Pharma iQ a division of IQPC Presents:

PHARMACEUTICAL
PACKAGING & LABELING FORUM

Co-located with the **2nd Pharmaceutical Traceability Forum** for double the value at no extra cost!
See pg. 3 for details

NOVEMBER 16-18, 2015

Boston Park Plaza, Boston, MA

PACKAGING
- Innovate with new, cost-effective package design
- Maximize flexibility and efficiency of your packaging lines
- Increase patient safety with child-resistant and tamper evident packaging features

LABELING
- Ensure compliance with global labeling regulations
- Streamline change control processes to reduce time to market
- Maintain translation accuracy and effectiveness on multi-language labels

THE TOP INDUSTRY-LED EVENT to drive new innovation, achieve compliance, and streamline your operations

ARTWORK
- Reduce medication error by redesigning artwork and label format
- Develop best practices to reduce artwork error and minimize product recalls

SERIALIZATION
- Maximize space available on labels to accommodate required serialization data
- Choose the right vendors when upgrading your packaging lines to facilitate serialization capabilities

MEET OUR HIGH-LEVEL SPEAKING FACULTY:

REGIS GAUTIER
Director, Global Packaging Technology
BRISTOL-MYERS SQUIBB

JULIE BATAL
Sr. Director Global Labeling
TAKEDA PHARMACEUTICALS

GUIDO SCHMITZ
Head of Packaging & Technology Innovation
BAYER HEALTHCARE

ALADIN ALKHAWAM
Associate Director of Packaging
PAR PHARMACEUTICAL

JULIE RETZINGER
Sr. Director of Regulatory Affairs – Global Labeling
VERTEX PHARMACEUTICALS

Sponsor: pharma INTERNATIONAL INC

Media Partners: 3PL NEWS Currents in Supply Chain Innovation · BioPortfolio · PharmaVOICE · Securing Industry · showmetransport

PHARMACEUTICAL
PACKAGING & LABELING FORUM

November 16-18, 2015
Boston Park Plaza • Boston, MA

The **TOP INDUSTRY-LED EVENT** to drive new innovation, achieve compliance, and streamline your operations

Dear Colleague,

Your job isn't getting any easier. If you're a **pharmaceutical packaging, labeling or artwork professional**, chances are you face a series of significant challenges on a daily basis. Packaging teams must continually drive new innovation to meet higher standards for **patient compliance, child resistance, tamper evidence and ease of use** –all under the constant pressure to keep production high and costs low. Labeling and artwork teams are hard-pressed to **juggle multiple regulatory filings** for a plethora of domestic and international regulations, while also carving out more real estate on product labels to **accommodate an ever-increasing quantity of required information.** And all these teams must cooperate seamlessly to overcome these hurdles and get product to market as quickly as possible. These pressures drive industry innovators like yourself to constantly develop quicker, more cost-efficient ways of meeting these multiple, crucial requirements.

That's why this event exists. And why should you attend?

We've assembled a select speaking faculty of only the top industry experts who are at the forefront of innovation and compliance. From their many years of practical experience, they'll share their top insights on how to:

- Ensure the compatibility of **new package designs** with existing packaging line capabilities
- **Reduce the incidence of artwork** error to minimize the risk to patients and your brand reputation
- Ensure the proper **validation of packaging lines** and equipment
- Maximize the space available on your label to **accommodate required serialization data**
- Explore new opportunities of **label printing on-demand**
- I**ncrease packaging line efficiency** while reducing downtime and material waste
- Accurately manage label translations to **comply with international regulations on multi-language packaging**
- Streamline your process of end-to-end label implementation
- **Manage your label change control approvals** between multiple cross-functional departments

With market competition and regulatory enforcement on the rise, packaging, labeling and graphic design teams must meet these goals as quickly and efficiently as possible. In a series of **in-depth workshops, real-life case studies, and high-level presentations,** we'll share the practical tools and strategies you need to go above and beyond these benchmarks.

Looking forward to meeting you in Boston,

Lauren Delapenha

P.S. Make sure you visit the 2nd Pharmaceutical Traceability Forum right next door at no extra cost!

INTENSIVE WORKSHOPS

DON'T MISS THE FOLLOWING WORKSHOPS ON NOVEMBER 16:

A **Tracking Your End-to-End Implementation of Labeling and Artwork to Minimize Error and Streamline Change Control**

Value: Eliminate guesswork when it comes to updating packaging and labels to minimize turnaround time

B **Serialization 101: Adjusting and Updating Your Packaging, Labeling and Graphics Processes to Comply with Fast-Approaching Serialization Requirements Worldwide**

Value: Improve your collaboration with serialization teams by clarifying packaging line changes and labeling format changes needed to comply with serialization regulations

C **Ensuring Patient Protection with Innovative, Cost Effective Package Design**

Value: Learn how industry peers have sourced affordable materials and achieved management buy-in to successfully spearhead new innovations in package design

See pg. 4 for more details

VENUE & ACCOMMODATION

Boston Park Plaza
50 Park Plaza, Boston, MA 02116
Website: www.bostonparkplaza.com
Phone: 617-654-1976

The special room rate of $159 has been established to make your reservation process easy. **Call 800-225-2008 and give the group name IQPC – Pharmaceutical Packaging & Labeling no later than November 2, 2015.**

CLICK HERE TO RESERVE

WHICH SESSIONS ARE YOU LOOKING FORWARD TO?

