DSCSA 2023
THE VERIFICATION ROUTER SERVICE: ALIGNING TO THE STANDARD

rfxcel DSCSA 2023 Webinar Series, Part 1

June 15, 2021

Presented by Brian Files, rfxcel Global Executive Advisor

YOUR PRESENTER, BRIAN FILES

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AGENDA

1. Why this DSCSA 2023 webinar series?
2. What is the VRS?
3. What do you need to do to be ready for 2023?
4. Q&A

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WHY THIS DSCSA 2023 WEBINAR SERIES?

Uncertainty, Changes, Action

THE DSCSA TIMELINE: THE ROAD TO 2023

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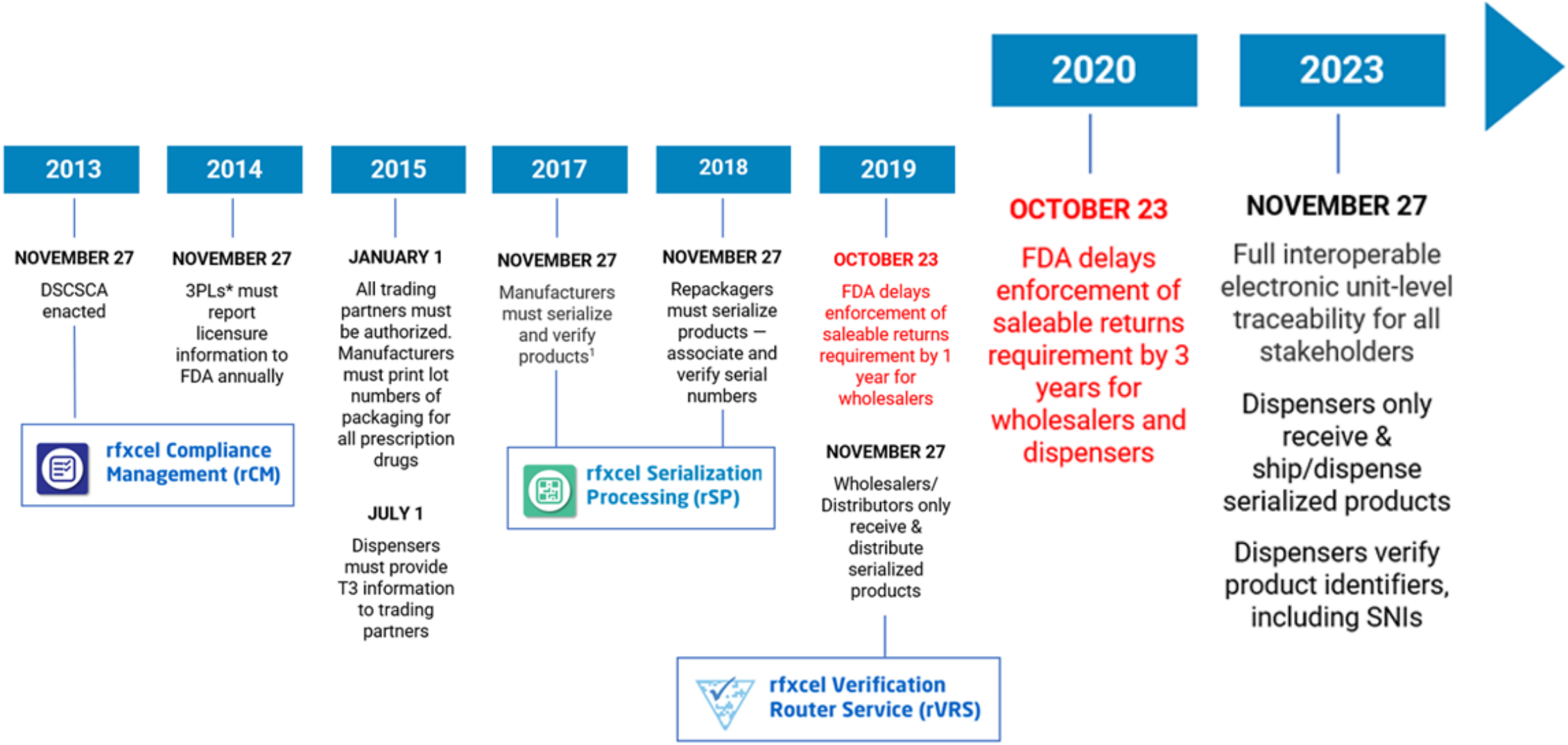


WHY THINK ABOUT DSCSA 2023 RIGHT NOW?

