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DRUG INFORMATION ASSOCIATION

5th Annual Electronic Submissions Conference

eCTDs: *Entering the Mainstream*

November 1, 2006 – Tutorials | November 2-3, 2006 – Conference
Westin Horton Plaza Hotel, San Diego, CA

PROGRAM CHAIRS

MARY L. COLLINS
Director, Regulatory Affairs
Image Solutions, Inc.

GARY M. GENSINGER
Director, Regulatory Review Support Staff,
Office of Business Process Support, CDER, FDA

PROGRAM COMMITTEE

JOHN W. AITKEN, PHD
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Elan Pharmaceuticals, Inc.

ROBERT M. CONNELLY
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GlaxoSmithKline

WAYNE R. KUBICK
Senior Vice President, Phase Forward/
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Principal, Don Rosen Consulting

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Vice President, Regulatory Affairs
Octagon Research Solutions, Inc.

KENNETH R. VANLUVANEE
President and Chief Executive Officer, Apyx, Inc.

GEOFF WILLIAMS, PHD
Site Head of Regulatory Operations,
Roche Products Limited, UK
Chairman of the EFPIA eCTD Topic Group

TARGET AUDIENCE: This program will benefit

- **Regulatory affairs/operations personnel**
- **Document and data managers**
- **Technical and medical writers**
- **Project managers**
- **Information technology professionals**

CONTACT INFORMATION

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Jessica Kusma, Phone +1.215.442.6182
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Erin Gilliland, Phone +1.215.442.6149
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OVERVIEW

In response to a growing demand for a comprehensive electronic submission conference, this year's conference will be expanded to multiple tracks. As more and more companies gain experience or contemplate the transition to electronic submissions, and as the electronic submission environment changes, it is imperative that the stakeholders (agency, industry and service providers) maintain open communication regarding new regulations, guidance, and the experience of the implementation.

This conference will focus on:

- how to optimize the experience if you are just getting started,
- lessons learned for the experienced and more advanced, and
- how converging electronic standards and formats drive the future vision (5-year horizon) of interactions between the life sciences industry, regulators, and the public.

OPTIONAL TUTORIALS

Wednesday, November 1 *(See page 8 for registration.)*

8:30 am-12:00 pm

#1 INDs in eCTD Format
#2 eSubmission Basics

1:30-5:00 pm

#3 eCTD Lifecycle Management
#4 eSubmission Basics

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

- Create guidance-compliant electronic submissions
- Identify challenges and benefits of transitioning from paper to electronic submissions and what this means for small, medium and large companies
- Discuss how to register for and use the new FDA electronic submission gateway
- Differentiate requirements and manage multiregion electronic submissions
- Discuss the regulatory view of the pros and cons of eLabeling implementations, and how to maximize the compliance of your company's future submissions
- Recognize the role and status of critical standards initiatives relevant to FDA electronic submissions
- Identify the process for planning and executing the transition to eCTD and how to avoid costly mistakes during this transition
- Demonstrate how to transition existing paper INDs to eCTD INDs and identify life cycle management concerns
- Describe the differences in FDA-sanctioned electronic submission formats and understand the importance of electronic submission standards
- Apply practical application of the ICH M2 eCTD Specification and the challenges faced by CMC professionals

THIS PROGRAM HAS BEEN DEVELOPED BY THE **DOCUMENT AND RECORDS MANAGEMENT, ECLINICAL, ELECTRONIC REGULATORY SUBMISSIONS, MEDICAL WRITING, AND REGULATORY AFFAIRS** SPECIAL INTEREST AREA COMMUNITIES

SIAC

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DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

Accreditation and Credit Designation
The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. Participants attending the conference and completing two tutorials can receive 18.5 pharmacy credits (1.85 CEUs).

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. Participants attending the conference and completing two tutorials can receive 1.9 IACET CEUs.

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

Tutorial 1: 3.25 pharmacy contact hours (.325 CEUs), 286-000-06-034-L04; .3 IACET CEUs. **Tutorial 2:** 3.25 pharmacy contact hours (.325 CEUs), 286-000-06-035-L04; .3 IACET CEUs. **Tutorial 3:** 3.25 pharmacy contact hours (.325 CEUs), 286-000-06-036-L04; .3 IACET CEUs. **Tutorial 4:** 3.25 pharmacy contact hours (.325 CEUs), 286-000-06-035-L04; .3 IACET CEUs.