PACKAGING

SESSIONS NOT TO MISS:

- **CASE STUDY:** Balancing Cost-Effectiveness with Innovation to Drive New Packaging Design and Achieve Management Buy-In
- Explore the Latest Innovations in Child-Resistant and Tamper Evident Packaging Design to Increase Consumer Safety and Comply with Consumer Product Safety Commission (CPSC) Regulations
- Increasing the Efficiency of Stability Testing and Qualification Around the World
- Increase the Flexibility and Cost-Efficiency of Your Packaging Lines to Increase ROI

ARTWORK

SESSIONS NOT TO MISS:

- Leveraging Graphics Compliance Strategies from Medical Devices to Pharmaceuticals
- Utilizing Artwork to Reduce the Incidence of Medication Error
- Strategies to Maximize Space on Product Labels While Maintaining Legibility, Brand Image and Regulatory Compliance
- Improving Accuracy to Minimize Artwork Error and Reduce the Incidence of Costly Product Recalls

4 FOCUS AREAS

LABELING

SESSIONS NOT TO MISS:

- **WORKSHOP A:** Tracking Your End-to-End Implementation of Labeling and Artwork to Minimize Error and Streamline Change Control
- Ensuring Accurate Label Translation to Maximize Patient Safety on Multi-Language Packages
- Looking Ahead to the FDA's Proposed Electronic Labeling Regulation: How Will it Affect Your Artwork Development and New Product Launches?
- **PANEL DISCUSSION:** Achieving Greater Cooperation Between Cross-Functional Teams to Streamline Change Control Processes

SERIALIZATION

SESSIONS NOT TO MISS:

- Don't miss our 4 Crossover Sessions with our 2nd Pharmaceutical Traceability Forum:
- How to Effectively Facilitate Data Transfer Between your Packaging Line and Your Central Data Repository
- Evaluating, Selecting and Integrating your Third-Party Line-Level Vendors to Achieve the Right Fit for your Company's Needs
- Integrating Serialization Capabilities into Your Packaging Operations
- PANEL DISCUSSION: Understanding Aggregation from a Manufacturer and Distributor Perspective

PHARMACEUTICAL TRACEABILITY FORUM

0101100011101 00101 001 2015

2 FOR 1: DUAL ACCESS TO THE 2ND PHARMACEUTICAL TRACEABILITY FORUM

CRAFT YOUR OWN AGENDA

For the first time ever, you'll be able to access BOTH the Pharmaceutical Packaging & Labeling Forum AND the 2nd Pharmaceutical Traceability Forum…all with ONE REGISTRATION. This is the only pharma packaging & labeling conference of its kind that allows you to essentially develop your own agenda between two events. More interested in a panel discussion next door? No problem. You have full access to pick and choose whichever topics are most relevant to you, ensuring maximum value at no additional cost.

DOWNLOAD THE DRAFT AGENDA HERE!

ADAPT YOUR PACKAGING AND LABELING FOR UPCOMING SERIALIZATION DEADLINES

We co-located these two events so that packaging, labeling and artwork teams can clarify global serialization requirements and improve their implementation strategy. Don't miss our focused, two-hour workshop on serialization and 4 key crossover sessions on Main Conference Day 2!

PRE CONFERENCE **WORKSHOP DAY**

Monday November 16, 2015

Welcome to the ONLY Pharmaceutical Packaging & Labeling conference that allows you to CRAFT YOUR OWN AGENDA! You can attend any session at any time between this event and the **2nd Pharmaceutical Traceability Forum** happening right next door! **Download the brochure for more information.**

8:30 AM **Registration Workshop A**

9:00 AM - 11:00 AM

WORKSHOP A: Tracking Your End-to-End Implementation of Labeling and Artwork to Minimize Error and Streamline Change Control

Labeling and artwork professionals are tasked with staying up-to-date with industry regulations and then adjusting their processes to ensure full and timely compliance. However, making a simple change to comply with regulations may involve a long chain of time-consuming back-and-forth discussions between marketing, regulatory, manufacturing, supply chain, project management and legal departments in order to receive necessary approvals. Then, all systems need to register that change so they can identify any errors to avoid the danger and expense of sending incorrect labels out to the market. On top of that, communicating across mergers, acquisitions and multiple production sites further complicates these processes, since different companies use a variety of change control technology. Now more than ever before, inter-functional departments in both large and small pharma need to develop a comprehensive system to monitor regulatory changes in multiple international markets, and then develop best practices to integrate and simplify the approval workflow for the packaging, labeling and graphics updates that follow. In this focused, two-hour workshop, we'll be doing just that.

