RESOURCES

Mutual Drug Q&A: Understanding Saleable Returns and Verification

If you're a wholesale distributor or manufacturer, November 2019 is going to introduce daunting operational changes with the Drug Supply Chain Security Act (DSCSA) Saleable Returns Verification requirement.

To learn what wholesale distributors are doing now to prepare for saleable returns, TraceLink talked with Andy Meyer, Senior Systems Analyst/Traceability Lead at North Carolina Mutual Wholesale Drug Company. Meyer, who has over 17 years of experience in IT in the pharmaceutical distribution industry, has been involved in track and trace serialization since 2006.

We asked how Mutual Drug, who has been working with TraceLink for DSCSA compliance since 2014, is preparing for saleable returns and learned about the serialization and verification challenges faced by wholesale distributors and manufacturers alike.

How do saleable returns factor into today's wholesale distributor operations?

Saleable returns consistently account for between 2 and 2.5 percent of our sales. It's important to be able to turn around and get that product back out so that we can sell it. Most distributors run with a fairly thin inventory, or as thin as we can,

which means that if we have products that we're counting on, we need to factor in returns. If we can’t resell those products, that creates a problem on our side. Plus, it’s important for us to be able to have the product whenever our customers need it.

What are some of the things that trigger a saleable return? Why would you get product back?

When products are discontinued from our catalog, customers start to return them for credit in order to buy and carry the new product line instead.

The other common reason for a saleable return is that a pharmacy enters an order and, instead of asking for 10 bottles, they accidentally order 100, so they send back the 90 bottles that they didn't need.

From an internal operations perspective, how will the next level of the DSCSA requirements affect Mutual Drug?

Once 2019 hits, with the verification requirement, our plan is to scan everything on our outbound sales and record that data, so that whenever we receive that product back, we can verify that we indeed shipped it. Because we purchase directly from trusted sources, the chance for counterfeiting is very low, so we are using the data that was supplied by the manufacturer in the barcode—which we stored in our database during the pick quality control process—to verify our saleable returns.

What challenges are wholesalers going to face with 2019?

The biggest challenge that every wholesaler will face is to have some version of a database to verify serialization. In some form or fashion, they're going to need a way to know what serial numbers they have, whether it be API calls to TraceLink or whether or not they build a database internally.

The other reason that people are going to need a database is once we get to the

actual 2023 DSCSA requirements, you can only sell what you're supposed to have. Right now, you can only take returns on what you've had, and on good product. However, in the future, you can only sell what you've been told that you've been given.

What is the manufacturers' role in the saleable returns verification challenge?

The biggest thing that would help wholesale distributors and manufacturers work together to meet the requirement would be a verification routing service (VRS) system.

Without a VRS, we would need to plug into APIs on each manufacturer's enterprise resource planning (ERP) system or connect via email, web portal, or a phone call. The thought of that is frustrating because if everybody goes that way, we're now going to have 300 to 400 connections that we have to maintain and monitor, and that isn't viable.

What is the role of a Verification Routing Service in saleable returns verification?

My thought process is that I would like to verify every product whenever I touch a saleable unit in my warehouse. We would be doing this because we won't be scanning on receipt of a product—and we do not want to find any erroneously aggregated product during pick QC. Instead, we would prefer to find it well ahead during replenish or cycle counting when we have more time to take appropriate action. This becomes realistic if you have something like a VRS. If you have to reach out and manually ping a manufacturer, it becomes less realistic. A VRS would make verification very easy to do if it could have close to sub-second response.

What capabilities should a VRS have?

I would like some intelligence built into a red light/green light model that provides multiple reasons for a red light. For example, there's a difference between a red light that's issued from a recall and one because we know that a product was stolen.

Once we become serialized, or even before, manufacturers should have an idea of where their lots are going. That way, if a semi-trailer is lost, they'll know the products on that truck could be tampered with or stolen.

Once they know that a set of products is gone, there's no reason why those products should be back into the marketplace, unless somebody sold it that is a bad actor. In that scenario, you do want to give a red light and kick off an investigation.

Why is product master data so critical in verification of all kinds but especially in saleable returns?

For verification, we have to have a way to discern that we have the right GTIN [Global Trade Item Number] for the right packaging, aligned with the product line. Accurate, up-to-date product master data is crucial because it holds the data set that is needed to create the product transaction information to be sent downstream, as well as providing the key in the form of the GTIN that will allow us to connect SNI [Standardized Numerical Identifier] information to a specific NDC [National Drug Code] in our possession.