

Target Audience

This tutorial is designed for managers and personnel in R&D departments who generate, maintain, and use electronic records, documents, and submissions in information technology, regulatory affairs, compliance, and submissions organizations, as well as regulatory submission content contributors and project managers.

3:00 - 7:00pm Exhibit Registration and Set-up

4:00 - 6:00pm Attendee and Speaker Registration

Wednesday, February 6

7:30 - 8:30am Registration and Continental Breakfast

8:30 - 8:45am **Welcome and Opening Remarks**

Kay Bross
Senior PKI Specialist, Information Security and Solutions, Procter & Gamble Company

Ronald D. Fitzmartin, PhD, MBA
President, Drug Information Association
Vice President, Informatics and Knowledge Management, Daiichi Sankyo, Inc.

Linda McGoldrick, MBA, MSW
Worldwide Executive Director, Drug Information Association

8:45 - 9:30am **Keynote Address**

High Quality Medical Care Costs Less: The Role of Standardization

Janet Marchibroda, CEO, eHealth Initiative

An overview of the national Health IT efforts underway at regional and national levels for improved patient healthcare and what part document management plays in the process.

9:30 - 10:15am **Data Standards**

Charles Jaffe, MD, PhD, FACMI
CEO, Health Level 7

An overview of activity related to data standards and why it's important as local and regional initiatives focus on compatibility for broad Health IT gains.

10:15 - 10:45am Refreshment Break in the Exhibit Hall (Hall opens at 9:30am)

Parallel Tracks

10:45am - 12:15pm TRACK A

Electronic Health Records – What You Need to Know ... NOW

Session Chair
Bill Rosen
Executive Director, Pharmacovigilance Information Management Standards and Policy, Pfizer Inc

Think the Electronic Health Record (EHR) doesn't immediately impact you today? Think again. The underpinnings of an electronic healthcare network have existed for many years in the form of electronic medical records (EMRs), created and held mostly by individual healthcare providers. The contents of EMRs offers a wealth of information and value to the biopharmaceutical industry. While the most obvious hurdle may appear to lie within the technical problems of accessing and aggregating information contained within EMRs, perhaps a more immediate challenge to the biopharmaceutical industry is how to proactively participate in the evolving electronic standards discussion within the healthcare environment. Until now, EMRs have been developed mostly by healthcare providers, with little or no involvement of the biopharmaceutical industry. As an industry, we need to assume more of a leadership role in EHR standards development and implementation, and to take a seat at the table with other key stakeholders from the healthcare industry.

This session will introduce key components of EHR, including electronic standards, key organizational stakeholders, similarities and difference in medical records and EHR terminology, and emerging trends in EHR. Additionally, this session will identify key areas where our industry can (and must) become involved now, so that we can begin to have critical influence on the evolution of electronic healthcare.

The Standards Environment
Bob Birmingham
Director of Technical Operations, Johnson & Johnson PRD, LLC

The eHR, PHR, eMR and their Relevance to You
Bill Rosen
Executive Director, Pharmacovigilance Information Management Standards and Policy, Pfizer Inc

Emerging Efforts and Trends for the eHR in the EU
Suzanne Markel-Fox, PhD
Director, Strategy & Process Excellence, GlaxoSmithKline

10:45am - 12:15pm TRACK B

Document Management

Session Chair
Janis A. Gyzen
Assistant Director, Submission Programs, TAP Pharmaceuticals, Inc.

The ability to streamline the internal processes of documents for regulatory submission has a profound impact on the introduction of a product to the marketplace. TAP will describe how it has integrated its legacy document management systems as well implemented standard processing of documents for inclusion in our eCTDs. The standard processes include preparation, review and electronic approval of submission-ready documents. Additionally, we have integrated our document management system with our existing electronic records management system. This integrated approach has improved user acceptance, compliance, and document quality.

Integration of Document and Records Management Experience Driven Model for an Integrated Enterprise for Document Management
Janis A. Gyzen
Assistant Director, Submission Programs, TAP Pharmaceuticals, Inc

Experience Driven Model for an Integrated Enterprise for Document Management
Michael M. Sauter
Senior Director, Global Regulatory Operations, Biogen, IDEC

CASE STUDY: Moving Documentaum from a Departmental Solution to an Enterprise Solution at Amgen
Jeffery J Stovall
Director, Global Regulatory Affairs & Safety Operations, Amgen, Inc

10:45am - 12:15pm TRACK C

Records Management

Session Chair
Dimitri Stamatiadis, PhD, MBA
Project Leader EDMS, Merck Serono International, Switzerland

Best practices have long been the "Holy Grail" for development organizations struggling to put their arms around electronic records and electronic document management. What seemed to be a trivial task one day, looked like a mountain to climb the next. Where are we today? Do we, at long last, have a set of rules to refer to as "Best Practices"?

