Monday, September 24, 2018 // Preconference Workshop

1:30-4:00 PM

Workshop: Explore the End-to-End Process of Labeling to Packaging a Drug

It is extremely important to successfully manage packaging and labeling products. It involves a lot of key stakeholders in the planning process and its essential to have an end-to-end labeling to packaging process. This workshop will outline guidelines, challenges, key inspection findings and important standards and procedures to ensure the integrity of your product.

- Review carton and labeling development
- Highlight regulations that need to be followed for your product
- Focus on how to develop the package, content, how we determine, develop the package and commercial it and what is it going to look like
- Piece together how to build the label content all the way to the package
- Detail how labels should be legible, readable and easy to understand
- Understand considerations for containing labels and carton labeling design to minimize medication errors

Hernan D. Gonzalez, *Manager — External Supply,* **PFIZER**

Helen Cocuzza, *Sr. Manager, Regulatory Affairs,* **FOAMIX PHARMACEUTICALS**

Madhu Anant, *Former VP, Regulatory Affairs,* **MALLINCKRODT PHARMACEUTICALS**

Tuesday, September 25, 2018 // Main Conference, Day One

8:00 Registration and Continental Breakfast

9:00 **Co-Chairpersons' Opening Remarks**

9:15 **The Future State of End-to-End Labeling**

- Integrate SPL and IDMP in the process
- Content Authoring of labeling documents
- Automating the tracking process

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

10:00 **Exploring the Regulatory Environment for Combination Products**

- Understand the evolving regulatory landscape for combination products
- Highlight the direction that combination products are heading
- Explore best practices for regulatory filings of combination products
- Understand evolving requirements for digital technology, such as mobile apps

Suraj Ramachandran, *Director, Regulatory Affairs, Drug-Device Center of Excellence,* **MERCK**

10:45 Networking Break

11:15 **EU Medical Device Reporting for Drug Device Combination Products**

- Understand the impact of the regulations in EU drug device and medical products
- Review the new upcoming EU Medical Devices Regulation
- Outline the medical device supply chain through UDI
- Establish regulatory checkpoints in the supply chain
- Examine regulatory challenges of drug-device combinations in the EU

Hilde Viroux, *Global Head EU MDR Compliance,* **ALCON**

> *"Very timely and engaging."*
>
> *—Associate Director, Labeling Artwork,* **MERCK**

12:00 **Studying and Simulating the Dynamics of Distribution**

- Mapping your supply chain and distribution channels
- Analyzing distribution dynamics
- Laboratory simulation and consensus standards
- Research and the future of laboratory simulation

Patrick McDavid, *Instructor,* **MICHIGAN STATE UNIVERSITY**

1:45 **Global Labeling's (Regulatory) Evolutionary Role with Digital Health Medical Devices**

- Review labeling digital mobile medical apps and digital health device regulations
- Discuss this hot topic in the industry and understand some of the challenges and future directions
- Describe the evolutionary role of a pharmaceutical company labeling department's support of medical mobile applications (MMAs) and connected systems

Gina Monteiro, *Manager — Global Regulatory Affairs, Global Labeling Department,* **ELI LILLY AND COMPANY**

2:30 **Impact on Production for Labeling and Packaging**

- Communicate electronic systems for structured product labeling and labeling documentation verification
- Cover serialized packaging to meet serialization mandates in multiple countries
- Grasp Global Packaging Services, the standardized content translations and technical drawing processes
- Highlight some of the packaging/artwork in North America and Europe

Hernan D. Gonzalez, *Manager — External Supply,* **PFIZER**

3:15 Networking Break

3:45 **Strategic Management of Labeling Content for Drug/Combination Products**

- State some labeling best practices for drug/combination products
- Address project management best practices during labeling content management
- Gather the importance of human factors in Instructions for Use (IFU) creation

