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23rd Annual Electronic Document
Management Conference

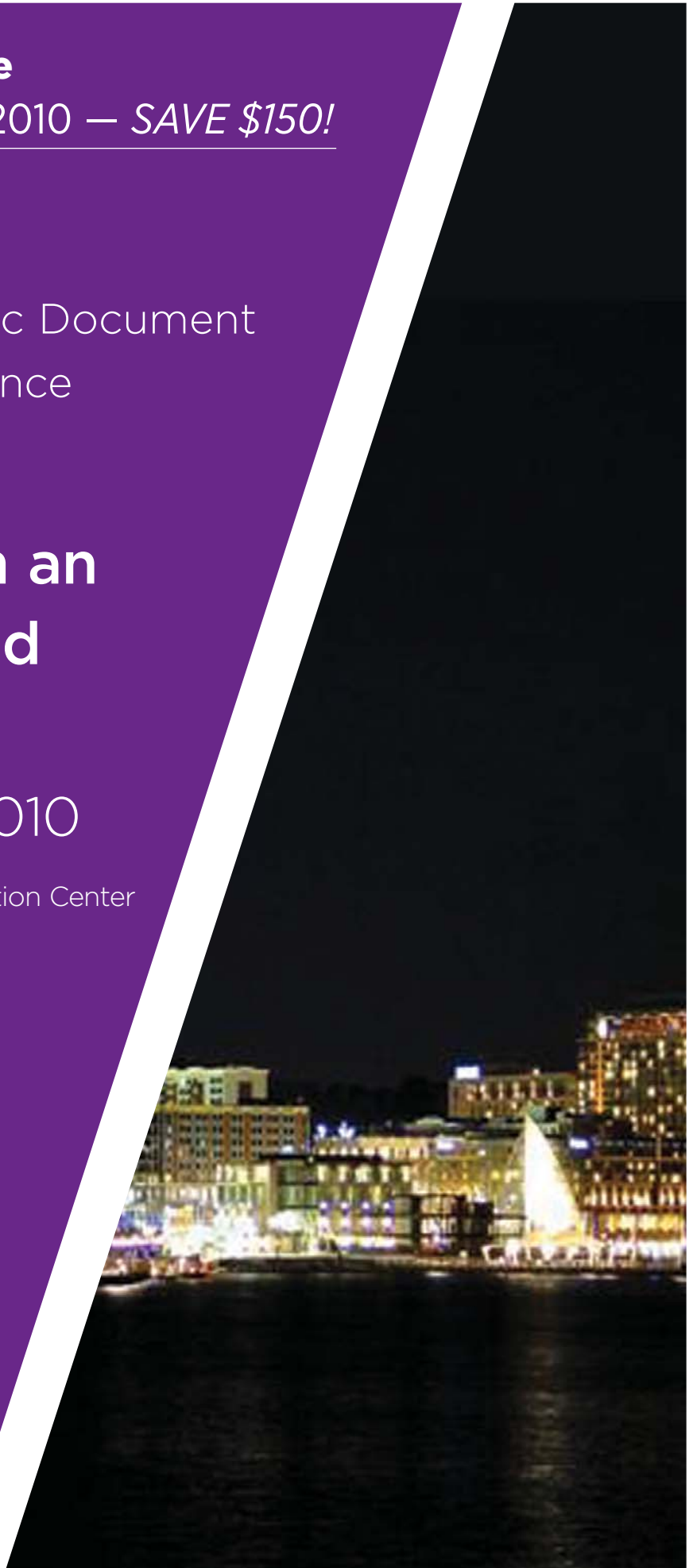
Global Content Management in an Electronic World

February 16-19, 2010

Gaylord National Resort & Convention Center
National Harbor, MD, USA



www.diahome.org



23rd Annual Electronic Document Management Conference

Global Content Management in an Electronic World

Conference: February 17-19, 2010 Tutorials: February 16
Gaylord National Resort & Convention Center
National Harbor, MD, USA



Program Co-chairpersons



Joseph A. Cipollina
Senior Director
Regulatory Information
and Submission
Standards, Worldwide
Regulatory Operations,
Pfizer Inc



Daniel F. Orfe, MS
Vice President
Global Regulatory
Submission Services,
Datafarm, Inc.