What you will learn:

- Establish or improve your change control protocol to simplify updates to package and graphic design across departments
- Considerations for collaboration across functions and how to open the lines of communication
- Streamline communication between multiple cross-functional teams to minimize time-consuming circulation
- Tips for tracking systems that can be integrated into your existing infrastructure

How you will benefit:

- Eliminate guesswork when it comes to updating packaging and labels to minimize turnaround time
- Share your experiences with workshop attendees and learn from others
- Increase the efficiency of cross-departmental communication
- Minimize time spent on non-value-added work

Julie Batal I Sr. Director, Global Labeling I **Takeda Pharmaceuticals**
Beata McCormack I Associate Director, Regulatory Labeling I **Sanofi**

11:15 AM **Registration Workshop B - *Lunch will be served during this workshop***

11:30 AM - 1:30 PM

WORKSHOP B: Serialization 101: Adjusting and Updating Your Packaging, Labeling and Graphics Processes to Comply with Fast-Approaching Serialization Requirements Worldwide

For many artwork, packaging and labeling departments, serialization comes as an added burden to the day-to-day processes that already consume the majority of their time and resources. For packaging, serialization means the retrofitting of your packaging lines with very expensive equipment and installing compatible IT systems to print, apply, verify and store serialization data. Aggregation complicates those renovations further still. Meanwhile, labeling and graphics teams have to carve out space from the already limited real estate on product labels to make way for barcodes, serial numbers and other required information.

What you will learn:

- Anticipate the unexpected costs involved in retrofitting your packaging line to accommodate required serialization capabilities
- Adopt best practices in training your line operators to handle new equipment and software
- Clarify country-specific serialization requirements and map out how that changes your label information and artwork layout
- Learn how aggregation will impact your packaging and labeling process, and how best to implement these changes

How you will benefit:

- Budget correctly to avoid massive overspending
- Avoid equipment damage and line holdups due to improper or insufficient training
- Improve your collaboration with serialization teams by understanding what upcoming regulations require you to do
- Maximize the efficiency of your track & trace capabilities by supporting effective aggregation

2:15 PM **Registration Workshop C**

3:00 PM - 5:00 PM

WORKSHOP C: Ensuring Patient Protection with Innovative, Cost-Effective Package Design

Package development professionals all share two major pressures: keeping costs low and facilitating maximum consumer safety. Thought leaders in each of these fields have developed a variety of effective strategies to address each of these concerns separately, but the interests of each oftentimes conflict. Exorbitant cost in just one area of product development, even by one cent, can terminate an otherwise promising project. Conversely, cheaper alternatives sometimes fall short in making desired advances in the ease-of-use and safety features for consumers. In this groundbreaking session, we'll examine the most common roadblocks that drive up the cost of packaging, labeling and artwork in developing new products, and develop innovative methods of harmonizing cost and consumer safety. You can't afford to miss it.

What you will learn:

- Understand how product-centered design combines with user-centered design to the benefit of healthcare
- Ideas for simulating varied perceptual, cognitive and physical capabilities of consumers
- 7 principles of Universal Design
- Human Packaging Interaction Model – a tool for organizing the multitude of factors influencing ease of use that can be used either in the design or evaluation of packaging
- Keep patient safety as your top priority without breaking your budget
- Maintain the integrity of your brand by not compromising on safety features

How you will benefit:

- How can the principles of Universal Design be leveraged to provide insight for the benefit of your patients?
- What actions do your products afford and how can the signal strength related to those affordances be improved to enhance package function?
- Are there ways that your product packaging can be redesigned to better meet the needs (even unexpressed) of the healthcare providers and patients that use them?
- How can you use low fidelity simulation as a means to garner insights into the design process?
- How to reduce cost without sacrificing product quality and safety
- Gain practical insight into real-life examples of how to lower production cost within your department and across functional areas

Dr. Laura Bix IAssociate Director, School of Packaging I**Michigan State University**
Aladin Alkhawam I Director, Packaging I **Par Pharmaceutical**

8:15 AM **Registration & Coffee**

8:45 AM **Chairperson's Welcome and Opening Session**

As part of our unique co-location, you can craft your own agenda by choosing any session from the Pharmaceutical Packaging & Labeling Forum or the 2nd Pharmaceutical Traceability Forum.