Conference: 12 pharmacy contact hours (1.2 CEUs), 286-000-06-037-L04; 1.2 IACET CEUs.

TUESDAY • OCTOBER 31

6:00-8:00 PM REGISTRATION

WEDNESDAY • NOVEMBER 1

7:00-8:30 AM REGISTRATION

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

TRACK 1

#1 INDs IN eCTD FORMAT

FACILITATORS

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

Robin L. Zumbrunnen
Director, Global Regulatory Affairs, Technical Services and Support, Quintiles, Inc.

This half-day tutorial will focus on the practicalities and processes of creating and maintaining INDs in the eCTD format. Use of XML and the specifications needed for various types of submissions will be presented along with common pitfalls and issues. Practical examples of how to track continuous applications will be discussed, an activity on gathering metadata, and case studies will all be part of this interactive workshop.

Demonstrations of a pilot eCTD as both IND and NDA will be provided.

Tutorial 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
- Identify process change and improvement needs when preparing for eCTD
- Explain how to effectively collect and organize metadata
- Recognize the study tagging file utility

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

TRACK 2

#2 eSUBMISSION BASICS

FACILITATORS

John W. Aitken, PhD
Senior Director, Regulatory Operations, Elan Pharmaceuticals, Inc.

Jeanie Kwon
Associate Director, eDocument Services, Image Solutions, Inc.

This tutorial is aimed at individuals who have little or no experience of preparing electronic submissions for FDA, and who need a basic overview of what's involved. The tutorial will cover the preparation of electronic documents for eCTD submissions, and the compilation of different types of eCTD submissions.

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

- Prepare template-based Word documents
- Prepare granular CSRs for the eCTD
- Prepare eSubmission-ready documents and other file types that are acceptable to regulatory agencies
- Prepare an eCTD demo for FDA
- Build different types of eCTD submissions
- Submit electronically to FDA using the ESG

Please note that lunch will not be provided by DIA.

OPTIONAL AFTERNOON TUTORIALS
1:30-5:00 PM

TRACK 1

#3 eCTD Lifecycle Management

FACILITATORS

Kenneth R. VanLuvanee
President and Chief Executive Officer, Apyx, Inc.

Geoff Williams, PhD
Site Head of Regulatory Operations, Roche Products Limited, UK
Chairman of the EFPIA eCTD Topic Group

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 life cycle of an eCTD.

Tutorial 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 life-cycle management from a records management perspective

OPTIONAL AFTERNOON TUTORIALS
1:30-5:00 PM

TRACK 2

#4 eSubmission Basics

FACILITATORS

John W. Aitken, PhD
Senior Director, Regulatory Operations, Elan Pharmaceuticals, Inc.

Jeanie Kwon
Associate Director, Consulting Services, Image Solutions, Inc.

This tutorial is aimed at individuals who have little or no experience of preparing electronic submissions for FDA, and who need a basic overview of what's involved. The tutorial will cover the preparation of electronic documents for eCTD submissions, and the compilation of different types of eCTD submissions.

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

- Prepare template-based Word documents.
- Prepare granular CSRs for the eCTD.
- Prepare eSubmission-ready documents and other file types that are acceptable to regulatory agencies.
- Prepare an eCTD demo for FDA.
- Build different types of eCTD submissions.
- Submit electronically to FDA using the ESG

THURSDAY • NOVEMBER 2

7:00-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-10:00 AM **Plenary Session 1 – Electronic Submissions: An Overview and Introduction to Conference Topics**

CHAIRPERSON

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

This session provides an introduction to conference topics, and a progress report on electronic submissions in the United States and Europe, including acceptable electronic submission types and formats. Electronic submission standards will also be discussed including a presentation on CDISC standards and why sponsors should be applying submission standards, a review of the current status and upcoming plans of the various data standards relevant to electronic submissions.

US Electronic Submission Update
Gary M. Gensinger, Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

EU Electronic Submission Update
Timothy Buxton, Head of Sector, Project Management, EMEA, EU

The Why and How of eSubmission Data Standards
Wayne R. Kubick, Senior Vice President, Phase Forward/Lincoln Technologies, Inc.

