



## Managing DSCSA Exceptions using POET

**tracelink**<sup>®</sup>  
NETWORK FOR GREATER GOOD

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## Introduction to POET

### Learning Objective

This course introduces Process Orchestration for Empowered Teams (POET) for handling DSCSA compliance exceptions. After completing this course you will be able to:

- Understand POET and its Framework.
- Explain how POET supports DSCSA compliance exceptions.
- Identify methods to capture compliance exceptions.
- Use Email integration for exception handling.
- Use SOM integration in exception handling.

### Overview

POET manages business processes and emphasizes, collaboration, visibility, and adaptability. It empowers teams to make decisions and drive outcomes.

Instead of relying on rigid, top-down workflows, POET coordinates people, systems, and data across departments in real time.

When applied to empowered teams, it means:

- Teams have ownership over their part of the process.
- The process is transparent, so everyone knows the current state, blockers, and responsibilities.

### Where POET fits into the OPUS Platform

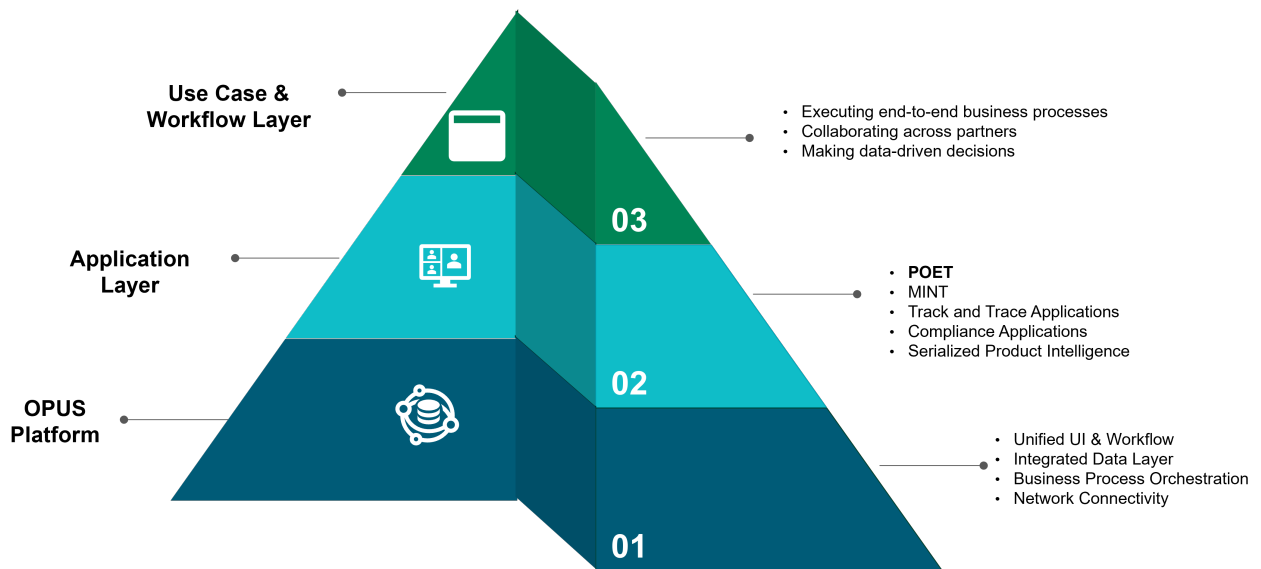
OPUS is TraceLink's platform to build and manage digital supply networks.

POET, on the other hand, is a purpose-built application on the OPUS platform, just like other applications such as MINT. What makes POET unique is that it comes with a powerful embedded orchestration engine and methodology that brings supply chain processes to life.

It brings structure, ownership, and agility to processes that span multiple teams and systems. It empowers teams to:

- Design and own their part of the process
- Collaborate seamlessly
- Continuously improve based on real-time data

The following pyramid illustrates the relationship between OPUS, applications, and use cases.