And with that regulations kept showering on us: 21 CFR Part 11, Sarbanes-Oxley and now the Amended Federal Rules of Civil Procedure: Our powerful, 21 CFR Part 11-compliant systems can allow an orderly application of retention schedules and records disposition rules but how confident will we be in case of a legal action or a regulatory audit?

Maybe the most intriguing challenge of eDM are eTMFs. Electronic Trial Master Files. How can we turn this heterogeneous collection of documents into an orderly set of electronic files? And for what purpose? Which is the "original," the "official" or the "archival" version? In a word, can absolutely every document be grounded down to "ones" and "zeros"?

Exploring Best Practices in an Electronic Document Management Solution
John Spencer
Senior Manager, Global Regulatory Affairs and Safety, Amgen, Inc.

Preparing for Tomorrow, Today: Establishing a Defensible Records and Information Management Program in the Wake of the Amended Federal Rules of Civil Procedure
Jeffrey S. Wills, PMP
Senior Manager, Informatics Enterprise Content Management, Records and Information Management, Forest Research Institute

Trial Master Files – the De-centralized Communication Challenge
Karen Jane Roy, MPharm
Head of Business Development and Global eTMF Solutions, Phlexglobal Limited, UK

12:15 - 1:30pm Luncheon in the Exhibit Hall

Parallel Tracks (continued)

1:30 - 3:00pm TRACK A

Electronic Health Records – Understanding the Critical Building Blocks

Session Chair
Michael Brennan, PhD
Vice President, Global Regulatory Operations, Centocor, Inc.

This session builds on the prior session that focused on standards ("Electronic Health Records – What You Need To Know ... NOW") and shifts the focus to the more practical implications of electronic health records within the pharmaceutical clinical drug development process. Two specific areas will be discussed:

1) The exchange of information from patient electronic health records with clinical data capture systems for the recruitment, medical history, and patient follow during clinical trials,

2) The importance of electronic health records for enhancing pharmacovigilance systems. The session will address the potential as well as the issues of incorporating electronic health records into the data collection process.

How Does eHR Relate to Pharmaceutical Research
Michael Brennan, PhD
Vice President, Global Regulatory Operations, Centocor, Inc.

How Does eHR Relate to Adverse Event Reporting and/or Possibilities for Signal Detection/Signal Evaluation
Michael Ibara, PharmD
Head of Pharmacovigilance Information Management, Pfizer Inc

Overview of What Different Companies are Doing with the eHR
David Isom
Senior Director, Healthcare Informatics, Pfizer Inc

1:30 - 3:00pm TRACK B

Content Reuse Across the Common Technical Document: Opportunities for Nonclinical Information

Session Chair
Alison Buno
Senior Director, Worldwide Regulatory Operations, Pfizer Inc

The introduction of a common standard for the presentation of information such as the common technical document, and the application of technology is allowing companies to manage information electronically in granular components. This has allowed us to redefine the way we manage and reuse information. This session will include an overview of how to prepare to manage and reuse information in a structured manner, and where structured content authoring is being applied for business process improvement.

Nonclinical Information in the Common Technical Document
Peggy Zorn, MS, MBA
Associate Director, Publishing, MPI Research

Sue Mattano, PhD, DABT
Head, Regulatory Strategy and Compliance, Drug Safety Research and Development, PGRD Pfizer Inc

A Case Study: Developing a System to Facilitate Content Reuse of Nonclinical Information
Joyce Zandee, MS
Partner, Integrated Nonclinical Development Solutions, Inc

James Silva, MS
Senior Manager, Development and Medical Informatics Program Architect, Pfizer Inc

1:30 - 3:00pm TRACK C

How Recent Developments in CTD Content and Structured Content Affect Medical Writers

Session Chair
Barbara R. Snyder
Manager, Scientific Writing & Editing, Procter & Gamble Company

Being an integral part of the submission process in the Pharma industry, medical writers need to know how the documents they write can be used and reused as part of a larger scheme. This session will cover how we can better manage the content of documents that will ultimately be used in CTDs and address how the advent of structured content may affect how we write and use information from protocols and clinical reports.