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM **Plenary Session 2 – Regulatory Perspectives**

CHAIRPERSON

Gary M. Gensinger, Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

Presentations in this session provide a regulatory update on electronic submissions, including a review of the most current guidance documents, reviewer acceptance and feedback on the review of electronic submissions, and future direction of electronic submission initiatives.

eCTD and Related Guidance Issues
Gary M. Gensinger, Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

eCTD Submissions and Challenges
FDA Representative Invited

eCTDs: The Reviewer's Perspective
FDA Representative Invited

12:00-1:30 PM LUNCHEON

CONCURRENT SESSION 3A
1:30-3:00 PM

TRACK 1

eCTD – INDs

CHAIRPERSON

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

The use of the eCTD (Electronic Common Technical Document) in submitting and managing an IND forces companies to look at the level of documentation, or granularity of the information they provide to FDA in order to leverage the promise of XML. This session will provide case studies from the point of view of a major pharmaceutical company that transitioned from paper INDs to eCTD IND submissions. Included in this presentation are the benefits and challenges the organization faced in order to achieve successful team collaboration for the submission of a high-quality eCTD IND.

In addition, the Chemistry, Manufacturing and Controls (CMC) section of a dossier is perhaps the most dynamic of all the modules in the CTD, especially during the drug development process of the IND. A second industry presentation aims to share challenges of CMC dossier management in the eCTD environment from an industry point of view.

Transitioning from a Paper IND to eCTD IND Submissions
Michael Lisjak, Senior Manager, Global Regulatory Affairs, Wyeth Pharmaceuticals

Practical Implementation of the eCTD: Perspectives from Regulatory CMC
Deanna Murden, Regulatory Scientist, Pfizer Global Research and Development

Practical Implementation of the eCTD: Perspectives from Clinical Regulatory Documentation
Leah Kleylein, Manager, Global eSubmission Standards and Processes, Worldwide Regulatory Affairs, Centocor, Inc.

CONCURRENT SESSION 3B
1:30-3:00 PM

TRACK 2

Transitioning to eCTD: Part 1

CHAIRPERSON

John W. Aitken, PhD
Senior Director, Regulatory Operations, Elan Pharmaceuticals, Inc.

Transitioning to eCTD includes many levels of preparation, such as implementing new processes for authoring and publishing eSub-ready documents, selecting and implementing an eCTD system, converting existing submissions to eCTD format, and learning about new eCTD-related standards. This session, aimed at companies preparing their first eCTD, will provide a comprehensive review of many of the factors involved in transitioning from other eSub formats and paper to eCTD.

Part 2 will be presented in Session 4B from 3:30-5:00 pm.

Creating and Supporting Publishing-Friendly Authors
Jack Lipkin, Director, Regulatory Operations, Apyx, Inc.

eSubmissions: Moving Towards eCTD for the Mid-size Organizations
Laura Sherman, MBA, Vice President, Submissions and Validation Services, Impact Systems, Inc.

Case Study: Transitioning to an eCTD NDA
Erika S. Gooby, Manager, Regulatory Affairs, Neurocrine Biosciences, Inc.

3:00-3:30 PM REFRESHMENT BREAK

CONCURRENT SESSION 4A
3:30-5:00 PM

TRACK 1

eCTD: Marketing Applications

CHAIRPERSON

Matthew J. Neal
Senior Manager, Global Regulatory Affairs and Safety, Amgen Inc.

This session will cover the following topics:

- Regional challenges and re-use
- Lifecycle management of an NDA and the importance of the cumulative view
- Identification of challenges and benefits of transitioning to eCTD from the archiving and records management perspectives
- Evaluation of archiving solutions

Thomas Noto, Senior Director, Regulatory Affairs, PharmaNet, Inc.

Ryan Claringbold, GRO, Global Dossier Leader, Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Lois M. Householder, Manager, Regulatory Affairs Operations, TAP Pharmaceutical Products Inc.

CONCURRENT SESSION 4B
3:30-5:00 PM

TRACK 2

Transitioning to eCTD: Part 2

CHAIRPERSON

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

This session will focus on case studies from organizations directly involved in the eCTD transition. The presentations will provide a unique opportunity to learn from the experiences of others who have recently adopted this new submission model.

New and Future XML/Data Standards and the eCTD
Patrick Thomas, Associate Director, Regulatory Affairs, Octagon Research Solutions, Inc.

Converting from eNDA Annual Reports to eCTD Annual Report Submissions
LeeAnne Samsel, Senior Regulatory Submission Specialist, Wyeth Pharmaceuticals

A Business and Technical Strategy for an Effective and Efficient Transition to eCTD
Daniel F. Orfe, MS, Associate Director, Worldwide Regulatory Operations, Merck & Co., Inc.