1. The bottom layer is the OPUS platform. This is the foundation of TraceLink’s digital supply network. It provides the infrastructure, data integration, and orchestration across the network.
2. The middle layer is the application layer, in which solutions are built on OPUS. These applications are built to solve specific business problems. POET, SOM, and MINT are such applications.
3. At the top of the pyramid are the real-world use cases and business processes executed by end-users. These workflows are powered by the applications and orchestrated using capabilities like those provided by POET.

## POET Process Orchestration Framework



### Role-based Responsibilities and Visibility

POET emphasizes clarity, collaboration, and accountability rather than rigid control. Two critical roles in this framework are the Process Owner and the Process Partner.

The POET Owner is the individual or team that owns the POET application and, by extension, owns the process network defined within it. POET Owners own process performance, governance, and design.

POET Owners are responsible for:

- Configuring the process network in POET
- Linking with external or internal POET Partners to enable collaboration

The POET Partner is an invited collaborator within the process network. They are typically from another company or business partner and are responsible for executing specific parts of the process as defined by the POET Owner.

POET owner links to a partner (such as a supplier or quality team) to complete their designated tasks or approvals.

POET Partners:

- Contribute domain expertise to the process
- Execute assigned tasks or deliverables
- Provide real-time feedback and raise risks or blockers
- Suggest improvements based on their operational perspective

In terms of visibility:

- POET Owners have full end-to-end visibility into the process network including all participating partners, task statuses, performance metrics, and exception trends.
- POET Partners have focused visibility. They see only the tasks and data relevant to their role, but can contribute to the overall process through collaboration and

feedback.

## **Partner Onboarding**

POET owners create links with their partners in order to collaborate with the partners on compliance exceptions.

There are typically 3 steps involved in the process:

### **Step 1: Check if the partner already exists in Partner Master Data. Add the partner if they are not there.**

- Add the partner in Partner Master Data and make sure to include a global identifier such as a DEA, DUNS, HIN, or GLN.
- This identifier is essential to establish a unique and traceable connection between systems.

### **Step 2: Create the POET Link in OPUS Admin**

Navigate to OPUS Admin to establish a POET link with the partner.

- Use the same global identifier from Step 1 (typically a GLN).
- Assign the role 'Partner Member' to this link.
- This role enables the partner to interact with the owner's POET instance.

**Note:** After creating the POET link, a partner administrator must add specific users to grant access. This step is typically handled by the partner's system administrator, usually the Network Service Manager (NSM) admin on the partner side.

## Step 3: Submit a Partner Onboarding Request

The screenshot shows the TraceLink Customer Success Portal interface. At the top, there is a navigation bar with the TraceLink logo, 'Home', 'Support', and 'Quick Links' links, along with a search bar. Below the navigation bar is a large banner with the text 'TraceLink Customer Success Portal' and a sub-header 'The world's largest track and trace network for connecting the Life Sciences supply chain and eliminating counterfeit drugs from the global marketplace.' The main content area is divided into several sections: 'SUPPORT' with a 'CONTACT SUPPORT' button; 'TRACELINK ANNOUNCEMENTS' with a list of recent updates; 'Cases' with a 'My Organization's Cases' dropdown and a table of cases; and 'Quick Links' with a list of helpful resources. A red box highlights the 'REQUEST TRADE PARTNER ONBOARDING' button in the 'CONTACT SUPPORT' section, with an arrow pointing to it from a callout box that says 'Request Trade Partner Onboarding Support'.

When the POET link is in place, proceed to the Customer Success Portal and complete the Partner Onboarding Request form. This form is used to request specific partner users to be added to the POET link.

This final step ensures that the right individuals at the partner organization can access the POET environment as intended.

### To Add Partner Information

**Note:** Perform this procedure only if the Partner does not already exist in Master Data.

1. Log in to *opus.tracelink.com*.
2. Select **My Networks** from the **Main Menu** ☰.
3. Select the **Master Data** from the **Network** drop-down.
4. In the side menu, select **Partner** drop-down and then select **Partners**.
5. Click **New**.
6. Update the required information in the **Partner Information** section.

7. Update the required information in the **Identifiers** section.
8. Click **Save**.  
The **Partner** screen displays a table with the newly added partner.



