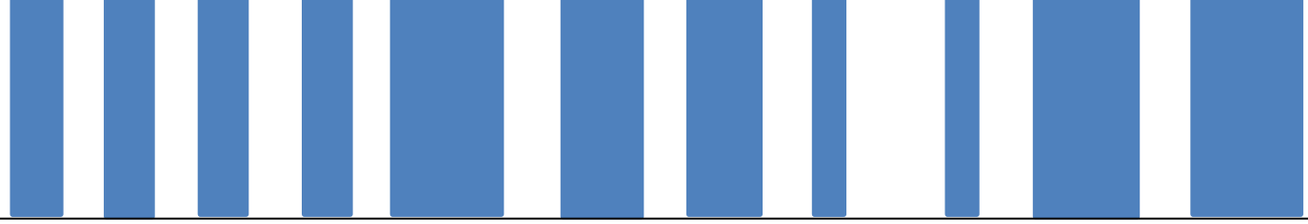

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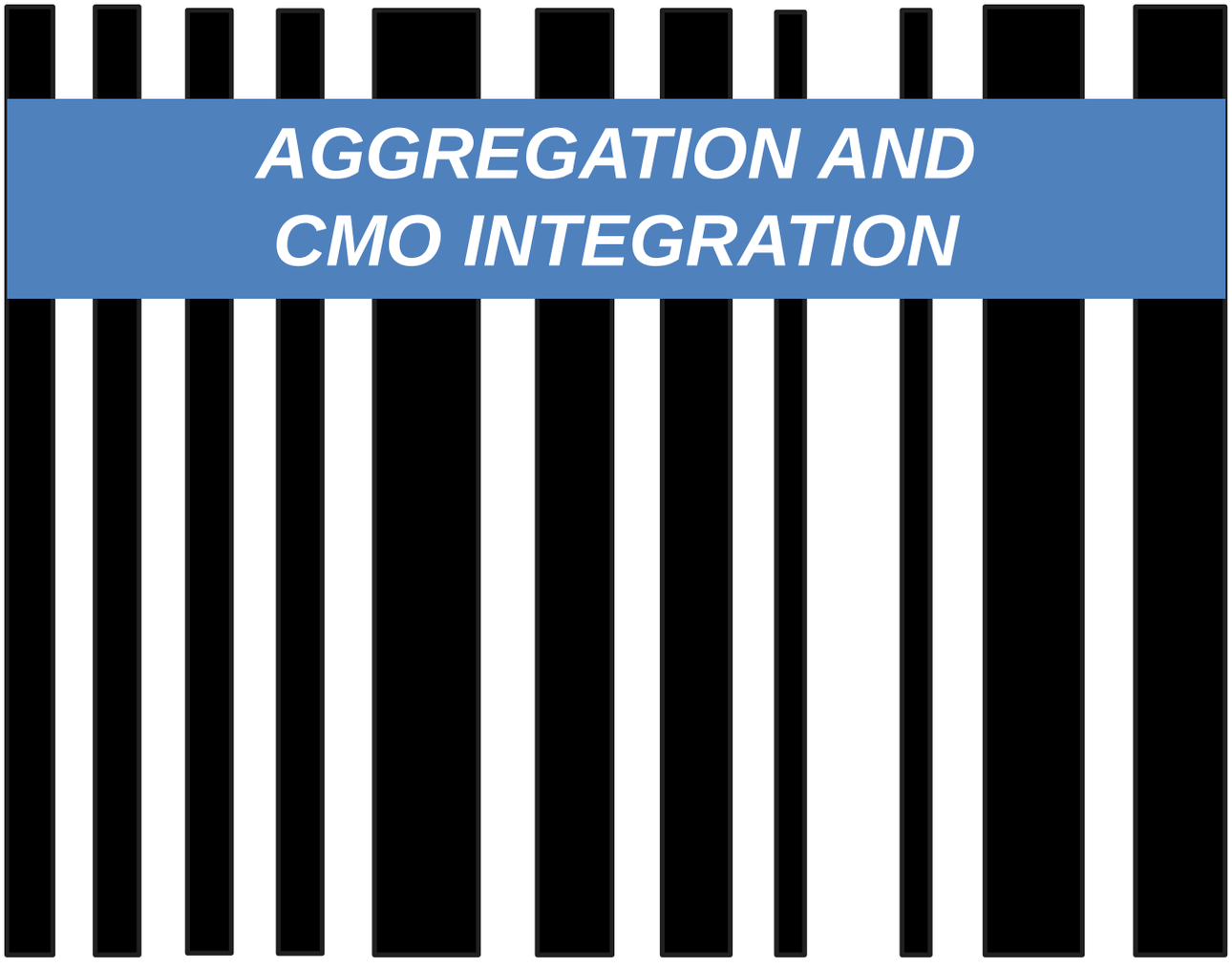
4TH PHARMACEUTICAL TRACEABILITY FORUM