PHARMACEUTICAL PACKAGING & LABELING FORUM

9:00 AM

KEYNOTE CASE STUDY: Using a Holistic Design Approach to Drive New Product Development: What Pharmaceutical Packaging Can Learn from Consumer Innovation

- Understand the motivation for changing consumer packaging of Aspirin from Bayer
- Explore how the packaging was redesigned to increase business value
- Leverage the innovation principles of consumer packaging to increase the effectiveness and ROI of pharmaceutical packaging

Guido Schmitz | Head of Packaging & Technology Innovation | **Bayer Healthcare**

9:45 AM

CASE STUDY: Michigan State's Innovative Studies in How Information Formatting on the Product Label PDP Impacts Consumer Attention for Seniors

- What elements of the PDP (Principal Display Panel) do seniors (aged 65+) pay attention to in OTC drugs?
- How well do older consumers assess drug appropriateness?
- How does information display influence consumer assessment of whether or not the drug is appropriate for them to use?
- What factors influence assessment of drug appropriateness?

Dr. Laura Bix |Associate Director, School of Packaging | **Michigan State University**
Co-author: Langing Liu | Research Student, School of Packaging | **Michigan State University**

10:30 AM **Networking Break**

11:15 AM

Utilizing Cost-Effective Graphic Design to Ensure Patient Compliance

- Explore strategies to keep artwork productivity high and costs low across over 100 global markets
- Analyze concrete examples of how pharma companies have manipulated product graphics to boost patient adherence
- Maximize your use of artwork management technology to ensure high-quality artwork production

Hinrik Petursson | Executive Director, Global Artwork | **Allergan**

PHARMACEUTICAL TRACEABILITY FORUM

KEYNOTE: Beyond Compliance: Leveraging Your Company's Serialization Investments to Derive Holistic Business Value

- Define all of the business process implications of serialization, current and future
- Identify key sponsors for both the near term tactical implementation and longer term business value opportunities
- Use serialization as a strategic business opportunity rather than a tactical response to regulatory requirements
- Take a holistic view of serialization to optimize your resources across multiple countries and functional departments
- Create new business opportunities across the product and data value chain

Mike Wallace | Former Director of Global Standards & Serialization | **Abbott**

Integrating Serialization Capabilities into Your Packaging Operations

- Revise your packaging operations to make the move from lot-level requirements to serialized traceability
- Assess and prepare for the downtime incurred by package line retrofitting and anticipate the impact on your supply chain so you can prioritize serialization upgrades effectively
- Compose a checklist of crucial requirements to discuss with your CPO/line level vendor in order to develop realistic lead-times for implementation and compliance
- Negotiate and benchmark a percentage of use per production line to determine whether or not to invest in retrofitting that line
- Plan an effective pilot deployment strategy to test the effectiveness of your upgraded production line and identify hiccups in advance of the Nov. 27, 2017 DSCSA deadline

Aladin Alkhawam | Director, Packaging | **Par Pharmaceutical**

USA: Preparing for DSCSA Requirements for Product Serialization, Lot-level Management, and Item-Level Traceability Using the GS1

Standard of EPCIS

- Explore the challenges and opportunities of meeting the DSCSA requirements for product serialization, and item-level traceability using EPCIS
- What are the options for Master Data Exchange, including pros and cons?
- What are the opportunities for adoption of EPCIS: costs, complexity, and challenges?

Peter Sturtevant | Sr. Director Industry Development – Pharmaceuticals | **GS1 US**

12:00 PM

Plan, Harmonize, Maintain Your CCDS to Ensure Global Harmonization

- Plan your CCDS updates in order to avoid unnecessary overhaul for teams in specific label regions
- Utilize a CCDS tracking portal to generate and analyze metrics for core data review lead times
- Leverage your core data metrics to provide organizational transparency regarding the status of labeling updates

Patricia Walsh | Director, Global Regulatory Affairs – Labeling | **Jazz Pharmaceuticals**

Moving Towards a Global Interoperable Data Transfer Using EPCIS

- Take a step-by-step approach towards using EPCIS transmit serialization data throughout the supply chain
- Analyze recent EPCIS pilot programs to anticipate the challenges of interoperable data transfer

Scott Mooney | Vice President, Distribution Operations | **McKesson Corporation**

12:45 PM **Networking Lunch Break**

1:45 PM

CASE STUDY: Balancing Cost-Effectiveness with Innovation to Drive New Packaging Design and Achieve Management Buy-In

- Collaborate with marketing teams to produce the most attractive package design at minimum production cost
- Maximizing your use of packaging components across multiple therapeutic areas to increase order size and lower the price of production
- Design your package with the flexibility necessary to make it adaptable to multiple functions
- Negotiate with third-party packagers to find reasonably priced packaging solutions

Regis Gautier | Director, Global Packaging Technology | **Bristol-Myers Squibb**

2:30 PM

PANEL DISCUSSION: Achieving Greater Cooperation Between Cross-Functional Teams to Streamline Change Control and Regulatory Reporting Processes