### To Create POET Link

1. Log in to *opus.tracelink.com*.
2. Select **Administration** from the **Main Menu**.
3. From the side menu, select **Links**, then select **Network Links**.
4. Click **New**.
5. In the **Network** section, fill in the following information:
  - **Application** drop-down field - Required. The app that the Partner or internal location must be linked to.
  - **Network** drop-down field - Required. The network that the Partner or internal location must be linked to.
6. In the Entity section, fill in the following information:
  - a. **Entity** drop-down field - Required. The name or identifier of the Partner or internal location to link to the app or network, sourced from the Partners and locations entered in Master Data Exchange.  
  
**Note:** When linking with a Partner or an internal location, use a TraceLink ID to avoid any issues.
7. In the Roles section, select the **Partner - Member** from the Roles drop-down.
8. Click **Save**.  
TraceLink automatically creates the Link and the user can begin exchanging data with the linked entities.



### Workflow Base States and Transitions

There are 4 workflow base states and transitions:

- **Draft** - This is the initial state for all exceptions, whether created automatically through integrations or manually through the UI or API. Exceptions in the Draft state are not visible to external partners.
- **To Do** - The exception is ready for internal review. Depending on the configuration, the owner may grant partner visibility at this stage.
- **In Progress** - It represents that the exception is actively being worked on. This is typically the stage where communication and file sharing with external partners occurs to facilitate resolution.
- **Done** - This is the final resolved state of the exception. This state is used when the issue has been successfully closed, corrected, or determined to be invalid.

Once an exception leaves Draft, users cannot return it to Draft. Other workflow states may allow bidirectional transitions as configured.



## How Teams Interact through POET Workflows

The process of interaction typically begins with an Exception Creator creating an exception, either manually or via system integration. An Exception Creator can be an Owner or a Partner, depending on who reports the exception. Initially in the Draft state, the exception is visible only to the Exception Creator for internal preparation.

Once moved to “To Do”, the exception becomes visible to the relevant Exception Responder (external or cross-functional teams), signaling readiness for review and potential collaboration. As the exception progresses to In Progress, both Exception Creator and Exception Responder actively interact, sharing files, exchanging messages, and coordinating actions to resolve the issue. This is the most collaborative phase, where cross-team communication is essential.

When the issue is resolved, the exception transitions to the Done state. Even after closure, the Exception Creator and the Exception Responder may add updates to the closed exception.

Overall, POET workflows ensure clear ownership, staged visibility, and timely collaboration, streamlining how teams work together to resolve exceptions efficiently.

## Types of DSCSA Compliance Exceptions

The Healthcare Distribution Alliance (HDA) Exception Handling Guidelines for the DSCSA, v2.0 provided 5 different categories for compliance exceptions:

- **Data, No Product** - The system received electronic data but the physical product did not arrive.
- **Product, No Data** - This happens when you receive the physical product but have incomplete or missing data.
- **Data Issue** - This refers to any form of data misalignment, such as incorrect lot numbers or typos in the data.
- **Packaging & Labeling**- Issues with label readability, barcode quality, or aggregation errors that prevent proper scanning or data association.
- **Unavailable for Distribution** - Product is flagged as recalled, suspect, or illegitimate, and cannot be distributed under DSCSA rules.

## Ways to Capture Exceptions

There are primarily 4 ways to capture exceptions in POET:

- **User Interface (UI)** - You can manually create exceptions within the POET web interface. This method allows for detailed input, including exception type selection, description, file attachments, and assignment of roles. It is ideal for ad-hoc issue reporting and for users who require a guided, interactive experience.
- **Application Programming Interface (API)** - POET provides robust APIs that allow external systems (such as ERP, WMS, or TMS platforms) to automatically create exceptions. These APIs are typically used to capture exceptions triggered by system events or business rule violations like shipment delays, quantity mismatches, or quality failures. The API allows structured data submission, ensures exceptions are created consistently and with all required metadata. This method supports high automation and is ideal for scalable, integrated environments.

- **Email** - Exceptions can also be triggered through monitored email inboxes. For example, when a partner or internal user sends an email to a designated address with specific email format or keywords, POET can parse the content and automatically generate an exception. This method is useful for partners or teams who may not have direct access to the UI or API but need a simple way to report issues.

