Regulatory Information Management 2013

April 3-4, 2013
Baltimore Marriott Inner Harbor at Camden Yards
Baltimore, MD

PROGRAM COMMITTEE:

Sarah Powell, RAC
Executive Director, Regulatory Affairs and Writing ServicesLiquent, Inc.

Linda F. Bowen, MS, RAC
Head of US Regulatory Policy and Intelligence
Sanofi

Dominique E. Lagrave, PharmD, MSc
Director, Regulatory Affairs OperationsDendreon Corporation

Andrew P. Marr, PhD
Managing DirectorMarr Consultancy Ltd.

SOLUTIONS TO YOUR REGULATORY PROCESS

Modern computer and other scientific technologies have made it possible for drug researchers and developers to generate and analyze more data than ever before. In response to louder calls for patient safety, and the multiple review jurisdictions called into multinational or global clinical trials, such data are also subject to more (and more intense) scrutiny during regulatory review and approval than ever before. As a result, for the past several years, regulatory departments have been asked to do more than ever before.

The need to understand the regulatory requirements for filing, timelines, what products are approved in which markets is becoming a critical regulatory need for both industry and regulators. Effective regulatory information management processes and tools are needed to ensure the organization remains compliant with its product registrations.

The DIA Regulatory Affairs Special Interest Area Community and an expert program committee have developed this conference, which will feature plenary sessions on the latest trends and regulations. Sessions are separated into two tracks: a business-focused track and a technology-focused track. The Business Track will provide the opportunity to interact and share experiences related to processes for obtaining and managing regulatory information and the organizational impact. The Technology Track will focus on standards related to submission of regulatory information, the tools necessary to effectively manage the information, and associated implementation experiences and lessons learned. The conference will end with a Vendor Showcase.

LEARNING OBJECTIVES

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

- Identify key business drivers for establishing a global regulatory information management system
- Describe industry best practices related to standards and processes needed for effective regulatory information management
- Recognize the important role of regulatory intelligence in a regulatory information management strategy

WHO SHOULD ATTEND

Professionals involved in:

- Clinical Research & Development/Clinical Supplies
- eClinical
- Global Project Management
- Information Technology
- Regulatory Affairs/Operations
- Regulatory Information Management
- Regulatory, Medical, and Technical Writing

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CONTINUING EDUCATION CREDITS

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

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer 1.1 CEUs for the program. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

Continuing education credits are not available for the Plenary Session 9: Vendor Showcase.

DIA's Certificate Program

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

- Clinical Research Certificate Program: 6 Elective Units
- Regulatory Affairs Certificate Program: 6 Elective Units

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

If you would like to receive a statement of credit, you must attend the program, sign-in at the DIA registration desk each day of the program, and complete the on-line credit request process through My Transcript. To access My Transcript, please go to www.diahome.org, select "Login to My DIA" and you will be prompted for your user ID and password. Select "My Transcript" (left side bar) and "Credit Request" to process your credit request. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on Thursday, April 18, 2013.

Disclosure Policy

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

DAY 1 | WEDNESDAY, APRIL 3

7:15–8:15 AM PROGRAM REGISTRATION AND CONTINENTAL BREAKFAST

8:15–8:30 AM WELCOME AND OPENING REMARKS

8:30–9:15 AM PLENARY SESSION 1

Rebuilding Regulatory Affairs from the Top Down

Art Ciociola
Vice President, Head Global Regulatory Affairs
Alcon Laboratories, Inc.

9:15–10:00 AM PLENARY SESSION 2

How FDASIA is Shaping the Regulatory Environment

James Lindsay Cobbs
Associate Director, US Regulatory Affairs
Johnson & Johnson PRD

10:00–10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM CONCURRENT SESSION 3

SESSION 3A: BUSINESS TRACK

Global Product Classification: Identifying Challenges in Registration & Approval

Session Chair

Kimberly Belsky
Executive Director, Policy and Communication, Global Regulatory Affairs
Bausch + Lomb

Companies may seek to bring their products to new global markets during the initial approval process or post-approval process. Leveraging a US dossier may present unanticipated challenges since the classification of a product and dossier requirements may change in the target country or region. This session will explore the challenges of geographic expansion and provide points to consider when planning the regulatory strategy and potential roadblocks.

Brooke Casselberry
Director, Regulatory Affairs
Liquent, Inc.

Mary Jane Nehring
Executive Director, Global Regulatory Affairs
Bausch + Lomb

Lauren Quinn, JD
Head of US Regulatory Affairs
Novartis Consumer Health, Inc.

SESSION 3B: TOOLS AND TECHNOLOGY TRACK

Ensuring Global Readiness for the ISO IDMP Standards

Session Chair

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

By 2016, XEVMPD will transition from the 39 fields currently required to more than 120 fields required by ISO IDMP. Additional supporting documents will be required to be submitted. The FDA and other Health Authorities will require submissions based on these standards. This session will cover the steps to ensure global readiness.

John W. Kiser, MSc
Senior Director, Regulatory Operations
Abbvie

FDA Speaker Invited

William Mandarino
Associate Director, Global Regulatory Systems and Technology
UCB, Inc.