- Achieve greater collaboration between package design/engineering, labeling, artwork, marketing, regulatory strategy and commercial regulatory affairs, manufacturing, and supply chain departments to meet deadlines for product launches and updates
- How to easily retrieve required label implementation/update information from supply chain systems
- Explore the most effective technology available to grant central access to information needed by the FDA
- Implement an effective approvals tracking system to easily identify outstanding tasks that delay product launches and updates

Panelists:

Ellen Cravens | Sr. Manager Labeling | **Astellas**

Ingrid Bryzinski | Director, Strategic Global Labeling, Regulatory Affairs | **AbbVie**

PANEL DISCUSSION: A Hospital's Perspective – Optimizing Interoperability to Efficiently Manage Track & Trace Data Throughout the Supply Chain

- Maximize your use of AIDC (Automated Information Data Capture) to move information seamlessly between key stakeholders without human intervention
- How to leverage interoperability to detect counterfeit pharmaceuticals
- Standardize your data transfer by migrating data from multiple disparate systems into one master database
- Adopt best practices to incorporate new data systems during expansions and acquisitions, within limited resources

Moderator:

Sandi Michel | Director of Supply Chain Systems & Quality | **Franciscan Missionaries of Our Lady Health System (FMOLHS)**

Panelists:

Bruce Leavitt | Hospital Pharmacy Operations Director | **Intermountain Healthcare**

Michael Keegan | Director, Policy & Regulatory Affairs | **National Community Pharmacists Association (NCPA)**

Lakisha Bradley Bowie | Consulting Manager | **Franciscan Missionaries of Our Lady Health System (FMOLHS)**

USA & The EUROPEAN UNION: Upgrade Your IT Systems to Comply with GMPs on Computer Validation

- Fully grasp the step-by-step requirements and differences between the FDA's 21 CFR part 11 and the EMA's GMP Annex 11 for the formal testing of your computer systems
- Create a single validation summary report that saves time by consolidating your compliance strategy for both US and EU validation
- Consider key factors when choosing your software supplier to make sure they adhere to GMP requirements
- Accurately record an audit trail of serial number use to improve traceability and supply chain security
- Implement effective change control process to safely track how and when data gets changed in serialization records
- Communicate effectively between OEMs and serialization management partners to ensure that their capabilities work together to support smooth serialization

Earlene Gibbons | Sr. Director, Operational Technology | **United Therapeutics**

3:30 PM **Afternoon Coffee Break**

4:00 PM

Improving Label Accuracy to Minimize Artwork Error and Reduce the Incidence of Costly Product Recalls

- Identify the types of artwork error that can occur, when they occur, and how to avoid them
- Strike the right balance between electronic and human artwork review to catch various kinds of errors with maximum efficiency
- Establish a comprehensive system of checks and controls to limit the likelihood of releasing artwork errors to market

Bill Bosley | Manager, Global Labeling and Graphics | **BioMarin Pharmaceutical Inc.**

4:45 PM

INTERACTIVE ROUNDTABLES

TABLE 1: Best Practices in Managing Dependent Country Labeling

- How do you define basis labeling or reference labeling?
- In what situations do you consider shared packs, multi-packs and international packs?
- What documentation or justification is acceptable to allow shared labeling?
- How do you manage safety updates for countries with shared labeling/packaging?

Julie Batal | Sr. Director, Global Labeling | **Takeda Pharmaceuticals**

TABLE 2: Managing Artwork Creation in the Midst of Timelines Becoming Increasingly Shorter

- Implement time-saving strategies to make required label and artwork modifications within extremely tight turnaround times
- Discuss experiences with In-House artwork design models versus Outsourced models
- Explore labeling development processes and reorganize flow to reduce the frequency and length of rejection-iteration loops

Bill Bosley | Manager, Global Labeling and Graphics | **BioMarin Pharmaceutical Inc.**

TABLE 3: Risk Evaluation and Mitigation Strategies (REMS) Draft Guidance

- What's in the draft guidance?
- What documents are involved?
- Are patients/HCPs receiving the information they need?

Patricia Walsh | Director, Global Regulatory Affairs – Labeling | **Jazz Pharmaceuticals**

Brazil Track and Trace: Meeting Complex Regulations and the Six Key Challenges to Global Compliance

- Hear updates on the current Brazil compliance landscape from RDC 54 to potential future regulations
- Explore lessons learned from dozens of companies implementing Brazil pilot programs and global serialization and track and trace commercial programs
- Understand key business, supply network and IT infrastructure issues to master for Brazil compliance
- Ensure your business is ready for evolving global mandates

Brian Daleiden | Vice President of Industry Marketing | **TraceLink Inc.**

COUNTRY-SPECIFIC ROUNDTABLES

TABLE 1: CHINA: Adhering to China's Highly Unique Serialization Requirements in Time for December 31, 2015

- How to request and obtain serial numbers from the Chinese government
- How to distinguish between requirements vs. opinions when interpreting Chinese serialization requirements
- How and where to position serial numbers for bulky cartons
- How to deal with file size restrictions when uploading mandatory serialization reports to the China FSDA system

TABLE 2: EUROPEAN UNION: Clarify the Safety Features Required by the FMD 2011/62/EU in Time for January 2018

- Clarify the safety features and barcode requirements that packaging and labeling teams will need to implement to ensure compliance
- Develop a cohesive system of serial number generation
- Choose a tamper evidence solution that's both affordable and effective
- Key factors to consider before applying to the "white list" or "black list" for your product

5:30 PM **End of Day One**

"It was intimate and information-packed. A lot of great opportunities to meet and network with people."