Email-generated exceptions must follow the HDA guideline.

- **Serialized Operations Manager (SOM)** - SOM generates exceptions when serialized data flows encounter discrepancies (invalid serials, failed validations, traceability gaps). These exceptions are captured in real time and passed into POET for resolution, ensuring that serialization and compliance-related issues are tracked and addressed efficiently.

Currently, there are 3 types of exceptions that can be raised through SOM.

1. First is **Data, No Product** - the system received electronic data but the physical product did not arrive.
2. Second is **Product, No Data** - when a product is received and there is no accompanying serialization information for that product.
3. Last is **Damaged Product** - when a damaged, unusable, stolen, or missing product is received.

Note that this exception-handling use case is primarily relevant to POET Owners who are wholesalers or dispensers, as the exception creation occurs during SOM receiving. It is not applicable to POET Owners who are Marketing Authorization Holders (MAHs), as they are not involved in the receiving process where SOM exceptions are generated.



## To Create Compliance Exceptions

1. Log in to *opus.tracelink.com*.
2. Select **My Networks** from the **Main Menu** ☰.
3. Select the POET network from the **Network** drop-down.

**Note:** The name of the network is defined by the owner of the POET solution. It is typically the name of the company followed by the name of the solution.

4. Click **GO**.
5. In the side menu, select **Compliance Exception**.
6. Click **New**.
7. In Title, enter the title for the new compliance exception.
8. In Business Priority, select the level of priority for the compliance exception. Select from Low, Medium, High, and Critical.
9. In Category, select the category of the compliance exception.
10. Click **Save**.  
The compliance exception is created in Draft state. To update additional information for the compliance exception, edit the compliance exception in Draft state.



### To Edit Compliance Exceptions

1. Log in to *opus.tracelink.com*.
2. Select **My Networks** from the **Main Menu** ☰.
3. Select the POET network from the **Network** drop-down.  
**Note:** The name of the network is defined by the owner of the POET solution. It is typically the name of the company followed by the name of the solution.
4. Click **GO**.
5. In the side menu, select **Compliance Exception**.
6. Select the **Display Identifier** of the compliance exception to edit.
7. Click **Edit**.
8. Update the required information in the following fields:
  - Description
  - Due Date

- Assignee User
- Delivery and PO details
- Delivery Information
- Comments and Attachments
- Impacted Products
- Contact Information

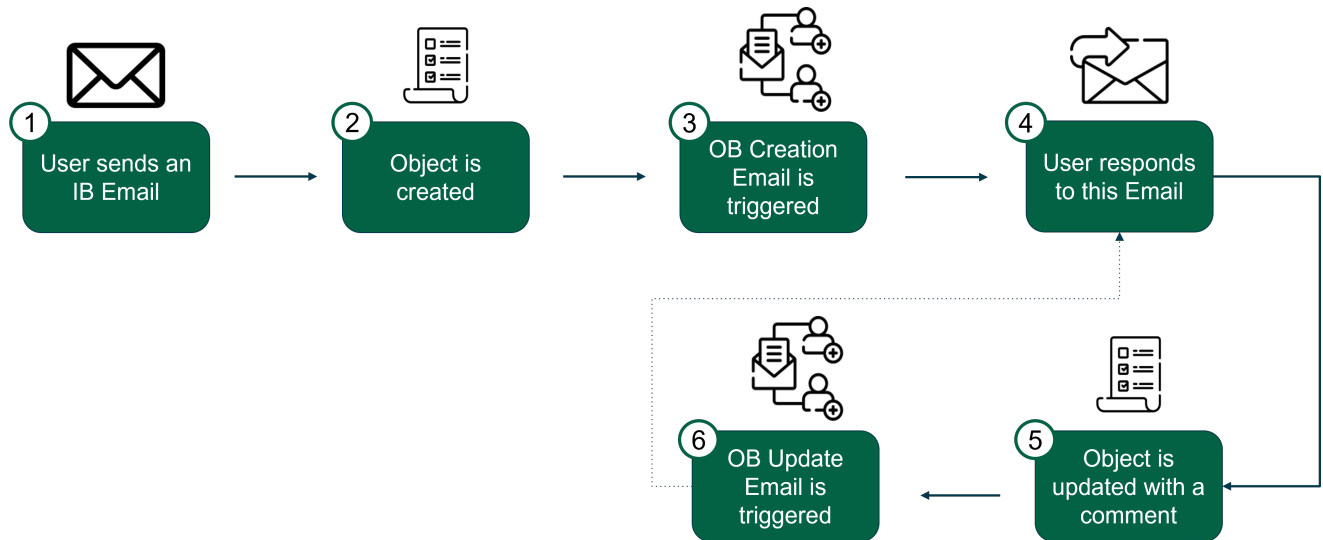
In addition to the above fields, update other fields if required.