12:00–1:30 PM LUNCHEON AND NETWORKING OPPORTUNITY

1:30-3:00 PM CONCURRENT SESSION 4

SESSION 4A: BUSINESS TRACK

Access and Transparency of Information for Regulated Industry and the Customer

Session Chair

Linda F. Bowen, MS, RAC
Head of US Regulatory Policy and Intelligence
Sanofi, United States

This session will provide an update on clinical trial transparency in the US and EU. Access to information and disclosure: FOIA Requests will be discussed from US and Canadian perspectives.

Marlene S. Bobka
Senior Vice-President
FOI Services, Inc.

João Da Silva Duarte
Regulatory Intelligence & Policy Manager
H. Lundbeck A/S
Lundbeck SAS

Mary Speagle
Executive Director, Canadian Regulatory Affairs
OptumInsight

SESSION 4B: TOOLS AND TECHNOLOGY TRACK

Case Study: Prescription Labeling Alignment and Compliance in a Global Environment

Session Chair

Mauricha Marcussen
Program Manager, Global Label Alignment, Regulatory Affairs, Global Labeling & Ad Promo
Operations and Compliance, AbbVie Inc
CEO, Auditgraph, LLC

In this session, presenters will share the methodologies and processes used to maintain alignment across global labeling content in compliance with a Corporate Integrity Agreement (CIA).

Antoinette Eber-Rose
Director, Regulatory Affairs
BS Pharmacy

Jeff Elderton
CEO
Pivotstream, LLC

3:00–3:30 PM AFTERNOON REFRESHMENT BREAK

3:30-5:00 PM CONCURRENT SESSION 5

SESSION 5A: BUSINESS TRACK

Using Compliance (Regulatory) Intelligence to Facilitate Regulatory Compliance

Session Chair

Anita Fenty
Senior Manager, Regulatory Policy and Compliance
Covance Inc.

This session will emphasize that Compliance Intelligence (CI), although similar to regulatory intelligence, is a powerful tool that can be used to facilitate regulatory compliance thus allowing the user to be proactive rather than reactive.

Ann Ferriter
Office of Compliance, CDRH, FDA

Penny Levin, MS
Director Global Regulatory Intelligence & Policy
Teva Global Branded Products

Arpita Shah, PharmD, RPh
Senior Manager, Regulatory Intelligence & Policy
Celgene Corporation

SESSION 5B: TOOLS AND TECHNOLOGY TRACK

Structured Content Management

Session Chair

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

This session will have presentations on: A Custom Database to Manage Key Regulatory Aspects of Investigator Initiated INDs/IDEs in an Academic Research Center, Deriving Business Value from Rules-driven Automated Assembly of Narratives: A Structured Content Management Success Story, and Comparison of CRT data in legacy vs. SDTM formats.

Shankar Srinivasan, PhD, CCRC (ACRP)
Senior Regulatory Specialist, Office of Research Regulatory Support
Mayo Clinic

Tina Sacro
Clinical Documentation
Sanofi

Shifu Zhao
FDA Commissioner's Fellow
FDA

5:00–6:00 PM NETWORKING RECEPTION

DAY 2 | THURSDAY, APRIL 4, 2013

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

8:30-10:00 AM CONCURRENT SESSION 6

SESSION 6A: BUSINESS TRACK

Creating a Regulatory Intelligence Function: Challenges and Opportunities

Session Chair

Brian Michael Mayhew
Director
Biogen Idec Inc.

This session will provide a brief overview of the roles and responsibilities of regulatory intelligence functions (and differences at different sizes of companies). Presenters will explore the key challenges in establishing and maintaining regulatory intelligence functions and offer resolutions for companies to consider to successfully implement regulatory intelligence functions.

João Da Silva Duarte
Regulatory Intelligence & Policy Manager
H. Lundbeck A/S
Lundbeck SAS

Penny Levin, MS
Director Global Regulatory Intelligence & Policy
Teva Global Branded Products

SESSION 6B: TOOLS AND TECHNOLOGY TRACK

A Case Study of Global Regulatory Affairs Information Management (RIM)

Session Chair

Dominique E. Lagrave, PharmD,MSc
Director, Regulatory Affairs Operations
Dendreon Corporation

Traditional RIM systems have focused on the relatively narrow focus of regulatory submissions and related tracking activities. The growing number of factors contributing to a demand for more expansive RIM solutions will be discussed.

Rachel Carle
Sr. Director, Regulatory Operations
Genzyme Corporation

Meredith Sewell
Director, Global Regulatory Publishing
Allergan Inc.

10:00–10:30 AM REFRESHMENT BREAK

10:30 AM–12:00 PM CONCURRENT SESSION 7

SESSION 7A: BUSINESS TRACK

Regulatory Intelligence Tools (Free and for Fee) to Create a Regulatory Strategy

Session Chair

Meredith E. S. Brown-Tuttle
Regulatory Affairs
Regulatorium

Every regulatory strategy is unique; however, the questions that need to be addressed for each regulatory strategy are typically similar. The session will ask relevant development questions, which are components of the strategy and then illustrate the use of regulatory intelligence tools.