Anoop K. Padival, *Manager, Strategic Global Labeling,* **ABBVIE**

4:45 Day One Concludes

Wednesday, September 26, 2018 // Main Conference, Day Two

8:00 Continental Breakfast

8:45 **Co-Chairpersons' Recap of Day One**

9:00 **Japan and Asia Updates**

CASE STUDY

- Review labeling and risk management in East Asia
- Explain e-labeling in Asia and the process from paper to digital
- Discuss updates in China and the status of electronic labeling
- Touch on the new preparations for the new regulation (Japan regulation will be effective 2019), Compare safety information in Japan
- Walk through updates in China and the status of electronic labeling

Rie Matsui, R.Ph. *Director, Regional Labeling Head for Asia, International Labeling Group,* **PFIZER**

9:45 **Security of Supply Chain**

- Explore ensuring the integrity of your product
- Hear best practices on supply chain security and learn key roles
- Understand new technology used for shipments

Chuck H. Forsaith, *Senior Director,* **PCSC**

10:30 Networking Break

11:00 **GS1 US, Product Digital Format**

- Explore how to tackle the product and follow the life cycle from sterilization to traceability
- Highlight on activity in the pharmaceutical supply chain
- Review any updates on GS1 Standards

Siobhan E. O'Bara, *SVP, Industry Engagement and Services,* **GS1 U.S.**

11:45 **Building Essentials for Global Labeling: How to Transform From 'Biotech' to 'Commercial Biotech'**

CASE STUDY

Stephanie Bodo Kamga, *Director Regulatory Affairs Labeling,* **IRONWOOD PHARMACEUTICALS**

12:30 Luncheon

1:30 **Safety Labeling and Packaging Challenges on How to Successfully Reduce Errors in Your Products**

PANEL

- Hear how to reduce errors starting from the label and the way to the package
- Explore consistency in labeling and best practices
- Establish how to improve on the end-to-end labeling process to minimize risks and improve safety
- Discuss recent trends and the future of pharmaceutical packaging
- Incorporate packaging processes, common issues and challenges

Madhu Anant, *Former VP, Regulatory Affairs,* **MALLINCKRODT PHARMACEUTICALS**

2:15 **Challenges for Generic Drug Labeling**

- Capitalize on the progress of updating the label for generic drug labeling in Japan, Australia and the rest of the world
- Highlight on the gap between signal detection and the implementation of the label
- Grasp the process of the label for generic drugs in the U.S.

Jaylaxmi Nalawade, *Senior Manager — Drug Safety and Risk Management,* **LUPIN PHARMACEUTICALS**

3:00 Conference Concludes

Testimonials

"Excellent mix of speakers and got a better understanding of the challenges faced by the regulatory group. Now I understand why it takes so long for me to get artwork from my customers!"

—Associate Director Supply Chain, **LTS**

"I've gained more knowledge about pharmaceutical products labeling."

—Quality Assurance Specialist, **HENRY SCHEIN INC.**

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Registration

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registration@exlevents.com

ExL Events, 494 Eighth Avenue, 4th Floor, New York, NY 10001

Registration Fees for Attending ExL's 2nd Safety Labeling and Packaging Summit

EARLY BIRD PRICING—*Register by August 17, 2018*	
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Conference + 1 Workshop	**$2,145**
STANDARD PRICING—*Register After August 17, 2018*	
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Do you have a question or comment that you would like addressed at this event? Would you like to get involved as a speaker or discussion leader? Please contact Conference Production Director, Kelly Osmulski at kosmulski@gmail.com

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CONFERENCE CODE: C1049

September 24-26, 2018
Hyatt Regency Morristown / Morristown, NJ

2nd 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

FEATURED SPEAKERS

Rie Matsui, R.Ph.,
PFIZER

Gerrit-Jan Nijveldt,
SANOFI

Stephanie Bodo Kamga,
IRONWOOD PHARMACEUTICALS

Hilde Viroux,
ALCON

Anoop Padival,
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Suraj Ramachandran,
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Siobhan E. O'Bara,
GS1 U.S.

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