



### DSCSA 2023 ASN TO EPCIS: INDUSTRY CHANGE, YOUR CHALLENGE

rfxcel DSCSA 2023 Webinar Series, Part 2 June 16, 2021

Presented by Brian Files, rfxcel Global Executive Advisor

#### YOUR PRESENTER, HERB WONG





Herb Wong is rfxcel's vice president of marketing and strategic initiatives. You may recognize him from the many other DSCSA-related webinars he's hosted over the years.

A DSCSA guru, Herb led our FDA-approved VRS pilot and provides technical guidance within the company and to our many customers in the pharma industry.

Herb graciously jumped at the opportunity to fill in for Brian Files for today's discussion of ASN and EPCIS.





### AGENDA

- 1. Why this DSCSA 2023 webinar series?
- 2. What are ASN and EPCIS?
- 3. What do you need to do to be ready for 2023?
- 4. Q&A

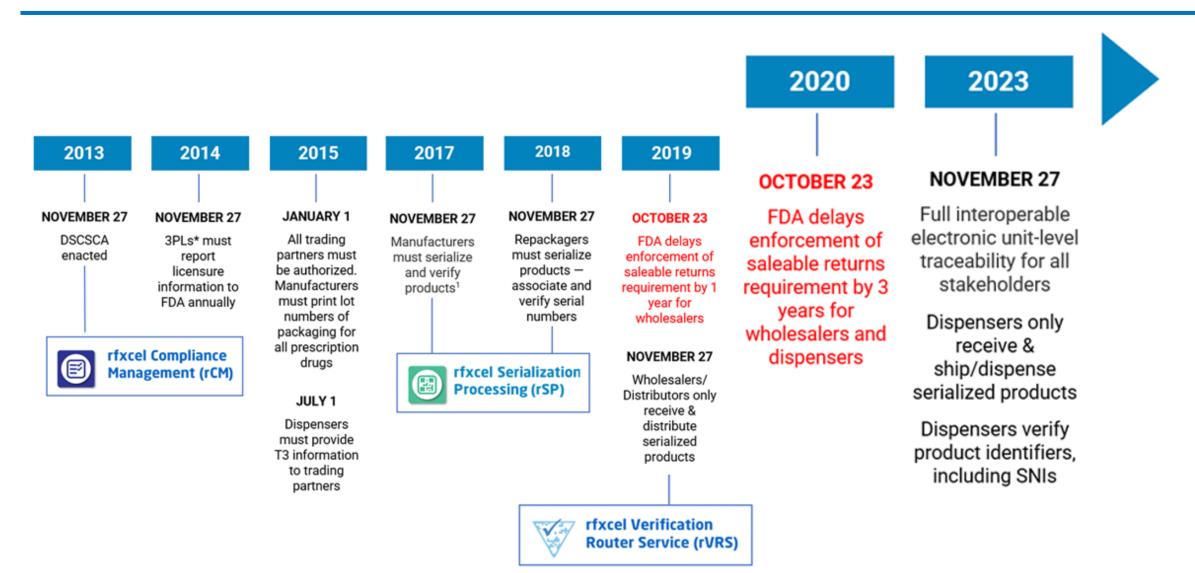


## WHY THIS DSCSA 2023 WEBINAR SERIES?

Uncertainty, Changes, Action

#### THE DSCSA TIMELINE: THE ROAD TO 2023





#### WHY THINK ABOUT DSCSA 2023 RIGHT NOW?



#### TO ADDRESS UNCERTAINTY

- The FDA is dragging its heels with key aspects of the DSCSA.
- The industry is wondering what the FDA will decide.
- FDA guidance What does it mean?
- How, specifically, are we going to get to 2023?

#### TO ANTICIPATE THE CHANGES

- Full electronic interoperability
- Shift from lot-level tracking to full serialization
- New language, new responsibilities

#### TO INSPIRE IMMEDIATE ACTION

- Focus on nearer-term objectives while keeping eye on 2023.
- Talk with trading partners this is critical.
- Engage with the FDA and other industry players to help steer the ship the changes aren't happening in a vacuum.

#### **NOVEMBER 27, 2023**



#### THE "UNION OF CONCERNED SCIENTISTS"







Planning Workgroup

#### FOUR PILLARS OF DSCSA 2023

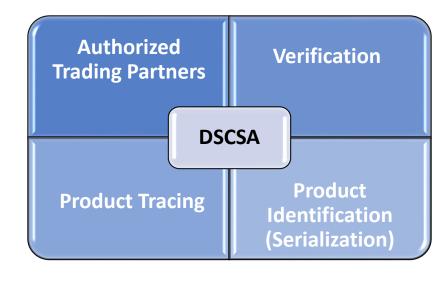


#### **Authorized Trading Partners:**

Ensure no "bad actors" enter the network. Solution must answer two questions: Are you who you claim to be? Are you authorized to conduct business?

