by GAINING a more analytical view of the current FDA regulations, SPL conversion challenges, and EFFICIENTLY TRACKING labeling compliance.”

Overcome labeling compliance challenges

From keeping up with new regulations, developing a labeling strategy, analyzing Structured Product Labeling, and tracking label compliance, it is important to manage every aspect of label development.

Featuring Sessions by Leading Pharmaceutical Labeling Professionals Including:

- Colleen A. McGraw, Director, Labeling & Product Communications Regulatory Affairs, Vertex Pharmaceuticals
- Una Ortell, M.Sc. RAC, Global Head, Labeling & Promotion, Global Regulatory Affairs, Takeda Global Research & Development Center, Inc.
- Linda S. Pollitz, Director, Regulatory Affairs, Advertising & Promotion, Alkermes, Inc.
- Antoinette Eber-Roe, Director, Regulatory Affairs, Global Labeling & Ad Promo, Operations & Compliance, Abbott Laboratories
- Patricia A. Walsh, Director, Global Labeling Operations, Bristol-Myers Squibb
- Nina Sherak, Associate Director, Global Labeling Group, AstraZeneca
- Mauricha F. Marcussen, Regulatory Affairs, Global Labeling & Ad Promo, Operations & Compliance Program Manager, Global Labeling Alignment, Abbott Laboratories
- Kathleen M. Bulgreen, Associate Director, Global Labeling, Regulatory Affairs, Eisai
- Mary Elicone, Associate Director, Global Regulatory Affairs Labeling, Sanofi US
- Amy Ebel, PharmD, Director, Global Regulatory Affairs, Labeling Strategy, GlaxoSmithKline
- Teodora Doherty, Associate Director, Global Regulatory Labeling, Janssen Research & Development, LLC
- Tara Baer, Senior Manager, Labeling Development, Boston Scientific
- Corey Holstrom, Manager, Packaging and Labeling Compliance / Formulation and Ingredients Operations, Pfizer Global Quality Operations
- Amy Dailey, Global Clinical Trials Supplies-Supervisor, Allergan, Inc.
- Heather Magyar, Manager, Global Labeling Operations, Alcon, a Novartis company
- Marion Scocca, M.S., Director, Advertising, Labeling & Promotion, Biogen Idec
- Julie Batal, Associate Director, Regulatory Labeling & Promotion, Millennium: The Takeda Oncology Company

Who Should Attend: marcus evans invites Vice Presidents, Heads, Directors, Senior Managers and Managers with responsibilities in:

- Global Labeling
- Global Labeling Operations
- Regulatory Affairs Labeling
- Labeling and Product Communications
- Global Regulatory Affairs
- Labeling Strategy

March 20-21, 2013
Boston, MA
8:00 Registration and Morning Coffee

8:30 Chairperson’s Opening Address

8:45 Evaluating Labeling Compliance to Gain a Deeper Understanding of Complying with the Current FDA Regulations
- Discussing the different aspects of labeling compliance evaluated the impact on label creation
- Creating effective internal and external communication of labeling updates to meet FDA requirements
- Managing general label compliance by choosing the correct label of the product
- Analyzing the most effective way to execute label alignment to highlight the label’s horizontal and vertical display of content

Corey Holstrom, Manager, Packaging and Labeling Compliance/Formulation and Ingredients Operations, Pfizer Global Quality Operation

9:30 Mastering Different FDA Guidelines and Timelines to Accelerate Label Approval
- Assessing the rule of Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products to gain a greater understanding of the label horizontal and vertical display of content
- Understanding and meeting new labeling revisions with the Improved FDA Prescription Drug Labeling Activity
- Evaluating the Pregnancy and Lactation Labeling Rule and its prospective changes to Physician Labeling

Amy Ebel, PharmD, Director, Global Regulatory Affairs, Labeling Strategy, GlaxoSmithKline

10:15 Networking Break

10:45 Looking at the Organization of a Label in Compliance with the Physician Labeling Rule (PLR)
- Investigating the changing FDA regulations and staying up to date with required PLR label formats
- Creating packaging inserts that are accurate with the PLR labeling format
- Analyzing the different types of inserts: physician insert, patient insert, and pouch insert and their role in the final labeled product
- Evaluating the proposed Patient Medication Information and its affect on the PLR rule in 2015

Sara A. F. F. Clancy, Director, Global Regulatory Affairs, Advertising & Promotion, Biogen Idec

11:30 Designing a Successful Labeling Strategy That Will Accelerate the Label’s Approval in the FDA
- Developing a streamlined label strategy that meets FDA requirements to expedite label approval
- Understanding the importance of creating a specific labeling strategy for a particular drug indication
- Analyzing the best ways to address the life cycle of the label from Target Product Profile (TPP) through post-marketing
- Evaluating the competition of products in the same space and creating a label that will differentiate itself from the competition
- Documenting key information required to create the label that will gain faster approval and optimize marketing claims

Panelist:
Linda S. Pollitz, Director Regulatory Affairs, Advertising & Promotion, Alkermes, Inc.