– John Hahn (FFF Enterprises)

8:15 AM **Registration & Coffee**

8:45 AM **Chairperson's Welcome and Opening Session**

SERIALIZATION AND TRACEABILITY

9:00 AM **KEYNOTE PANEL DISCUSSION: Understanding Aggregation from a Manufacturer and Distributor Perspective**

- How will aggregation streamline and simplify product recalls?
- What's your tolerance of errors in aggregation?
- How do you accurately project the cost of aggregating? And how do you quantify the cost of not aggregating products before shipment?
- How can manufacturers and wholesalers collaborate to develop a mutually beneficial aggregation process?
- How can you negotiate with your 3PL to establish protocol for handling deaggregation when you don't sell all your products by the case?
- How do you address the discrepancy when various companies aren't preparing for aggregation on the same timeline?

Panelists:
Scott Mooney | Vice President, Distribution Operations | **McKesson Corporation**
Mike Wallace | Former Director of Global Standards and Serialization | **Abbott**

9:45 AM **Collaborating with your Contract Packager (CPO) to Benchmark Essential Compliance Requirements in Preparation for November 27, 2017**

- Choose a cost-effective EPCIS provider flexible enough to communicate with the various platforms used by your CPOs
- Negotiate and benchmark a percentage of use per production line to determine whether or not to invest in retrofitting that line
- Plan an effective pilot deployment strategy to test the effectiveness of your upgraded production line and identify hiccups in advance of the Nov. 27, 2017 deadline

Ann Schaefer | Associate Director, Supply Chain | **Acorda Therapeutics**

10:30 AM **Networking Break**

CONCURRENT SESSIONS

PHARMACEUTICAL PACKAGING & LABELING FORUM

11:15 AM **Developing and Maintaining Labeling Lifecycle Management to Ensure a Time-Efficient Workflow**

- Develop a realistic timeline for label development (content and artwork) to meet submission and launch deadlines on time
- Optimize cross-functional communication to maintain inter-departmental transparency
- Expedite the manufacturing of labeling to keep within tight production schedules

Ellen Cravens | Senior Manager, Labeling | **Astellas**

PHARMACEUTICAL TRACEABILITY FORUM

ROUNDTABLE DISCUSSION: Utilizing Serialization and Traceability to Achieve Greater Brand Protection and Supply Chain Security

- Integrate the expertise and goals of multiple scattered, cross-functional teams to craft effective, holistic serialization and traceability programs
- How to extract and divide resources to facilitate traceability and product security initiatives
- Balance the emphasis placed on top priorities: patient safety vs. commercial viability
- Increase flexibility within your serialization program to reduce overhaul when making future modifications
- Maximize your use of serialization to decrease the lead time to get your product to the patient
- Include product threat assessments early in the drug development process

Eugene Hackett | Global Brand Protection Director | **Bristol-Myers Squibb**

12:00 PM

PART I: Ensuring Accurate Label Translation to Maximize Patient Safety

- Pros and cons of translation vendors vs affiliate translations – timing, cost, accuracy, type of submission process, number of rounds of translations
- Do you need a headcount to coordinate the translations between vendor and affiliate?
- Case study from recent label review project
- Acquire translations that accurately capture the nuances of medical and technical language to ensure that consumers can fully understand crucial instructions – medical director input, affiliate education of product early on, devices

Ingrid Bryzinski | Director, Strategic Global Labeling, Regulatory Affairs | **AbbVie**

Forecasting the Price of Serialization in Order to Budget Effectively in Advance of Implementation

- Calculate your serialization costs by holistically examining all elements involved in your implementation strategy
- Consider certain key factors when anticipating implementation costs, including underlying dependencies, validation costs, and lower productivity levels due to increased downtime
- Adjust your budget to accommodate changes in local and international traceability regulations

Erik Bronander | Senior Director of Sales - Americas | **Adents**

12:45 PM **Networking Lunch Break**

1:45 PM

Utilizing Artwork to Reduce the Incidence of Medication Error

- Understand how the medication use process will impact your label design to mitigate medication errors
- Clarify global guidance from the US, Canada and the EU to gage how to streamline your label design for full international compliance
- Utilize human factors engineering in your product label design according to increase consumer safety

