Regulatory Information Management 2014

February 25-26 | Bethesda, MD
Bethesda North Marriott Hotel and Conference Center

PROGRAM COMMITTEE

Sarah Powell, RAC
Executive Director, Regulatory Affairs
and Writing Services
Liquent, Inc, a PAREXEL Company

Kimberly Belsky, MS
Executive Director
AdPromo, Labeling and Policy
Valeant Pharmaceuticals

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Head of US Regulatory Policy and Intelligence
Sanofi

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

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

Dominique E. Lagrave, PharmD, MSc
Principal Consultant
Parexel International

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OVERVIEW:

With an increased focus on getting innovative therapies to market, ensuring patient safety and regulatory compliance with approved application information, organizations are challenged to operate with a global perspective. The ability to access and use information in the data-rich world of the biopharmaceutical and medical device industries is critical to success. Effective regulatory information management (RIM) processes and tools are needed to ensure organizations are effectively and efficiently developing new products and conducting life cycle management while also remaining compliant with approved product registrations. Key thought leaders will share strategies on interpreting the regulatory requirements for filing, best practices for managing information, and review of many new or changing regulatory requirements.

This two-day annual conference features plenary sessions on the latest trends and regulations, as well as business and technology focused tracks. 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 as well as gain a greater understanding of key issues shaping the global regulatory environment. 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 conference, participants should be able to:

- Identify key business drivers for establishing a global regulatory information management system
- Share 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
- Gain understanding of critical changes in the global regulatory environment

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TUESDAY, FEBRUARY 25

7:30-8:25AM REGISTRATION AND CONTINENTAL BREAKFAST

8:25-8:30AM WELCOME AND OPENING REMARKS

Sarah Powell, RAC
Executive Director
Regulatory Affairs and Writing Services
Liquent, Inc, a PAREXEL Company

8:30-9:15AM PLENARY SESSION 1

Managing Regulatory Effectiveness

Alison Maloney
Head Regulatory Affairs
Bayer

Successful regulatory outcomes require focused strategy and efficient processes. How do you achieve high quality regulatory dossiers, with optimal labeling while still remaining compliant with approved product registrations? This session will focus on achieving business strategy success through implementation of key performance indicators.

9:15-10:00AM PLENARY SESSION 2

FDA Update on FDASIA

Jonca C. Bull, MD
Director
Office of Minority Health
Office of the Commissioner, FDA

The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012, expands the FDA's authorities and strengthens the agency's ability to safeguard and advance public health. FDA will highlight developments around key pieces of FDASIA, including demographic subgroup inclusion and regulatory science, an increased focus on the patient voice in drug development, informing new initiatives such as breakthrough therapies, drug shortages, orphan drugs/rare diseases, and FDA efforts in advancing scientific initiatives. Time will be given for questions.

10:00-10:30AM REFRESHMENT BREAK

10:30-12:00PM CONCURRENT SESSION 3

SESSION 3A: BUSINESS TRACK

Case Studies on Regulatory Information Management and Data Migration

Session Chair

Brooke Casselberry
Director
Regulatory Affairs
Liquent, A PAREXEL Company

This session will provide case studies on data migration and regulatory information managed over a number of projects. Lessons learned, successes, and skills essential for this type of endeavor will be discussed.

Speakers

Brooke Casselberry
Director
Regulatory Affairs
Liquent, A PAREXEL Company

Hans van Bruggen
Senior Regulatory Affairs Scientist
eCTDconsultancy B.V.

Jason Moyer
Director, Regulatory Information Management
Merck

SESSION 3B: TOOLS AND TECHNOLOGY TRACK

RIM System Improvement Life Cycle

Session Chair

Antonietta Falbo
Director
Regulatory Information Management (RIM) Program Office
Janssen Pharmaceutical Inc.

Continuing to explore the difficulties in building and maintaining a robust RIM system, this session will present the results of a year-long project that focused on RAPID (Regulatory Affairs Product Information Database). Attendees will gain a deeper understand of the necessity of data integrity/quality, data monitoring and importance of defining discrete data entry and ownership roles as they relate to either implementing a new RIM System or updating an existing RIM program.

Speakers

Meredith K Sewell
Director, Global Regulatory Publishing
Allergan Inc.