CTD Content Management
Michelle Herrera Foster, PhD
Principal, Senior Regulatory Affairs Consultant, CTD Quality Consulting

Moving to Structured Content for eCTD Components
Chris Roach
Senior Consultant, Jacquette Consulting, Inc.

Repurposing Protocol Content to Improve R&D Productivity
Fredric J. Cohen
Vice President, Clinical Strategy, Fast Track Systems

3:00 - 3:30pm Refreshment Break in the Exhibit Hall

3:30 - 5:00pm TRACK A

Harmonization of Standards and Health Information Technology as it Relates to eHealthcare across Regulatory Authorities and Regions

Session Chair
Steve Ward
Manager, External Business Integration, Global Medical and Regulatory IT, Eli Lilly and Company

This session will focus on standards and health information technology as it relates to eHealthcare across regulatory authorities and regions. Representatives from FDA will offer perspectives for the future. Industry representatives from PhRMA and/or BIO-IT will discuss the industry's priorities. Key topics to be discussed in the session include standards development and implementation, the need to focus on end-to-end business processes during standards development, the need to focus on "national" and "international" standards and the implications of emerging standards for the biopharmaceutical industry within the larger healthcare community.

The session will include presentations from FDA and industry representatives and a discussion panel.

FDA Strategic Planning for Standards and HIT
Malcolm Bertoni
Assistant Commissioner for Planning (Acting) FDA

The BIO/PhRMA Roadmap
Edward S. Tripp
Program Director, eSubmissions, Abbott Laboratories

Panel Discussion:
Steve Ward, Chair

Panelists:
Michael Brennan
Edward S. Tripp
Malcolm Bertoni
David Isom
Suzanne Markel-Fox

3:30 - 5:00pm TRACK B

Leading Change of Your Evolving Document Management System

Session Chair
Laura Sherman
Vice President, Enterprise Publishing Solutions, Impact Systems Inc.

In this ever-changing world of regulations and technology, the daunting task of deploying and upgrading complex systems with new technologies designed to increase regulatory compliance and enhance business efficiencies is encountered. This session will explore strategies related to document management evolving to an enterprise content and knowledge management system.

Practical holistic tribulations and approaches will be discussed during the establishment of standards, data centralization, controlling information access, distribution and including systems training and communication techniques. Submission content will be examined in regards to the challenges associated with standardization and submission readiness. Focus on process analysis, how good monitoring techniques can provide "upstream" measurements and improvements.

Also a critical success factor is training and communication; a case study will examine how clear communication, end user-centric support and targeted training options can best position an organization for managing change.

Building an Enterprise Knowledge Management Function
Edsel David
Senior Director of Knowledge Management, Daiichi Sankyo

Importance of Process Analysis in Global Submissions Management
James Reilly
Consultant, Software Implementation, Octagon Research Solutions Inc.

Tilting the Scales Toward Success: Leading Change through Communication, Training and Support when Upgrading Document Management Systems
Brian Hamilton
Associate Director, Quality Systems and Training, Abbott Laboratories

Parallel Tracks (continued)

3:30 - 5:00pm — **TRACK C**

Managing Submissions with Partners

Session Chair
Michael J. Brennan, PhD
Vice President, Global Regulatory Operations, Centocor, Inc.

This session will discuss the challenges that can be encountered when preparing submissions with partners from a number of different perspectives: relationship with a third party contract research organization, internal cross-company relationship, and external partner relationships. This session will examine the impact of these different relationships on different aspects of the submission preparation process including reaching agreement on basic authoring and publishing standards and processes and applications, managing through responsibilities for review and approval of content, access to information and transfer of information.

Preparing Submissions with Partners: Best Practices
Patrick Thomas
Associate Director, Regulatory Affairs, Octagon Research Solutions, Inc

Managing through Review and Approval Process with External Partners
Deanna Kornacki
Manager, Medical Writing, Centocor, Inc.