Gary M. Gensinger, MBA
Deputy Director
Office of Business
Process Support
CDER, FDA

PROGRAM COMMITTEE

Cindy Cullen

Associate Director, Digital Signature and
Certificate Services, Bristol-Myers Squibb
CTO, SAFE BioPharma Association

Kaye H. Fendt, MSPH

Director, Quality Assurance and Regulatory Compliance
Duke Clinical Research Institute

Shari Perlstein, MBA, PMP

Senior Manager, Worldwide Technology, Quality
and Compliance, Pfizer Inc

Laura J. Sherman, MBA

Managing Partner, Distributed Compliance Solutions, LLC

Kenneth R. VanLuvanee

Vice President, Global Consulting Services
Image Solutions, Inc.

Virginia Ventura

Regulatory Information Specialist, Office of Business
Process Support, CDER, FDA

Stephen E. Wilson, DrPH, CAPT. USPHS

Director, Division of Biometrics III, CDER, FDA

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

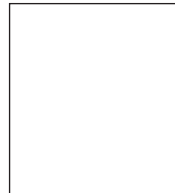
Strategies for Managing eInformation and Ensuring Regulatory Compliance

This year's conference will focus on core document management practices, including aspects of the changing evolution of eStandards, regulations, technology, and the growing volume of information generated along the drug development continuum. Take advantage of this unique opportunity to:

- Discuss strategies for optimizing the management and repurposing of information across the enterprise for submissions to worldwide regulatory authorities.
- Learn how far our industry has progressed toward realizing the shared regulatory and industry goal of an eOnly environment.
- Examine the shift from traditional paper records management toward a fully electronic document management system, and
- Examine the shift from traditional paper records management toward a fully electronic document management system including eSignatures.

Keynote Speakers

Wednesday, February 17, 9:00 am



Theresa Mullin

Associate Director, Office of Planning and
Informatics, CDER, FDA



John Oidtman, Vice President, Worldwide
Regulatory Operations and Worldwide Regulatory
Strategy - Established Products, Pfizer Inc

See page 5 for Dr. Sharfstein's biography.

Who Should Attend

- Professionals who work in EDM and are 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,

This program has been developed
by the Document and Records
Management and Electronic
Regulatory Submissions SIAC.



CONTINUING EDUCATION

PLEASE MONITOR THE DIA WEBSITE FOR CONTINUING EDUCATION CREDIT INFORMATION – www.diahome.org.

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.

Learning Objectives

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

- ▶ Identify the challenges associated with managing information in a global environment and maintaining national and regional regulatory compliance,
- ▶ Recognize the importance of aligning international standards with business processes and the implications of interoperability,
- ▶ Review current initiatives and the future vision of FDA and international regulatory authorities,
- ▶ Evaluate optimizing the overall document management life cycle process in the drug development continuum from eDiscovery to eArchival,
- ▶ Share best practices on good document and records management.

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.

DAY 1 | TUESDAY, FEBRUARY 16

8:00-9:00 AM TUTORIAL REGISTRATION AND CONTINENTAL BREAKFAST

9:00 AM-5:00 PM FULL DAY TUTORIAL

TUTORIAL #1

Creating Compliant Electronic Submissions for the US, EU and Canada

INSTRUCTORS:

Nancy Smerkanich

Vice President, Regulatory Affairs
Octagon Research Solutions, Inc.

Hans van Bruggen

Senior Regulatory Affairs Consultant
eCTDconsultancy, The Netherlands

This all day tutorial will focus on the practicalities and processes of simultaneously creating compliant electronic submissions for the US (eCTD), EU (eCTD and NeES) and Canada (eCTD). For companies that wish to file Investigational New Drug applications (IND) or New Drug (marketing) applications (NDA) in the US, Marketing Application Authorizations (MAA) in the EU, and NDS and IND in Canada, there are regional requirements and best practices that must be incorporated into the submissions. Moreover, in the EU, managing eCTDs for EU Centralized Procedure differs from managing eCTDs in MRPs (including repeat use), and DCPs. Managing eCTDs for the legacy National Procedures are even more challenging. The recreation of eCTD/NeES sequences for various types of submissions will be presented along with common pitfalls and issues.

Practical examples of how to track applications will be discussed; an activity on gathering metadata and review of case studies will all be part of this interactive workshop. There will be an emphasis on the US, EU and Canadian Module 1 requirements, including V1.4 for the EU (facilitating the new Variation Regulation), the dataset portion of US applications, as well as contrast between the regions. Specific lessons learned from implementations both at the health authorities and at sponsor companies will be shared. Demonstrations of electronic submissions from the US, EU and Canada will be utilized as a teaching tool.

