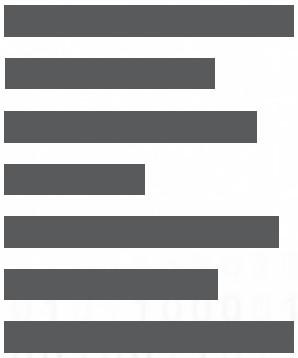

PHARMACEUTICAL TRACEABILITY FORUM | INTERACTIVE

Remaining informed, engaged and prepared for the changes & challenges ahead.

DECEMBER 7TH - 8TH, 2017

WASHINGTON, DC


BRINGING OUR MOST
INTERACTIVE PROGRAM YET
TO WASHINGTON DC FOR
THE 6TH ITERATION!

REACHING MILESTONES TOGETHER...

Whether you are celebrating hitting the 2017 DSCSA deadline, or catching up with help from the FDA enforcement discretion, getting this far is an accomplishment. **There is still a lot more ground to cover!** Global serialization compliance is an ongoing process that needs continual adjustments to account for bottlenecks, validation challenges, data inconsistencies, onboarding new supply chain partners, and more. How can we ultimately reach the 2023 DSCSA deadline of a fully interoperable system if we cannot work out all the kinks occurring now? Looking past the US, we must remain ahead of changing international deadlines from the EU to Russia to China.

Learning from each other is the key to success. We must have the hard conversations around inaccurate data transfers, packaging & labeling mistakes, aggregation, and saleable returns, to name a few. And then we can take things up a notch.....**What will 2023 and beyond ultimately look like? How will new technology like cloud & block chain affect us?** *What does the pharma supply chain look like in 2030?*

At our **6th Pharmaceutical Traceability Forum** we will provide the platform to move our industry forward. Join us in Washington DC to discuss the most pressing concerns and continue the conversations from the FDA workshop being held earlier in the week.

I will see you in DC!

Sincerely,

Jody Tropeano

Jody Tropeano
Program Director
IQPC

PHARMA TRACEABILITY STRATEGY TEAM

Brian Tarantino
Principal
The Tracer Group

Kevan MacKenzie
Director of Serialization Technologies
McKesson

Karen Giraudo
Associate Director for Operational Excellence
Pacira Pharmaceuticals

Lydia Hemphill
Senior Manager Supply Chain Business Operations
BioMarin Pharmaceuticals

Robert Celeste
Founder
Center for Supply Chain Studies

Dave Mason
Global Program Serialization Lead
Sandoz

Matt Sample
Senior Director of Secure Supply Chain
Amerisource Bergen Corporation

Eric Marshall
Senior Director
Leavitt Partners & RxGPS

Timothy Marsh
Senior Director Traceability, Provenance, Sustainability
GS1 Global

Senthil Rajaratnam
Affiliate Serialization Account Manager
Eli Lilly & Company

"IF EVERYONE IS MOVING FORWARD TOGETHER, THEN SUCCESS TAKES CARE OF ITSELF."
– Henry Ford

ENGAGEMENT LEADERS

Brian Tarantino
Principal
The Tracer Group

Kevan MacKenzie
Director of Serialization Technologies
McKesson

Karen Giraudo
Associate Director for Operational Excellence
Pacira Pharmaceuticals

Lydia Hemphill
Senior Manager Supply Chain Integrity
BioMarin Pharmaceuticals

Robert Celeste
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Matt Sample
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AmerisourceBergen Corporation

Travis Buel
Director Manufacturing & Packaging Engineering
Iroko Pharmaceuticals

Brian Lee
Director Serialization Market Integration
Bristol-Myers Squibb

Nora Carey
Associate Director, Serialization Integration
Ipsen Pharmaceuticals

Quentin Dittman
Director of Operations Technology and Track & Trace
Cardinal Health

Chris Howell
Senior Director, Global Engineering & Technology
Patheon Inc.