TO ADDRESS UNCERTAINTY

- The “State of the State” – the industry is shaping standards.
- 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

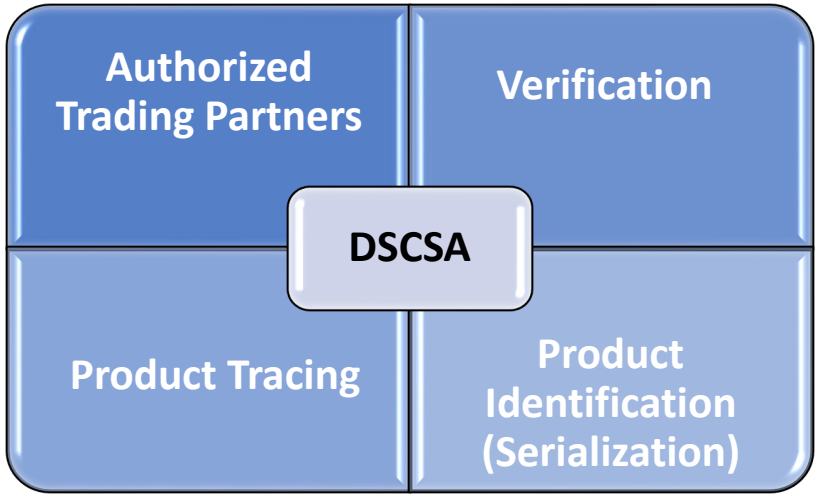
- Focus on nearer-term objectives while keeping eye on 2023.
- Talk with trading partners — this is critical.
- Engage with the FDA and other industry players to help steer the ship — the changes aren’t happening in a vacuum.

NOVEMBER 27, 2023

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?

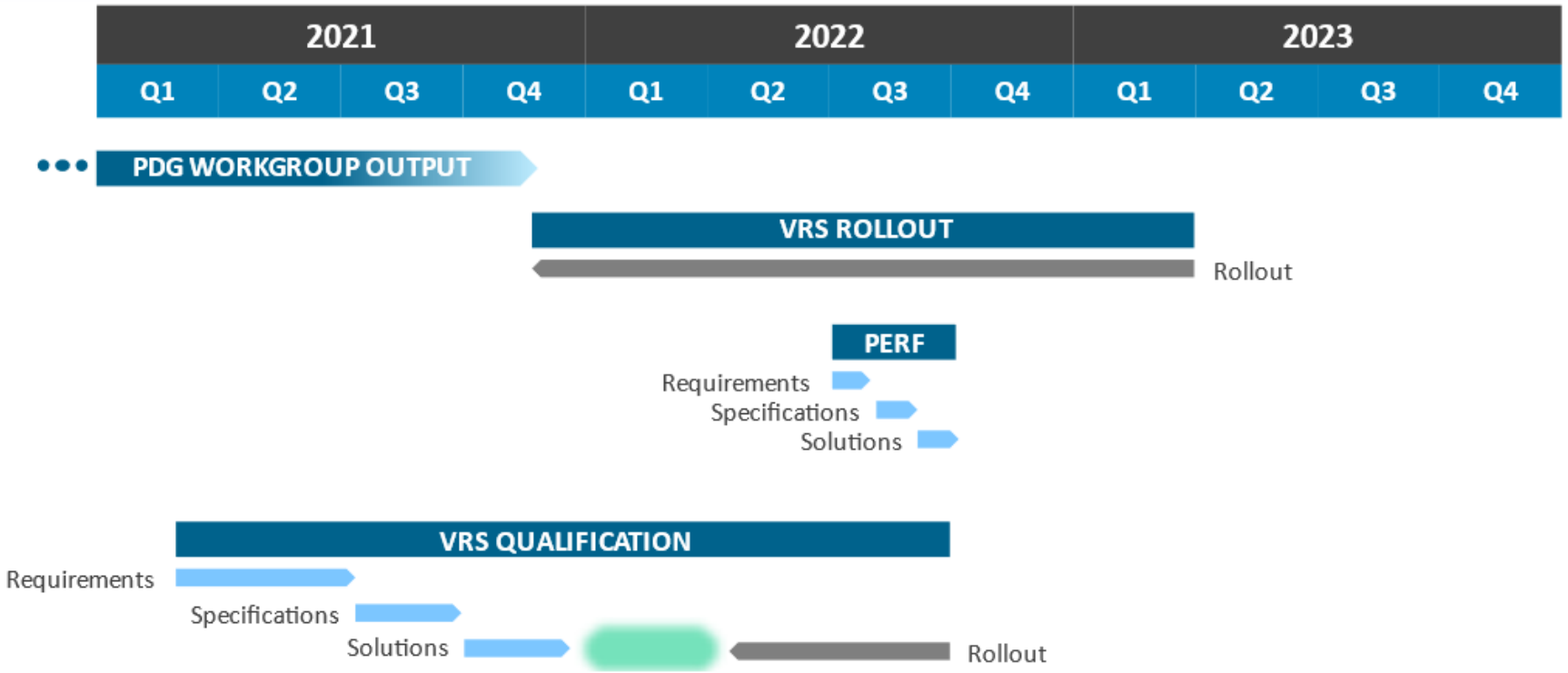
Product Tracing:
Focus shifting from lot-based tracking with “T3” information to full serialization.