Linda F. Bowen, MS, RAC
Head of US Regulatory Policy and Intelligence
Sanofi

Jacqueline Kline
Senior Director
Global Regulatory Affairs
Eisai

SESSION 7B: TOOLS AND TECHNOLOGY TRACK

Regulatory Information Management (RIM): Concepts for Strategic Use of Regulatory Information

Session Chair

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

Now, more than ever, it is critical for companies to have a strategy to ensure the right systems, data governance, and reporting processes, are in place so that regulatory information is readily accessible within the company, accurate, and suitable for transmission to regulatory authorities. This session will describe the benefits of Regulatory Information Management.

Jennifer Ann LaFleur
Head of Dossier Management Office II,
Regulatory Affairs Operations
Boehringer Ingelheim Pharma Gmbh & Co.
KG

Jake Doran
IT Director, Global Regulatory Affairs & Quality Assurance
Janssen Research & Development

Steve Gens
Managing Partner
Gens and Associates Inc.

12:00–1:30 PM NETWORKING OPPORTUNITY AND LUNCHEON

1:30–3:00 PM CONCURRENT SESSION 8

SESSION 8A: BUSINESS TRACK

Implications of Working With FDA under FDASIA: A Primer for Successful Planning, Submission, and Approval of Applications

Session Chair

Lisa A. Jenkins
Vice President, Regulatory Strategy and Content Development
Virtual Regulatory Solutions

In 2012, FDASIA (including PDUFA V, MDUFA III, and GDUFDA) was signed into law. This session describes and interprets the new provisions from an FDA and Industry perspective and makes strategic recommendations for multiple disciplines.

Kimberly Belsky
Executive Director, Policy and Communication
Global Regulatory Affairs
Bausch + Lomb

Ronald Trust
Executive Director, Regulatory Affairs
Durata Therapeutics, Inc.

SESSION 8B: TOOLS AND TECHNOLOGY TRACK

Standardization of Electronic Drug Application Data: A Critical Factor in Improving the Effectiveness and Efficiency of the Regulatory Review Process

Session Chair

Dominique Lagrave, PharmD
Director, Regulatory Affairs Operations
Dendreon Corporation

Data standards are a critical factor in improving the overall effectiveness and efficiency of the regulatory review process. This session will provide an overview of FDA's commitment to the use of open, consensus-based data standards that will facilitate the efficient review of regulatory submissions.

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

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

Steve Wilson, DrPH, CAPT USPHS
Director
Division of Biometrics III
CDER, FDA

3:00 – 3:30 PM AFTERNOON REFRESHMENT BREAK

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:00 PM PLENARY SESSION 9

Vendor Showcase

Session Chair

Dominique E. Lagrave, PharmD, MSc
Director, Regulatory Affairs Operations
Dendreon Corporation

The RIM Vendor Showcase provides a fantastic opportunity for attendees to evaluate a number of currently available services and tools. During this session, a number of participating vendors will participate in an interactive question & answer panel.

5:00 PM WORKSHOP ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

Regulatory Information Management 2013
Event #13005
April 3-4

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

Member Early-bird Opportunity Available on nondiscount member fee only	On or before MAR. 12	After MAR. 12
Member Fee	US $1340 ❑	US $1490 ❑

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www.diahome.org/Membership

MEMBERSHIP US $175 ❑

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

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

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Government (Full-time)	US $595 ❑	US $770 ❑
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**If paying a nonmember fee, please check one box above, indicating whether you want membership.*

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

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

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

TRAVEL AND HOTEL The most convenient airport is Baltimore Washington Airport and attendees should make both airline and hotel reservations as early as possible to ensure availability. **Baltimore Marriott Inner Harbor at Camden Yards is holding a block of rooms at the reduced rate below until March 11, 2013 for the DIA event attendees.** Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $149 / Double $149

Attendees must make their own hotel reservations. A limited number of rooms are available at the reduced rate shown below (DIA rate is guaranteed until March 11, 2013, or until room block is filled). Attendees can visting www.diahome.org/RIM2013 to make their hotel reservations, or by calling +1.212.532.1660 or in the USA at 1.800.221.3531. If making your hotel reservation by phone, please select option 1 for "Hotel Reservations", inform the phone agent that it is a DIA event, and provide them with the date and title of the meeting.

PLEASE NOTE: In order to receive the reduced room rate, hotel reservations must be made as noted above, and not directly with the hotel.

CANCELLATION POLICY: On or before MARCH 11, 2013
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Preconference Workshop (if applicable) = $50

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

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

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

EXHIBIT INFORMATION
Attendees may visit the exhibits during the event and receptions. Please contact:
Jeff Korn, Exhibits Associate
+1.215.442.6184 | Fax **+1.215.442.6199**
Jeff.Korn@diahome.org

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Please check the applicable category:

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

Last Name _____

First Name _____ M.I.

Degrees _____ ❑ Dr. ❑ Mr. ❑ Ms.

Job Title _____

Company _____

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

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