#### **Product Tracing:**

Focus shifting from lot-based tracking with "T3" information to full serialization.



#### **Verification (of PIs):**

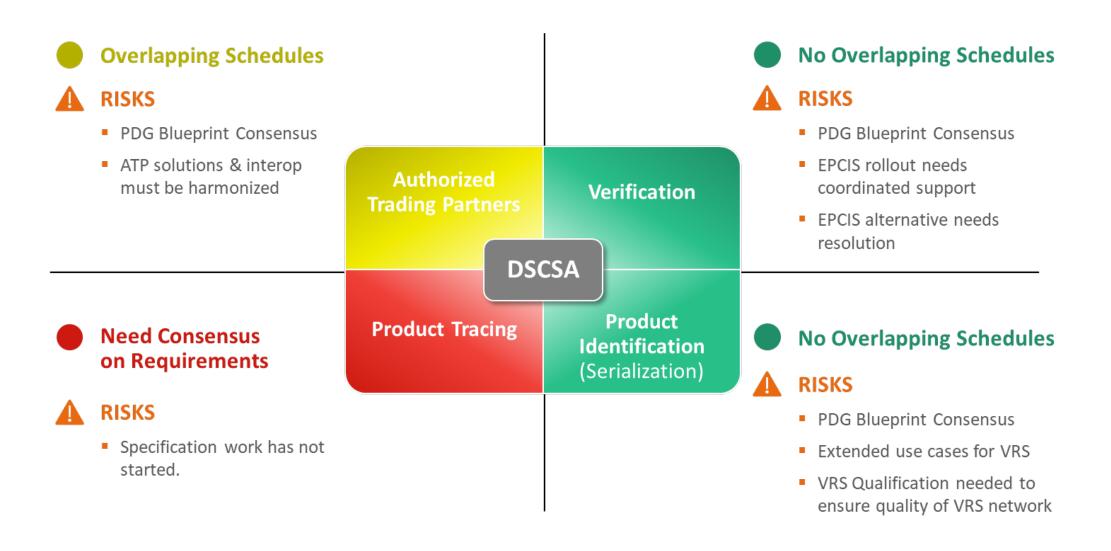
Initial focus on implementing the VRS. Able to extend beyond saleable returns?

#### **Product Identification:**

Add a unique ID to all regulated products; focus on applying a serial number (i.e., bar code) on all products and ensuring the serialized data is exchanged.

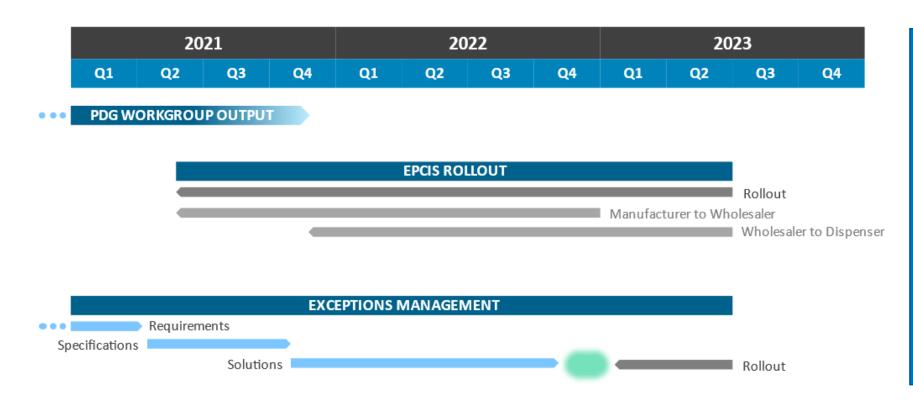
#### **HEAT MAP OF RISKS FOR 2023**





#### OPEN ACTIVITIES FOR PRODUCT IDENTIFICATION





Accelerate Rollout: Ensure EPCIS data is flowing in volume to ensure readiness of all supply chain partners.



## WHAT ARE ASN AND EPCIS?

Advanced Shipping Notice, Electronic Product Code Information Service

#### DSCSA DATA EXCHANGE NOW — AND CHANGES FOR 2023



#### **DSCSA REQUIREMENTS**

- Trading partners must provide transaction information (TI) and a transaction statement (TS)
  to the subsequent owner of a product "prior to, or at the time of, each transaction."
- TI must "be **exchanged in a secure, interoperable, electronic manner** in accordance with the standards established [through FDA guidance]."
- TI must "include the product identifier at the package level for each package included in the transaction."
- FDA sees this as more than a legal requirement: The "electronic, interoperable exchange of TI is also foundational to achieving **electronic interoperable tracing** and **verification** ... ."

