AUTHORIZED TRADING PARTNERS: THE OCI SOLUTION

rfxcel DSCSA 2023 Webinar Series, Part 3
June 17, 2021

Presented by Brian Files, rfxcel Global Executive Advisor

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AGENDA

1. Why this DSCSA 2023 webinar series?
2. What are authorized trading partners?
3. Meeting the ATP Challenge: What is the OCI?
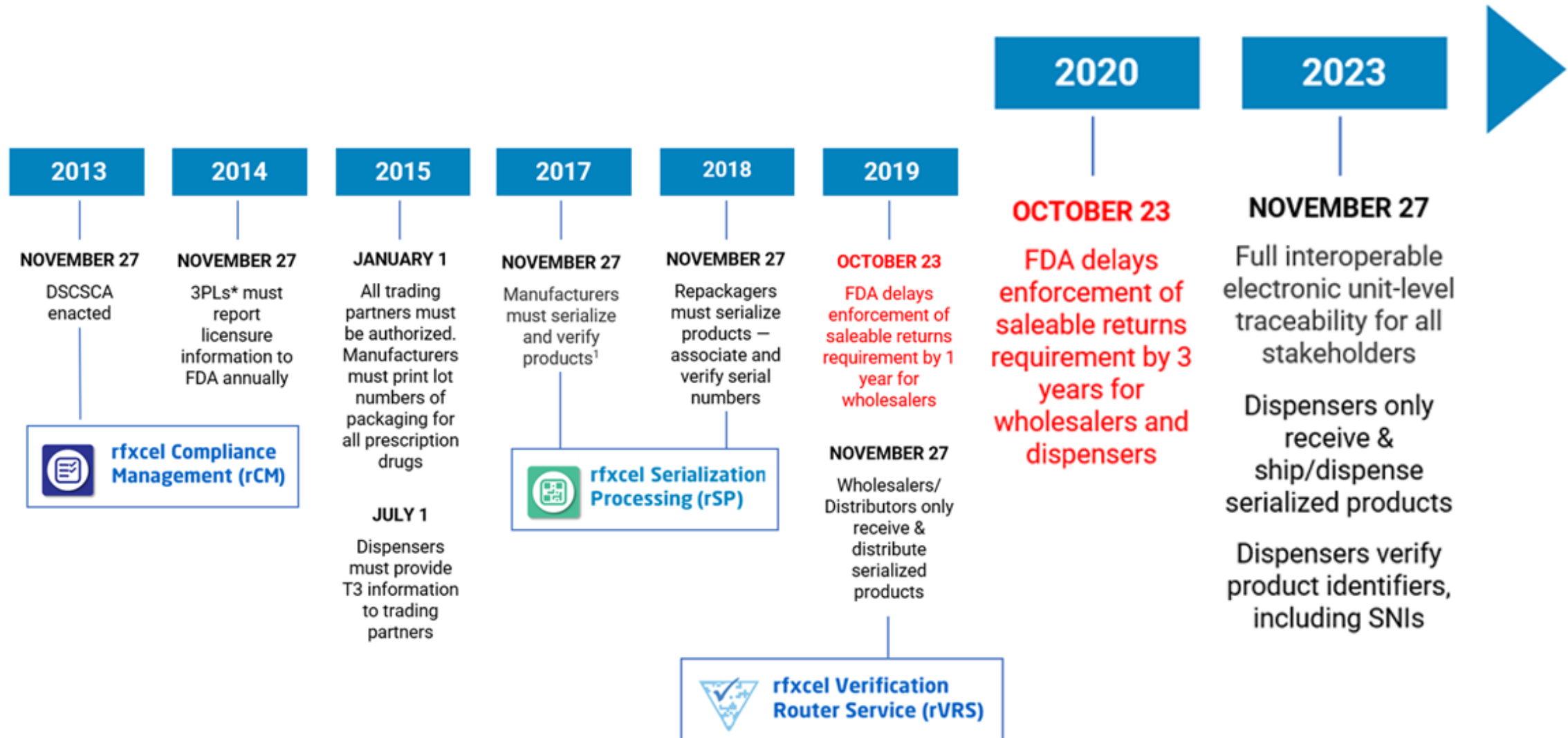4. What do you need to do to be ready for 2023?
5. Q&A

WHY THIS DSCSA 2023 WEBINAR SERIES?