12:30 Luncheon

1:30 Developing a Label and Managing it through Labeling Approval and Post-Approval Maintenance
- Conceptualizing a labeling strategy to create the product’s label
- Managing label content efficiently on paper and electronically
- Guiding affiliates to work independently while developing the label for approval
- Creating packaging inserts that are accurate with the PLR labeling format
- Managing post-approval label changes in the real world: Core Data Sheet and local labels

Colleen A. McGraw, Director, Labeling & Product Communications Regulatory Affairs, Vertex Pharmaceuticals Incorporated

2:15 Interactive Panel Discussion
Generating Core Labeling Content to Determine What to Include in the Final Label
- Understanding the value of considering labeling early in development
- Determining core content in the early stages of label creation
- Utilizing core data as a method of harmonizing international labeling
- Using the core data sheet as a main point of reference to document the safety of the product

Panelists:
Julie Batal, Associate Director, Regulatory Labeling and Promotion, Millennium: The Takeda Oncology Company
Nina Sherak, Associate Director, Global Labeling Group, AstraZeneca
Marion Scocca, M.S., Director, Advertising, Labeling & Promotion, Biogen Idec

3:15 Networking Break

3:45 Creating a Core Data Sheet in a Clear and Concise Manner
- Submitting accurate core data sheets when labeling a new product
- Discussing populating adverse drug reactions and what to include and how to present it in the label
- Utilizing this global referencing document to effectively direct local affiliate labeling
- Determining changes that needed to be made after the label is submitted to the local region

Una Ortell, M.Sc. RAC, Global Head Labeling and Promotion Global Regulatory Affairs, Takeda Global Research & Development Center, Inc.

4:30 Leveraging and Accessing Structured Product Labeling (SPL) Data through XML Process Tools
- Addressing current SPL Guidance’s in order to meet FDA Regulatory Policies
- Overcoming SPL XML Conversion Challenges through utilizing different XML publishing tools and proof reading
- Utilizing SPL style sheets as tools to re-use the product label’s content and access it in any location
- Determining whether to use outsourcing or in-house SPL conversion software in creating a product’s label
- Evaluating how SPL data can be used to determine Medicare claims

5:15 Closing Remarks of the Chair & End of Day One
Day Two | Thursday, March 21, 2013

8:00  Registration and Morning Coffee
8:25  Chairperson’s Opening Address

EVALUATING CURRENT STRUCTURED PRODUCT LABELING AND DESIGN METHODS WHILE MEETING FDA GUIDELINES

8:30  Producing Clear and Safe Labels that Will Minimize Adverse Events
- Understanding the safety requirements from the FDA to having the label accurately displayed on Daily Med
- Creating clear and concise labels that are easily comprehensible by patients and physicians
- Maintaining the product labels are legible and readable for consumers taking the products
- Designing the label to have the most accurate and safe prescription information to eliminate any confusion

Heather Magyar, Associate Director, Global Labeling, Regulatory Affairs Eisai

10:00  Networking Break

TRACKING GLOBAL LABELING COMPLIANCE TO ASSESS THE PRODUCT’S INFLUENCE IN THE LOCAL REGIONS

10:15  Translation Management: Suppliers, Quality Control and Compliance
- Defining and measuring performance
- Managing your suppliers and affiliates
- Identifying and communicating roles and responsibilities
- Writing for translation: linguistic choices and minimalism

Tara Baer, Senior Manager, Labeling Development
Boston Scientific

11:15  Label Translations and Global Issues with the Ever-Changing Regulations for Clinical Labeling – Challenges and Resolutions
- Considering timelines and additional timing needed when dealing with global labeling and translations
- Analyzing country specific in Core Texts; what is true Core Text?
- Working and dealing with the wants vs. the needs in labeling requirements when dealing with country specific requirements and translated text
- Requiring excess content in translations in accordance with country regulations and dealing with limited real estate on labels
- Overcoming the lack of consistency in translated text

Amy Dailey, Global Clinical Trials Supplies-Supervisor
Allegan, Inc.

12:00  Luncheon
1:00  Labeling Considerations in the European Union and its Impact on Global Labeling Compliance
- Analyzing labeling in the EU
- Understanding the Centralized Procedure (CP)
- Reviewing QRD requirements
- Maintaining national approvals and the move to EU SPC harmonization
- Addressing PSUR Worksharing

Mary Elicine, Associate Director, Global Regulatory Affairs Labeling
Sanofi US

TESTIMONIALS:

Designing a product label is a long and complex process, from the amount of time that is needed, to creating a label that is compliant with the current FDA regulations. At this conference, we are looking at new ways to overcome these challenges by analyzing the new FDA timelines and regulations that will impact the life cycle of a label. We will also look at one of the hottest topics, Structured Product Labeling (SPL) evaluating how pharmaceutical companies are converting their word documents into XML format, as well as discussing the benefits of Downstream Structured Product Labeling (SPL). We will then assess the way the product label is designed and how make sure that it will be both safe and meet pharmacovigilance requirements. After the labeled product is completed, we will be able to analyze how to track the label’s global compliance by assessing the label’s prominence in multiple regions around the world.

Attending this event, delegates will gain a comprehensive view of how to meet the most up to date FDA regulations that their companies must follow in order to create a label. This conference will provide delegates with the information to create a successful labeling strategy, and making sure to document the core content in an accurate and efficient manner in the core data sheet. To analyzing how industry leaders are conducting SPL conversion of Structured Product Labeling (SPL) and Downstream Structured Product Labeling (SPL) as well as investigate the prospective future of paperless labeling and its future prospects in the labeling industry. We will finalize the conference by documenting that the labels are both safe and meeting pharmacovigilance so they can be sent worldwide to different local regions.
The Regulatory Affairs Professionals Society (RAPS) is a global membership organization of regulatory professionals in the rapidly growing medical device, pharmaceutical and biotechnology sectors. As regulatory professionals, RAPS members perform vital work in all areas of the healthcare product lifecycle, ensuring these products are safe and effective, while driving organizational strategy and sound decision-making.

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[Image of RAPS logo]

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