5:00 - 6:30pm — Networking Reception in the Exhibit Hall

Thursday, February 7

Regulatory Authority Day

7:30 - 8:30am — Registration and Continental Breakfast

8:30 - 10:00am — Regulatory Update Session 1

Regulatory Update Session 1

Session Chair
Gary M. Gensinger, MBA
Director, Regulatory Review Support Staff, CDER, FDA

This first Update Session by key FDA representatives presents an up-to-date progress report, with a focus on current FDA strategies, guidance, regulations, submission projects and standards, and compliance initiatives. The topics to be addressed include development of common systems and standards, electronic review tools, and regulatory submission guidance development.

FDA Strategic Planning for Electronic Submission and Review – 5-year IT Plan
Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics, III, CDER, FDA

FDA Standards Initiatives
Lise Stevens Hawking
Project Manager, Office of the Director, CBER, FDA

FDA Labeling Update
Lonnie Smith
Project Manager, Office of the Center Director, CDER, FDA

10:00 - 10:30am — Refreshment Break in the Exhibit Hall

10:30am - 12:00pm International Regulatory Update

International Regulatory Update

Session Chair
Mary L. Collins
Director, Regulatory Affairs, Image Solutions, Inc.

This session provides an overview and status of agency acceptance, review and approval of electronic submissions. Representatives from FDA and European agencies will discuss accepted electronic formats, agency readiness, progress to-date, and future expectations of electronic submissions.

Status of US/eCTD Implementation
Gary M. Gensinger, MBA
Director, Regulatory Review Support Staff, CDER, FDA

Status of European eCTD Implementation and eSubs
Timothy Buxton, LLB
Head of Sector, Project Management, Communications and Networking Unit, EMEA, EU

Status of Japan eCTD Implementation and eSubs
Kiyohito Nakai, PhD
Priority Review Director, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

12:00 - 1:30pm Luncheon in the Exhibit Hall

1:30 - 3:00pm Regulatory Update Session 2

Regulatory Update Session 2

Session Chair
Gary M. Gensinger, MBA
Director, Regulatory Review Support Staff, CDER, FDA

During this session, you will hear from FDA reviewers and policymakers on the topics of eCTD, clinical data, and CMC issues within electronic submissions. FDA staff will share their perspectives on what they'd prefer to see, what the regulators require, and how to arrange a submission for optimal review.

A Chemist's Perspective
Sarah Pope, PhD
Pharmaceutical Assessment Lead, Branch IV, Office of New Drug Quality Assessment, FDA

Safety Review and the eCTD (Incorporating ISS/ISE)
Howard Chazin
Medical Officer Guidance and Policy Team, Office of New Drugs CDER, FDA

A Clinical Reviewer's Perspective
Leslie Anne Furlong
Medical Officer, Division of Reproductive and Urology Drug

3:00 - 3:30pm Refreshment Break in the Exhibit Hall (Exhibit Hall closes at 3:30pm)

3:30 - 4:45pm Regulatory Update Session 3

Regulatory Update Session 3

Session Chair
Gary M. Gensinger, MBA
Director, Regulatory Review Support Staff, CDER, FDA

This final session of Regulatory Day focuses on the most up-to-date information and instructions on submitting your electronic dossier to the FDA. Key staff will discuss the Gateway, the much awaited Validation Checks document and the Waiver Policy, including how to get one and who needs to request one. The goal of this session will be to de-mystify these topic areas, and provide frank information you can use right away.

Electronic Secure Gateway
Michael Fauntleroy
Director, Electronic Submission Program, CBER, FDA

eCTD Validation Checks
Donovan F. Duggan, II, MBA
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

FDA Waiver Policy for eCTD Submission
Virginia R. Ventura
Regulatory Information Specialist, Office of Business Process Support, CDER, FDA

Regulatory Authority Day (continued)

4:45 - 5:30pm — **Town Hall Q&A**

Town Hall Q&A

Session Chairs

Kim W. Nitahara, MBA
Principal Consultant, META Solutions, Inc

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Division of Biometrics III, CDER, FDA

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 FDA and European agency representatives will be available to answer questions and share dialogue with the industry. This is a unique opportunity to learn about the latest FDA and European agency initiatives and to obtain current and practical advice from key agency FDA 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 (subject: "Questions for the FDA").

