HDA DSCSA Exceptions Handling Guidelines & PDG Root Causes

DSCSA efficient exception management has been and remains a tough target across the supply chain. As ever, the devil's in the details.

As the supply chain moves toward 2025 compliance, the mandatory interoperable exchange of serialized data adds significant complexity to sector operations due to instances with a mismatch between data quality and product.

TraceLink's 2023 benchmarking survey revealed that exception management SOPs showed the lowest level of preparedness. Only 25% of health systems and 39% of retail pharmacies had these SOPs "well underway."

PDG, HDA, and GS1 have been leaders in addressing challenges of exception handling. PDG, HDA, and GS1 jointly hosted an Exception Handling Workshop on February 6-7, 2023 in Washington, DC, which I attended. They collaborated to create a workshop report that summarizes the discussions and action items from the workshop. Please, feel free to share this report, which can be found on PDG's website, within your organization.

In 2023, HDA published its Exceptions Handling Guidelines document, prepared by technical experts of the HDA Exceptions Handling Work Group. These guidelines were developed to address exceptions that may arise when passing or failing to pass DSCSA-required transaction information and transaction statement data to authorized trading partners. Scenarios covered in the guidelines document focus on five categories of transactions:

- Data issue
- Product no data
- Data no product
- Packaging and labeling
- Unavailable for distribution

In 2024, HDA also created its "DSCSA Exceptions Handling Communication Guide," an addendum to its guidelines to clarify communications around DSCSA exception incidents between trading partners. It's based on evolving DSCSA understanding of requirements, providing recommendations on what should be communicated during certain exceptions, including example use cases and sample messages.

In 2024, PDG convened a workgroup to discuss root causes of the issue and craft an educational document, titled "Exception Root Cause Document." On Sept. 5, 2024, PDG emailed members and stakeholders an educational resource to aid individual companies to "consider the root causes of misalignment exceptions" and how they fit into the broader misalignment handling process. The Exception Root Cause Document is specifically and narrowly focused on the root causes of misalignment exceptions, not the handling of misalignment exceptions once they occur. Those root causes stem from individual business practices — people, processes, and technology.

The solution providers (e.g. TraceLink, Systech, rfxcel, and others) are also focused on creating effective work management systems for DSCSA compliant exception handling and exception management by manufacturers.

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