Learning Objectives:

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

- Implement Practical Planning, recognizing the following -
 - Effect on authors of IND sections, specifically around document granularity
 - Importance of tracking documents across functional areas
 - Document mapping from 21 CFR 312 to CTD Modules
 - Life cycle Management
- Preparing for eCTD: Identify process change and improvement needs
- Collecting and organizing metadata
- Recognize the Study tagging file utility

Target Audience:

This tutorial is designed for individuals in Regulatory Operations, Regulatory Affairs, Project Managers and others who contribute content to Investigational New Drug Applications.

Level: Intermediate

TUTORIAL #2**What EDM Costs Us: Economics and the Realities of Our Technology Investment****INSTRUCTORS:****Nancie E. Celini**

President
CAB, Inc.

James Averback

Partner
Life Science Integration Partners

This full day session will provide a new perspective in 2010 as we find ourselves in the midst of major change, increasing regulatory demands in a shared global model and scarcity. It is time for a new look and fresh ideas about the true costs of electronic document management and the realities of the challenges we all face and the payback that we may not get from our technology investments. We will start with a look at the fundamentals of the technology and the outcomes we should be getting.

The session will examine the realities of today's economic, organizational and start-up concerns and introduce strategies for how to acquire content management solutions efficiently and cost effectively. The session will explore the advantages of leveraging the "EDM Reference Model" and hosted solutions as well as the under-exploited advantage to integrate learning solutions in your organization that can help you meet your regulatory obligations.

Learning Objectives:

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

- Define traditional document management terms and concepts
- Propose an expanded model of content management
- Identify the key issues/problems that content management addresses today
- Define life cycle management and the importance of workflow
- Perform more efficient use of resources for a fast start-up and lower cost project

Target Audience:

This tutorial is designed for beginning / intermediate EDM project team members involved with the assessment, selection and implementation of systems; end users of EDM systems; and system decision makers.

Level: Beginning / Intermediate

12:00-1:00 PM LUNCH FOR FULL DAY TUTORIAL ATTENDEES ONLY

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

TUTORIAL #3**Practical Management of eCTD Life Cycle****INSTRUCTORS:****Kenneth VanLuvanee**

Vice President, Global Consulting Services
Image Solutions, Inc.

Laura Sherman, MBA

Managing Partner
Distributed Compliance Solutions, LLC

The eCTD life cycle 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 life cycle 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 life cycle model starting from initial submission
- Explain what the life cycle 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.

Level: Intermediate**TUTORIAL #4****XML Pharmaceutical Standards and the Practical Implementation****INSTRUCTORS:****Gary G. Walker**

Associate Director, Enterprise Data Standards
Quintiles Transnational Corporation

Terry D. Hardin

President and CEO
PerfiTech Consulting

Over the past several years XML has matured as a mechanism for submitting a variety of regulatory data. As part of this evolution several standards have adopted to this new world of XML to reflect this growing acceptance - including the HL7 SPL, RPS and ICSR standards, as well as the CDISC standards that are advancing to meet regulatory expectations.

Learning Objectives:

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

- Identify the various XML standards currently in use in the pharmaceutical industry
- Describe XML for eCTD submissions (standards and specifications)
- Identify what is needed from authors to prepare for an XML/eCTD submission (metadata, file granularity and templates)
- Describe the concept of life cycle management and how it affects file archiving and retrieval

Target Audience:

This tutorial is designed for Regulatory and IT staff wanting a regulatory perspective and overview of XML and its usage in the pharmaceutical industry.

Level: Beginners

1:30-5:00 PM

CONCURRENT AFTERNOON TUTORIALS**TUTORIAL #5****My Company Has Decided to Go Paperless... Now What???****INSTRUCTORS:****Kay Bross, MEd**

CEO

Interop/K.Bross Consulting, LLC

Julie Gable

President

Gable Consulting, LLC

So we've decided to go electronic.... we have all of these electronic documents.... how can I ensure that they:

- go through their processes (life cycle) appropriately
- are sent to and reviewed by the right individuals (work flow)
- are signed by the individuals that are supposed to sign them
- are ready to be archived and will 'live' as long as policy requires

What tools exist to help me make these steps happen and let me track it?