Questions will be compiled and finalized by the **EDM Program Committee** and the **DIA Document Management SIAC Core Team.** The DIA will provide the final list of questions to the panelists prior to the session for their consideration. ***Please note that not all questions may be answered due to time limitations.***

6:30 - 8:30pm — **Reception – Wine Tasting for Dummies** *See page 2 for more details.*

Friday, February 8

7:30 - 8:30am — **Registration and Continental Breakfast**

Parallel Tracks

8:30 - 10:00am — **TRACK A**

Standards-based Approach to Identity Management and Digital Signatures for Interoperability across the Pharmaceutical and Healthcare Sectors

Session Chair

Kay Bross
Senior PKI Specialist, Information Security and Solutions, Procter & Gamble Company

The growing culture of collaboration within the pharmaceutical and healthcare industries requires working with a broad community of resources – each constituting its own island of information. Standardizing the way identity is determined and how documents can be digitally signed is possibly the single most important change that will allow the many information islands to communicate efficiently. Over the past few years, the pharmaceutical industry has collaborated to develop the SAFE digital identity and signature standard, which provides a secure, enforceable, and regulatory compliant way to verify the identities of parties involved in business-to-business and business-to-regulator electronic transactions.

The learning objectives of this session are: 1) recognize the importance of aligning standards and technology with the process and interoperability implications; and 2) share best practices in streamlining and mapping the process and flow of information within your organization.

Growing Use of the SAFE Standard and Report on Use of SAFE Digital Signatures by P&G™s Research Organization to Sign eLaboratory Notebooks
Kay Bross
Senior PKI Specialist, Information Security and Solutions, Procter & Gamble Company

Report on AstraZeneca's Use of SAFE Digital Signatures to Sign Submissions Made through the FDAs eSubmissions Gateway
Mollie Shields-Uehling
CEO, SAFE-BioPharma Association

Ways to Remedy Identity Management Issues Faced by Health Information Exchanges across the Country
Christine Bechtel
Vice President, Public Policy and Government Relations, eHealth Initiative

8:30 - 10:00am TRACK B

Metadata: The Future of Electronic Document Management

Session Chairs

John Aitken, PhD
Managing Director, West Coast Operations, Octagon Research

Brad Goebel, MS
EDMS Project Lead, FDA Regulated Systems Architect, Management and Technology Solutions Inc.

Document management systems in the pharmaceutical industry are designed to capture metadata, either automatically or manually. However, the metadata in those systems is often incomplete and is sometimes never used for any business purpose. In addition, the metadata in one DMS cannot easily be transferred to another.

As big pharma becomes more and more dependent on small pharma and biotech for innovation and future products, and as the technology for creating and managing documents becomes more sophisticated, the need to find truly effective user-friendly solutions for document management has become critical, as has the necessity to efficiently transfer documents between document management systems at different companies. New metadata-based solutions can make it easier for users to work with DMSs and deliver more organized and manageable content for use in eSubmissions.

This session will examine technologies that can be used to capture metadata either in a DMS or embedded into document files, and provide users with tools to easily apply and utilize metadata. An example will also be presented of how metadata can be used across multiple DMSs within a pharmaceutical company to help drive business analysis and planning.

Intelligent Enterprise Content Management via Metadata Driven Solutions
Gabor Fari
Life Sciences Industry Solution Specialist, Microsoft

Adding Intelligence to Content with the Extensible Metadata Platform
Ed Chase
Standards Engineer, Adobe Systems, Inc

Maximizing the Value of Metadata in Lifecycle Regulatory Submission eArchives
Dennis Oberhofer
Associate Director, Pfizer Inc

8:30 - 10:00am TRACK C

Managing Quality Topics in the eCTD: A Year in Review

Session Chair

Deanna Murden
Chair, eCTD/CMC Industry Discussion Group, Michigan Regulatory Specialists, LLC

Quality Modules described in the eCTD Specification are subject to varied interpretation for a guidance compliant submission construct. This session describes experience from industry on both eCTD implementation and lessons learned from a CMC perspective.

Strategies for the Use of the QOS for eIND and eCTD
Shuyen L. Huang, PhD
Regulatory Affairs-CMC, TAP Pharmaceutical Products Inc.