5:30-7:00 PM NETWORKING RECEPTION Sponsored by the Special Interest Area Communities Listed on the Cover of this Program

FRIDAY • NOVEMBER 3

7:00-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

CONCURRENT SESSION 5A
8:30-10:00 AM

TRACK 1

eCTD: Multiregional eCTDs

CHAIRPERSON

Robert M. Connelly
Program Manager, Regulatory Operations, GlaxoSmithKline

This session will focus on multiregional eCTD applications. We will look into the strategic planning and operational management needed to ensure successful multi-regional applications. Key regional differences between the US, the EU, Canada and Japan will also be highlighted.

Geoff Williams, PhD, Site Head of Regulatory Operations, Roche Products Limited, UK, Chairman of the EFPIA eCTD Topic Group

Document Reuse for eCTDs: Case Study on an NDA/MAA
John W. Aitken, PhD, Senior Director, Regulatory Operations, Elan Pharmaceuticals, Inc.

CONCURRENT SESSION 5B
8:30-10:00 AM

TRACK 2

Organizational Impact of eCTD

CHAIRPERSON

Kenneth R. VanLuvanee
President and Chief Executive Officer, Apyx, Inc.

Publishing in eCTD format presents a breadth of possible changes and considerations for organizations looking to make the move. This session will discuss the organizational changes that must be considered when moving to eCTD. Topics discussed will include implications for IT, medical writing, templates, tools selection, process considerations, implementation, project management, and addressing legacy submission formats.

Writing, Editing, and Document Review as Part of the eCTD Lifecycle
Elizabeth Whitson, MA
Director, Development Editing and eSubmissions, Genentech, Inc.

From Paper to Megabytes: Transitioning from Paper to Electronic Submissions
Kevin Cooke
Regulatory Operations Manager, PDL BioPharma, Inc.

10:00-10:30 AM REFRESHMENT BREAK

10:30-11:30 AM **Plenary Session 6 – eLabeling**

CHAIRPERSON

Don Rosen, Principal, Don Rosen Consulting

SPL is mandatory in the US and PIM is in production for the centralized procedure at EMEA. Hear from the regulators about their current experience with these eLabeling submissions, and future plans.

SPL: Experiences to Date and Future Directions – The Regulators' View
FDA Representative Invited

PIM: Experiences to Date and Future Directions – The Regulators' View
Timothy Buxton, Head of Sector, Project Management, EMEA, EU

11:30 AM-1:00 PM LUNCHEON

1:00-3:00 PM **Plenary Session 7 – Current and Emerging Standards for Interoperability**

CHAIRPERSON

Wayne R. Kubick, Senior Vice President, Phase Forward/Lincoln Technologies, Inc.

This session will review a variety of current and emerging standards initiatives relevant to electronic submissions and provide practical advice on how and when to apply them.

A Guided Tour of the Standards Environment
Joel Hoffman, PhD, Director, Life Sciences, Insightful Corporation

The CDISC ADaM/SDTM Submission Pilot: Implications and Next Steps
Edward D. Helton, PhD, MA, Chief Scientist, Regulatory and Biomedical Affairs, SAS Institute and CDISC Board of Directors (Chair Elect)

Streamlining Clinical Trial Operations with Electronic Information Exchange
Ashley Evans, Chief Marketing Officer, SAFE-BioPharma Association

Regulated Product Submission: The Future of eSubs
Jason Rock, Chief Information Officer, GlobalSubmit, Inc.

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM **PLENARY SESSION 8 – REGULATORY TOWN HALL: QUESTIONS & ANSWERS**

CHAIRPERSON

Gary M. Gensinger, Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

This interactive session will allow members of the audience to submit questions to senior leaders from regulatory authorities. The topics discussed will depend entirely on the interests of the audience.

PANELISTS

FDA Representatives Invited

Timothy Buxton, Head of Sector, Project Management, EMEA, EU

CLOSING REMARKS

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

Gary M. Gensinger
Director, Regulatory Review Support Staff, Office of Business Process Support, CDER, FDA

5:00 PM CONFERENCE ADJOURNED

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.

TRAVEL AND HOTE

The most convenient airport is Lindberg Airport and attendees should make airline reservations as early as possible to ensure availability. The Westin Horton Plaza Hotel is holding a block of rooms at the reduced rate below until October 13, 2006, for the DIA conference attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $219 **Double $219**

Please contact the Westin Horton Plaza Hotel by telephone at +1-800-westin-1 or +1-619-239-2200 and mention the DIA conference. The hotel is located at 910 Broadway Circle, San Diego, CA 92101, USA.

