

3rd Safety Labeling and Packaging Summit

Utilize best practices to develop and enhance an end-to-end process to ensure a compliant label for your drug packaging

September 24-25, 2019
Hyatt Regency Morristown
Morristown, NJ

FEATURED SPEAKERS



Georgina Lee,
Associate Director, Regulatory Affairs,
AGIOS



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



Kathleen Salazar,
Director, Global Labeling Operations,
JANSSEN



Mark Collins,
Global Labeling Lead,
CSL BEHRING



Hernan Gonzalez,
Manager – External Supply,
PFIZER



Stephanie Huguette Bodo Kamga,
Senior Director Global Regulatory Affairs,
IPSEN

EVENT HIGHLIGHTS

- **UNDERSTAND** FDA updates on the implementation of generic drug labeling requirements
- **SHARE** best practices on how to manage the end-to-end process of labeling and packaging products
- **REVIEW** the product labeling processes and procedures used to establish effective label design
- **EXPLORE** challenges in CDS, carton, and container labeling development
- **ADDRESS** labeling operations and development: Best practices and common hurdles that are occurring the industry
- **EXPLORE** recent trends and how to ensure the security of the chain and how it is achieved in the product's quality
- **COMPARING** the organizational differences not only between Biotech and Pharma, but Big Pharma vs. Small Pharma and what will be best for you

EVENT SPONSOR



To Register, Call 201 871 0474 or [Click Here](#)

3rd Safety Labeling and Packaging

Dear Colleague,

Labeling is a critical tool for the safe and effective use of prescription drugs, biologics, and medical devices. Its purpose is to convey the essential information needed by providers, patients, and payers to make decisions about product access, prescription, and personal use. In today's environment of increasingly complex labeling requirements, it is especially challenging to market products in multiple regions, requiring worldwide consistency of information essential to physicians and patients.

The **3rd Safety Labeling and Packaging Summit** provides a platform for biotech and mid-sized and big pharma professionals to gain an overview of global labeling-related policies and regulatory changes and best practices to streamline your operations.

Join our esteemed speaking faculty to gain valuable strategies and insights, and for the unique opportunity to network and engage with your peers.

I look forward to seeing you in September!

Sincerely,

Michael Keogh

Michael Keogh
Conference Director
ExL Events, a division of Questex, LLC

WHO SHOULD ATTEND

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

- ▶ Labeling
- ▶ Drug Safety
- ▶ Regulatory Affairs
- ▶ Pharmacovigilance
- ▶ Medical/Clinical
- ▶ Risk Management
- ▶ Legal
- ▶ Product Safety Management
- ▶ Packaging
- ▶ Supply Chain
- ▶ Package Engineering/Technology
- ▶ Product Safety and Security
- ▶ Medical Affairs
- ▶ Sterilization



VENUE INFORMATION

Hyatt Regency Morristown

3 Speedwell Ave / Morristown, NJ 07960

To make reservations, please call (973) 647-1234 or 877-803-7534 and request the negotiated rate for **ExL's September Meetings**. You may also make reservations online using the following weblink: <https://bit.ly/2WSB2VF>. The group rate is available until **September 3, 2019**. 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, housing 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 exlinfo@questex.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 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 your needs.

To Register, Call 201 871 0474 or [Click Here](#)

8:00 Registration and Continental Breakfast

8:45 **Chairperson's Opening Remarks**

9:00 **Best Practices for Meeting Labeling and Packaging Timelines**

- Share strategies for developing and setting goals and being able to manage timelines
- Build and train a team to prepare for each step of production
- Explore the efficient use of technology, such as digital printing, to speed production

Kathleen Crowder, Sr. Manager, Global Regulatory Affairs, Labeling, **BAXTER INTERNATIONAL**

10:00 **Achieve Supply Chain Efficiency During Packaging and Labeling**

- Understand the importance of packaging and labeling and how it can be essential for effective supply chain logistics
- Maintain brand value and retain the quality of the packaging
- Establish effective collaboration between packaging, labeling, and supply chain teams
- Redefine the supply chain's role in the packaging sector

Kathleen Salazar, Director, Global Labeling Operations, **JANSSEN**

10:45 Networking Break

11:15 **Align Quality Measures Across Various Stages of the Product Life Cycle to Reduce Waste and Labeling Defects**