Uncertainty, Changes, Action

THE DSCSA TIMELINE: 2020 VERSUS 2023

2013

NOVEMBER 27

DSCSCA enacted

rfxcel Compliance Management (rCM)

2014

NOVEMBER 27

3PLs* must report licensure information to FDA annually

2015

JANUARY 1

All trading partners must be authorized. Manufacturers must print lot numbers of packaging for all prescription drugs

JULY 1

Dispensers must provide T3 information to trading partners

2017

NOVEMBER 27

Manufacturers must serialize and verify products[1]

rfxcel Serialization Processing (rSP)

2018

NOVEMBER 27

Repackagers must serialize products — associate and verify serial numbers

2019

OCTOBER 23

FDA delays enforcement of saleable returns requirement by 1 year for wholesalers

NOVEMBER 27

Wholesalers/ Distributors only receive & distribute serialized products

rfxcel Verification Router Service (rVRS)

2020

OCTOBER 23

FDA delays enforcement of saleable returns requirement by 3 years for wholesalers and dispensers

2023

NOVEMBER 27

Full interoperable electronic unit-level traceability for all stakeholders

Dispensers only receive & ship/dispense serialized products

Dispensers verify product identifiers, including SNIs

WHY THINK ABOUT DSCSA 2023 RIGHT NOW?

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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?

Verification (of PIs):
Initial focus on implementing the VRS. Able to extend beyond saleable returns?

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

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.

WHAT ARE AUTHORIZED TRADING PARTNERS?

The key supply chain stakeholders

AUTHORIZED TRADING PARTNERS (ATPs)

- Manufacturers, wholesale distributors, repackagers, 3PLs, and dispensers

- ATPs may engage in transactions only with other ATPs.

- All their trading partners must be ATPs.

- Precise definition of each stakeholder

- Different criteria to be considered an ATP

EXAMPLE: CRITERIA TO BE A "MANUFACTURER" AND THE RESPECTIVE ATP REQUIREMENT

1. Manufactured the product

   - Must be registered w/FDA in accordance w/FD&C Act Section 510 "§360. Registration of producers of drugs or devices"

2. Approved application holder, or co-licensed partner of the approved application holder who obtained the product directly from the application holder or person who manufactured the product

