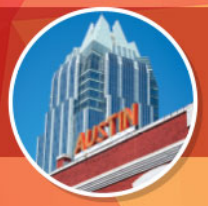
2018 | HDA DISTRIBUTION MANAGEMENT Conference and Expo

Meeting the DSCSA 2019 Verification Deadline

Verification Router Service (VRS)

Update, 2018 Objectives, Call to Action



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Verification Router Service (VRS)

Update, 2018 Objectives, Call to Action

Panelists

- **Pablo Medina** Associate Director, Product Protection & Commercial Serialization, Genentech Inc.
- **Michael Rowe** Manager – Operations Technology (Track & Trace), Cardinal Health, Inc.
- **Matt Sample** Senior Director, Secure Supply Chain, AmerisourceBergen Corporation

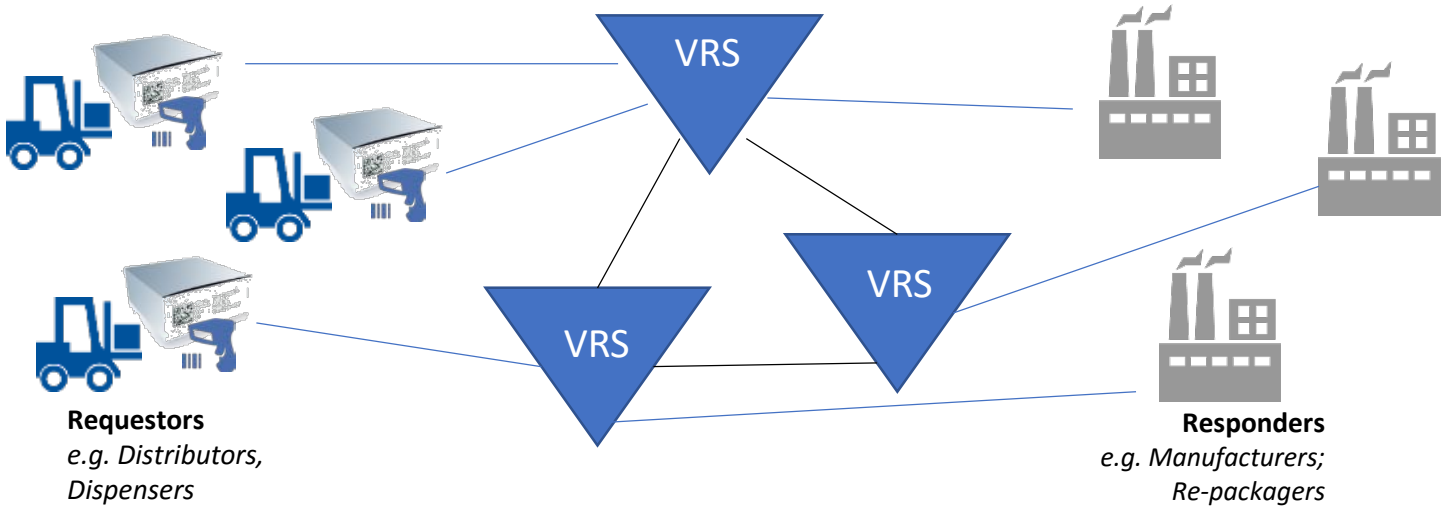
- **Dave Colombo** Director, Life Sciences Advisory, KPMG, LLP (moderator)

Purpose

- Refresher on Verification Router Service (VRS)
  - What is it?
  - Why is it needed?
  - How will it work?
- Provide update on 2018 activities and work plan
  - Technical Development / Test team
  - Governance / Stewardship team
- Respond to your questions & obtain your feedback

What is a Verification Router Service?

An interoperable solution used to manage the acceptance, formatting, and delivery of requests and responses in order to support DSCSA verification requirements.