#### **WHAT'S CHANGING IN 2023?**

- Right now, TI and TS are being electronically exchanged at the lot-level.
- This is usually done with an advance ship notice (ASN).
- However, in 2023, TI must include the product identifier (PI).
- Therefore, in 2023, the TI must include serial numbers and expiration dates. The supply chain will be fully serialized.

#### THE TRANSITION FROM ASN TO EPCIS

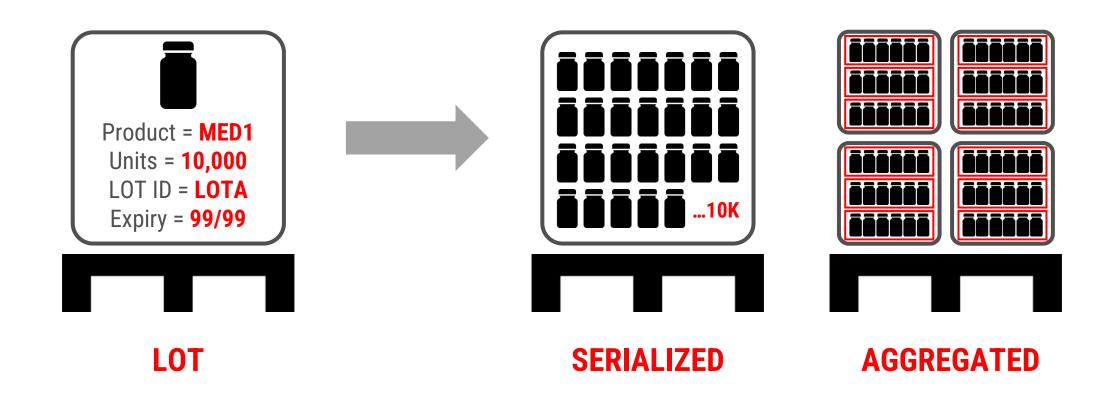


**ASN: Lot-Based** 

**Advanced Shipping Notice** 

**EPCIS: Serialized** 

**Electronic Product Code Information Services** 





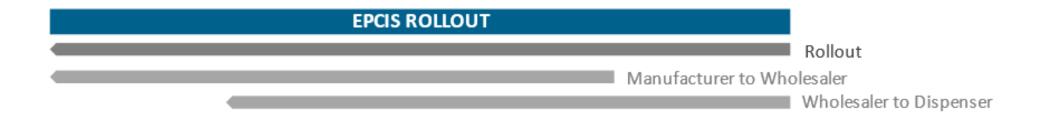
# WHAT DO YOU NEED TO DO TO BE READY FOR 2023?