- Designate and understand all stages of the life cycle
- Outline pre-commercial, supply chain, and post-commercial activities
- Ensure the quality is upheld from all stages of manufacturing

Georgina Lee, Associate Director, Regulatory Affairs, **AGIOS PHARMACEUTICALS**

12:00 **Carousel Discussion Exercise**

This conversational forum is ideal for sharing and exploring best practices. Each group is assigned a different operational challenge that professionals face. After 20 minutes, they begin a rotation in which they spend 10 minutes reading the recorded solutions of other groups then add their own. The goal of this activity is a comprehensive digest of participants' best practices in relation to the following operational themes:

12:45 Luncheon

1:45 **Manage Packaging and Labeling at Contract Manufacturing Organizations**

- Maintain quality through the translation process, setting goals, and management
- Quantify vendor goals and standards
- Establish clear and concise timeline management and goals

Hernan Gonzalez, Manager – External Supply, **PFIZER**

2:30 **Prepare for an Evolving and Changing Labeling Regulatory Landscape**

- Improve the efficiency of your document preparation from beginning to end
- Increase productivity through the knowledge and understanding of breakthrough software
- Use proven information collecting strategies to prepare for regulatory changes

Jaylaxmi Nalawade, Associate Director, Pharmacovigilance and REMS, **LUPIN PHARMACEUTICALS**

3:15 Networking Break

3:45 **Presentation by Indegene**

Anand Kiran, Executive Vice PResident, **INDEGENE**

4:30 Day One Concludes

8:00 Continental Breakfast

8:45 **Chairperson's Recap of Day One**

9:00 **Manage the Complexities of Global Labeling Requirements**

- Maintain quality through the evolving and complex global regulatory environment
- Examine the effective use of labeling systems to assist in the labeling process
- Satisfy regulatory requirements through the use of electronic document management

Stephanie Huguette Bodo Kamga, Senior Director Global Regulatory Affairs, **IPSEN**

9:45 **Continuous Improvement and Change to Global UDI**

- Balance a singular and changing UDI global strategy
- Understand and prepare for UDI regulation changes
- Use technology to increase efficiency and standardization

Roger Peterson, Manager, Global Labeling Systems, **ARTHREX**

10:30 Networking Break

11:00 **Regulatory Grey Areas in Labeling and Packaging**

- Explore the unique challenges presented in the labeling with respect to regulatory compliance
- Establish successful collaborations with health authorities and the EMA
- Maintain brand image and identity when preparing and submitting

Mark Collins, Global Labeling Lead, **CSL BEHRING**

11:45 **EU MDR/IVDR Labeling Consideration and Implications**

- Understand how EU MDR/IVDR impact your labeling content, processes, and technology
- What is really changing as a result of the regulation changes?
- Expectations when preparing for compliance with labeling

Zak Macht, Senior Manager, Labeling Global Regulatory Operations, **BECTON DICKINSON COMPANY**

12:30 Luncheon

1:30 **Progress Your Journey and Innovate Through a Fully Digitalized Labeling Strategy**

- Increase patient engagement through electronic labeling
- Use electronic updates to improve labeling strategies
- Utilize digitally printed for labeling while adhering to regulations and boost the brand impact

Remon Zakhary, Packaging Design and Development, Senior Group Lead, **BAYER HEALTHCARE**

2:15 **Package for the Future and Advancements in Safety Labeling**

- Understand and prepare for the environmental impact of the pharmaceutical packaging industry
- Develop sustainable methods to increase environmental friendliness
- Learn technologies that can prepare for the future of pharmaceutical packaging

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

3:00 Conference Concludes

MEDIA PARTNERS



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 791819 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.

To receive a refund or voucher, please email exlcancel@questex.com or fax your request to 888-221-6750.

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.

To Register Click Here, or

Mail Directly To:

PMA Conference Management
PO Box 2303
Falls Church VA 22042
201 871 0474
Fax 253 663 7224
register@pmaconference.com

REGISTRATION FEES FOR ATTENDING EXL'S 3RD SAFETY LABELING AND PACKAGING SUMMIT

EARLY BIRD PRICING	STANDARD PRICING	ONSITE PRICING
Register by Friday, August 9, 2019	Register After Friday, August 9, 2019	
\$1,895	\$2,095	\$2,295

GROUP DISCOUNT PROGRAM

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.

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% PER PERSON WHEN REGISTERING THREE

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