**Note:** When an Assignee Company is selected and the workflow state transitions from Draft to To Do, the exception is assigned to the selected partner.

9. Click **Save**.
10. To move the compliance exception to To Do, click **Move to** under the To Do state.
11. To move the compliance exception to In Progress, click **Move to** under the In Progress state.
12. To close a compliance exception, click **Move to** under the Done state.

## Compliance Exception - Email Integration

### Email Flow for Collaboration



The following is a typical email flow for collaboration with POET:

1. First, a user sends an email to a designated POET email address to initiate collaboration. This email is called an Inbound (IB) email, which triggers the creation of a new collaboration object in POET.
2. POET automatically creates a new collaboration object. The object is assigned a unique identifier and initial metadata. The originating user is recorded as the initiator or requester.
3. Once the object is created, POET sends an Outbound (OB) creation Email to relevant stakeholders. This email contains:
  - The object ID and summary
  - A snapshot of the initial content
  - A link to view or interact with the object in POET

This email serves as a confirmation and notification of object creation.

4. The user or the stakeholders can reply to the OB creation email to continue the collaboration. The reply is captured by POET and linked to the existing object. The body of the reply is parsed and stored as a comment or update on the object.
5. The reply content is added to the object’s activity log or comment section. This ensures the full conversation history is preserved within the object. Any attachments or inline images from the reply are also stored with the object.
6. After the object is updated with the new comment, POET sends an OB update email to notify relevant participants. This update email includes:
  - A summary of the new comment or change
  - A link to the object for further action
  - A history of recent activity for context

This keeps all stakeholders informed and engaged in the collaboration process.



## Inbound Email Transaction

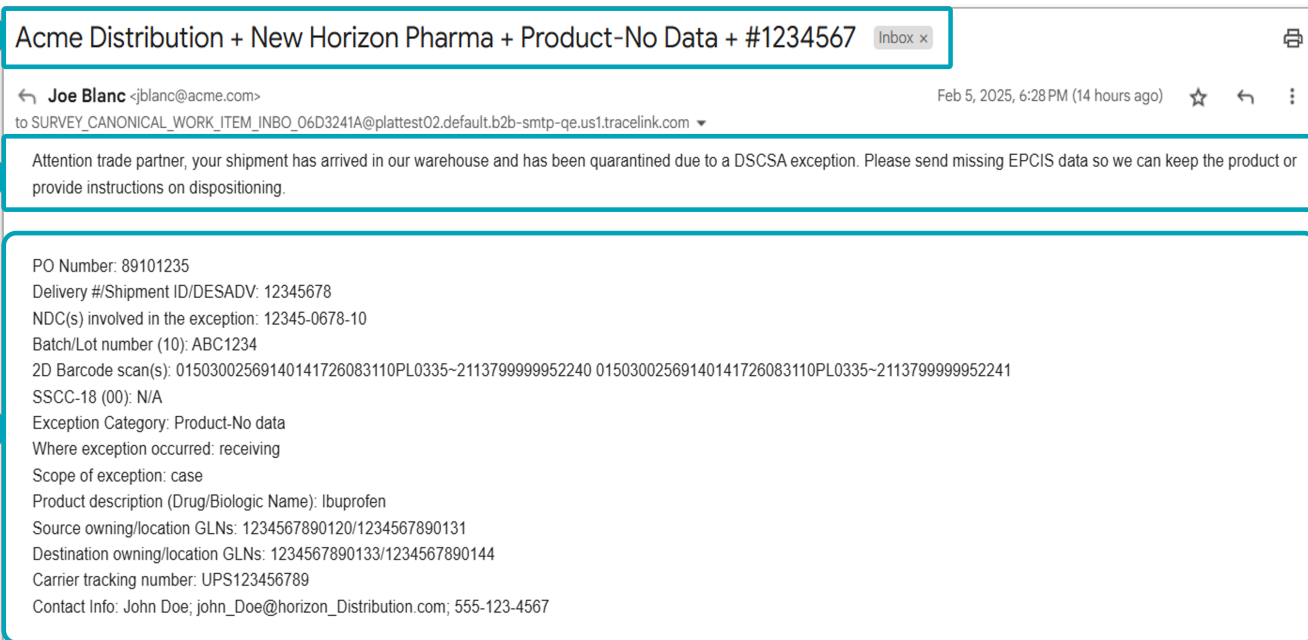
Attribute	Default/Derived Value
Title	Subject line of the Email
Comment	Body of the Email
Display Identifier	System Generated
Initiating Company	Based on the Sender’s Email Address
Assignee Company	<ul style="list-style-type: none"> <li>▪ Do Not Set (if created by Owner)</li> <li>▪ Set to Owner Company (if created by Partner)</li> </ul>
Due Date	Conditional (Based on configuration)
State	Default to Draft
Assignee User	Not Set