DSCSA Verification Requirements Snapshot*

DSCSA Requirement:	Stakeholder:	Timing:	Impact Level:
582 (b)(4)(A) ▪ Suspect Product Investigation **582 (b)(4)(C)** ▪ Verification Requests **582 (b)(4)(E)** ▪ Manufacturer Saleable Returns	Manufacturer	▪ 27-Nov-2017 ▪ 27-Nov-2017 ▪ 27-Nov-2017	Low Low-Med Low
582 (b)(4)(A) ▪ Suspect Product Investigation **582 (b)(4)(C)** ▪ Verification Requests **582 (b)(4)(E)** ▪ Manufacturer Saleable Returns	Repackager	▪ 27-Nov-2018 ▪ 27-Nov-2018 ▪ 27-Nov-2018	Low Low Low
582(c)(4)(A) ▪ Suspect Product Investigation **582(c)(4)(D)** ▪ **Distributor Saleable Returns Requirement**	Distributor	▪ 27-Nov-2019 ▪ **27-Nov-2019**	Low **High**
582(d)(4)(A) ▪ Suspect Product Investigation	Dispenser	▪ 27-Nov-2020	Low

* Refer to the DSCSA regulation for all requirements and associated details:
https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm

Saleable Returns by the Numbers*

Annual Saleable Returns - Unit Volume:

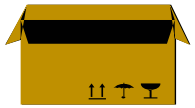
~59 Million Units

2-3% of total sales are saleable returns

Annual Saleable Returns - Return Lines:

~31 Million Lines

Weekly / Daily Breakdown



~1.1 Million Units / Week

~226K Units / Day

Peak # Saleable Returns Units/Day for DC:

4,500 Units

Peak # Saleable Returns Units/Day for Large DC:

10,000 Units

- Large Distributor Annual Volume: **~19 million**
- Avg. Distributor Annual Volume: **~475 thousand**
- Large Generic Manuf. Annual Volume: **~2 million**
- Large Branded Manuf. Annual Volume: **~1.8 million**
- Average Manuf. Annual Volume: **~90 thousand**

Distributor Landscape**

Companies: 34

Facilities: 203

**Source:
HDA 2016 Factbook

*Data is based on returns processed by participating wholesale distributors November 2014 - October 2015

Why a Router Service model?