Mary Anne Anderson
Director, Program Management
Fresenius Kabi USA, LLC

J. Aaron Graham
Executive Director – Brand Safety & Security
Boehringer Ingelheim Pharmaceuticals, Inc.

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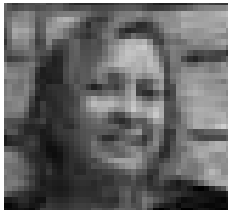
Tawni Koutchesfahani
Director, Manufacturing, Strategy
Relypsa, Inc



Earlene Gibbons
Senior Director of Operational Technology
United Therapeutics

Mark Hendrickson
Senior Director of Sciences and Regulatory Affairs
Association of Accessible Medicines

Joe Alessandrini
Vice President of Clinical Services
Inspira Health Network

Peter Sturtevant
Senior Director Industry Development, Pharmaceuticals
GS1 US

Scott Hatakeyama
Director - Buy to Pay
Kaiser Permanete

PHARMA TRACEABILITY IS GOING INTERACTIVE...

Address the top industry concerns in our new interactive program format that gets the whole audience involved in the conversation.

Bottleneck Breakouts:
Candidly discuss your top issues when operationalizing serialization in an intimate discussion group format to get all your main concerns addressed. Bring your questions ahead of time!

IDG's (Interactive Discussion Group) with RECAP PANEL DISCUSSIONS:
Join your direct peers in this open-format IDG (Interactive Discussion Group) to come up with your action plan & priority list to then report back to the entire audience in a recap panel discussion.

2023 Election & IDG's:
Listen to all the "candidates" aka the key solutions to help us along the path to achieving a fully interoperable data system, and then pick your top choice for a follow up IDG (Interactive Discussion Group).

The Great Debate:
Aggregation is highly important, but highly disagreed upon in the industry. Let's hear both sides of the story and choose our own opinions from there. Be prepared to chime in!

AUDIENCE OVERVIEW

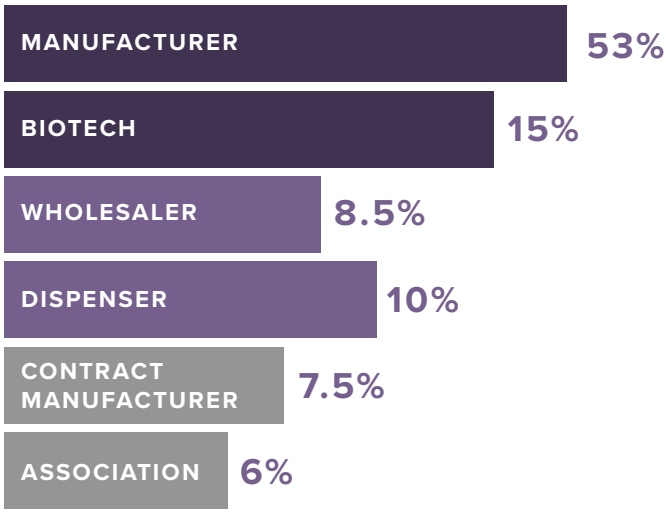
ATTENDEE JOB FUNCTION

- 26% OPERATIONS/PROJECT MANAGEMENT
- 8% BRAND PROTECTION/SECURITY
- 22% IT/TECHNOLOGY
- 24% SUPPLY CHAIN/LOGISTICS/MANUFACTURING
- 10% COMPLIANCE/REGULATORY AFFAIRS
- 10% PACKAGING/LABELING