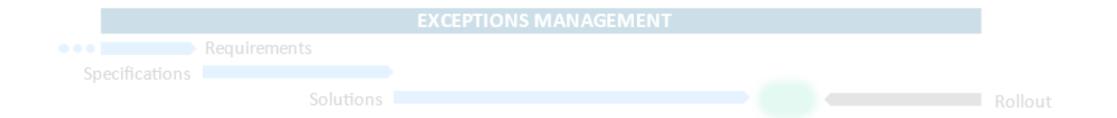
#### ROLLOUT OF EPCIS DATA





#### PDG WORKGROUP OUTPUT





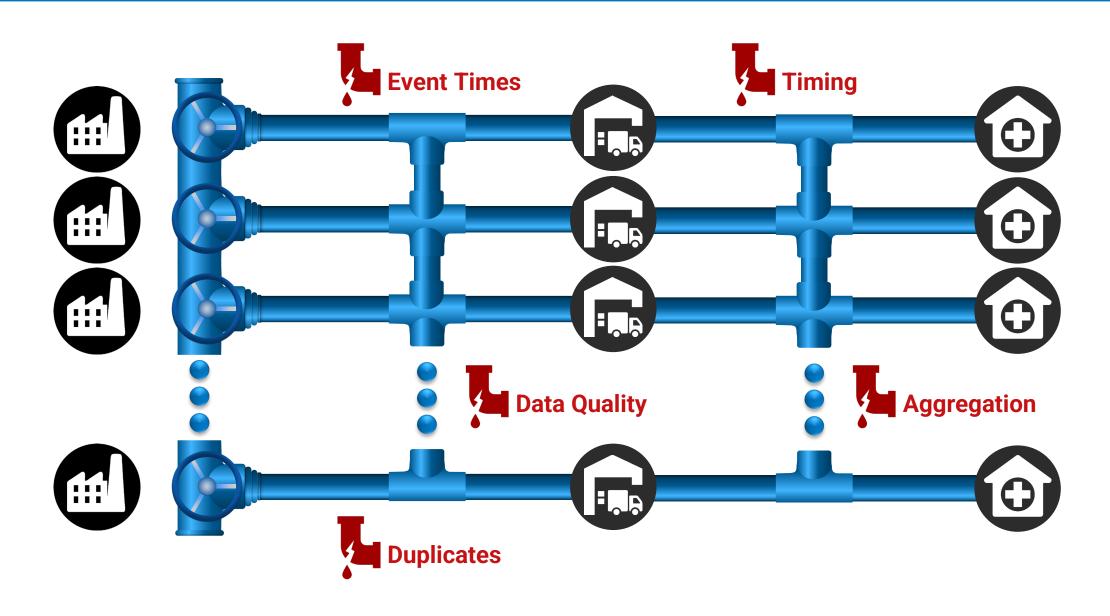
#### ROLLOUT OF EPCIS DATA - DETAILED VIEW



Task Name					2022						2023			
	▼ Duration ▼	y Start →	Finish 🔻	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr
Product Identification (Serialization)	594 days?	Mon 3/22/21	Fri 6/30/23											
▶ PDG WORKGROUP OUTPUT	2 days?	Mon 3/22/21	Tue 3/23/21											
△ EPCIS ROLLOUT	540 days	Fri 5/21/21	Thu 6/15/23										ı	
△ ROLLOUT	540 days	Fri 5/21/21	Thu 6/15/23										ı	
From Manufacturer to Distributor	420 days	Fri 5/21/21	Fri 12/30/22								1			
100% Complete	0 days	Fri 12/30/22	Fri 12/30/22							1	12/3	0		
90% to 100% Progress	60 days	Fri 10/7/22	Fri 12/30/22						ſ	-	M			
70% to 90% Progress	60 days	Fri 7/15/22	Fri 10/7/22							P				
50% to 70% Progress	60 days	Fri 4/22/22	Fri 7/15/22					(						
30% to 50% Progress	60 days	Fri 1/28/22	Fri 4/22/22											
10% to 30% Progress	60 days	Fri 11/5/21	Fri 1/28/22											
0% to 10% Progress	120 days	Fri 5/21/21	Fri 11/5/21											
From Distributor to Dispenser	420 days	Fri 11/5/21	Thu 6/15/23										ı	
100% Complete	0 days	Thu 6/15/23	Thu 6/15/23									ŕ	6/15	
90% to 100% Progress	60 days	Fri 3/24/23	Thu 6/15/23								Н		<b>k</b> ₽	
70% to 90% Progress	60 days	Fri 12/30/22	Fri 3/24/23							ſ		7		
50% to 70% Progress	60 days	Fri 10/7/22	Fri 12/30/22						ſ	-	P			
30% to 50% Progress	60 days	Fri 7/15/22	Fri 10/7/22						, The same of the	P				
10% to 30% Progress	60 days	Fri 4/22/22	Fri 7/15/22					_						
0% to 10% Progress	120 days	Fri 11/5/21	Fri 4/22/22					<b>~</b>						

#### THE IMPORTANCE OF SENDING DATA THROUGH "THE PIPES"





#### INDUSTRY CENTER OF EXCELLENCE FOR EPCIS





#### A TIDE THAT LIFTS ALL BOATS

- Involve solution providers and industry leaders.
- Develop processes & incentives to encourage an accelerated rollout of EPCIS.
- Implement quantifiable metrics to track progress and risk to the industry.

#### FINAL THOUGHTS



#### **ARE YOU READY FOR THE CHANGING TIDE?**

- Can you send/receive serialized data?
- Can you send/receive aggregated data?
- Do you have SOPs and training in place to support serialized data exchange?
- Drop us a line if you want to extend the EPCIS conversation.



## QUESTION & ANSWER

www.rfxcel.com

#### YOUR QUESTIONS ABOUT ASN & EPCIS



- When will companies start sending EPCIS?
- What percentage of companies are sending or receiving (manufacturers, wholesalers, dispensers)?
- What happens if my supplier will not send EPCIS and points to a Web portal?
- What do you anticipate as the challenges for EPCIS?



## THANK YOU!

Join us tomorrow, same time, same place: "Authorized Trading Partners: The OCI Solution"