



Guideline to Support Interoperability in Notifying Trading Partners of Identified Exceptions

Misalignment exceptions—instances when there is a misalignment between the physical supply chain and data associated with it—are an inevitable part of DSCSA interoperability. As FDA has acknowledged in multiple joint forums with PDG, data perfection is not expected given the required volume and granularity of data.¹ Rather, it is critical to have risk-based processes for managing the expected exceptions.

To that end, the PDG Blueprint requires trading partners to implement systems and processes to identify,² understand,³ and resolve,⁴ misalignment exceptions. This Guideline document is intended to support interoperability in the process by which one trading partner notifies another trading partner that a misalignment exception has been identified. This Guideline recognizes and builds upon the Healthcare Distribution Alliance’s [Exceptions Handling Guidelines For The DSCSA](#) and its [DSCSA Exceptions Handling Communication Guide](#) by providing a complementary message structure to support interoperability.

Benefits of Interoperable Notification

Greater standardization and interoperability in notifying trading partners of misalignment exceptions offer multiple benefits to the supply chain.

1. **Complete information speeds resolution.** Providing complete information in the initial notice of a misalignment exception reduces the initial back-and-forth between trading partners and allows them to rapidly move on to understanding and resolving the exception.
2. **Consistent information enables more efficient processing.** When notification information is provided consistently, the recipient can more efficiently receive the notification and move on to understanding and resolving the exception.
3. **Structured data supports the identification of trends and root causes.** Varying terminology across notifying parties limits the recipient’s ability to aggregate notifications and identify trends and patterns, supporting the identification and addressing of exceptions’ root causes. A structured message—most notably, defined exception categories and types—enables such continuous improvement activities.

¹ <https://dscsagovernance.org/wp-content/uploads/2025/04/2025-PDG-FDA-Manufacturer-Town-Hall-Summary-FINAL.pdf>

² Identify means a trading partner identifies that a misalignment exception exists.

³ Understand means the trading partner that identifies the misalignment exception, in coordination with its trading partners, will take various steps to understand the cause of the misalignment exception, specifically whether the misalignment exception is the result of a data error or reflects the presence of a suspect/illegitimate product.

⁴ Resolve means the trading partner that identifies the misalignment exception takes steps to address the exception.



Guideline Limitations

This Guideline is limited to notifying that a misalignment exception has been identified. It does not address the back-and-forth communication that is often necessary to understand the exception and its cause or the communication necessary to resolve the exception.

It is also important to note that this Guideline is not mandatory and is intended to support *movement toward* interoperability in the notification process.

- This Guideline provides a starting point for greater interoperability in the notification process for trading partners still early on their DSCSA journey.
- For those trading partners with established notification systems and processes, it is recognized that revisions to those systems and methods are not anticipated in the near term. However, this Guideline can support migration toward greater interoperability in the long term.

Along with this Guideline, PDG is making available multiple templates and standardized messages that can be used to support its implementation. These templates and messages may be helpful to certain trading partners, but they are not the only way this guideline can be implemented. For example, the structured message in this Guideline can be incorporated into the text of a basic email message.




Using this Guideline⁵

The Exception Notification message defined in this Guideline is intentionally flexible, with many fields designated as optional. This allows trading partners to tailor the information provided to support their specific operational needs and relationships.

To effectively implement this Guideline:

1. **Engage with Your Trading Partner**
Review the Exception Notification message together. Identify which optional fields are relevant and beneficial for your business relationship and exception resolution processes.
2. **Select and Standardize the Fields You Will Use**
Choose a consistent subset of fields—including optional ones—that will:
 - Improve the clarity and completeness of your notifications.
 - Reduce delays by minimizing the need for follow-up.
 - Support data alignment between partners.
3. **Incorporate Selected Fields into Your Notifications**
Using email, system-generated messages, or a structured data exchange, consistently apply the selected fields across all notifications to streamline interpretation and response.
4. **Use the Field List as a Reference Tool**
When preparing or reviewing a notification, consult the complete field list in this Guideline to determine if additional context may aid in resolution. Include clarifying details in the Exception Description or attach supporting documents if needed.

⁵  **Note:** This Guideline is not prescriptive. It is designed to support increased interoperability while respecting each organization's operational maturity and system constraints.