Learning Objectives:

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

- Define the electronic document life cycle
- Share electronic documents with appropriate individuals
- Choose the required individuals for approval signature
- Organize the document to reside in a long term archive
- Apply tools to help make the above steps happen

Target Audience:

Attendance is encouraged by those who handle documents in an electronic format – Regulatory Operations, Regulatory Affairs, Archives, Records Management, Clinical Operations, and Corporate Libraries.

Level: Beginning / Intermediate

12:00-1:30 PM

TUTORIAL REGISTRATION**TUTORIAL #6****Guidance-compliant eCTDs****INSTRUCTORS:****Gary M. Gensinger, MBA**

Deputy Director

Office of Business Process Support

CDER, FDA

Virginia Ventura

Regulatory Information Specialist

Office of Business Process Support

CDER, FDA

Christine Nguyen, MD

Medical Officer

Division of Reproductive and Urologic Products

Office of New Drugs

CDER, FDA

David Roeder

Associate Director for Regulatory Affairs

Office of Antimicrobial Products

Office of New Drugs

CDER, FDA

Norman R. Schmuff

Branch Chief

Division of Pre-marketing Assessment II

Office of Pharmaceutical Sciences

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

3:00-7:00 PM

EXHIBITOR REGISTRATION AND SET UP

4:00-6:00 PM

ATTENDEE AND SPEAKER REGISTRATION

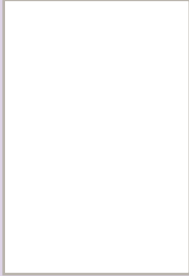
DAY 2 | WEDNESDAY, FEBRUARY 17

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

8:45-9:00 AM WELCOME AND OPENING REMARKS

9:00-10:00 AM KEYNOTE ADDRESSES

Theresa Mullin Food and Drug Administration



John Oidtman Pfizer Inc



John Oidtman is Vice President, Worldwide Regulatory Operations & Worldwide Regulatory Strategy – Established Products, Pfizer Inc. He also serves as Groton/New London Site Lead for Worldwide Regulatory Affairs and Quality Assurance (WRAQA). In this capacity, he is responsible for directing the resources required for preparation and submission of regulatory dossier across R&D and commercial; securing, retaining, managing and disposition Pfizer's R&D records both in hard copy and electronic format; managing product labeling information Pfizer; implementing information systems designed to enhance the working processes of Regulatory Affairs, Quality Assurance and R&D; development and execution of regulatory product strategies to support Pfizer's mature product portfolio; supporting product defense and Health Authority interactions for Pfizer mature products.

John represents the Pfizer Regulatory Affairs and Quality Assurance organization on key internal governance boards focusing on allocation of resources to support development and implementation of standards across the worldwide development continuum. John earned a BS in Zoology at the University of Maryland.

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

How did we get here? The Development and Governance of Submission Standards

SESSION CHAIRPERSON

Cynthia Piccirillo

Director, Regulatory Submission Domain, Bristol-Myers Squibb

The standards to support electronic regulatory submissions have been rapidly evolving over the last decade as a result of many factors. These include innovative thinking and technology capabilities, as well as lessons learned from roll-out and implementation of earlier versions of the standards. There is a clear realization that collaborative involvement of the suppliers of the information (industry) and technology support (vendor) with the customer (health authorities) throughout development of a standard results in a more consistent and innovative approach.

Timothy Buxton

Head of Sector, Information & Communications Technology Development, European Medicines Agency, European Union

Industry Perspective**Geoff Williams**

e-Regulatory Liaison
Roche Products Ltd

Vendor Perspective**Shy Kumar**

President and CEO
Datafarm, Inc.

TRACK B

Electronic Trial Master File (eTMF)

SESSION CHAIRPERSON

Shari Perlstein, MBA, PMP

Senior Manager, Worldwide Technology, Quality and Compliance, Pfizer, Inc.

This track will take the attendees through the various phases of a typical eTMF implementation from performing stake holder analysis, setting up requirements, selecting the vendor, scoping the project, informal testing, formal release, qualification / validation to go-live, roll-out and change management. Valuable lessons learned are highlighted. Additional activities – like introducing a new training concept and setting up automatic user creation – are also discussed.

Electronic Source Documents – Removing the Burden of Paper from Sites and Sponsors
Edward Stephen Sequine Jr.

President, Clinical Ink

Is One Global Standard for Trial Master File Contents, Naming, Structure and Metadata Possible?