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To obtain schedule information and the best fares, call United Airlines's Specialized Meeting Reservations Center at **1-800-521-4041**. ***Make sure you refer to Meeting ID Number 571AK.*** Dedicated reservationists are on duty 7 days a week from 8:00 AM to 10:00 PM EST.

This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

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 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.

DRUG INFORMATION ASSOCIATION http://www.diahome.org

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DATA ON DEMAND

The Optimization of Clinical Data Management

September 26-27, 2006, Sheraton Philadelphia City Center, Philadelphia, PA

PROGRAM CHAIRS

RONALD D. FITZMARTIN, PhD, MBA
Vice President, Informatics and Knowledge Management, Daiichi Sankyo Pharma Development, Daiichi Sankyo, Inc.

CHRIS A. LEGRAND, MS
President, Constella Health Sciences, Constella Group, LLC

Don't miss this unique opportunity!

This meeting is being co-located with

BONUS OFFERING! Attend 4 meetings for the price of one!

- *The Changing Pharma and Biotech Industry: Re-negotiating the Role of Project Management*
- *DIA Outsourcing Summit*
- *Global Electronic Labeling*

Register for **any of these** meetings and enjoy increased networking opportunities during joint breaks, luncheons and receptions ***PLUS*** access to the shared Exhibit Hall.

This program will address a paradigm shift that must occur to realize an optimal process for the conduct of clinical data management. These components include: 1) an integration and utilization of database/warehousing technologies with data capture solutions in both hosted and non-hosted computer environments, 2) emphasis on data capture technicians, and 3) a focus on data review for rapid decision making, rather than data cleaning for rapid lock and "relock." The program will also explore models for "engineering" the CDM process, enabled by measurement and technology, to be continually maturing to optimization.

Keyword Search: **06018**

PROJECT MANAGEMENT

Planning, Executing and Controlling Projects in Pharmaceuticals and Biotechnology

October 16-17, 2006, DIA Worldwide Headquarters, Horsham, PA

POTENTIAL FACULTY

MARTIN D. HYNES, III, PhD
Director, Product Research and Development, Lilly Research Laboratories, Eli Lilly and Company

ROBERT L. JUDD, III, PE, PMP, SCPM
Senior Consultant, Integrated Clinical Solutions, Inc.

JOAN KNUTSON, PMP
President, PM Guru Unlimited

KEY TOPICS

- **CURRENT STATE OF PROJECT MANAGEMENT IN PHARMACEUTICALS, BIOTECH AND MEDICAL DEVICES**
- **INITIATING, PLANNING, CONTROLLING AND CLOSING PROJECTS**
- **RISK ASSESSMENT**
- **TEAM DYNAMICS**

This course is designed for individuals who want to learn more about the role of project managers and project leaders in the pharmaceutical or biotechnology industry. During this 2-day program, participants will learn the elements of a project plan and how to use the plan to execute and control a project. Participants will also learn how to motivate team members to achieve the project goals. A case study and interactive exercises using pharmaceutical/biotechnology examples will stimulate developing a more in-depth understanding of planning, executing and controlling of projects.

Keyword Search: **06455**

CALL FOR ABSTRACTS DUE BY AUGUST 23, 2006

EDM'S 20TH ANNIVERSARY CONFERENCE
Reconnecting the Process to the Delivery of Safe and Effective Medical Products

February 6-9, 2007, Loews Philadelphia Hotel, Philadelphia, PA

PROGRAM CHAIRS

STEPHEN E. WILSON, DrPH, CAPT. USPHS
Director, Office of Business Process Support, Deputy Director, Division of Biometrics II, CDER, FDA

KAY BROSS
Senior PKI Specialist, Information Security and Solutions, Procter & Gamble Company

LAURA J. SHERMAN, MBA
Vice President, Submissions and Validation, Impact Systems Inc.

Over the past 20 years, the DIA EDM Conference has served as a platform for the discussion of emerging standards and processes for the creation, submission and retention of regulatory information. Within the past 2 to 3 years, there has been an increasing recognition of a broader and more complex environment that critically needs interoperability standards to create, electronically exchange and manage this ever growing array of medical and regulatory information. Being proactively positioned and strategically aligned will require internal thought and planning to facilitate process re-engineering and re-tooling. While change is inevitable, the need for readily available current information while still ensuring data protection is essential. Traditional business roles are being remodeled and re-scoped with the convergence of disciplines and cultural change. It is essential in this complex environment to not only continuously re-analyze the business and information process, but to analyze the impact to touch points, intersections, interdependencies, and interoperability connectors all along the drug development continuum to ensure the delivery of safe and effective medical products.