   - Must be compliant w/FD&C Act Section 510

3. Affiliate of manufacturer who obtained the product directly from the application holder or person who manufactured the product
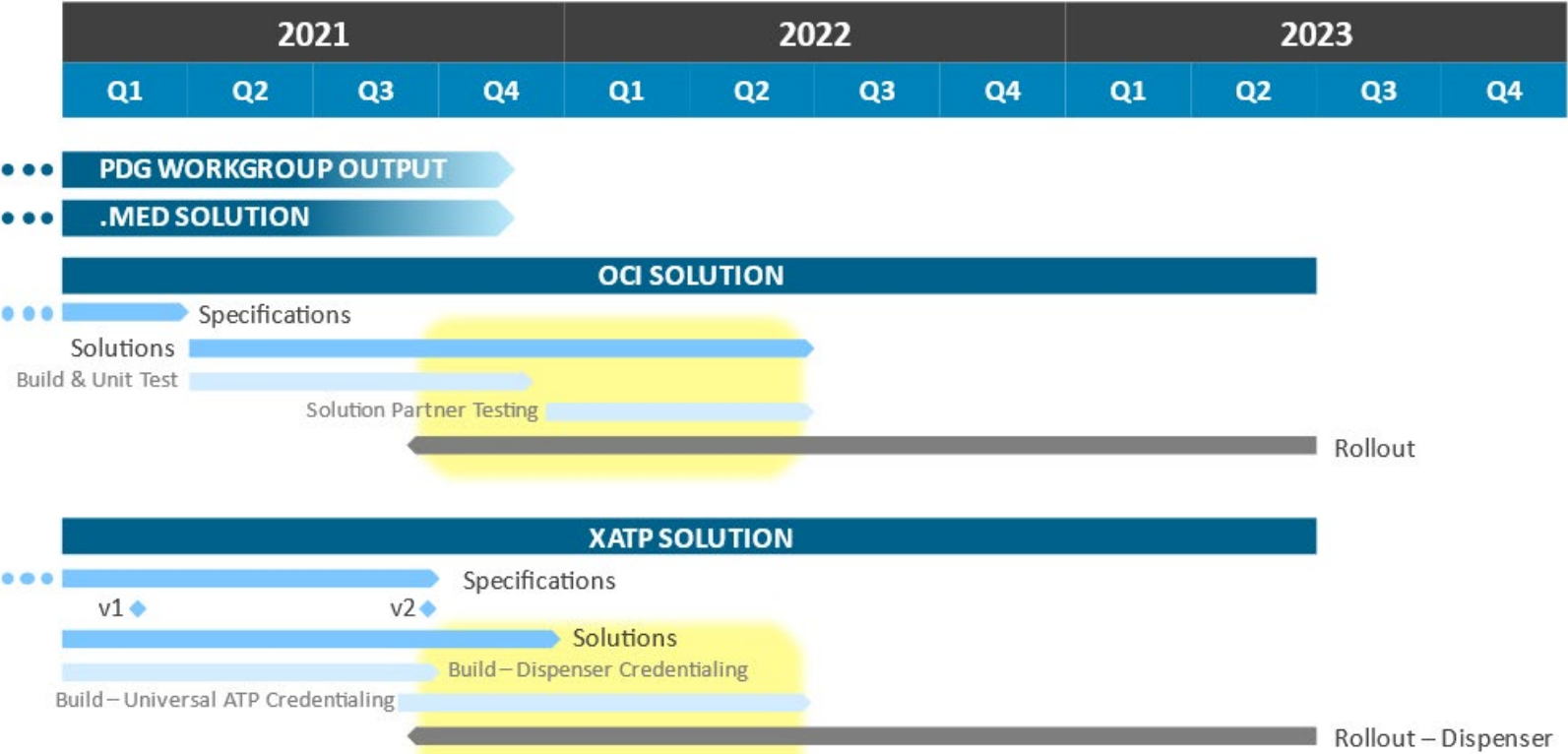
   - Must be compliant w/FD&C Act Section 510

USING DSCSA AUTHORIZED TRADING PARTNER CREDENTIALS

Source: Bob Celeste and the Center from Supply Chain Studies   https://www.youtube.com/watch?v=y7aWEPUgYbA

OPEN ACTIVITIES FOR ATPs

2021				2022				2023			
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4

PDG WORKGROUP OUTPUT

.MED SOLUTION

OCI SOLUTION
- Specifications
- Solutions
- Build & Unit Test
- Solution Partner Testing
- Rollout

XATP SOLUTION
- Specifications
  - v1
  - v2
- Solutions
- Build – Dispenser Credentialing
- Build – Universal ATP Credentialing
- Rollout – Dispenser

Schedule: Document schedule for .MED solution.

Overlap: Address the overlap between ATP readiness and rollout.

Interoperability: Determine how/if the three ATP solutions can work with each other.

MEETING THE ATP CHALLENGE: WHAT IS THE OCI?

Verifying all key supply chain stakeholders

OPEN CREDENTIALING INITIATIVE
for ATP status verification

Trading Partners

Advisors')

NOVARTIS

Bristol-Myers Squibb

Johnson-Johnson

ATLANTIC

AmerisourceBergen

Integration Partners

SAP

tracelink
NETWORK FOR GREATER GOOD

RFXCEL
ANTARES VISION GROUP

RxScan

NAVITAS
LIFE SCIENCES

Credential Issuer

LEGISYM

Supporting Organizations

HDA

GS1

Wallet Provider

SPHERITY

Management

CENTER
Supply Chain Studies

THE OPEN CREDENTIALING INITIATIVE (OCI)

BACKGROUND

- Born from the DSCSA ATP Pilot (April 2020-February 2021).