Karen Roy

Director
Medical Research Network, LLC UK

Implementing Electronic Trial Master File for Clinical Trials

Jesper Møller Hougaard

Head of Section, Electronic Content Management, Lundbeck

TRACK C

Progress Report – The Business Case for the DIA EDM Reference Model

SESSION CHAIRPERSON

Antoinette Azevedo

President and CEO
eSubmissionsSolutions.com

This session will present case study results from three companies that used the DIA EDM Reference Model version 1.0 to design and implement commercial-off-the-shelf systems to manage submission documents. Presenters will discuss the business case for the EDM Reference Model, along with the benefits and challenges of the Reference Model compared with alternative approaches.

Implementing Open Source Content Management using the EDM Reference Model
Virginia Viau

Director of Quality Systems
Alnara Pharmaceuticals, Inc.

Implementing Content Management to Support a Virtual Pharmaceutical Business using the EDM Reference Model

Anne Marra

Senior Director, Regulatory Operations
NPS Pharmaceuticals, Inc.

Extending a Quality Document Management System to Manage eCTD Documents using the EDM Reference Model

Ronald Hernando, MBA

Senior Manager, Regulatory Operations
Molecular Insight Pharmaceuticals, Inc.

12:00-1:30 PM LUNCHEON IN THE EXHIBIT HALL

1:30-3:00 PM

PARALLEL TRACKS

TRACK A

Content Challenges with Mergers and eCTD Publishing

SESSION CHAIRPERSON

Terry D. HardinPresident and CEO
PerfiTech Consulting

As the development of partnerships become more and more prevalent, the merging of processes and technologies becomes critical and much more challenging. This session will look at how to standardize data from trial designs to submission reporting and why making standards a normal part of project planning and implementation is so important.

A Data Warehouse Works to Meet Industry Challenges for eCTD Submissions**Terry D. Hardin**President and CEO
PerfiTech Consulting**Migrating eCTD Submissions: Overcoming Migration Challenges when Maintaining eCTD Applications Created in Different Publishing Tools****Scott H. Cleve**Associate Director, Regulatory Affairs
Astellas Pharma Global Development, Inc.**Two Companies + One NDA = Lots of Document Management and Authoring Issues****Marc J. Stern**Associate Director, Document Formats and Standards
Forest Research Institute

TRACK B

Labeling

SESSION CHAIRPERSON

Keith ThomasProduct Strategist
Infrastructures for Information, Inc.

The combination of metadata and XML provide a set of powerful new tools for managing electronic information. They allow bridges to be built in a way that can begin the transition from document management based on document flow to information management based on concept vocabularies, events and process models.

Use of Structured Product Labeling (SPL) to Improve Regulatory Compliance, Increase Efficiencies, and Reduce Costs**Doris Sincak**Project supervisor, US Regulatory Affairs for Marketed Products
sanofi-aventis**Anand Ramanathan**Sr. Manager, Regulatory Solution
sanofi-aventis**XML: What's it All About and Why are They Doing This to Me?****Don Bridges**Life Sciences Manager
Data Conversion Laboratory, Inc.**The Role of Metadata in Coordinating Corporate Labeling and Listing Processes****Keith Thomas**Product Strategist
Infrastructures for Information, Inc.

TRACK C

EDM Reference Model: Emerging Standards and Technologies

SESSION CHAIRPERSON

Kenneth VanLuvaneVice President, Global Consulting Services
Image Solutions, Inc.

Participants can expect to leave this session with an understanding of the current trends in document management deployments and how their organizations could benefit. This session will focus on several emerging standards and technologies in the market that are helping to improve the world of document management in which life science companies live every day.

EDM Reference Model Extensions for US Labeling**Patricia Cowall-Hanover, PhD**Principal Consultant, Regulatory
Eli Lilly and Company**Benefits and Importance in Utilizing Industry Standards for Technology as well as Taxonomy/Metadata in Your Document Management System Deployments****Matt Walz**Chief Technology Officer
NextDocs Corporation**Improving Batch Record Review with EDM****Thomas Quinn**President, CISSP
The Hollis Group, Inc.

3:00-3:30 PM

REFRESHMENT BREAK IN THE EXHIBIT HALL

3:30-5:00 PM

PARALLEL TRACKS

TRACK A

Managing Global eSubmissions

SESSION CHAIRPERSON

Dominique E. LagraveSenior Director, Regulatory Operations and Innovation
NovoNordisk, Inc.

