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, New Jersey

Featured Speakers:

Suzette Bergmark Hildenbrand
Labeling Cluster Head
PFIZER

Mark Collins
Global Labeling Lead
CSL BEHRING

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

Jayson Diaz
Project Senior Engineer
ROCHE

Madhu Anant
Vice President, Global Regulatory Affairs
MALLINCKRODT PHARMACEUTICALS

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**

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

Safety Labeling and Packaging Summit

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

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

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

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/2ruY70i.** The group rate is available until **August 24, 2017**. Please book your room early, as rooms available at this rate are limited.

**ExL Events is not affiliated with Exhibition Housing Management (EHM)/Exhibitors Housing Services (EHS) or any third-party booking agencies, bureaus or travel companies. ExL Events is affiliated with event company Questex, LLC. In the event that an outside party contacts you for any type of hotel or travel arrangements, please disregard these solicitations and kindly email us at info@exlevents.com. ExL has not authorized these companies to contact you and we do not verify the legitimacy of the services or rates offered. Please book your guest rooms through ExL's reserved guest room block using the details provided.*

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 Presidsent, 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**

PANEL

- 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**

PANEL

- 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

4:00 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:

MEDtube sharing medical knowledge™ · Packaging-Labelling.com™ · packaging today Europe's Packaging Magazine · pharmaphorum bringing healthcare together · PharmaVOICE · PM360 THE ESSENTIAL RESOURCE FOR PHARMA MARKETERS · www.PharmCast.com – Pharmaceutical Internet – · pharmaLEADERS News. Resources. Community. · TECHNOLOGY NETWORKS

REGISTRATION
to register CLICK HERE or

Call: 201 871 0474
fax: 253 663 7224
email: register@pmaconference.com/
web: http://pmaconference.com/
Mail: POB 2303 Falls Church Va 22042

Registration Fees for Attending ExL's Safety Labeling and Packaging Summit

EARLY BIRD PRICING—*Register by Friday, August 4, 2017*	
Conference	**$1,895**
STANDARD PRICING—*Register after Friday August 3, 2017*	
Conference	**$2,095**
ONSITE PRICING	
Conference	**$2,195**

Group Discount Program

Save 25% **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.

Save 15% **Save 15% per person when registering three**

Can only send three? You can still save 15% off of every registration.

Offers may not be combined. Early bird rates do not apply. To find out more about how you can take advantage of these group discounts, please call 201 871 0474

TERMS AND CONDITIONS: By registering for an ExL Events ("ExL") event, you agree to the following set of terms and conditions listed below:

REGISTRATION FEE: The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

PAYMENT: Make checks payable to ExL Events and write C918 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options.

Please Note: There will be an administrative charge of $300 to substitute, exchange and/or replace attendance badges with a colleague within five business days of any ExL conference.

CANCELLATION AND REFUND POLICY: If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:

- Four weeks or more: A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
- Less than four weeks: A voucher to another ExL event valid for 12 months from the voucher issue date.
- Five days or less: A voucher (minus a $395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

CREDIT VOUCHERS: Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees' behalf, the credit voucher will no longer be valid.

ExL Events does not and is not obligated to provide a credit voucher to registered attendee(s) who do not attend the event they registered for unless written notice of intent to cancel is received and confirmed prior to the commencement of the event.

SUBSTITUTION CHARGES: There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference.

ExL Events reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other expenses incurred by registrants.

ExL Events' liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, speakers and/or venue.

*The opinions of ExL's conference speakers do not necessarily reflect those of the companies they represent, nor ExL Events.

Please Note: Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, significant effort to find a suitable replacement will be made. The content in ExL slide presentations, including news, data, advertisements and other information, is provided by ExL's designated speakers and is designed for informational purposes for its attendees. It is NOT INTENDED for purposes of copywriting or redistribution to other outlets without the express written permission of ExL's designated speaking parties. Neither ExL nor its content providers and/or speakers and attendees shall be liable for any errors, inaccuracies or delays in content, or for any actions taken in reliance thereon. EXL EVENTS EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, AS TO THE ACCURACY OF ANY CONTENT PROVIDED, OR AS TO THE FITNESS OF THE INFORMATION FOR ANY PURPOSE. Although ExL makes reasonable efforts to obtain reliable content from third parties, ExL does not guarantee the accuracy of, or endorse the views or opinions given by any third-party content provider. ExL presentations may point to other websites that may be of interest to you, however ExL does not endorse or take responsibility for the content on such other sites.

REGISTRATION
to register CLICK HERE or

Call: 201 871 0474
fax: 253 663 7224
email: register@pmaconference.com/
web: http://pmaconference.com/
Mail: POB 2303 Falls Church Va 22042

Name: _____ Title: _____

Company: _____ Dept.: _____

Address: _____

City: _____ State: ____ Zip: _____

Email: _____

Phone: _____ Fax: _____

❑ Check ❑ Credit Card

Make checks payable to ExL Events.

Card Type:

❑ MasterCard ❑ Visa ❑ Discover ❑ AMEX

Card Number: _____

Exp. Date: _____ CVV: _____

Name on Card: _____

Signature: _____

❑ YES! Register me for this conference!

Please contact me:

❑ I'm interested in marketing opportunities at this event.

❑ I wish to receive email updates on ExL Pharma's upcoming events.

exl pharma

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 Hildenbrand
PFIZER

Mark Collins
BEHRING

Charles Forsaith
PURDUE PHARMA LP

Jayson Diaz
ROCHE

Madhu Anant
MALLINCKRODT PHARMACEUTICALS