- Pilot successfully demonstrated the use of W3C standard verifiable credentials, GS1 messaging standards and data attributes, and other standards to establish ATP status between trading partners.

- OCI being organized as an incubator project within the Center for Supply Chain Studies.

GOALS

- Maintain and enhance piloted architecture and documents in an open environment.

- Work with standards organizations to standardize portions of the architecture.

- Shepherd governance considerations from the pilot.

- Provide a place for others to learn and adopt the architecture.

- Explore other uses for the architecture and its components to other use cases

WHAT VALUE DOES OCI BRING TO THE ECOSYSTEM?

Efficiency

Verify ATP status instantaneously, only via API call, leveraging existing GS1 VRS standard

Interoperability

Enables ATP verifications across VRS providers (GS1) and uses standardized DID & credentialing technology (W3C)

Trust

Verify as trading partner the ATP status through cryptographic resolution and validated processes

Conformance

Keeps framework of conformance criteria for issuing Identity and ATP credentials

Standardization

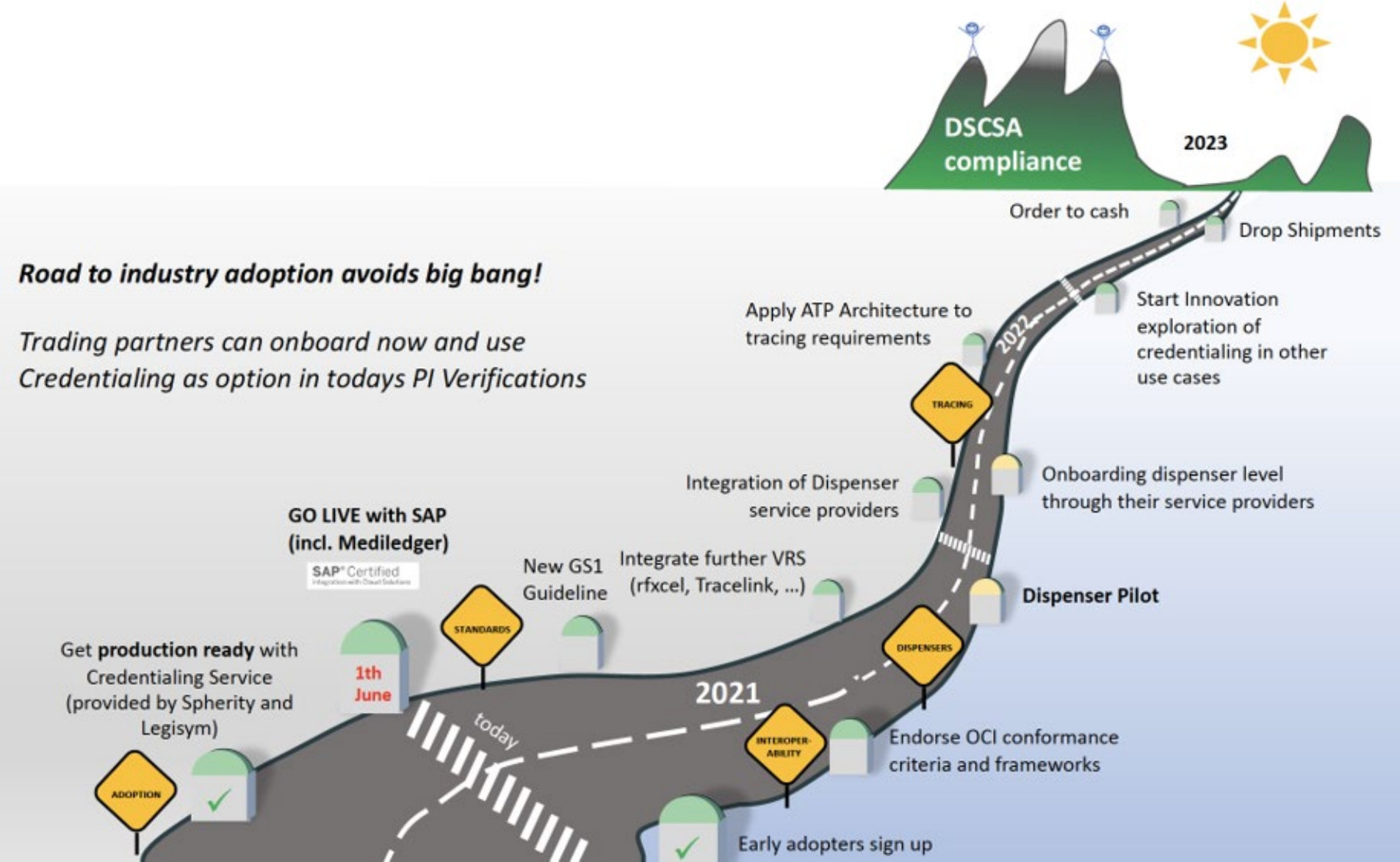Assures usage of global and open standards (GS1, W3C)