A shrinking economy, expanding competition and the global migration toward eCTD has placed tremendous pressures on life science companies to find new ways to do things faster and cheaper without sacrificing on quality. This session will review the concept of global submission management in light of the further globalization of our work environment, including how industry can leverage current resources.

Global Submission Management: A New Frontier**Dominique E. Lagrave**Senior Director, Regulatory Operations and Innovation
NovoNordisk, Inc.

TRACK B

e-Signatures

SESSION CHAIRPERSON

Cindy CullenAssociate Director, Digital Signature and Certificate Services
Bristol-Myers Squibb

The emergence of digital signatures in clinical operations has risen dramatically in the past 3 - 5 years. Having a digital signatures capability to reduce time lags and increases data/document security has provided huge benefits.

The Emergence of Digital Signatures in Clinical Operations**Rodd Schlerf**FDA & USDA markets Manager
ARX, Inc.

TRACK C

A New Paradigm for Accurate, Efficient Regulatory Submissions

SESSION CHAIRPERSON

Linda Fossati WoodPresident
MedWrite, Inc.

The three presenters in this session (all members of the EDM Reference Model team) will explore the impact of a topic-based content authoring paradigm. At the end of this session, participants will understand how a comprehensive, well designed, and topic-based content architecture for scientific and operational document enables streamlined content creation, enhanced sharing of knowledge and high-quality regulatory submissions.

Industry Standards for Content and Metadata to Create and Manage Delivery of Key Documents**James Averback**Partner
Life Science Integration Partners

TRACK A (continued)

Managing Global eSubmissions

eSubmissions Driven by Requirements or Common Sense?

Hans Van Bruggen

Senior Regulatory Affairs Consultant
eCTDconsultancy B.V.

TRACK B (continued)

e-Signatures

Deciding on Digital: The SAFE BioPharma Digital Standard and How Companies are Using it to Work Faster and More Efficiently

Mollie Shields-Uehling

President and CEO
SAFE-BioPharma Association

Decision Making Process to Make Global Electronic Submissions

Jeffrey Morrison

Global Submissions Publishing, Global Regulatory Operations
GlaxoSmithKline

TRACK C (continued)

A New Paradigm for Accurate, Efficient Regulatory Submissions

Impact of topic-based Content Design of Key Nonclinical and Clinical Regulatory Documents

Nancy Katz

President and Principal Medical Writing Consultant
Illyria Consulting Group, Inc.

Case Study – Content Design Paradigm

Michelle Herrera Foster

Principal, Senior Regulatory Affairs Consultant
CTD Quality

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

DAY 3 | THURSDAY, FEBRUARY 18, 2010

REGULATORY AUTHORITY DAY

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

8:30-10:00 AM REGULATORY UPDATE SESSION 1

Future Directions

CHAIRPERSON:

Mark Gray

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

This first update session, presented by key FDA officials, focuses on the future directions within CDER regarding development of common data standards and the Computational Science Center.

Computational Science Center Update

Chuck K. Cooper

Medical Officer, Office of Biostatistics, QSPG
Office of Translational Sciences, CDER, FDA

CDER Data Standards Plan

Marni Hall, PhD, MPH

Principal Analyst, Office of Planning and Analysis, CDER, FDA

Regulated Products Submission (RPS)

Mark Gray

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

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

10:30 AM-12:00 PM INTERNATIONAL REGULATORY UPDATE

CHAIRPERSON:

Norman R. Schmuff

Branch Chief, Division of Pre-marketing Assessment II, Office of Pharmaceutical Sciences, CDER, FDA

This unique international session delivers reports and perspectives from Canada, Switzerland and European Medicines Agency, European Union. No need to fly to a foreign country for these valuable global regulatory updates.

The Introduction of eCTD in Switzerland: First Experience and Further Developments

Claudia Zerobin Kleist, MHA

Case Manager
Swiss Agency for Therapeutic Products

Update on Electronic Submissions at Health Canada

Vianney Caron

E-Review Project Lead, Therapeutic Products Directorate, Health Canada

Timothy Buxton

Head of Sector, Information & Communication Technology Development
European Medicines Agency, European Union

12:00-1:30 PM LUNCHEON IN THE EXHIBIT HALL

1:30-3:00 PM **REGULATORY UPDATE SESSION 2****Review of the Electronic Clinical Submission**

CHAIRPERSON:

Stephen E. Wilson, DrPH, CAPT. USPHS

Director, Division of Biometrics III, CDER, FDA

During this session you will hear from FDA reviewers on the topics of eCTD, clinical data, and general administrative and review issues with eCTD. FDA staff from the Office of New Drugs and Office of Pharmaceutical Science will share their perspective as reviewers.