Julie Retzinger | Sr. Director Regulatory Affairs – Global Labeling | **Vertex Pharmaceuticals**

CASE STUDY: How the FMOLHS (Franciscan Missionaries of Our Lady Health System) Created an SOP to Achieve Timely DSCSA Compliance

- Learn from the FMOLHS effective compliance strategy to achieve if you haven't already met DSCSA requirements
- Formulate a realistic, concrete compliance plan for upcoming DSCSA deadlines

Sandi Michel | Director of Systems & Quality | **Franciscan Missionaries of Our Lady Health System (FMOLHS)**

2:30 PM

CASE STUDY: How Merck Collaborated with the FDA and Used Human Factors Engineering to Decrease Medication Error by Redesigning Tablet and Capsule Bottle Labels

Between 2008 and 2011, a cross-functional team of labeling experts at Merck worked closely with the FDA to renovate the label design for tablet and capsule products. Their groundbreaking process was so successful that the FDA asked them to publish their results, which will be appearing in The Journal of Safety Research under the title "Applying Human Factors to Develop an Improved Package Design for (Rx) Medication Drug Labels in a Pharmacy Setting" in December, 2015. Having been at Merck for more than 15 years, Julie Gerhart-Rothholz was part of the committee that spearheaded this innovation, and will share her exclusive insight in this dynamic case study.

- How Merck made the case to innovate label changes in the absence of immediately visible ROI
- Examine the specific changes that Merck implemented to increase text legibility, ease of use and patient safety
- Understand Merck's unique, step-by-step approach in gathering feedback and scientific research from pharmacists, human factor engineers and pharmacists while developing their new label design

Julie Gerhart-Rothholz |Associate Director, Pharmacy Affairs | **Merck**

Facilitating Data Transfer Between Line-Level Packaging Systems and Your Master Data Management

- Identify the serialization data that will be required from your ERP to build a one-time SAP
- Choose a cost-effective EPCIS provider flexible enough to communicate with the various platforms used by your CPOs and in-house packaging lines
- Choose serialization solutions that are compatible across levels before investment and installation
- Update your server capacities to effectively move serialization data from your global repository to your line-level systems
- Effectively return commissioned data from your packaging line back to your global repository to ensure accurate documentation for circulation with stakeholders

Panelists:

Eugene Hackett | Global Brand Protection Director | **Bristol-Myers Squibb**

3:15 PM **Afternoon coffee break – Network over refreshments**

3:30 PM

PART I: Clarifying Requirements for Child-Resistant Requirements and Testing in the US and Internationally

- Examine key differences between the 16 CFR 1700.20 in the US, versus the ISO 9001 standard in the rest of the world
- Weigh the efficiency of the adult test in child resistant packaging regulations and standards

PART II: How to Make Packaging Easier to Open for 540 Million Elderly Patients Worldwide

- Explore latest developments in the ISO 17480:2015 standard in packaging-accessible design for seniors

Stephen Wilkins | CEO | **Child Safe Packaging Group**

How Small/Mid-Size Pharma Can Overcome Unforeseen Hurdles Serialization Effectively within Tight Timelines and Limited Resources

- Best practices for complying with regulations in a cost-effective manner within a very short timeframe
- Gain a thorough understanding of serialization requirements to present your project effectively to an ever-smaller pool of vendors
- Make smart vendor choices: don't try to do everything yourself

4:15 PM **End of Day Two**

MEET OUR SPONSOR:

pharma INTERNATIONAL INC

Website: www.pharma-ii.com/packaging

Pharma International (PII) designs, develops, and manages bipharmacutical labeling artwork–in English and 75+ languages. We help improve accuracy, speed, and control of labeling development. We serve start-up companies launching a first product to leading, global biopharmas managing the life cycle of many brands.

Our services are customized to your needs. Whether looking to outsource artwork development or partner with experienced labeling developers, we are an experienced team you can rely on.

We keep current on GMP and global labeling regulations and are expert in designing compliant, organized, easy-to-read labeling components that maintain brand integrity while at the same time satisfying the requirements of all constituencies -- regulatory, legal, manufacturing (captive or contract), prescribers, patients.

PII staff averages 9 years in labeling development work. We have produced thousands of labeling components in just about every language.

Cartons, Labels, Blister Packs, Foil Pouches, Package Inserts, IFUs, Starter Kits…and more.