When a user sends an Inbound email to TraceLink with the intent to create a compliance exception, the system interprets the email and automatically creates a new instance of

the appropriate object or subtype. The subject line of the email is used as the title of the compliance exception, the body of the email is entered as the initial comment, and any attachments included in the email are added to the compliance exception. The system intelligently determines which business object or subtype to create based on the content and context of the email.

Users can also update existing compliance exceptions by replying to an outbound email notification from POET. When a reply is received, the system identifies the related compliance exception using the original email thread. The subject line is inherited from the original message, the body of the reply is logged as a new comment, and any attachments are added to the existing compliance exception. This allows for seamless, threaded collaboration without requiring users to log into the system directly.

## HDA Guided Email Template for Exception



1 Acme Distribution + New Horizon Pharma + Product-No Data + #1234567 Inbox x

← Joe Blanc <jblanc@acme.com> Feb 5, 2025, 6:28 PM (14 hours ago) ☆ ↶ ⋮  
to SURVEY\_CANONICAL\_WORK\_ITEM\_INBO\_06D3241A@plattest02.default.b2b-smtp-qe.us1.tracelink.com ▼

2 Attention trade partner, your shipment has arrived in our warehouse and has been quarantined due to a DSCSA exception. Please send missing EPCIS data so we can keep the product or provide instructions on dispositioning.

3

PO Number: 89101235  
Delivery #/Shipment ID/DESADV: 12345678  
NDC(s) involved in the exception: 12345-0678-10  
Batch/Lot number (10): ABC1234  
2D Barcode scan(s): 01503002569140141726083110PL0335~2113799999952240 01503002569140141726083110PL0335~2113799999952241  
SSCC-18 (00): N/A  
Exception Category: Product-No data  
Where exception occurred: receiving  
Scope of exception: case  
Product description (Drug/Biologic Name): Ibuprofen  
Source owning/location GLNs: 1234567890120/1234567890131  
Destination owning/location GLNs: 1234567890133/1234567890144  
Carrier tracking number: UPS123456789  
Contact Info: John Doe; john\_Doe@horizon\_Distribution.com; 555-123-4567

The Healthcare Distribution Alliance (HDA) provides guidelines for handling exceptions. These guidelines aim to standardize communication between trading partners to help resolve exceptions more quickly and efficiently.

To align with these guidelines, POET standardizes a template for creating and submitting exception notices through email. The template is broken down into the following 3 parts:

1. First part is a standard subject line. This should include the trading partners involved, the exception category, and the issue tracking number. This helps the recipient immediately understand the context.
2. Next, includes a brief narration of the exception. Keep this explanation short and focused. Avoid repeating information that will already be included in the detailed fields of the email body.
3. Last part is the body of the email. This contains all the required attributes of the exception such as Purchase Order number, Delivery or Shipment ID, National Drug Codes (NDCs), Batch and lot numbers and so on.