Keyword Search: **07003**

CALL FOR ABSTRACTS DUE BY SEPTEMBER 8, 2006

22ND CLINICAL DATA MANAGEMENT
Integration across the Clinical Trial Continuum

March 18-20, 2007, Hilton Hotel in the Walt Disney World Resort, Orlando, FL

PROGRAM CHAIR

KRISTIN M. NEFF, MS, Boston Scientific Corp.

PROGRAM COMMITTEE

PAUL BLEICHER, MD, PhD
Phase Forward

TED Y. CHIN, PhD, MBA
GlaxoSmithKline

PATRICK GENYN
Johnson & Johnson

REBECCA D. KUSH, PhD
CDISC

DENISE DERENZO LACEY, MA, MS
Waife & Associates, Inc.

JOHANN PRÖVE, PhD
Bayer Vital GmbH, Germany

STEPHEN E. WILSON, DrPH, CAPT. USPHS
CDER, FDA

Please join us in celebrating the 22nd year of this hallmark meeting!

This annual meeting will deliver the latest information to attendees about the evolving clinical data management function, as well as provide opportunities to meet and network with colleagues in the industry. The sessions will highlight and address changes in the overall clinical development environment due to new approaches to data management and new technologies supporting data management. The result is a paradigm shift of the role of data management in a changing industry. We are seeking abstracts which address the CDM continuum within this new paradigm. For a valuable guide as you develop your abstract, visit DIA's website. You will find a list of the themes representing issues and topics that the Program Committee would like to have addressed.

Keyword Search: **07004**

eCTDs Entering the Mainstream

Westin Horton Plaza Hotel
San Diego, CA, USA Meeting ID #06030

November 1, 2006 | Tutorials
November 2-3, 2006 | Conference

OPTIONAL TUTORIALS — Wednesday, November 1

#1 INDs in eCTD Format
#2 eSubmission Basics
#3 eCTD Lifecycle Management
#4 eSubmission Basics

PLENARY SESSIONS — Thursday and Friday, November 2-3

Electronic Submissions: An Overview and Introduction to Conference Topics
Regulatory Perspectives
eLabeling
Current and Emerging Standards for Interoperability
Regulatory Town Hall: Questions & Answers

CONCURRENT SESSIONS — Thursday and Friday, November 2-3

eCTDs – INDs
eCTD: Marketing Applications
eCTD: Multiregional eCTDs
Transitioning to eCTD: Part 1
Transitioning to eCTD: Part 2
Organizational Impact of eCTD

MEMBER EARLY BIRD *Register by October 12, 2006* **SAVE $175**

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 & TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the conference and during receptions (if applicable).

Conference information: Contact Jessica Kusma at the DIA office by telephone +1-215-442-6182, fax +1-215-442-6199 or email Jessica.Kusma@diahome.org.

Tabletop exhibit information: 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 a tabletop exhibit application, please check.**

GROUP DISCOUNTS (not available online or on already discounted fees)

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.
See page 6 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 OCT. 12, 2006	After OCT. 12, 2006
Member Fee	US $1125 ❑	US $1300 ❑

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 $1430 ❑

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 $ 300 ❑	US $ 430 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 650 ❑	US $ 780 ❑

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

TUTORIALS

#1	8:30 am-12:00 pm	US $ 350 ❑	**#3**	1:30-5:00 pm	US $ 350 ❑
#2	8:30 am-12:00 pm	US $ 350 ❑	**#4**	1:30-5:00 pm	US $ 350 ❑

CANCELLATION POLICY: On or before OCTOBER 27, 2006

Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial = $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.

❑ **I cannot attend but please keep me informed of DIA's future events.**
(requires completion of name, postal address and email address on this form)

REGISTRATION FORM

Do not remove mailing label. Please return this entire page. **06030**
PLEASE CONSIDER THIS FORM AN INVOICE

Please check the applicable category:
❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student *(Call for registration information)*

Last Name Check if part of group registration ❑ First Name M.I.

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Address As required for postal delivery to your location Mail Stop

City State Zip/Postal Country

email Required for confirmation

Phone Number Fax Number Required for confirmation

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.

☐ Visa ☐ MC ☐ AMEX *Exp Date* _____

Card # _____

Name (printed) _____

Signature _____

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

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