



## PDG Point of View on Communications and Corrective Actions Between Trade Partners

### Introduction:

In today's interconnected global economy, effective communication and collaboration between trading partners is crucial for ensuring smooth supply chain operations. However, issues and exceptions can arise that require prompt resolution to maintain efficiency and prevent disruptions. Requirement-Ser-026 of Chapter 1 of the PDG *Blueprint* requires that each trading partner have systems and processes in place to identify, understand, and resolve misalignment exceptions. This document provides a set of recommendations for trading partners to enhance their communication and implement corrective actions in meeting that requirement.

### Issue Analysis:

#### **1. Develop a mutual understanding of the issue:**

When an exception occurs, it is essential for trading partners to establish a common understanding of the problem. Clear and concise communication, including the sharing of relevant information, helps avoid misunderstandings and promotes efficient problem-solving.

##### **Consider if data latency is the root cause of product, no data:**

Product, no data issues can occur in situations where a Supplier's shipping point is near the ship-to location or because of data latency issues. Consider moving to real-time processing, and more frequent integration of processing systems.

##### **Consider if the product is under a Waiver, Exemption, or Exception:**

Consult with the supplier of the product to determine if the product is part of a Waiver, Exemption, or Exception. If the product is part of a Waiver, Exemption, or Exception, communicate the product status to downstream trading partners.

#### **2. Consider if multiple exceptions are part of the same overall issue:**

Sometimes, multiple exceptions might be interconnected, indicating an underlying systemic problem. It is important to identify and analyze such patterns to address the root cause effectively rather than treating each exception in isolation.

#### **3. Determine the impact of the issue:**

Understanding the impact on customer satisfaction, regulatory compliance, and overall supply chain performance helps allocate appropriate resources and attention. Assessing the potential challenge associated with an issue is crucial for prioritizing corrective actions.

#### **4. Distinguish between records issues and product-related issues:**

Differentiate between data/no product, product/no data exceptions, which primarily



impact records, and physical product (ex: damaged or incorrect labeling and packaging) issues, which can be caught during receiving/pick/pack processes. This distinction allows for a more targeted and efficient approach to resolving each type of exception.

**5. *Isolate data in error from verification or tracing functions:***

To prevent data discrepancies, it is important to differentiate TI/TS exchange erroneous data from functions such as product verification or tracing. This helps avoid confusion and ensures accurate information is utilized for decision-making.

**6. *Determine the root cause of the issue:***

To mitigate the reoccurrence of the issue, identify the factors, conditions, and precise cause of a particular problem. Rather than settling for reactive, quick fixes, root cause analysis investigations dig deep into the systematic issues below the surface to find permanent solutions and prevent the issues from occurring.

**7. *Assess system capabilities:***

Evaluate the capabilities of the seller and buyer systems involved in the supply chain process. Determine if both systems are capable of handling the corrective actions or if additional system integration is required. Adjustments to individual systems may be necessary to ensure a smooth implementation for seller systems to apply corrective actions internally, communicate and send corrections in a standardized interoperable manner and for buyer systems to accept and process the corrective actions received.

**Corrective Actions<sup>1</sup>:**

**1. *Address future shipments and duplicates:***

When correcting an issue, it is essential to adjust systems to prevent future shipments from being affected by the same error. Additionally, duplicate records or data should be appropriately flagged or removed to maintain data integrity and avoid confusion.

**2. *Decide on the path to correction:***

Once the risks are identified, trading partners must collaborate to determine the required corrective actions. This may involve evaluating alternative solutions, considering cost implications, and selecting the most effective path forward.

**3. *Review corrective actions:***

Before accepting and applying corrective events, trading partners should thoroughly review them to ensure they address the identified issues effectively. This step helps prevent further complications and ensures that the proposed corrections align with the desired outcomes.

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<sup>1</sup> **Corrective Actions:** Action taken to eliminate the causes of existing non-conformities or other undesirable situations, to prevent recurrence.



#### **4. *Retain issue/solution documentation:***

Maintaining comprehensive documentation of the identified issues and implemented solutions is crucial for future reference. This documentation serves as a valuable resource for analyzing trends, identifying recurring problems, and involving additional trading partners if necessary<sup>2</sup>. Documenting issue resolution helps in ensuring that the resolution of the same root cause issues is consistent in the future and saves considerable effort.

### **Preventative Actions<sup>3</sup>:**

#### **1. *Periodic review of processes in place:***

Regularly reviewing processes to determine if processes aren't meeting planned requirements, and assessing these shortcomings could point out systemic problems. This includes internal audits and customer audits, as well as certification audits.

#### **2. *Periodic review of data:***

Regularly reviewing and archiving aged or obsolete data from the system is important for maintaining data accuracy and system performance. Additionally, observations made during the receiving process can help identify concealed items or anomalies that require attention.

#### **3. *Utilize standard EPCIS events:***

Electronic Product Code Information Services (EPCIS) events provide a preferred standardized framework for capturing and sharing supply chain data. Trade partners should leverage these events when possible to ensure consistent and interoperable communication between their systems. Exception corrections should adhere to EPCIS event standards as defined by GS1 implementation guidelines for DSCSA and DSCSA exception management.

### **Conclusion:**

Effective communication and swift corrective actions are essential for smooth collaboration between trade partners. By developing a mutual understanding of the issues, utilizing standardized events, and making necessary system adjustments, trade partners can ensure the integrity of their supply chains. Regular clean-up of data and distinguishing between records issues and product-related risks further contribute to a robust and efficient supply chain ecosystem. By implementing these best practices, trade partners can strengthen their relationships, enhance operational efficiency, and mitigate potential disruptions in the supply chain, ultimately leading to improved customer satisfaction and overall patient safety.

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<sup>2</sup> See FDA "[Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act](#)" (currently draft Guidance).

<sup>3</sup> **Preventative Actions:** Action taken to prevent potential problems, generally because of a risk analysis.