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.
<table>
<thead>
<tr>
<th>DSCSA Requirement:</th>
<th>Stakeholder:</th>
<th>Timing:</th>
<th>Impact Level:</th>
</tr>
</thead>
<tbody>
<tr>
<td>582 (b)(4)(A)</td>
<td>Manufacturer</td>
<td>27-Nov-2017</td>
<td>Low</td>
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<tr>
<td>▪ Suspect Product Investigation</td>
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<tr>
<td>582 (b)(4)(C)</td>
<td>Manufacturer</td>
<td>27-Nov-2017</td>
<td>Low-Med</td>
</tr>
<tr>
<td>▪ Verification Requests</td>
<td></td>
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<tr>
<td>582 (b)(4)(E)</td>
<td>Manufacturer</td>
<td>27-Nov-2017</td>
<td>Low</td>
</tr>
<tr>
<td>▪ Manufacturer Saleable Returns</td>
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<td></td>
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582 (b)(4)(A)     | Repackager | 27-Nov-2018 | Low         |
| ▪ Suspect Product Investigation | | | |
| 582 (b)(4)(C)     | Repackager | 27-Nov-2018 | Low         |
| ▪ Verification Requests | | | |
| 582 (b)(4)(E)     | Repackager | 27-Nov-2018 | Low         |
| ▪ Manufacturer Saleable Returns | | | |

582(c)(4)(A)     | Distributor | 27-Nov-2019 | Low         |
| ▪ Suspect Product Investigation | | | |
| 582(c)(4)(D)     | Distributor | 27-Nov-2019 | High        |
| ▪ Distributor Saleable Returns Requirement | | | |

582(d)(4)(A)     | Dispenser   | 27-Nov-2020 | Low         |
| ▪ Suspect Product Investigation | | | |

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

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

Distributor Landscape**
Companies: 34
Facilities: 203

**Source: HDA 2016 Factbook
Why a Router Service model?

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

<table>
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<tr>
<th>Quality / Compliance</th>
<th>Speed / Time</th>
<th>Cost</th>
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<tbody>
<tr>
<td>Accuracy</td>
<td>Data Access / IT Availability</td>
<td>Physical Space Considerations</td>
</tr>
<tr>
<td>Risk / Security</td>
<td>Governance</td>
<td>Solution Complexity / Scalability</td>
</tr>
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</table>
How will it work?

**Dispenser**

**Distributor Facility**

**Verification Router Service**

**Manufacturer**

**Distributor System**

**QUALITY CHECKS**

**PRODUCT IDENTIFIER:**
- GTIN (01)00309011234013
- SN (21)12345654321
- EXP (17)211231
- LOT (18)A123456

**Non-Saleable Inventory**

**Saleable Inventory**

**DSCSA VERIFICATION**

**Verification Router Service**

**PI Data**

**PI**

**Verification:**
- Y = ✔️
- N = ✗

**Present**

**NOV 2019**
Update and planned activities

2017 - 2018

- Business Requirements Document (BRD)
- Solution Architecture Reference Document (SARD)

2018

- Charter: Governance [draft]
- Technical Specs
- Solution Provider Build
- Solution Provider Unit Test
- Connectivity Testing
- Test Protocol & Test Scripts

JULY-AUG

1. End-to-end Industry Testing Round 1
   - Revise / Refine Solutions

SEPT-OCT

2. End-to-end Industry Testing Round 2
   - Revise / Refine Solutions

2019

- 2019 Implementation Roadmap
- Document Revisions
## 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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Cognizant Technology Solutions
CVS Health
Eisai, Inc.
Endo/PAR Pharmaceuticals
Excellis Health Solutions
Fresenius Kabi
Genentech
Gilead Sciences, Inc.
GlaxoSmithKline
GS1 US
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Sandoz
Sanofi US
SAP SE
Smith Drug Company
Sunovion Pharmaceuticals Inc.
Systech International
TraceLink Inc.
Value Drug Company
ValueCentric, LLC

>50 companies engaged in this effort!
Your questions & comments