November 30th - December 2nd, 2016
Sheraton Philadelphia University City Hotel,
Philadelphia, Pennsylvania

EXPERT INSIGHT INTO TOP PHARMACEUTICAL CHALLENGES SURROUNDING

SERIALIZATION:



AGGREGATION AND CMO INTEGRATION

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As the pharmaceutical industry prepares itself for serialization, many questions arise in regards to best practices that will ensure product traceability throughout the supply chain and compliance on an international scale. In particular, manufacturers have expressed concern as to how their contract partners are preparing for and planning to hit the 2017 DSCSA deadline and what they can do to help them along. Aside from supply chain partner readiness, the decision to aggregate serialized product prior to 2023 is a top area of interest. We are leaning on the expert opinions of top pharmaceutical professionals for further clarification on these pain points.

Matt Sample, *Senior Director, Secure Supply Chain* at AmerisourceBergen, discusses aggregation challenges, possible solutions, and hitting DSCSA deadlines. He will elaborate on these ideas and more at this year's Pharmaceutical Traceability Forum. **Christopher Howell**, *Senior Director, Global Engineering & Technology* at Patheon, Inc., shares his views on serialization and CMO integration, including some of the top challenges, possible explanations for increasing supply chain efficiency, and anticipated issues past 2017. Like Matt Sample and other distinguished speakers, he will also be presenting at the Pharmaceutical Traceability Forum.

Matt Sample:

The Top Challenges Wholesalers Face Regarding Aggregation

1. "Meeting our 2019 obligation without getting serialized information for products sold to us."
2. "Not all manufacturers plan on, or are willing to aggregate before the implied need for it in 2023."
3. "Based off initial estimates, aggregation requires 30% longer to execute."

Chris Howell:

The Top Challenges Contract Partners Face When Preparing for Serialization

1. IT integration testing
2. Artwork change development
3. Qualification

Complete Interviews Next Page

Matt Sample Interview

What do you feel are the top 3 challenges that wholesalers are facing in regards to aggregation?

"The biggest challenge we have is meeting our 2019 obligation without getting serialized information for products sold to us. We are assuming that manufacturers need to aggregate to get us that data efficiently. Given that information, we know that not all manufacturers plan on, or are willing to, aggregate before the implied need for it in 2023. As a wholesaling community we have ~58MM saleable returns a year; if we can't get data, how will we execute the verification of those products? Looking at 2023, we too will have to aggregate when we pick customer orders. Based off initial estimates, aggregation requires 30% longer to execute. We must look to make that loss up or we run the risk of not fulfilling customer orders on time."

How can all supply chain stakeholders work together to come up with one accepted standard for aggregating products?

"EPCIS is the industry accepted standard on aggregation. I think what we have to work together on is understanding what we do if or when we have exceptions related to aggregation errors. To do this, various stakeholders must work together via pilots, industry groups such as HDA, and collaborate to develop an "industry" approach to solving exception and aggregation issues."

What are you most excited to hear about at the Pharmaceutical Traceability Forum?

"For me, I'm interested in hearing about the progress the manufacturers and CMOs are making towards the 2017 deadline and the challenges they are facing."

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What major issues are you anticipating, once all DSCSA deadlines are met?

"EPCIS Data Exchange is going to be an issue from here well past the DSCSA deadline. EPCIS, although not new, is new for our pharmaceutical systems and for our B2B processes. I anticipate that we'll have issue testing and exchanging data for quite some time until we can all stabilize our systems. I also think labeling and data related exceptions will continue to occur well past the deadlines. What do we do when we have perfectly good drugs, a patient in need, and we have a technical or label related issue?"