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.

OPEN ACTIVITIES FOR VRS



Rollout: Ensure required users are exchanging data *before* 2023.

Performance: Retest performance of VRS after authorized trading partner (ATP) integration.

Qualification: Independent process for verifying VRS providers.

NEW: June 11 feedback from industry pending review and possible updates to VRS.

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WHAT IS THE VRS?

The DSCSA saleable returns verification requirement and the Verification Router Service

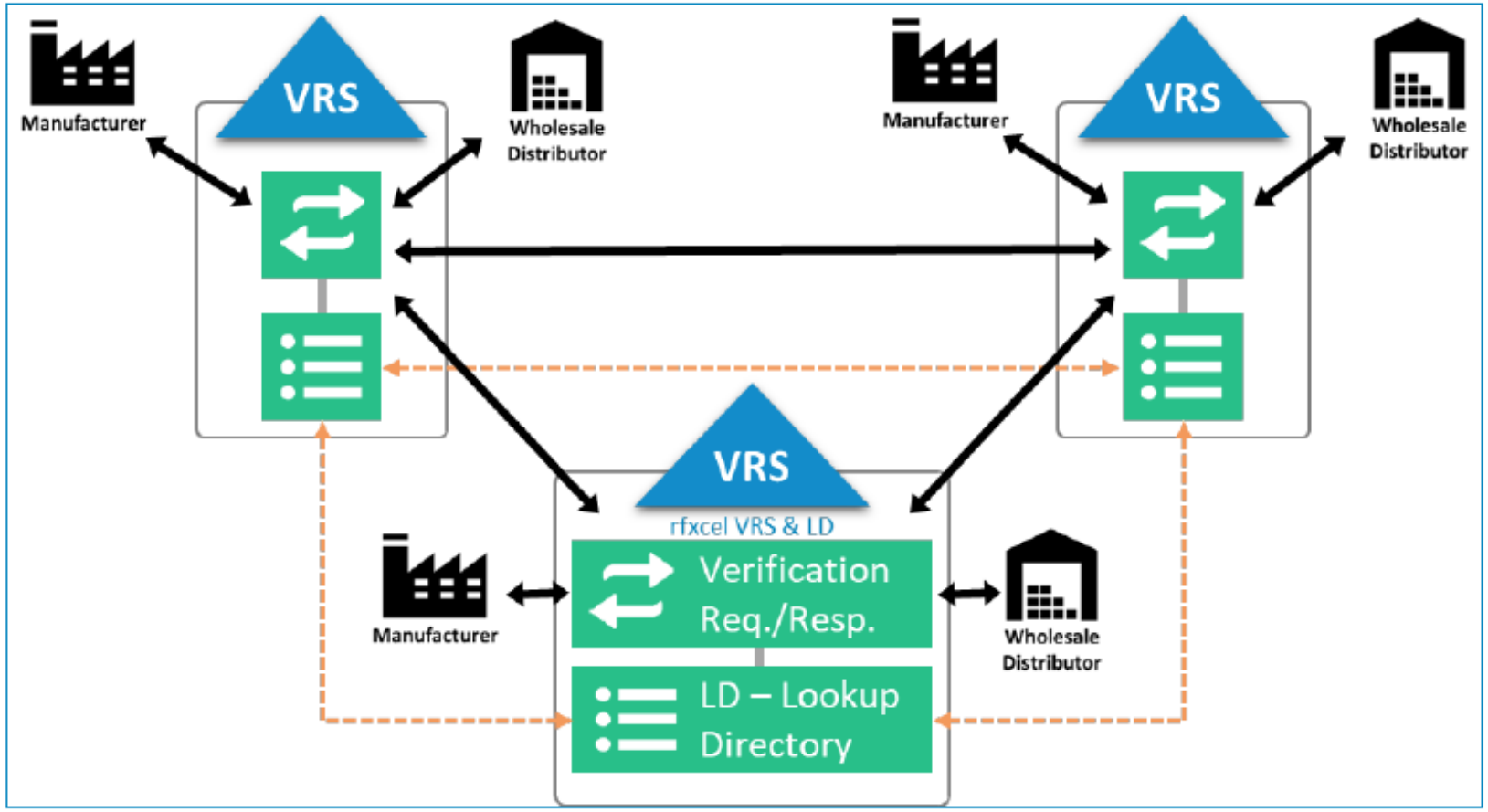
DSCSA SALEABLE RETURNS VERIFICATION REQUIREMENT

- Must verify saleable returns before they can be reintroduced to the supply chain.
- Every returned drug must be vetted — declared as safe and legitimate — before it can be sold again.
- Must verify the drug's **product identifier (PI)**, which includes:
  - Standardized Numerical Identifier (SNI): composed of a National Drug Code and a unique alphanumeric serial number
  - Lot ID
  - Expiration date
- Requestors and responders

NDC: 69514 811 42
SN: 1005029487620
EXP: NOV 27 2021
LOT: RF100230

VRS ARCHITECTURE

- Enables rapid, secure exchange of data between requestors and responders to meet the saleable returns verification requirement.
- VRS is an automated service that verifies if a PI is valid.
- Verification occurs in real time and the VRS ensures that information is accurate and up to date.
- A solution provider enables routing of verification requests.



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

ASSESS YOUR READINESS & ANTICIPATE ISSUES — 30,000 FT to 5 FT

- What is your business model? How complex is your supply chain?
- Are you compliant? Are you on the road to being compliant?