MEDIA PARTNERS:

3PL NEWS Currents in Supply Chain Innovation | BioPortfolio | PharmaVOICE | SECURING INDUSTRY | showmetransport

COMBINED EXHIBITION HALL

In our shared exhibition hall, you'll be able to explore a wider range of solution providers than ever before. During our networking sessions you can meet leading solution providers face-to-face to explore the latest innovations in line-level serialization systems, packaging technology, artwork management and so much more. This is the ideal opportunity to ask key questions you need to know before investing in essential solution partners and equipment/technology upgrades to facilitate full regulatory compliance and maintain your competitive advantage. **If you have a unique solution for packaging, labeling, artwork or serialization and want to join our elite group of featured vendors on-site, please contact Eric Pompei at 212-885-2693 or eric.pompei@iqpc.com**

"As someone new to the serialization arena, it was good to hear the case studies from various companies & vendors."
– Joanne Jones (Pfizer)

"I talked to various speakers & learned what they have accomplished to date & how. Advice!"
– Chris Calamita (Par Sterile Operations)

"Great chance to meet & network with colleagues working on the same challenges that I face in my responsibilities."
– Jim Kneece (LFB USA)

"Numerous sessions. Very informative & relative to current activities in the industry." **– Malinda Baumer (Apotex Corp)**

PRICING & REGISTRATION

3 EASY WAYS TO REGISTER:

www.pharmapackaginglabeling.com | 1-800-882-8684 | enquiryiqpc@iqpc.com

End-Users:	Register & Pay By 10/30/15	Standard
Main Conference	$1,999 **(SAVE $100)**	$2,099
All Access: Main Conference + All 3 Workshops BEST VALUE	$2,499 **(SAVE $100)**	$2,599
One Workshop	$549	

Vendors:	Register & Pay By 10/30/15	Standard
Main Conference	$2,899 **(SAVE $100)**	$2,999
All Access: Main Conference + All 3 Workshops BEST VALUE	$3,499 **(SAVE $200)**	$3,699
One Workshop	$549	

ALL REGISTRATIONS INCLUDE FULL ACCESS TO THE CO-LOCATED 2ND PHARMACEUTICAL TRACEABILITY FORUM!

**IQPC reserves the right to determine an organization as an End-User or Vendor

TERMS & CONDITIONS:

*IQPC reserves the right to determine who is considered an End-User or a Vendor upon registration for an event. Those who are determined a vendor will be denied access to End-User pricing. These prices are featured as a limited time only promotion. IQPC reserves the right to increase these prices at its discretion.

Please note multiple discounts cannot be combined. A $99 processing charge will be assessed to all registrations not accompanied by credit card payment at the time of registration.

MAKE CHECKS PAYABLE IN U.S. DOLLARS TO: IQPC

*CT residents or people employed in the state of CT must add 6.35% sales tax.

Team Discounts: For information on team discounts, please contact IQPC Customer Service at 1-800-882-8684. Only one discount may be applied per registrant.

Details for making payment via EFT or wire transfer:
Bank Name: JP Morgan Chase & Co.
Name on Account: Penton Learning Systems LLC dba IQPC
Account #: 937-332641
ABA/Routing #: 021000021
Reference: IQPC: 25811.001

Payment Policy: Payment is due in full at the time of registration and includes lunches and refreshment. Your registration will not be confirmed until payment is received and may be subject to cancellation. For IQPC's Cancellation, Postponement and Substitution Policy, please visit www.iqpc.com/cancellation

Special Dietary Needs: If you have a dietary restriction, please contact Customer Service at 1-800-882-8684 to discuss your specific needs.

ABOUT PHARMA IQ

Pharma iQ
a division of IQPC

Pharma IQ, a division of IQPC, provides useful training courses, conferences and expositions for pharmaceutical executives to network and learn the latest pharma business development and trends occurring in organizations today. Pharma IQ focuses on establishing an interactive experience featuring practical, objective, and up-to-date insight from pharma industry leaders. **www.pharma-iq.com**

REGISTRATION FORM

(Email this form to enquiryiqpc@iqpc.com or fax to 646-378-6025)

YES! PLEASE REGISTER ME FOR:

❑ All Access ❑ Main Conference ❑ Workshops: ❑ A ❑ B ❑ C

DELEGATE DETAILS

Please photocopy for each additional delegate

❑ Mr ❑ Mrs ❑ Miss ❑ Ms ❑ Dr ❑ Other

First Name: _____

Last Name: _____

Job Title: _____

Tel No.: _____

Email: _____

Organization: _____

Nature of business: _____

Address: _____

Postcode: _____ Country: _____

Telephone: _____ Fax: _____

Approving Manager: _____

Name of person completing form if different from delegate:

_____

Signature: _____

❑ I agree to IQPC's cancellation, substitution and payment terms

Special dietary requirements:
❑ Vegetarian ❑ Non-dairy ❑ Other (please specify) _____

Please indicate if you have already registered by ❑ Phone ❑ Fax ❑ Email ❑ Web

❑ Please keep me informed via email about this and other related events.

PAYMENT METHOD

Charge my: ❑ AmEx ❑ Visa ❑ MasterCard ❑ Discover

☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Exp. Date: _____/_____ CVM Code: _____

Name On Card: _____

Signature: _____

Billing Address (if different from below): _____

City/County/Zip: _____

Check enclosed for $_____

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