Security-by-design

Protects against fraud and malicious actors

Source: OCI

OCI ATP ARCHITECTURE: VRS

SALEABLE RETURNS VERIFICATION (VRS)

DISPENSERS ONBOARDED TO ATP ARCHITECTURE
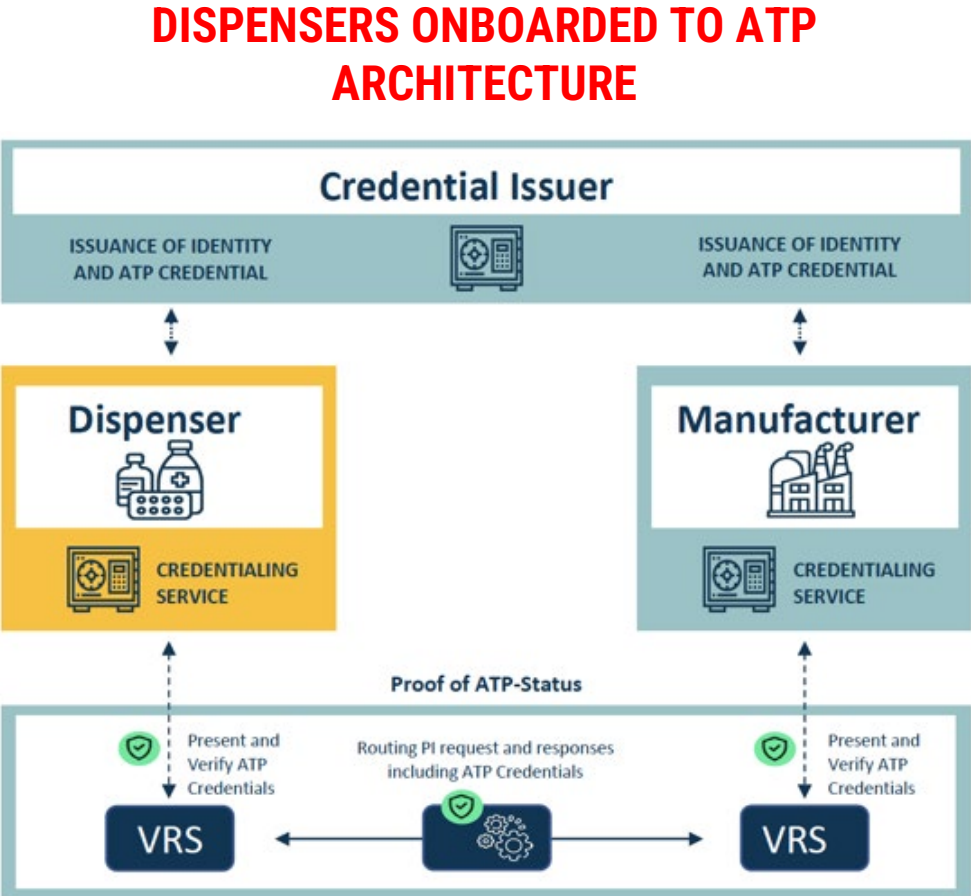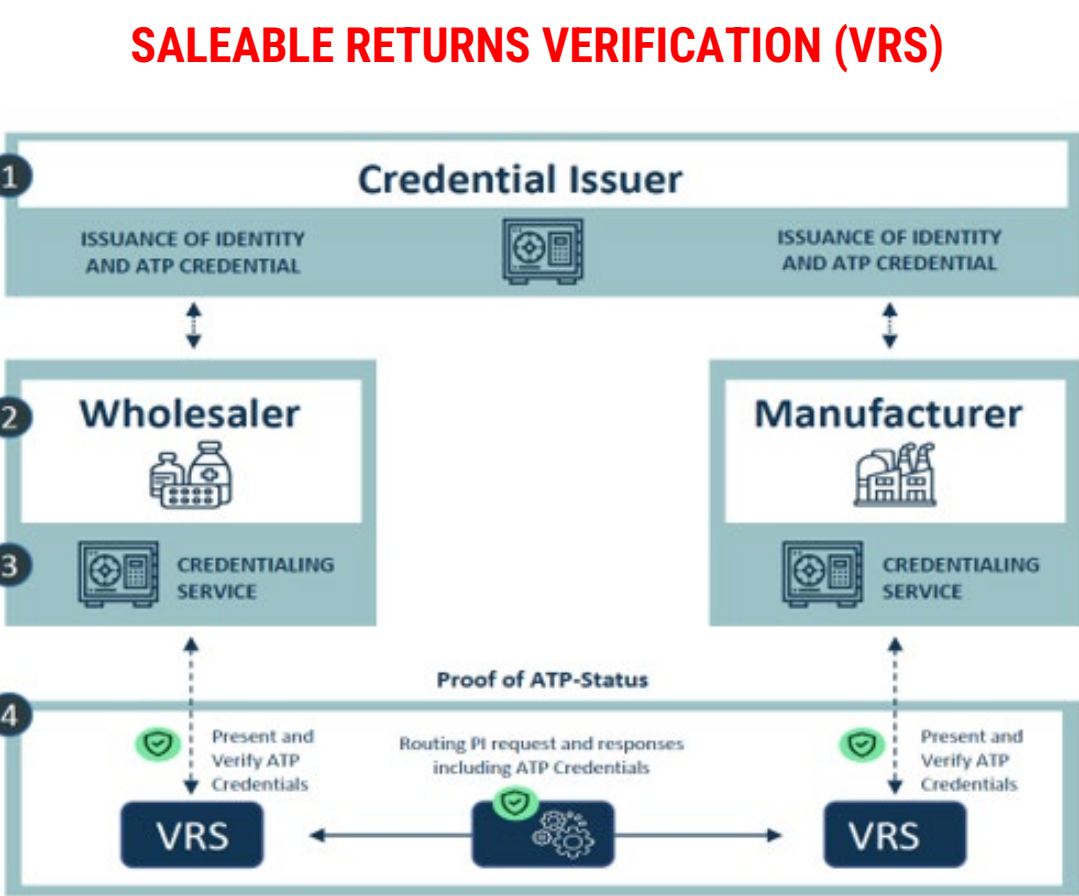
OCI PILOT TO BE FINALIZED Q3 2021

Source: OCI

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

ASSESS YOUR READINESS & ANTICIPATE ISSUES

- Are you currently using manual processes or services?

- 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?
  - ❖ Do you have a **budget**? Do you know the **scale** of your needs?

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

- Preparing to pilot changes for 2023 — marrying ATP to VRS and EPCIS pilots

- Drive the conversation — downstream

- Assess the other pilots (.MED, XATP, NABP) — will be designed to work with each other

- Minimal cost pressure

FINAL THOUGHTS

- Keep your eyes on 2023 and beyond.

- Learn what *your* ATP requirements are. For example, do you have to have a valid license under state law? Do you have to be registered w/the FDA in accordance w/Section 510 of the FD&C Act?

- Find your solution. Figure out how you'll prove you're credentialed so your business won't be interrupted.

- Worth repeating: Talk to your trading partners — make sure they're on the path to being credentialed ATPs.

- Look for an email next week with a link to download all three of our DSCSA 2023 webinars.

- Drop us a line if you want to talk more about ATPs or anything DSCSA 2023.

www.rfxcel.com

THANK YOU!

Look for an email next week with links to download our entire DSCSA 2023 webinar series!