  - ❖ Do you need a DSCSA audit?
  - ❖ What resources do you have?
  - ❖ Is your IT infrastructure (and team) up to snuff?
  - ❖ Are your trading partners on board? Are you talking with them? (YOU SHOULD BE!!)
  - ❖ Do you have a budget? Do you know the scale of your needs?

IF YOU'RE NOT COMPLIANT, WHAT IS YOUR GAME PLAN?

- Look at the calendar. It's June 2021. November 2023 will be here before you know it.
- Find your VRS solution ASAP and devise a process to manage it.
- Focus on purpose and efficiency.
- Always remember HDA and PDG standards — they're the drivers.
- BUT … always maintain *your own* standards!

FINAL THOUGHTS

- Keep your eyes on 2023 and beyond.
- Talk to your trading partners.
- Learn how the VRS works — and how it will fit in your operations.
- Find your solution ASAP — off-the-shelf solutions probably won't be ready in 2023.
- Look for opportunities to engage with the FDA and other industry players to help shape the future.
- Don't miss the other webinars in our DSCSA 2023 series!
  - Tomorrow: "ASN to EPCIS: Industry Change, Your Challenge"
  - Thursday: "Authorized Trading Partners: The OCI Solution"
- Drop us a line if you want to extend the VRS conversation.

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QUESTION & ANSWER

YOUR QUESTIONS ABOUT VRS

- Are there any new developments that the industry should be aware of?
- What's the current implementation rate and use of VRS?
- When do I need to implement?
- My wholesale distributor takes care of this for me. What is my responsibility here? And am I covered if I were to be audited?

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THANK YOU!

Join us tomorrow, same time, same place:
“ASN to EPCIS: Industry Change, Your Challenge”