10th Annual Pharma Packaging and Labeling East Coast Conference

February 21st – 22nd, 2018 | Philadelphia, USA

2018 Speaking Faculty

Patricia Walsh, Director, Head of Global Labeling, **Jazz Pharmaceuticals**
Bob Celeste, Founder**, Center for Supply Chain Studies**
Kashappa-Goud Desai, Associate Fellow**, GlaxoSmithKline**
Christy Wood, Senior Manager Global Labeling, **Jazz Pharmaceuticals**
Kamana Singh, Labeling Manager**, Sanofi**
Gerrit-Jan Nijveldt, Senior Director Regulatory Labeling, **Sanofi**
Guido Schmitz, Director of Packaging Design, **Bayer**
Gary Tuggle, Special Agent in Charge, **U.S. Drug Enforcement Administration**
Kathleen Kinkead Salazar, Director, Global Labeling Operations, **Janssen Pharmaceuticals**
Kathleen Bulgreen, Senior Manager U.S. Regulatory Affairs Labeling, **LEO Pharma Inc.**
Helen Cocuzza, Senior Manager, Regulatory Affairs, **Foamix Pharmaceuticals**
Matt Sample, Sr. Director, Secure Supply Chain, **BluePoint Laboratories**
Carl Accetura, Vice President, **PharmoRx Therapeutics Inc**
Nicole Quallis, Labeling Manager**, Valeant Pharmacetucials**
Remon Zakhary, Senior Group Lead Package Design & Development**, Bayer**
Jennifer Nixon Sekawungu, Associate Director Labeling Group, **Janssen Pharmaceuticals**
Niambi Daniels Harris, Director, Commercial QA-GMP, **Daiichi Sankyo**
Eugene Hackett, Director of Corporate Security, **Bristol-Myers Squibb**
Mary Zhang, CBP National Account Manager, **U.S. Customs & Border Protection**

	Pharma Packaging and Labeling East Coast 2018 | Philadelphia, Pennsylvania **Day One: February, 21st 2018**
08:15	Registration and refreshments
08:50	Chair's opening remarks
09.00	**Establishing an accurate global labeling tracking system to ensure your end-to-end labeling is inspection ready** • Appreciating complexities in tracking labeling changes when managing multiple teams across global sites to minimize challenges encountered due to variations at the individual country level • Recognizing current difficulties in ensuring end to end labeling to determine regulatory repercussion on your company • Evaluating current labeling tracking systems and suggesting improvements to your internal procedures to ensure preparedness for pharmacovigilance inspections • Establishing reporting systems which enable non-compliance changes to be detected quickly and prevent safety update delays and backlogs • Emphasizing improvements in end to end labeling to minimize risk and improve safety **Patricia Walsh**, Director, Head of Global Labeling, **Jazz Pharmaceuticals** **Christy Wood**, Senior Manager Global Labeling, **Jazz Pharmaceuticals**
09:30	**Session reserved for Intagras**
10:00	**Evaluating your inspection readiness strategy to guarantee you are on top of the changing labeling landscape and ready to comply** • Establishing internal tracking and reporting structures which allow you to react to global guideline alterations without compromising your current timelines • Designing cross departmental reporting systems that allow label amendments in your product portfolios within allocated timelines stipulated by regulators to ensure compliance • Ensuring your labeling documentation is adequately set up to handle inspections by regulators and prevent audits • Developing internal strategies to guarantee labeling information changes are quickly rolled into the supply chain to maximize patient safety • Determining whether internal rearrangements are best achieved through in-house restructuring or outsourcing to guarantee you are prepared for your next inspection **Gerrit-Jan Nijveldt**, Senior Director Regulatory Labeling, **Sanofi**
10:30	**Tech Spotlight Session reserved for CCL Label**
10.45	Morning refreshments and networking
11:15	**Harnessing branding as a story telling tool; remaining relevant in both the present and the future**

