Key Topics:

› Evaluate the differences and similarities of pharmaceutical and medical device labeling to ensure efficiency in industries

› Manage the end-to-end process of labeling and packaging a product

› Explore new strategies to better enhance meeting all regulatory requirements

› Increase the accuracy of information on your package, label and artwork by tracking the product throughout the lifecycle

Explore Global Labeling to Better Prepare for an Inspection to Answer Major Findings

Gerrit-Jan Nijveldt, Senior Director, Global Regulatory Affairs
Labeling, SANOFI

Implementation of a Global Labeling Tracking System: End-to-End from the Labeling Request to Audit Response

Paula Hudson, Director, Global Regulatory Affairs, ELI LILLY AND COMPANY

Surviving and Thriving During a PV Inspection: The Criticality of Labeling Preparation

Deb McNaughton, Senior Director, Global Labeling Management, PFIZER

How to Use the Core Data Sheets to Capture Safety Updates and Communicate the Same Message Globally

H. Stephanie Bodo Kamga, Associate Director, Labeling Strategy and Global Regulatory Affairs, SHIRE
Dear Colleague,

Drug labeling is a constantly changing field that requires multiple departments to manage label, content and packaging information. Labeling professionals are discovering new strategies to better enhance the documentation process and efficiently track the process from labeling to packaging a drug. All types of labeling products have requirements, and each drug and medical device classification should be shown on each product. It is important that industry leaders provide legible print throughout a product’s lifecycle to ensure the safety needed for patients and providers.

I invite you to attend ExL Events’ Safety Labeling and Packaging Summit on September 14-15 in New Jersey to better understand the key components of the end-to-end process of labeling to packaging a drug. Industry professionals will discuss recent strategies and common issues on how to manage information on the Core Data Sheet, successfully prepare for the process of the labeling and packaging a product, and ensure accuracy of the safety information on the label. Over the course of two days, conference delegates will:

› Gain a better understanding of how to manage the lifecycle of a drug from labeling to packaging
› Develop a strategy on how to prepare for regulatory changes that occur in the industry
› Increase awareness on safety consideration for labels and how to minimize medication errors
› Learn from labeling professionals who have successfully implemented packaging and labeling strategies that brought new products to the market faster

I look forward to welcoming you to New Jersey this fall!

Sincerely,

Kelly Osmulski
Conference Production Director
ExL Events, a Division of Questex, LLC
kosmulski@exlevents.com

VENUE NAME
Wyndham Hamilton Park
175 Park Ave
Florham Park, NJ 07081

To make reservations, please call 973-301-9717 and request the negotiated rate for ExL’s Safety Labeling and Packaging Summit or reference the Block Code: 09136880EX. You may also make reservations online using the following weblink: http://bit.ly/2nuY70i. The group rate is available until August 24, 2017. Please book your room early, as rooms available at this rate are limited.

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WHO SHOULD ATTEND:
This conference is designed for representatives from pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

› Labeling
› Labeling Strategy / Compliance
› Labeling Compliance
› Scientific Writing
› Drug Safety
› Regulatory Affairs
› Pharmacovigilance
› Medical/Clinical
› Legal
› Safety Management
› Packaging
› Package Engineering/Technology
› Product Safety and Security

This conference is also of interest to:
› Consultants
› Contract Packaging Organizations
› Drug Manufacturing Companies

SPONSORSHIP AND EXHIBITION OPPORTUNITIES
Do you want to spread the word about your organization’s solutions and services to potential clients who will be attending this event?

Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.
Thursday, September 14, 2017 / Main Conference, Day one

8:00 Registration and Continental Breakfast
9:00 Co-Chairpersons’ Opening Remarks

9:15 Evaluation and Progression of the Label
› Best practices on how the label has evolved from the Food and Drugs Act of 1906 to the first Patient Package Insert of 1970, the recent Physician Labeling Rule of 2006 and the Medication Guide of 2007
› Gather information on the regulations of labeling and prescription, and consumer product labeling
› Discuss the life of the label from the Investigator’s Brochure to Prescribing Information, Patient Package Insert, and Medication Guides
› Provide sufficient risk versus benefit information for medical judgment
› Effective tools on conveying safety and efficacy of the product, high exposure to recalls, and directing the promotion of the product

Madhu Anant, Vice President, Global Regulatory Affairs, MALLINCKRODT PHARMACEUTICAL

10:00 Prepare for an Inspection and Best Practices to Prevent Labeling Errors
› Understand how to develop and maintain your Company Core Date Sheet
› Walk through the labeling process for multiple products from the early phase to approval
› Examine information management tools and how to handle inspections by the FDA
› Explore label printing and how to carefully monitor all the steps to get your label approved

Gerrit-Jan Nijveldt, Senior Director, Global Regulatory Affairs Labeling, SANOFI

10:45 Networking Break

11:15 How to Use the Core Data Sheets to Capture Safety Updates and Communicate the Same Message Globally
› Capture how to use Core Data Sheets to assist in tracking the process of labeling to demonstrate control over process and timeline
› Discuss safety labeling perspectives and how to provide information to the stakeholder in a timely manner
› Conceptualize how to maintain consistency across your team to ensure success in your labeling process
› Review multiple strategies on how to leverage technology to track implementation from end to end

H. Stephanie Bodo Kamaga, Associate Director, Labeling Strategy, Global Regulatory Affairs, SHIRE

12:00 Safety Labeling in Asia-PAC: Explore the Lifecycle of Effective Risk Management
› Overview of the new regulations for Japan to ensure safety communication for patients
› Explain e-labeling in Asia and the process from paper to digital
› Master how to design safety package inserts for patient and healthcare providers
› Gain safety labeling requirements for packaging products and local policies