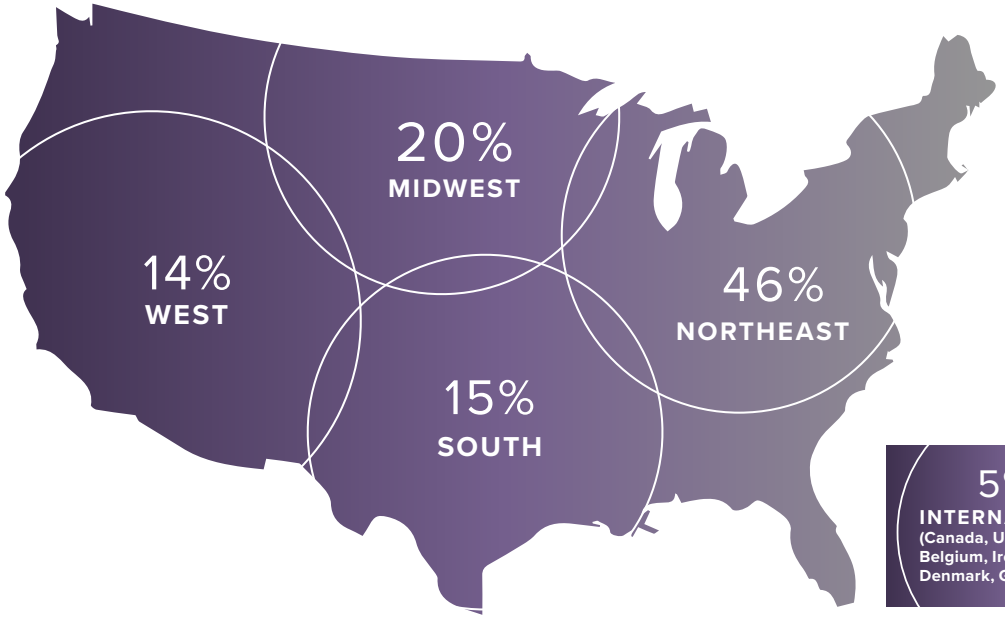
ATTENDEE SENIORITY

- 62% EXECUTIVE (DIRECTOR & UP)
- 15% SENIOR MANAGEMENT
- 23% OTHER

ATTENDEE INDUSTRY



WHERE THEY COME FROM



OUR ATTENDEES SAY IT BEST

"IQPC provides a unique opportunity to engage some of the smaller members of the supply chain that we as a large wholesaler don't communicate with frequently. Their engagement in DSCSA is just as critical."

- AmerisourceBergen Corporation

"Contacts are key for our industry as we must conduct pilots where we exchange Traceability Data for serialized product and the physical serialized product"

- McKesson

"The IQPC Serialization forum is a great opportunity to engage with solution teams from across the pharmaceutical industry as we work to enhance the security of the US supply chain and meet the requirements of the DSCSA."

- GlaxoSmithKline

"Opportunity to hear from a vast group of people/companies involved in serialization industry."

- Eli Lilly and Company

"All the major players from across the supply chain were present greatly enhancing discussion and learning."

- Fresenius Kabi

"Totally different from the regular trade shows; attendees are of senior level management, a whole new perspective learned from the attendees."

- Holo Technologies Inc.

PRESENTING YOUR 2017 PHARMA TRACE INTERACTIVE AGENDA

MAIN CONFERENCE DAY ONE | Thursday, December 7th 2017

8:00 **REGISTRATION & COFFEE**

8:15 **BREAKING NEWS BREAKFAST: Recap Session on Pressing DSCSA Updates Coming Out of the December FDA Workshop**

Candidly discuss the key takeaways from the 2-day FDA workshop earlier in the week and come up with a strategy to further flush out solutions over the course of our event.

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

9:00 **PANEL DISCUSSION: Preparing for 2019- Addressing Top Challenges for the Next Hurdle of DSCSA Compliance**

- Impact of serialization on saleable returns and reverse chargebacks- will the process be streamlined?
- What you need to be ready for exception management challenges? Understand the list of exceptions through the top 10 and how to best prepare
- Verification Router Service, what is it? What's the status?
- How to keep errors to a minimum through streamlined serialization processes
- How do the challenges differ between big & small pharma? Virtual and traditional manufacturers?

Matt Sample
Senior Director of Secure Supply Chain
AmerisourceBergen Corporation

Travis Buel
Director Manufacturing & Packaging Engineering
Iroko Pharmaceuticals

9:45 **KEYNOTE: Big Data's Impact: Predicting the Effect of Advanced Data Analytics on the Pharma Supply Chain & Patient Health**

- Examine how utilizing data in new ways will change the way we delivery drugs to patients
- What does 2030 look like? How will the supply chain professional's role change by then?
- Discuss the trends in big data and how it is being used to better track individual patient health
- Where does serialization fit in? How will serialization data be used in 2030?