	• Appreciating brand loyalty as a mechanism to generate a bond between your customer and your company that lasts a lifetime and increases your revenue • Developing a branding strategy with a clear target audience that focuses on generational differences and expectations to ensure your customer loyalty • Recognizing the need for you brand to adapt through time; pinpointing sustainability as a key focus of millennials and the impact this will have on your business model and strategy • Appreciating the role of consistent branding across markets to increase your companies global image • Assessing ways through which branding can differentiate your products from that of the competition to win a competitive advantage **Guido Schmitz**, Director of Packaging Design, **Bayer**
11:45	**Session reserved for BlueSoftware**
12:15	**Understanding the worst drug epidemic in US history: the link between prescription opioid and heroin abuse** • Explaining the US history drug epidemic to describe the increasing drug abuse in the States • Describing how prescript drug leads to heroin abuse to raise awareness of the seriousness • Highlighting DEA's efforts to reduce the abuse nationwide • Generating solutions to protect the public health **Gary Tuggle**, Special Agent in Charge, **U.S. Drug Enforcement Administration**
12:45	Lunch and networking
13:45	**Sourcing the right contract manufacturers throughout the globe to supply what you need, when you need it** • Assessing logistical complexities of engaging with multiple contract manufactures around the globe and suggesting ways to simplify this process • Outlining mechanisms to reduce timelines in finding compliant partners set out by global headquarters to guarantee supplier conformity • Establishing partnerships with in-country suppliers to ensure you do not need to ship low value supplies and incur added costs • Ensuring all packaging components can be produced by one supplier to streamline processes • Improving partnerships between CMO's and pharma to improve working relationships and prevent relationship disintegration **Remon Zakhary,** Senior Group Lead Package Design & Development**, Bayer**
14:15	**Session Reserved for Global Vision**

14:45	**DSCSA compliance, serialization, and why it's not just a barcode** • Serialized labeling and packaging, a supply chain paradigm shift towards standardization • Presenting product packaging and designing for downstream use beyond distribution • Understanding the supply chain impact of FDA's Enforcement Discretion and Grandfathering Guidance • Reviewing impacts of serialized exceptions in the supply chain in 2018 and beyond **Matt Sample**, Sr. Director, Secure Supply Chain, **BluePoint Laboratories**
15:15	Afternoon refreshments and networking
15:45	**Improving in-house department relationships as a simple and effective solution to guarantee in-house efficiency** • Outlining the need to pinpoint departmental priorities to guarantee internal awareness and prevent silos • Establishing strong connections between packaging and labeling teams to ensure there is a structure of interdepartmental cooperation which prevents task duplication • Harnessing technology to streamline internal communications and ensure optimal efficiencies in the packaging and labeling process • Determining methods for an internal communication strategy which can be traced throughout departments to ensure all parties involved are aware of timeline alternations • Considering how horizontal reporting structures can improve departmental relationships by establishing a clear responsibility framework **Kathleen Kinkead Salazar**, Director, Global Labeling Operations , **Janssen**
16:15	**Session reserved for Loftware**
16:45	**Uncovering FDA's final guidance's on Nonproprietary Naming of Biologics and Biosimilars and what this means for your current labeling strategy** • Appreciating highly complex manufacturing processes required for biologics to determine how the new guidelines will support pharmacovigilance efforts and minimize improper substitution • Uncovering nonproprietary naming and the importance this holds in today's labeling practices to guarantee you are up to speed with current regulations • Outlining difficulties in ensuring adequately labeled suffixes no all bio-similar products to ensure compliance with strict FDA requirements • Modifying your manufacturing process to ensure it is equipped to cope with additional labeling needs required by the guidelines • Assessing ways to ensure compliance with incoming regulations with regards to electronic prescribed information databases and its effect on biologics **Kamana Singh,** Labeling Manager**, Sanofi**

17:15	Chair's summary and close of conference

	Pharma Packaging and Labeling East Coast 2018 | Philadelphia, Pennsylvania **Day Two: February, 22nd 2018**
08:15	Registration and refreshments
08:50	Chair's opening remarks
09.00	**Exploiting blockchain technology to ensure compliance with the Drug Supply Chain Security Act (DSCSA)** • Examining blockchain to utilize technology as a tool to improve track and trace, recalls and reimbursements • Identifying blockchain strategies as a norm in the industry to simplify internal processes • Outlining serialization best practice to enable small and mid-size pharma to ensure compliance • Uncovering ways blockchains' evolving nature can improve record security, traceability and prevent cyber-attacks to utilize in your supply chain • Harnessing blockchains' power as an alternative way of doing business with your customer base to improve relationship management **Bob Celeste,** Founder**, Center for Supply Chain Studies**
09:30	**Session reserved for Amplexor**
10:00	**Exploring the role of US CBP and the Center of Excellence and Expertise, how we can assist industry** • Enhancing knowledge on National Account Management Program • Uncovering Customs-Trade Partnership Against Terrorism (C-TPAT) program • Developing appreciation for Importer Self-Assessment (ISA) program and how this impacts you • Addressing Trusted Trader program for your pack and label strategy **Mary Zhang**, CBP National Account Manager, **U.S. Customs & Border Protection**
10.30	Morning refreshments and networking
11:30	**Designing combination products which are high-quality, adaptable and evolve throughout the supply chain** • Design high-quality combination products by applying quality by design principles • Assessing current global regulatory landscape for CPs to ensure compliance • Uncover what are the correct packaging types, materials and designs needed to ensure that deceives are in line with regulatory expectations • Ensure labels and products are designed in a way which is adaptable as trials develop and move towards the commercial stage • Highlighting the added costs that current FDA guidelines will have on the industry as a whole to determine cost-saving alternatives • Maximizing Human Factor Studies (HFS) for CP's effective usage