Study Tagging File**Virginia Ventura**

Regulatory Information Specialist
Office of Business Process Support
CDER, FDA

Medical Officer Perspective**Christine Nguyen, MD**

Medical Officer, Division of Reproductive
and Urologic Products
FDA

The Data Review**Chuck K. Cooper**

Medical Officer, Office of Biostatistics, OSPG
Office of Translational Sciences, CDER, FDA

3:00-3:30 PM **REFRESHMENT BREAK IN THE EXHIBIT HALL (HALL CLOSES AT 3:30 PM)**3:30-4:45 PM **REGULATORY UPDATE SESSION 3****FDA Regulatory Operations Perspective**

CHAIRPERSON:

Virginia Ventura

Regulatory Information Specialist Office of Business Process Support, CDER, FDA

The goal of this last session of Regulatory Day is to provide you with practical, up-to-date information about the overall submission intake process within CDER, including specifics for submitting your electronic dossier to the FDA. Key staff will discuss the overall process, including SPL and the top issues with eCTD.

PMC/PMR**Cathryn Lee, MSN, CRNP, AOCN**

Postmarketing Requirements and Commitments
Program Manager, Office of New Drugs
Immediate Office, CDER, FDA

21st Century Review Process**Dan Brum, PharmD, MBA, RAC**

LCDR, U.S. Public Health Service
Senior Regulatory Project Manager
Division of Cardiovascular and Renal Products
CDER, FDA

eCTD Experiences and Recommendation:**An FDA User Perspective****Michael Folkendt**

Supervisory Consumer Safety
FDA

4:45-5:30 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 (subject: "Questions for the FDA")

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

DAY 4 | FRIDAY, FEBRUARY 19, 20107:30-8:30 AM **REGISTRATION AND CONTINENTAL BREAKFAST**8:30-10:00 AM **PARALLEL TRACKS****TRACK A****Streamlining the Submission Ready Process**

SESSION CHAIRPERSON

Laura Sherman

Managing Partner
Distributed Compliance Solutions LLC

How do you ensure content reuse instead of duplicate source copies scattered across multiple systems, submission ready and compliance with the increasing mergers/acquisitions, external collaboration, outsourcing. With global enterprise system deployments, business process standardization offers key benefits and ROI, there are associated challenges, investment costs and commitment required to organizational changes to assess. Three

TRACK B**Standards and CDISC**

SESSION CHAIRPERSON

Kaye Fendt

Director, Quality Assurance and Regulatory
Compliance
Duke Clinical Research Institute

The Clinical Data Interchange Standards Consortium (CDISC) was established to develop electronic data standards to meet the FDA's operational and submission requirements. This presentation will identify the challenges the industry is facing to implement new submission data standards and to provide guidelines and solutions to migrate legacy data into compliant submission ready format.

TRACK C**Collaboration – The Drive Towards Content and Rapid Integration of Process and Platforms**

SESSION CHAIRPERSON

Daniel Orfe

Vice President, Global Regulatory
Submission Services
Datafarm, Inc.

As industry moves towards the implementation of a comprehensive set of systems and data standards, it is important to establish new techniques for the integration of these platforms and the automation of flexible high level cross platform processes. This session will consider the increasing focus of regulatory information management away from final documents and back to the authoring process.

TRACK A (continued)

Streamlining the Submission Ready Process

case studies will share lessons learned while implementing standardized document and records management and rendering systems and provide advice on tools and techniques to make standardization efforts a success.

Streamlining Production of Submission-Ready Documents**Boris Braylyan**

Head of the Document Management Center of Excellence, Pfizer

Compliance and Collaboration**Joseph Baldari**

Manager, Document Formats and Standards
Forest Research Institute

Streamlining the Submission Process**Michael Brennan**

ERIS Business Owner, Pharma R&D IM
Centocor

TRACK B (continued)

Standards and CDISC**The CDISC/FDA Integrated Safety Data Pilot: A Case Study in Implementing CDISC Standards to Support an Integrated Review****Chris Decker**

Life Sciences Director
d-Wise Technologies, Inc.