10:30 **MORNING NETWORKING BREAK**

Continue discussing the hottest topics in our Expo Hall.

BOTTLENECK BREAKOUTS:
WE ARE ALL GETTING ON THE HIGHWAY AT ONCE, HOW CAN WE REDUCE THE TRAFFIC JAMS?
Choose the Interactive Discussion Group that most fits your current challenges.

	GRANDFATHERING	RESOURCE CHALLENGES	SOFTWARE UPDATES
11:15	• Discuss any potential FDA guidance to clarify non-serialized inventory • Does first expiry/first out still apply? • Is there an industry consensus position on what is grandfathered product? • Implications of customers getting both serialized and non-serialized products **Mary Anne Anderson** Director, Program Management **Fresenius Kabi USA, LLC**	• How to move your products higher on the priority list for contract partners if there is enforcement discretion • Dealing with incompatible systems between your various partners • Efficient ways to address data integrity issues with scant resources  **Earlene Gibbons** Senior Director of Operational Technology **United Therapeutics**	• What to do when your partner requires a software upgrade? How to ensure your lines won't go down? • Validation challenges when there is a coding update • How to ensure a smooth data integration with all partners in an upgrade event?

12:00

The Great Debate- AGGREGATION: Candidly Reviewing the Pros and Cons of Building Aggregation into your Processes

- Discuss the cost implications of aggregating product now- how much more will each package cost? Who is impacted the most by this cost increase?
- How much will aggregation impact the productivity of your packaging line?
- What alternatives exist for aggregation prior to 2023? Discuss the inference model of aggregation
- Review aggregations benefit to combatting counterfeiters and increased insight into inventory & forecasting
- If you are not aggregating now, will it cost more down the road to re-aggregate when required to do so?
- How does aggregation aide or hinder data integrity? How do you ac count for human error?

Moderator:

Mark Hendrickson
Senior Director of Sciences and Regulatory Affairs
Association of Accessible Medicines

Panelists:

Kevan MacKenzie
Director of Serialization Technologies
McKesson

Dave Mason
Global Program Serialization Lead
Sandoz

12:45

NETWORKING LUNCH BREAK
Make new connections while growing current partnerships!

AFTERNOON INTERACTIVE DISCUSSION GROUPS:
Supply Chain Stakeholder Specific Discussions

The challenges and needs surrounding serialization vary greatly depending on where your business falls within the supply chain. Discuss amongst your specific group what you would need from your up and down stream partners to achieve compliance to US and global serialization requirements. What needs are not being met now? How can you give your group more of a voice in the process? How can we better collaborate to develop a shared understanding of the model/requirements for 2023 through pilot programs.

	MANUFACTURERS	WHOLESALERS	DISPENSERS
1:45	• Where does your responsibility end, if at all? • How can wholesalers make reverse chargebacks and saleable returns easier to track? • How can you assist dispensers to ensure your products are secure through to the patient?	• What do you need in 2019 from your manufacturing partners that may not be officially required? • How will grandfathering impact your inventory? What can partners do to make it manageable? • What do you need from your partners to make 2023 possible	• What you would like to see for the format of the barcodes? • Where are there exceptions for small pharmacies and how will that impact the overall supply? • How can the last mile become a bigger voice in the industry's serialization initiatives?  **Scott Hatakeyama** Director - Buy to Pay **Kaiser Permanete**

2:30

RECAP PANEL DISCUSSION: Bridging the Communication Gap throughout the Pharma Supply Chain

Interactive Discussion Group Leaders from the previous breakout discussions will now join on stage to make the case for your group.

- What top challenges came out of your discussion groups?
- Key takeaways from the breakouts and items now on the top of your priority list
- Reveal the key needs your group decided you have from the other supply chain stakeholders
- Where do we go from here? What can we implement immediately to make progress?
- What pilots would you be interested in starting based on your groups finding?