How do you think the industry can use this serialized data to increase supply chain efficiency and better connect with patients?

"I really believe there are several opportunities beyond compliance; for one, we can automate a lot of the inventory control in the warehouses, pharmacies, hospitals, etc. Today, a pharmacist has to manually record lot and expiration date, tomorrow they'll be able to scan and capture that with improved accuracy. Internally in our distribution warehouses, serialization is going to increase order accuracy and in turn decrease inventory variances. We currently have one warehouse recording serial number shipments and they've seen manual errors (due to keying in lot numbers, etc.) reduced to zero, and their latest cycle count variance was 0% for serialized products."

Christopher Howell Interview

What do you feel are the top 3 challenges that contract partners face when preparing for serialization?

"Some of the challenges that contract partners face include IT integration testing, artwork change development and qualification. A disciplined on-boarding process will help combat the challenge in each of these areas."

How can CMOs and manufacturers optimize their communications to make this integration easier?

"At the Pharmaceutical Traceability Forum in December, I will present a case study titled, 'Fast-tracking Contract Partner Serialization Plans to Meet 2017 Deadline,' and will share best practices regarding how CMOs and pharma companies can work together to make this integration easier. These best practices include standardizing GS1 requirements, starting testing early and maintaining frequent communication with each other."

What major issues are you anticipating, once the 2017 goal is met?

"As a global industry provider, the onset of additional countries will continue to drive Patheon's focus past 2017. Beyond those known requirements, focusing on process improvements and optimization will be our main area of focus."

How do you think the industry can use this serialized data to increase supply chain efficiency and better connect with patients?

"Serialization and aggregation better position Patheon as a contract packager to respond more quickly to its brand owner clients to ensure product safety and identity."

"I am excited about the opportunity to share, learn and network with like-minded industry professionals at the Pharmaceutical Traceability Forum."

- Christopher Howell
Senior Director, Global Engineering & Technology
Patheon, Inc.

4TH PHARMACEUTICAL TRACEABILITY FORUM

At the 4th iteration of the Pharmaceutical Traceability Forum, **Aggregation, CMO Integration**, and other top challenges will be discussed by industry thought leaders and masters of traceability. Join us to hear their key lessons learned and solutions to fine-tune your own serialization plans!

Featured Speaker Sessions:

Creating a Standardized Packaging and Labeling Process to Meet Wholesaler Requirements

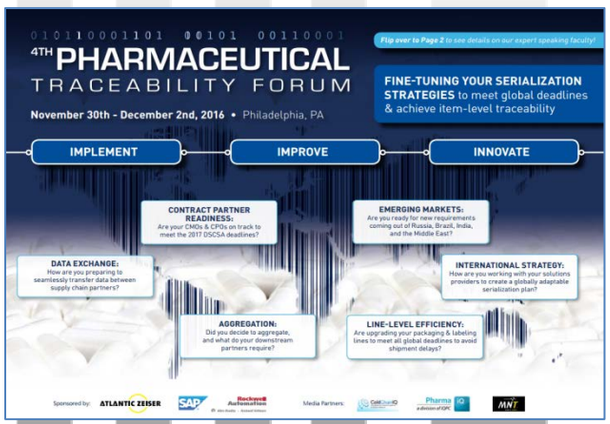
- Define your supply chain partners' guidelines on aggregation and adjust your processes to meet those needs
- Understand why all serialized labeling is not created equally and the preferred choices of supply chain partners
- Create one standard for labeling, and understand what "bad" labeling will mean come 2017 and beyond
- Examine the current state challenges with pharmaceutical packaging, specifically HIDA Guidelines and GS1 standards

Matt Sample
Senior Director, Secure Supply Chain
AmerisourceBergen

CASE STUDY: Fast-tracking Contract Partner Serialization Plans to Meet 2017 Deadline

- Collaborate with your contract manufacturing partners to insure your products are ready for serialization
- Communicate your specific serialization requirements and standards clearly with partners
- Test processes early and often to identify areas for improvement and further coordination
- Conduct qualification testing in order to streamline the transition of products to serialized operations

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



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To view all speaker sessions, download our agenda