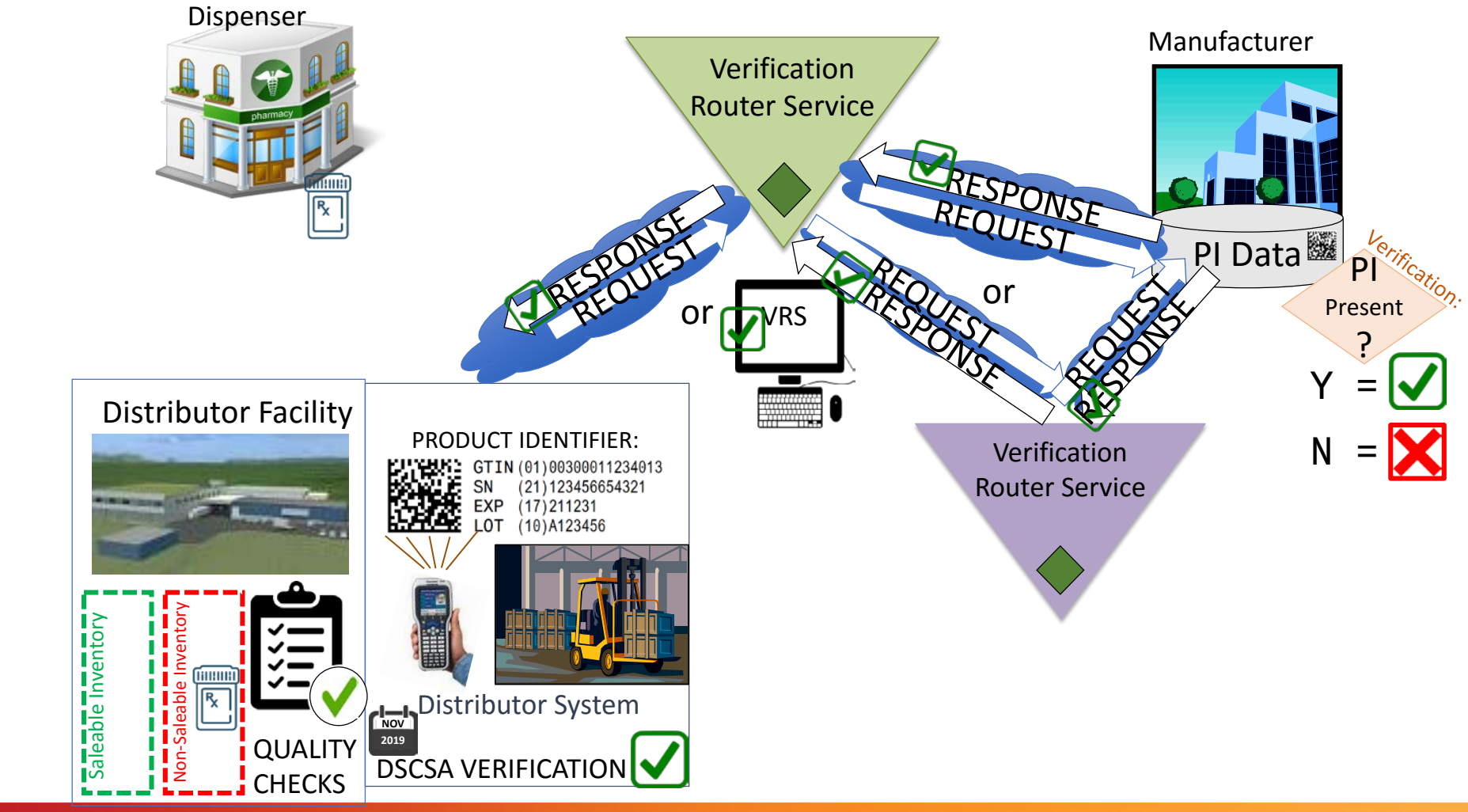
Quality / Compliance	Speed / Time	Cost
Accuracy	Data Access / IT Availability	Physical Space Considerations
Risk / Security	Governance	Solution Complexity / Scalability

Options assessed: 2016 Returns Pilot:

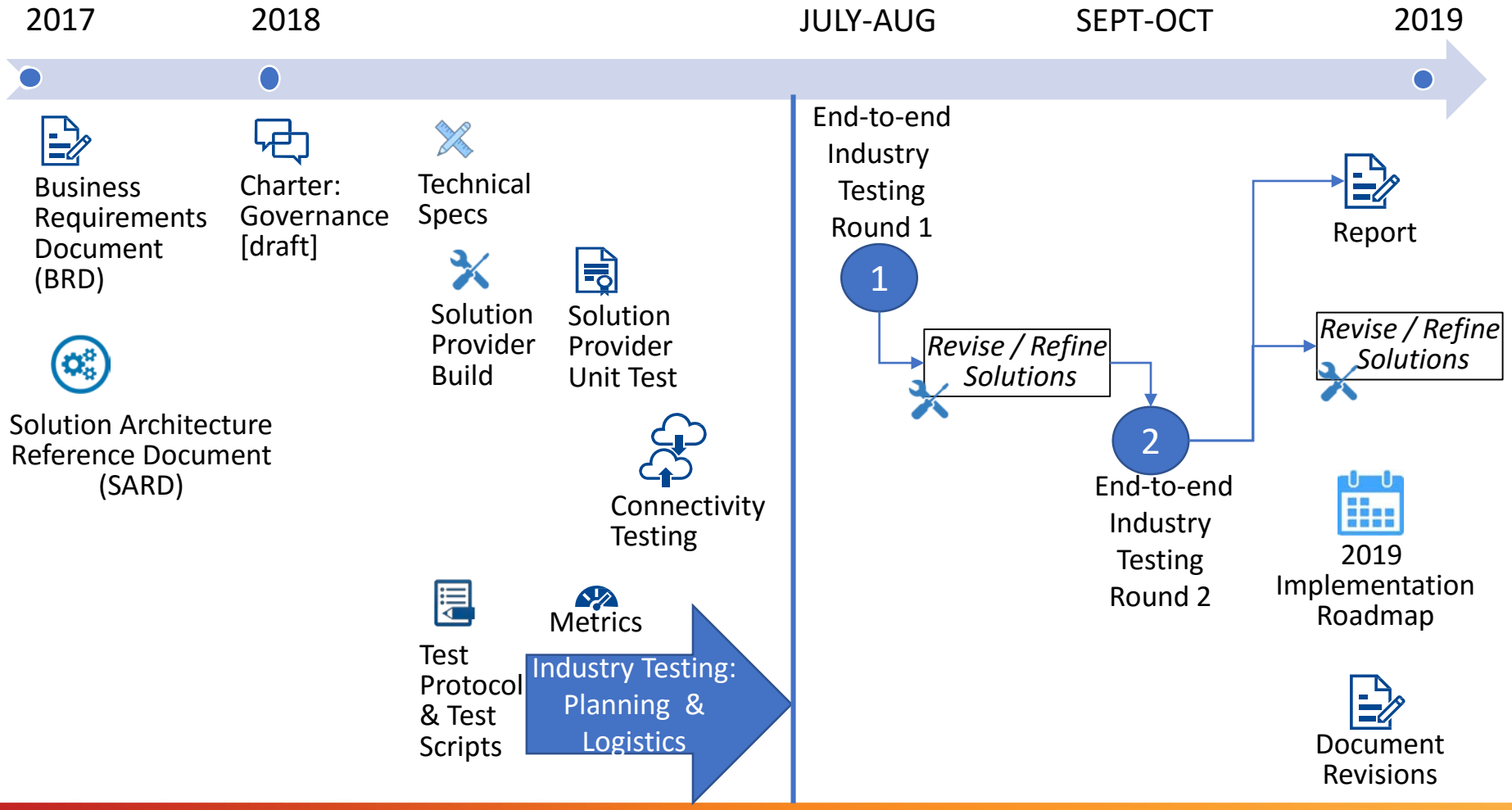
1. **Manufacturer scans PI at time of shipment and sends data to trading partner***
2. Manufacturer sends all PI to all direct trading partners
3. Manufacturer sends PI to central database
4. Distributor scans inbound
5. Distributor scans outbound
6. Distributor point-to-point interface with each Manufacturer
7. Distributor uses Manufacturer-provided portal
8. Distributor contacts Manufacturer (e.g. phone, e-mail)
9. **Router Service**

* most manufacturers / 3PLs are not ready to send PI data before 2019

How will it work?



Update and planned activities



Call to Action

Distributors	• Determine level of integration required with your internal systems. Consider factors such as return volume and frequency. • Conduct discussions with your trading partners – mutually understand the impact and the planned solution. • Continue testing and implementing receipt of serialized PI data from the manufacturer / manufacturer 3PL as they become capable.
Manufacturers	• Know your products and your responsibilities, *i.e.* co-licensing, divestiture – who is on point to respond to verification requests? • Talk to your solution provider and understand their plans and capabilities, *i.e.* how will they be supporting industry with meeting verification requirements? • Conduct discussions with your trading partners – mutually understand the impact and the planned solution.
Solution Providers	• Clearly define and communicate the scope of your solution moving forward: a) to create/route verification requests/responses; b) to accept requests and respond as manufacturer's serial number repository; or c) to support both • Update your product roadmap - does it align to the timeline for testing and ultimately production readiness? • Meet with your current customers to confirm their needs and share your plans.

Acknowledgements

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>50 companies engaged in this effort !

Your questions & comments