## **Outbound Email Transaction**

POET generates automated Outbound Email Transactions at key stages in the lifecycle of a compliance exception: Creation, Update, and Closure to keep stakeholders informed and support email-based collaboration.

When a compliance exception is created, an Outbound email is triggered automatically. This email includes a snapshot of the business object, capturing key base-type attributes, along with the current state of the object. The recipient can respond directly to this email, and their reply will be interpreted by POET as an update to the compliance exception.

Whenever a compliance exception or one of its subtypes is updated, POET sends an Outbound update email. This email contains the most recent snapshot of the object, including base-type attributes and its current state. Outbound emails include a recent activity summary and a link to view the full history in POET. If the compliance exception is assigned, the update email is also sent to users from the partner company. Users can reply to the email to continue collaboration, and their responses are recorded as comments on the compliance exception.

Finally, when a compliance exception is closed or marked as "Done", an Outbound closure email is triggered. Similar to other email types, it includes a snapshot of the business object and its final state. Users can still respond to this email, and their replies will be logged in the system, allowing for post-closure follow-ups if necessary.



## To Create a Compliance Exception by Sending an Email

1. Draft the email in the email format recommended by Healthcare Distribution Alliance (HDA).
2. Send the email to the email address provided by Tracelink. For more information on creating compliance exceptions by email, contact your Tracelink service representative.

A sample HDA format for a compliance exception email is provided below:

- A standard subject line: Trading partners involved + Exception Category + Issue tracking #
- A brief narration of the exception: Be as brief as possible in explaining the incident, refraining from stating any pieces of information already specified in the field list below.

Fields in the body of the email: The responding trading partner will typically need the following information (where applicable).

- PO Number
- Delivery #/Shipment ID/DESADV
- NDC(s) involved in the exception
- 2D Barcode scan:
  - Contact info (name/email/phone)
  - Carrier tracking number
  - Destination owning/location GLNs or ship-to address if GLN is not known
  - Source owning/location GLNs
  - Product description (Drug/Biologic Name)
  - Scope of exception (e.g., entire shipment, pallet, case, inner pack, package, etc.)

- Where/when the exception occurred (e.g., receiving, outbound picking, returns processing)
- Exception category (Product and No Data, Data and no product)
- SSCC-18 (00) as applicable
- For data no product exception where there is no physical product to scan, capture the GTIN, Serial number, batch and expiry from the incoming file.
- For product, no data exceptions where output of the scan cannot be provided, a photo of the 2D data matrix barcode inclusive the human readable [i.e. (GTIN (01), Serial # (21), batch/lot#(10), expiry(17) ] adjacent to the 2D barcode.



### To Reply to Outbound Emails

1. When a compliance exception is created, updated, closed, or assigned to partner, the followers will receive a notification email from Tracelink. If you are a follower, you can reply to this email to add a comment and attachment to the compliance exception.
2. Reply to the email received from Tracelink with a body and attachments (if any).  
**Note:** The body of the email will be added as a comment and the attachments will be added to the compliance exception.

## Compliance Exception - SOM Integration



### SOM and POET Integration

The integration between Serialized Operations Manager (SOM) and POET enables automatic communication of exceptions reported in SOM to POET, where structured collaboration can take place between partners to resolve those exceptions.

SOM allows companies to report exceptions during delivery processes, but it lacks built-in collaboration features. To address this, POET serves as the collaboration platform that

provides transparency, context-sharing, and coordination between the initiating and receiving parties.

Here is the functional flow:

1. A user reports an exception in SOM and provides key details (creation channel, exception category, priority, reporting user, and description).
2. After a user reports an exception in SOM, SOM sends the exception data to POET. POET creates an Exception record that includes a title, attachments, collaboration tools, status tracking, and field mappings.
3. After creation, both the initiator and assignee can collaborate within POET using the comments section to communicate updates. Users can also add supporting files in the Attachments section. This ensures both parties are aligned and can jointly work toward resolution