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

12:00-1:00PM LUNCHEON AND NETWORKING OPPORTUNITY

1:00-2:30PM CONCURRENT SESSION 4

SESSION 4A: BUSINESS TRACK

Leveraging Regulatory Agency Reviews to Develop Regulatory Strategic Plans

Session Chair

Sarah Powell, RAC
Executive Director, Regulatory Affairs and Writing Services
Liquent, Inc, a PAREXEL Company

Increasingly regulatory agencies have been launching "transparency" initiatives to render their marketing application approval decision making process accessible to industry. In particular, FDA, the European Medicines Agency (EMA), the Japan Pharmaceuticals Medical Devices Agency (PMDA), and Health Canada (HC) reviews and assessments of marketing authorization submissions are publicly available. These reviews provide a wealth of information to all regulatory strategists e.g., on agencies' challenges during their decision-making process, the prevailing regulatory "culture" or how the agencies integrate expert assessments in their decision-making process. A regulatory strategist may use these reviews as supporting evidence for global regulatory strategic planning, starting at inception of a global development project. A case study will be presented to demonstrate how the information contained in reviews of an approved ophthalmic products prepared by PMDA, US FDA and EMA can be used to build strategic knowledge on the regulatory interpretation of the data presented by the applicant. The case study will show examples of how the strategists can use these reviews to shape negotiation and contingency planning throughout development and beyond approval.

Speakers

Isabelle B. Lefebvre, MS, RAC
Director
Ophthalmics, Rx and Development
US Regulatory Affairs
Valeant Pharmaceuticals

Mary C. Speagle
Executive Director
Canadian Regulatory Affairs
OptumInsight

SESSION 4B: TOOLS AND TECHNOLOGY TRACK

Business Case Development for a Global RIM Capability: Tools, Techniques, and ROI

Session Chair

Steve Gens, MS
Managing Partner
Gens and Associates Inc.

How do you measure the business benefits of a comprehensive RIM capability from a global perspective? This session will cover both the quantitative and qualitative aspects of a business case along with the financial techniques to calculate business return on investment. Specific analysis techniques and category of benefits that require analysis will be reviewed.

Speakers

Steve Gens
Managing Partner
Gens and Associates Inc.

James Hanly
Director
Bristol Myers Squibb

Erik Hill
Senior Director Operations
Global Regulatory Affairs
Eisai

2:30-3:00PM REFRESHMENT BREAK

3:00-4:30PM CONCURRENT SESSION 5

SESSION 5A: BUSINESS TRACK

Integrating Regulatory Intelligence to Create a "Differentiating" Target Product Profile

Session Chair

Shanthi Sethuraman, PhD
Director
Regulatory Center of Excellence
Global Regulatory Affairs-US
Eli Lilly and Company

The Target Product Profile (TPP) is an FDA-recommended prescription drug product development tool. This is a powerful tool that can drive the development of the regulatory strategy and facilitate interactions with regulatory authorities and key stakeholders. Using this tool for internal project team interactions can help gain cross-functional alignment of clinical plans with desired/anticipated labeling claims and promotional messages throughout the drug development process. Leveraging regulatory intelligence is a critical imperative to the regulatory professional to differentiate a product based on approved drug labeling and promotional messages. The opportunities and challenges to integrate the right type and amount of regulatory information at the right times during drug development will be discussed during this session.

Speakers

Tracy Rockney, JD
Vice President
Regulatory Affairs, Global Labeling, Ad/Promo,
Regulatory Policy & Intelligence
AbbVie

Robin Wojcieszek, RPh
Senior Director Global Regulatory Affairs-US
Eli Lilly & Company

SESSION 5B: TOOLS AND TECHNOLOGY TRACK

Preparing for IDMP

Session Chair

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

The Identification of Medicinal Products (IDMP) standards in support of ICH M5 were published by the ISO in November 2012. The IDMP compliance challenge would be a game changer for the industry. It will not only change the compliance landscape but also result in a significant overall strategic growth for companies that truly adhere to these standards and organize their internal RIM processes around them. This session will include the FDA perspective.

Speakers

Vada A. Perkins, MSc, BSN, RN
Chief, Business Operations Staff
Office of Medical Products and Tobacco
CBER, FDA

Wim Cypers, MPharm
Vice President
Regulatory SPU
ArisGlobal

William Mandarino
Associate Director
Global Regulatory Knowledge Management
UCB, Inc.