Clinical Data Preparation for eCTD Submissions**Vijaya Hegde**

Manager, Regulatory Services
Datafarm, Inc

CDISC's SDTM Metadata Submission Guidelines: A Review and Update**Gary G. Walker**

Associate Regulatory Director, Global Data Management
Quintiles Transnational Corp.

TRACK C (continued)

Collaboration – The Drive Towards Content and Rapid Integration of Process and Platforms**Standardizing Process Implementations for Optimal ROI****Maryanne Quinn**

President
Integrated Submission Strategies LLC

A Knowledge Based Collaborative Model for the Rapid Integration of Platforms, People and Processes**Paul Fenton**

Vice President Pharmaceutical Processes and Technology
Montrium, Inc. Canada

From EDMS to Collaboration: The Drive Toward Content**Donald G. Palmer**

Associate Director, Regulatory Systems
MedImmune

10:00-10:30 AM

REFRESHMENT BREAK

10:30-12:00 PM

PARALLEL TRACKS

TRACK A

Review and Tracking Tools for Determining eCTD Strategy

SESSION CHAIRPERSON

Matthew Neal

Director, Global Regulatory Affairs and Safety
Amgen, Inc.

Companies spend countless hours carefully designing and building eCTDs for submissions. Since eCTD tools can interpret the specification differently, the manner in which eCTDs are built may not be the way Agency tools display them. eCTD metadata tracking can help you work more efficiently creating your current submission, planning your future submissions and obtaining metrics for reporting your quarterly work progress.

Using Agency Review Tools to Determine eCTD Strategy**Cheryl Bean**

Regulatory Submission Specialist I
Global Regulatory Submission Management
Pfizer Inc

eCTD Metadata Tracking for Efficient and Quality Publishing**Marlene McCallum**

Electronic Submissions Manager
Spectrum Pharmaceuticals, Inc.

Consolidated Information Management and the eCTD**Matthew Neal**

Director, Global Regulatory Affairs and Safety
Amgen, Inc.

TRACK B

Authoring Global Content Management

SESSION CHAIRPERSON

Daniel F. Orfe

Vice President, Global Regulatory Submission Services
Datafarm, Inc..

This session will provide an overview of the advantages and challenges related to authoring documents for electronic submissions, as well as the best practices for addressing each challenge in a time and cost effective manner. To facilitate a smooth review process, authors must plan for current electronic reviewing styles and implement strategies for successful document content, style and format for a consistent and clear message across the entire eCTD submission for ease of review by global Health Authorities. Best practices and recommendations to address common technical problems will be presented.

Getting it Right the First Time: An Introduction to Document Authoring Best Practices for eCTD Submissions**Sybille Sauter**

Regulatory Scientist,
Cato Research

Topic-based Authoring – Improving on Today's Document-centric Paradigm**Sara Bakes**

Associate Project Director
Pfizer Inc

Component-based Authoring**Peggy Boe**

Senior Director, Regulatory Writing
Image Solutions, Inc.

12:00 PM

CONFERENCE ADJOURNED

REGISTRATION FORM

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23rd Annual DIA Conference for Electronic Document Management Global Content Management in an Electronic World

Event #10003 • Tutorials: February 16 • Conference: February 17-19, 2010
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Full-day Tutorials:

#1 9 AM-5 PM US \$ 710 #2 9 AM-5 PM US \$ 710

Half-day Tutorials - Morning:

#3 8:30 AM-12 PM US \$ 405 #4 8:30 AM-12 PM US \$ 405

#5 8:30 AM-12 PM US \$ 405

Half-day Tutorials - Afternoon:

#6 1:30-5 PM 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.

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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 Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Gaylord National Resort and Convention Center is holding a block of rooms at the reduced rate below until January 25, 2010, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$170

Double \$170

Please contact the Gaylord National Resort and Convention Center by telephone at +1.301.965.2000 and mention the DIA/EDM meeting. The Gaylord National Resort and Convention Center is located at 201 Waterfront Street, National Harbor, MD 20745, USA.

CANCELLATION POLICY: On or before FEBRUARY 10, 2010

Administrative fee that will be withheld from refund amount:

Member or Nonmember = \$200

Government or Academia or Nonprofit (Member or Nonmember) = \$100

Tutorial (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:

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