Panelist:

 **Scott Hatakeyama**
Director - Buy to Pay
Kaiser Permanete

3:15 **AFTERNOON COFFEE BREAK- NETWORK OVER REFRESHMENTS IN THE EXPO HALL.**

3:45

PANEL DISCUSSION: Maintaining Data Integrity & Accuracy in a Post-Serialized Supply Chain

- What do you do if your product gets to your partner before your data does? What if your data doesn't match?
- Discuss trends in data management and how they will impact the pharma supply chain
- How and when are you submitting data to and from all players in the supply chain? What is required outside of the FDA?
- Review recent data exchange pilots and what key takeaways came from them
- Determine the "weak links" in your supply chain to mitigate data transfer issues ahead of time
- CFR Part 11? How and where does it apply?

Brian Tarantino
Principal
The Tracer Group

4:45

END OF DAY KEYNOTE: Breaking the Counterfeits- How Pharma can Continue to Outsmart Counterfeiters through Serialization and Increased Vigilance

- Discuss actual cases of counterfeiters being caught and how their tactics circumvented serialization then and will tomorrow.
- Is serialization the silver bullet? If not, what are the vulnerabilities?
- Methods beyond serialization that can be utilizes to combat counterfeiters
- How can we combat counterfeiters' ability to evolve along with the new procedures & technology that pharma is using to stop them?

J. Aaron Graham
Executive Director – Brand Safety & Security
Boehringer Ingelheim Pharmaceuticals, Inc.

5:30

END OF DAY ONE

5:30-
7:00

ANNUAL COCKTAIL RECEPTION

YOUR DSCSA AFTER PARTY!

Celebrate with your colleagues after a long day of learning.

MAIN CONFERENCE DAY TWO | Friday, December 8th 2017

8:30 **REGISTRATION & COFFEE**

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

KEYNOTE ADDRESS

9:00

KEYNOTE: EFPIA & EMVO Update on the EU Falsified Medicines Directive Requirement by 2019

- Introduction to EU FMD, stakeholders, basic requirements, and key dates
- Review Safety Features – Unique Identifier and Anti-Tamper Device impact on stakeholders
- Discussing EMVO / NMVOs: how will they work? How is funding achieved?
- Hear the EMVO on-Boarding process and basic steps needed to participate

Brian Lee
Director Serialization Market Integration
Bristol-Myers Squibb (on behalf of EFPIA and the EMVO)

9:45

PANEL DISCUSSION: International Regulatory Round Up- Openly Discussing the Changing Global Serialization Landscape's Effect to your Operations

Discussion Agenda: add small circle flags next to each region representing the country

Russia:
- Review the details of the region's new regulation with short deadlines & little clarity,
- Discuss issues surrounding their pilots

China:
- Discussion of PSM China study expected
- Will they consider moving towards more international harmonization?

Middle East:
- Discuss where the region will take traceability reporting requirements
- How will shared packs impact distribution to this region

Brazil:
- Review their draft serialization and reporting requirements
- What will their pilot phase look like?

India
- Discuss ongoing challenges with export requirements
- Where are the domestic requirement heading?

Global:
- How do you start to leverage serialization in high-risk markets that are not yet regulated?
- What lessons can be learned in the US from other countries?

Eric Marshall
Senior Director
Leavitt Partners & RxGPS

Timothy Marsh
Senior Director Traceability, Provenance, Sustainability
GS1 Global

MORNING INTERACTIVE DISCUSSION GROUPS:
Examining the Operational Complexities of Serialization specific to your Business Scope & Size

11:15

BIG PHARMA

- Review specific global regulations to look out for i.e. Russia, EU, Middle East
- What new pilots are necessary to work out the kinks in your system?
- When should we begin actively preparing for 2023 with supply chain partners?
- What if your data doesn't match? What to do when the unexpected happens?