4:30-5:30PM NETWORKING RECEPTION

WEDNESDAY, FEBRUARY 26

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

8:30-10:00AM CONCURRENT SESSION 6

SESSION 6A: BUSINESS TRACK

Actions to Streamline Data and Facilitate Global Submissions

Session Chair

Kimberly Belsky, MS
Executive Director
AdPromo, Labeling and Policy
Valeant Pharmaceuticals

Regulatory teams across companies are facing extraordinary market conditions, constantly shifting regulations with multijurisdictional requirements, and increased pressure to register their products with reduced budgets and significant resource constraints. Keeping abreast of changes in the endless surge of pending legislation, not to mention newly enacted and existing regulations that affect your regulatory approvals, can be a daunting task. This session will review solutions to identify, monitor, and track all potential regulatory changes, to anticipate risk opportunities and prepare for them with internal controls.

Speakers

Thomas Noto
Regulatory Operations Director
GE Healthcare Life Sciences

Tina Nyman
Director, Regulatory Operations
Sunovion Pharmaceuticals Inc.

Ravi Varahalu
Associate Director
Regulatory Operations
Makrocare

SESSION 6B: TOOLS AND TECHNOLOGY TRACK

Outsourcing Regulatory Activities

Session Chair

Dominique E. Lagrave, PharmD, MSc
Principal Consultant
Parexel International

Many companies are going through internal efficiency exercises to reduce cost and remain lean; all the while, increasing capacity to ensure volume targets can be met. This session will outline operational efficiency initiatives – outsourcing select regulatory operations activities (publishing and management of regulatory information). It will detail planning activities, vendor selection, onboarding, and training.

Speakers

Tony Catka
Global Regulatory Intelligence Lead
Accenture Accelerated R&D Services

Other Speakers Invited

10:00-10:30AM REFRESHMENT BREAK

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

SESSION 7A: BUSINESS TRACK

Intelligence from FDA Performance Metrics

Session Chair

Shanthi Sethuraman, PhD
Director
Regulatory Center of Excellence
Global Regulatory Affairs-US
Eli Lilly and Company

FDA publishes various reports and information in their website. This information, when mined appropriately can provide great insight on multiple fronts such division performance, opportunities for the various expedited pathways, postmarketing requirements/commitments, postmarketing supplements and more. This session will provide examples of analyses performed, information derived from the analyses and areas of opportunities to utilize this information to enable registration strategies.

Speakers

Michael Hay
Executive Vice President
Sagient Product Director
Sagient Research
Informa Business Information

Marija Popovic, PhD
Regulatory Center of Excellence
Eli Lilly and Company

SESSION 7B: TOOLS AND TECHNOLOGY TRACK

Quality Benefits for Regulatory Information Management

Session Chair

Sarah Powell, RAC
Executive Director, Regulatory Affairs and Writing Services
Liquent, Inc, a PAREXEL Company

One of the most important and yet difficult enterprise processes to manage, is the release of commercial drug product into global markets. From a RIM perspective, this process involves the regulatory assessment of changes, registration management, submissions management, product information management and label management; and touches most regulatory functional areas. This session will focus on the prevention of product recall and quality data.

Speakers

Casey Overman
Manager, IT
Biogen Idec

Kristofer Spahr
Director of Regulatory Services
TAKE Life Sciences

Nicholas Walzer
Director Regulatory Business Operation
Biogen Idec

12:00-1:00PM NETWORKING OPPORTUNITY AND LUNCHEON

1:00-2:30PM CONCURRENT SESSION 8

SESSION 8A: BUSINESS TRACK

FDASIA Update

Session Chair

Kim Quaintance
Head, US Regulatory Policy
Bayer Healthcare Pharmaceuticals

This session will continue the update on the Food and Drug Administration Safety and Innovation Act (FDASIA). The focus will be on expedited approval pathways and breakthrough therapy designation, the NME review program, and structured benefit-risk including Patient Focused Drug Development. Panelists will discuss what was in FDASIA/PDUFA V, implementation, industry experience, and looking ahead.

Speakers

Khyati N. Roberts
Senior Director, Regulatory and Policy Intelligence
Abbvie

Jayne C. Ware, MPH, MS
Director, Global Regulatory Policy
Merck & Co., Inc.

Other Speakers Invited

SESSION 8B: TOOLS AND TECHNOLOGY TRACK

US Module 1 Update and Implications

Session Chair

Dominique E. Lagrave, PharmD, MSc
Principal Consultant
Parexel International

This session will focus on the eCTD Module 1 specifications. This session will include an overview of the Module 1 administration and submission information.

Speakers

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

Douglas Kent
Submission Lead
Janssen Research & Development

2:30-3:00PM **REFRESHMENT BREAK**

3:00-4:00PM **PLENARY SESSION 9**

Vendor Showcase

SESSION CHAIR

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

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 Q & A panel.

4:00PM **CONFERENCE ADJOURNED**