	Kashappa-Goud Desai, Associate Fellow**, GlaxoSmithKline**
11:30	**Safety Triggers Leading to Labeling Updates** • Briefly exploring company Core Data sheets and impact on other National Data Sheets • Assessing types of triggers, internal and external, and its effect on timings, threshold criteria and hierarchy • Unpacking the importance of well-documented cases for your products • Outlining the need for deleting or downgrading safety information • Exploring class labeling and adverse drug reaction frequency **Kathleen Bulgreen**, Senior Manager U.S. Regulatory Affairs Labeling, **LEO Pharma Inc.**
12:00	**Compression Blow Forming (CBF), the new way into containers manufacturing** • Discovering the new CBF technology • Presenting ways to achieve an innovative blow molding process merging the best, most valued characteristics of the alternative technologies • Demonstrating examples of superior bottle quality • Exploiting benefits from CBF technology for your business **Ivan Bonzi,** Containers B. U. Director, Closures Containers PET Division, **Sacmi Imola S.C**
12:15	Lunch and networking
13:00	**Balancing regulatory requirements with brand design to prevent regulatory rejections and make sure you stand out amongst the crowd** • Recognizing the demands placed on packaging and labeling teams to ensure patient safety information is prioritized • Exploiting package and label surface area to ensure space is utilized to its fullest capacity and waste is minimized • Establishing priorities between labeling and branding teams to ensure these do not conflict and result in timeline delays • Outlining novel packaging designs which both hold all required information while standing out against your competition • Appreciating how electronic labels can free up packaging space and enable greater creativity to give you a competitive advantage **Helen Cocuzza**, Senior Manager, Regulatory Affairs, **Foamix Pharmaceuticals**

13:30	**Pushing the Crayola box to its limits; designing packaging which is appealing both to the regulator and the consumer** • Enhancing information flow between regulatory and artwork teams to guarantee documentation used in artwork approval process is a match with regulatory requirements to prevent delays • Addressing the need for improved proofreading to minimize downstream backlogs and prevent inaccurate packaging printing • Outlining FDA artwork requirements to ensure regulatory compliance • Promoting innovative packaging designs to guarantee your products stand out against those of the competition • Considering alternative color schemes to match FDA dosage outline requirements to ensure the professionalism of your product **Carl Accetura**, Vice President, **PharmoRx Therapeutics Inc**
14:00	Afternoon refreshments and networking
14:30	Speaker Hosted Roundtables Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Each roundtable session lasts for 45 minutes, and delegates may attend up to 2 roundtables
Roundtable 1	**Packaging & Labeling Development for New Product Launches** **Orna Bresler,** Director of US Account Services, **Perigord**
Roundtable 2	**Mastering your packaging to ensure your products integrity is guaranteed both while in storage and in transit** **Niambi Daniels Harris**, Director, Commercial QA-GMP, **Daiichi Sankyo**
Roundtable 3	**Discussing FDA's guidance with regards to DSCSA to improve industry standards** **Nicole Quallis**, Labeling Manager**, Valeant Pharmaceuticals**
Roundtable 4	**Establishing best practice to prevent counterfeits entering your drug supply chain** **Eugene Hackett**, Director of Corporate Security, **Bristol-Myers Squibb**
Roundtable 5	**Continuing the conversation on end-to-end labeling to improve patient safety** **Jennifer Nixon Sekawungu**, Associate Director Labeling Group, **Janssen Pharmaceuticals**

16:00	Chair's summary and close of conference