Structured Message for Notification

The following table summarizes the PDG structured message attributes for notification of a misalignment exception. The structure strives to keep the **required fields** as light as possible while providing the information to enable the trading partners to move efficiently to the more manual, back-and-forth engagement necessary to understand and resolve the exception. This table also identifies the related data element in the HDA Exceptions Handling Guidelines for the DSCSA that is being standardized. Additional details for each attribute follow this summary.

| PDG Notification Message Element | Required or Optional | Corresponding HDA Guideline Element |
|---|----------------------|-------------------------------------|
| General Organization Information | | |
| Notification ID | Required | N/A |
| Date, Time | Required | N/A |
| Notifying Organization Information | | |
| Notifying Organization Name | Required | |
| Contact Information | | |
| Person or Department Name | Required | Contact info (name/email/phone) |
| Organization Name | Required | Contact info (name/email/phone) |
| Phone | Required | Contact info (name/email/phone) |
| email | Required | Contact info (name/email/phone) |
| Notifying Organization GLN | Optional | N/A |
| Notified Organization Information | | |
| Notified Organization | Required | N/A |
| Notified Organization GLN | Optional | Source owning/location GLNs |
| References for this exception | | |
| Incident ID | Optional | N/A |
| Purchase Order Numbers | Optional | PO Number |
| Shipment ID | Optional | Delivery #/Shipment ID/DESADV |
| Shipment Receipt Date | Optional | N/A |
| Carrier Tracking Number | Optional | Carrier tracking number |
| Exception Location (where the exception was identified) | Optional | Where/when the exception occurred |
| Receiving Location Name | Optional | N/A |
| Receiving Location Address | | |
| Street 1 | Optional | Ship-to address if GLN is not known |
| Street 2 | Optional | Ship-to address if GLN is not known |



| PDG Notification Message Element | Required or Optional | Corresponding HDA Guideline Element |
|---|----------------------|---|
| City | Optional | Ship-to address if GLN is not known |
| State, Province or Region | Optional | Ship-to address if GLN is not known |
| Postal Code | Optional | Ship-to address if GLN is not known |
| Country Code | Optional | Ship-to address if GLN is not known |
| Receiving Location GLN | Optional | Destination owning/location GLNs or ship-to address if GLN is not known |
| | | |
| Exceptions (repeat for each exception) | | |
| Exception Line Number | Required | N/A |
| Exception Description | Required | Body of text |
| Buyer Supplied Information (Buyer-to-Seller notification) | | |
| Buyer Resolution Request | Optional | N/A |
| Buyer Action Taken | Optional | N/A |
| Seller Supplied Information (Seller-to-Buyer notification) | | |
| Seller Resolution Request | Optional | N/A |
| Seller Action Taken | Optional | N/A |
| Exception Category | Optional | Exception category |
| Exception Type | Optional | N/A |
| Exception Applies To | Optional | Scope of exception |
| Exception Priority | Optional | N/A |
| Exception Status | Optional | N/A |
| Information on the Physical Product | | |
| SSCC | Optional | SSCC-18 (00) as applicable |
| GTIN | Optional | GTIN |
| NDC | Optional | NDC(s) involved in the exception |
| Product Name | Optional | Product description |
| Lot Number | Optional | Batch |
| Serial Number | Optional | Serial Number |
| Expiration Date | Optional | Expiry |
| Barcode Scan | Optional | N/A |
| Notes | Optional | N/A |
| Data (EPCIS) Received | | |
| SSCC | Optional | SSCC-18 (00) as applicable |
| GTIN | Optional | GTIN |
| NDC | Optional | NDC(s) involved in the exception |
| Product Name | Optional | Product description |



| PDG Notification Message Element | Required or Optional | Corresponding HDA Guideline Element |
|---|-----------------------------|--|
| Lot Number | Optional | Batch |
| Serial Number | Optional | Serial Number |
| Expiration Date | Optional | Expiry |
| Notes | Optional | N/A |
| | | |
| Additional Information | | |
| Document Links | Optional | N/A |
| Documents Attached | Optional | N/A |



The PDG structured message for notifying a trading partner that a misalignment exception has been identified includes the following attributes.

General

Exception Notification ID (required)

Description: The notifying party assigns a unique ID to the notification.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Notification Date (required)

Description: The date the notification was created.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Notifying Organization Information

Notifying Organization Name (required)

Description: Name of the organization making the exception notification.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Notifying Organization Contact Information (required)

Description: Contact information is provided to the notified organization so that they can follow up with questions or find a resolution.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Includes:

- *Person or Department Name*
- *Organization Name*
- *Phone Number*
- *Email Address*

Notifying Organization GLN (optional)

Description: The GLN of the organization making the exception notification.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.



Notified Organization Information

Notified Organization Name (required)

Description: Name of the organization receiving the exception notification.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Notified Organization GLN (optional)

Description: The GLN of the organization receiving the exception notification.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

References

Incident ID (optional)

Description: A unique ID assigned to the incident by the notifying organization.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Purchase Order (optional, allow multiple)

Description: Purchase order numbers associated with the shipment.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Shipment ID (optional)

Description: Shipment ID from the shipment papers.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Shipment Receipt Date (optional)

Description: Date the shipment was received by the buyer.

Used in: Buyer-to-Seller Exception Notifications.

Carrier Tracking Number (optional)

Description: The tracking number assigned by the carrier.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Exception Location (optional)

Description: The location where the exception was identified in the notifier's operation.

Used in: Buyer-to-Seller Exception Notifications.