CMC Lifecycle Management: The Benefits and Pitfalls in an eCTD Environment
Joanna McEntee
Senior Regulatory Submission Specialist, Wyeth Pharmaceuticals Inc.

eCTD Readiness for CMC Documentation: A Case Study
Pamela Cafiero
Director, Drug Regulatory Affairs, Boehringer-Ingelheim

10:00 - 10:30am Refreshment Break

Parallel Tracks (continued)

10:30am - 12:00pm TRACK A

Regulatory Compliance and Computerized Systems Validation

Session Chair
Kim W. Nitahara, MBA
Principal Consultant, META Solutions, Inc

This session will focus on the current industry thoughts and trends regarding regulatory compliance and validation of electronic document management and electronic submissions systems and processes. These presentations will include several examples of identifying and assessing regulatory and business requirements, and then preparing and implementing regulatory-compliant solutions to meet both the regulatory and the business needs. The examples will include overviews of the regulatory and industry compliance expectations, and detailed discussions concerning the practical compliance issues that were encountered in recent projects. Key topics will include practical validation of off-the-shelf systems, risk-based requirements analysis, security, 21 CFR Part 11, and design of GxP-compliant electronic document and submission management systems and processes. Regulatory compliance during the typical activities or phases in a validation project will also be covered, including requirements definition, selection, acquisition, customization, installation, testing, user training, and the migration of document content.

Regulatory Compliance Requirements for Electronic Document and Submission Management Systems
Kim W. Nitahara, MBA
Principal Consultant, META Solutions, Inc.

Practical Experiences and Trends in Regulatory Compliance and Validation of Computerized Systems
Angela Bazigos
CEO, Virtual Validation Solutions

Current Concepts in Computerized Systems Validation from Red Apple II/Peach and What They Mean to Document Management
Richard L. Chamberlain, PhD
President, Executive Consultant Services, Inc.

10:30am - 12:00pm TRACK B

Process Integration through EDMS Solutions

Session Chair
Kenneth VanLuvanee
President and CEO, Apyx, Inc.

This session will discuss opportunities and real world examples of improving organizational performance through integrating EDMS, to deliver broader knowledge throughout the organization.

Notes from the Front Lines: Documentum Application Consolidation on a Mass Scale
Ken Lownie
Chief Operating Officer, Glemser Technologies Corporation

Re-designing the eDMS: Turning Lessons Learned into a New Streamlined Benefit
Sean Winslow
Director, Global Professional Services, QUMAS

What Your Company Needs to Implement a Successful ECM Solution – and Why It's Never Been More Important to Succeed in the Process
Paul Mattes
Industry Solutions Director, Microsoft

10:30am - 12:00pm TRACK C

eCTD Planning/Workflow

Session Chair
Guy Pawson, PhD
Manager, Electronic Submissions, Genentech, Inc.

This session addresses eCTD planning and workflow management from the point of view of the smaller company with limited submission resources. It will include a review of the available technology for automating preparation of eCTD components.

eCTD – It is All about Planning
Shylendra Kumar, MPH
President/CEO, Datafarm

Making Technology Fit the Process
Guy Pawson, PhD
Manager, Electronic Submissions, Genentech, Inc.

eCTD: Common Mistakes and How (or Not) to Recover
Donna Wolfington
Senior Regulatory Submission Specialist, Wyeth Pharmaceuticals, Inc.

12:00pm Conference Adjourns

SIAC – Special Interest Area Communities

Special Interest Area Communities (SIACs)

Special Interest Area Communities (SIACs) are just one of many member benefits that DIA offers. Each DIA SIAC provides a discipline-specific, global community where members can share common experiences and knowledge and connect with others in their particular field. SIACs assist DIA in identifying professional development needs in specific interest areas and in providing information to members about career and professional development, to meet those needs. Members will also find opportunities for leadership and networking within each SIAC.

SIAC Participation

Participation in a SIAC is open to all current DIA members. All DIA SIACs encourage balanced representation from professionals in industry, academia, contract service organizations, and government.

How Can I Become a SIAC Member?

By electing to join a SIAC, you will now receive SIAC specific information and communications including surveys and meeting promotions specific to your interest area. For more information about DIA's SIACs, please visit **http://www.diahome.org/DIAHome/Membership/SIAC.aspx**

Document and Records Management SIAC

Nancie E. Celini, North American Chairperson
Dimitri Stamatiadis, European Chairperson

DIA Contact: Mary.Hildebrandt@diahome.org

The Document and Records Management (DRM) SIAC will focus on the following areas: document management best practices, emerging technology and concepts, architecture, workflow, records retention, multipurposing of information, and document repositories, as well as information sharing and collaboration.