Rie Matsui, Director, Regional Labeling Head for Asia, PFIZER

12:45 Luncheon

1:45 PANEL: Overview of New Regulations for Pregnancy and Lactation Labeling Drugs (PLLR)
› Analyze Pregnancy and Lactation Labeling Drugs Final Rule
› Address the new regulations, changes in content and format for the information presented in prescription drugs
› Outline the changes in the new regulations
› Compare and contrast the current prescription labeling to the new PLLR requirements

Roshni Barbaria, Senior Manager, Global Labeling Compliance, Regulatory Affairs, ALLERGAN
Suzette Bergmark Hildenbrand, Labeling Cluster Head, PFIZER

2:45 CASE STUDY: How Roche Achieved World-Class Changeover Time to Improve Medical Device Products
› Clarify how information systems have changed over time and how to reinvent your package
› Define the efficient process of packing a product and how Roche has proved successful in this process
› Outline the importance of having an engaged team during the project lifecycle

Jayson Diaz, Project Senior Engineer, ROCHE

3:30 Networking Break

4:00 Security of Supply Chain: Best Practices in Ensuring the Integrity of the Product – In Both Storage and Transit
› Explore how to ensure supply chain handling security is a top priority by reviewing current best practices
› Learn how supply chain security intelligence plays a key role in reducing diversion and theft
› Understand the latest types of technology used to protect shipments in both transit and storage

Charles Forsaith, Director, Supply Chain Security, PURDUE PHARMA LP

4:45 An Overview of the Generic Drug Rule to Improve Generic Drug Safety
› Overview of the safety information, new regulations for generic drugs, and the need for documented processes for safety tracking and label updates
› Discuss the FDA’s proposed generic drug labeling rule and the approach to label changes for generic pharmaceuticals
› Learn how to comply with the new rule and how to present submissions for the product’s label

5:30 End of Day One

“Practical, Relevant Pointers for a Successful Strategic Program.”
—Program Manager, MALLINCKRODT PHARMACEUTICALS
Friday, September 15, 2017 / Main Conference, Day Two

8:00  Continental Breakfast

9:15  Co-Chairpersons’ Recap of Day One

9:30  Explore a Global Perspective on the Development of Core Data Sheets
› Explain the label content and placement, regulation guidance in the production of high-quality and timely Core Data Sheets
› Highlight on how to improve the labeling development within CCDS
› Uncover how to manage and develop a compliant local labeling process

Roshni Barbaria, Senior Manager, Global Labeling Compliance, Regulatory Affairs, ALLERGAN

10:15  PANEL: Address the Differences and Similarities of Pharmaceutical and Medical Device Labeling Challenges and Regulatory Issues
› Review how to develop a robust label from Core Data Sheets to the end result; content on the package
› Learn how to improve your labels for both medical devices and pharmaceutical products
› Recognize some of the common issues currently plaguing the industry

Madhu Anant, Vice President, Global Regulatory Affairs, MALLINCKRODT PHARMACEUTICAL

11:00  Networking Break

11:30  Surviving and Thriving During a PV Inspection: The Criticality of Labeling Preparation
› Address the importance of regulatory and global labeling of a PV inspection
› Understand the methods and concepts of labeling developments to ensure the importance of the end-to-end labeling tracking
› Assess how certain modules are impacting the label and how to prepare for future PV inspections

Deb McNaughton, Senior Director, Global Labeling Management, PFIZER

12:15  Luncheon

1:15  Implementation of a Global Labeling Tracking System: End-to-End from the Labeling Request to Audit Response
› Review the responsibility for oversight of global labeling
› Discuss key milestones needed for an end-to-end tracking system
› Challenges and lessons learned from the labeling lifecycle

Paula Hudson, Director, Global Regulatory Affairs, ELI LILLY AND COMPANY

2:00  PANEL: Building a Core Global Labeling Process
› Focus on the responsibilities for the global end-to-end labeling process
› Describe the role of labeling in a regulatory affairs environment
› Outline some global labeling challenges and how to ensure meeting regulatory requirements
› Communicate on how to establish safety information for labels

Mark Collins, Global Labeling Lead, CSL BEHRING

2:45  Networking Break

3:15  The Implementation from CCDS to the Packaging of a Drug to Approval
› Best practices on one company’s experience from CCDS to packaging and the common challenges that occur during this process
› Gather information on combination products inspections for packaging components
› Uncover the evaluating process of data packages and understand the document process for safety labeling

Conference Concludes

What Attendees are Saying about ExL Conferences:

“Very good! The conference met my expectations”
—Senior Manager, Corporate Communications, OTSUKA

“The conference, speakers and topics were great”
—Associate Director, Strategic Alliances, NOVARTIS

Media Partners:
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<th>Early Bird Pricing</th>
<th>Standard Pricing</th>
<th>Onsite Pricing</th>
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**Save 25% per person when registering four**

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

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View our website at http://pmaconference.com
Mail: POB 2303 Falls Church Va 22042
Safety Labeling and Packaging Summit

Understand the Key Components for the End-to-End Process of Labeling to Packaging a Drug

September 14-15, 2017 / Wyndham Hamilton Park / Florham Park, NJ

Featured Speakers:

Suzette Bergmark
PFIZER

Mark Collins
BEHRING

Charles Forsaith
PURDUE PHARMA LP

Jayson Diaz
ROCHE

Madhu Anant
MALLINCKRODT PHARMACEUTICALS