**Includes:**

- *Receiving*
- *Outbound Picking*
- *Returns Processing*
- *Reconciliation*
- *Other*

Receiving Location Name (optional)

Description: Name of the location where the product was received or was to be received (data no product).

Used in: Buyer-to-Seller Exception Notifications.

Receiving Location Address (optional)

Description: Address of the location where the product was received or was to be received (data no product).

Used in: Buyer-to-Seller Exception Notifications.

Includes:

- *Street Address Line 1*
- *Street Address Line 2*
- *City*
- *State Province or Region*
- *Postal Code*
- *Country Code*

Receiving Location GLN (optional)

Description: Global Location Number of where the product was received or was to be received (data no product).

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Exceptions (allow multiple)**Exception Line Number (required)**

Description: The reference number allows the buyer and seller to reference information in subsequent communications.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.



Exception Description (required)

Description: Documentation of issues observed by the notifier about the shipment, product, or information provided by the seller.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Buyer Supplied Information (optional)

Description: This data can be used when a buyer notifies a seller of an exception.

Used in: Buyer-to-Seller Exception Notifications.

Buyer Resolution Requests (optional, allow multiple)

Description: Preferred resolution outcomes if the notifier is the buyer.

Used in: Buyer-to-Seller Exception Notifications.

Includes:

- *Credit Account*
- *Debit Account*
- *Return Product*
- *Send Corrected Data*
- *Send Product*
- *Other*

Buyer Actions Taken (optional, allow multiple)

Description: The buyer has already acted due to the exception.

Used in: Buyer-to-Seller Exception Notifications.

Includes:

- *Product has been returned*
- *Shipment has been refused*
- *Other*

Seller Supplied Information (optional)

Description: This data can be used when a seller notifies a buyer of an exception.

Used in: Seller-to-Buyer Exception Notifications.



Seller Resolution Requests (optional, allow multiple)

Description: Preferred resolution outcomes if the notifier is the seller.

Used in: Seller-to-Buyer Exception Notifications.

Includes:

- *Send Back Product*
- *Other*

Seller Actions Taken (optional, allow multiple)

Description: The seller has already acted due to the exception.

Used in: Seller-to-Buyer Exception Notifications.

Includes:

- *Credit Applied*
- *RMA Sent*
- *Other*

Exception Applies To (optional)

Description: The shipment level to which the exception applies.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Includes:

- *Entire Shipment*
- *Items in Shipment*
- *Other*

Exception Category (optional)

Description: The exception category the notifying organization has assigned to the exception.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Includes:

- *Damaged Product*
- *Data Issue*
- *Data, No Product*
- *Packaging and Labeling*
- *Product, No Data*
- *Other*



Exception Type (optional)

Description: The exception type the notifying organization has assigned to the exception. Provides further detail to the category.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Includes:

- *Barcode Reading Issue*
- *Barcode Encoding Issue*
- *Certificate Issue*
- *Duplicate EPCIS Events*
- *EPCIS Event Formatting Issue*
- *EPCIS Event Timestamp Sequence*
- *Missing Attributes*
- *Missing EPCIS Events*
- *Unrecognized Buyer GCP and/or GLN*
- *Unrecognized Seller GCP and/or GLN*
- *Unrecognized Product Information*
- *Unrecognized Seller*
- *Unrecognized Buyer*
- *Unrecognized P.O. #*
- *Other*

Exception Priority (optional)

Description: The priority the notifying organization has assigned to the exception.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

- *High*
- *Medium*
- *Low*
- *Other*

Exception Status (optional)

Description: The status the notifying organization has assigned to the exception.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Includes:

- *Cancelled*
- *Closed*



- *In Progress*
- *In Review*
- *Open*
- *Pending Response*
- *Resolved*
- *Other*

Physical Product Information (optional)

Description: The information found on the shipment or product by the notifier can be provided for product-no-data exceptions or when there are issues with the data found on the product.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Includes:

- *SSCC*
- *GTIN*
- *NDC*
- *Product Name*
- *Lot Number*
- *Expiration Date*
- *Serial Numbers*
- *Bar Code Scans*
- *Notes*

Information Sent or Received (optional)

Description: The information found in the DSCSA Transaction Identification (TI) can be provided for data-no-product exceptions or when there are issues with the data found in the TI.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Includes:

- *SSCC*
- *GTIN*
- *NDC*
- *Product Name*
- *Lot Number*
- *Expiration Date*
- *Serial Numbers*
- *Notes*



Additional Information (optional)

Document Links (optional, allow multiple)

Description: The location of documents the notifier wishes to share with the notified organization. Examples are shipping documents, products, or shipment photos.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.

Documents Attached (optional, allow multiple)

Description: The names of documents the notifier has included with the exception notification. Examples are shipping documents, products, or shipment photos.

Used in: Seller-to-Buyer and Buyer-to-Seller Exception Notifications.