Electronic Regulatory Submissions SIAC

Mary L. Collins, North American Chairperson
Melanie J. Clare, European Chairperson

DIA Contact: Mary.Hildebrandt@diahome.org

The new Electronic Regulatory Submissions (ERS) SIAC will focus on the following areas: regional requirements, electronic submission technologies, electronic document formats and data, expanding types of electronic submissions, and current and emerging standards of impacting electronic submissions.

Medical Writing SIAC

Helle-Mai Gawrylewski, North American Chairperson
Jean H. Soul-Lawton, European Chairperson

DIA Contact: Mary.Hildebrandt@diahome.org

The mission of this SIAC is to provide a professional, neutral forum for discussion of issues related to the definition and development of medical writing for the pharmaceutical and biotechnology industries, both regulated and non-regulated documents.

To both determine and address the educational needs of DIA members whose interest area is medical writing through such activities as:

- Designing and conducting introductory, intermediate- and advanced-level courses and workshops under DIA auspices.
- Contributing to the Annual Meeting and EuroMeeting.

To publicize the field, to stimulate members to engage in the evaluation of writing issues and to encourage dialogue between regulators, academic institutions and industry.

TRAVEL AND HOTEL The most convenient airport is Philadelphia International Airport and attendees should make airline reservations as early as possible to ensure availability. The Philadelphia Marriott Downtown is holding a block of rooms at the reduced rate below until January 22, 2008, for the DIA meeting attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $155 **Double $175**

Please contact the Philadelphia Marriott Downtown by telephone at +1-215-625-2900 and mention the DIA meeting. The hotel is located at 1201 Market Street, Philadelphia, PA 19107, USA.

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.

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

DRUG INFORMATION ASSOCIATION

21st Annual DIA Conference for ELECTRONIC DOCUMENT MANAGEMENT

Member Early-bird Rate
Register by January 22
SAVE $180!

Managing Documents and Records—The Never-ending Process

Philadelphia Marriott Downtown Hotel, Philadelphia, PA, USA

FEBRUARY 5-8, 2008 | Meeting ID #08003

Register online or fax this page to +1-215-442-6199

DRUG INFORMATION ASSOCIATION
800 Enterprise Road, Suite 200
Horsham, PA 19044-3595 USA

CONTACT & EXHIBIT INFORMATION: **Conference:** Contact Joanne Wallace at the DIA office by telephone +1-215-442-6180, fax +1-215-442-6199 or email Joanne.Wallace@diahome.org. **Exhibit:** Contact Erin Gilliland, Exhibits Associate, at the DIA office by telephone +1-215-442-6149, fax +1-215-442-6199 or email Erin.Gilliland@diahome.org. For tabletop exhibit space, please check the box below.

❑ **To receive an exhibit application, please check.**

GROUP DISCOUNTS (not available online or on already discounted fees)
See page 15 for complete details.

Registration Fees: *If DIA cannot verify your membership upon receipt of registration form, 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 JAN. 22, 2008	After JAN. 22, 2008
Member Fee	US $1220 ❑	US $1400 ❑

Join DIA now to qualify for the early-bird member fee! **www.diahome.org/en/Membership/AboutMembership/AboutMembership**

MEMBERSHIP **US $ 130** ❑

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.

Nonmember Fee US $1530 ❑

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 $ 325 ❑	US $ 455 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 700 ❑	US $ 830 ❑

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

TUTORIALS Tuesday, February 5, 2008

Full-day Tutorial

#1 9am-5pm Electronic Odyssey — US $ 650 ❑

Half-day Tutorials – Morning

#2 8:30am-12pm eIND — US $ 375 ❑
#3 8:30am-12pm Practical Management of eCTD Lifecycle — US $ 375 ❑
#4 8:30am-12pm Compliance: Avoiding Costly Submission Errors — US $ 375 ❑

Half-day Tutorials – Afternoon

#5 1:30-5pm Guidance-compliant eCTDs — US $ 375 ❑
#6 1:30-5pm Authoring Medical Templates — US $ 375 ❑
#7 1:30-5pm Validation of Computerized Systems for Regulated Electronic Records, Documents, and Submissions — US $ 375 ❑

CANCELLATION POLICY: On or before JANUARY 30, 2008
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200 Tutorial = $50
Government or Academia or Nonprofit (Member or Nonmember) = $100

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.**

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Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

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.

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❑ **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.