SMALL PHARMA/BIOTECH

- What does your customer service channel look like for serialization? How are you linking all your departments to manage error resolution?
- Discuss drop ship challenges for low volume shipments
- Methods for mitigating labeling and barcoding issues at the line level
- Review validation challenges during system upgrades and cost implications
- Challenges for virtual manufacturers working with CMOs, how to maintain partnerships

Karen Giraudo
Associate Director for Operational Excellence
Pacira Pharmaceuticals

Tawni Koutchesfahani
Director, Manufacturing, Strategy
Relypsa, Inc

CPO & CMO'S

- How to prioritize your various customers?
- Methods to avoid a line going down and what to do when it happens
- How to best utilize your scarce resources to avoid losing customers?
- How to manage data exceptions and investigations
- How to best work with virtual manufacturing partners

Chris Howell
Senior Director, Global Engineering & Technology
Patheon Inc.

12:00

RECAP PANEL DISCUSSION: Bridging the Gap between Big, Small and Contract Pharma to Share Actionable Solutions

IDG Leaders from the previous breakout discussions will now join on stage to make the case for your group.

- What top challenges came out of your discussion groups?
- Key takeaways from the breakouts and items now on the top of your priority list
- How can each group better support each other and collaborate via new pilot programs
- Where do we go from here? What can we implement immediately to make progress?

Karen Giraudo
Associate Director for Operational Excellence
Pacira Pharmaceuticals

Tawni Koutchesfahani
Director, Manufacturing, Strategy
Relypsa, Inc

Chris Howell
Senior Director, Global Engineering & Technology
Patheon Inc.

12:45 **NETWORKING LUNCH BREAK**

YOUR 2023 ELECTION:

Hear from the Top Candidates that will make 2023 Interoperability a Reality

There are many stepping stones on the road to 2023. Listen to the top methods for reaching a fully interoperable data system and choose your candidate afterwards to join for an in-depth discussion longue to further dive into the details.

1:45

1:45-1:55
INTRODUCTION
What does the 2023 Interoperable Data System look like?

Review what it is supposed to look like and how we will get there. When are we going full scale?

1:55- 2:15
BLOCK CHAIN

Robert Celeste
Founder
Center for Supply Chain Studies

2:15- 2:35
CENTRALIZED DATABASE

2:35- 2:55
"PUSH" METHOD

Peter Sturtevant
Senior Director Industry Development, Pharmaceuticals
GS1 US

2:55- 3:15
ROUTER SERVICE

3:15 **AFTERNOON COFFEE BREAK – NETWORK OVER REFRESHMENTS**

PICK YOUR CANDIDATE:

Choose the Best Route to Achieve a Fully Interoperable System by 2023

3:30

BLOCK CHAIN	CENTRALIZED DATABASE	"PUSH" METHOD	ROUTER SERVICE
• Ensures your data requestors are legitimate with minimal effort • Does not require a central repository • Works seamlessly with GS1 EPCIS	• Removes the need for multiple data platforms by creating one hub • Tight protocols for allowing access to data • Easy access to data for further analysis	• Distributed databases • Sending EPCIS data (TI,TS) to forward trading partners. • One-up, One-down visibility	• Increased security by using a third party platform • Requirements for the specs for the router • Tool for leveraging a distributed database model

Robert Celeste
Founder
Center for Supply Chain Studies

Peter Sturtevant
Senior Director Industry Development, Pharmaceuticals
GS1 US

4:15

END OF CONFERENCE RECAP PANEL DISCUSSION: WHERE DO WE GO FROM HERE?

- Discuss the top challenges to expect moving into 2018 and how to reduce bottlenecks
- What to expect next out of the FDA? Will the gray area be cleared up at all around aggregation & grandfathering?
- What pilots should be planned next? Who are the key players? Where does your organization fall?
- How will we get to 2023? When should we begin planning and what will the pharma supply chain even look like by then?
- How can the industry collaborate effectively to get what you need out of regulators?

Brian Tarantino
Principal
The Tracer Group

5:00

END OF DAY TWO





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Join us to follow up on the FDA workshops earlier in the week in DC. Stay tuned for hotel booking information and details about our exclusive Welcome Reception on Wednesday evening!

*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. Theseprices are featured as a limited time only promotion. IQPC reserves the right to increase these prices at its discretion. Buy One, Get One Free offer is valid only to end users on packages only, off the standard price.

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