

User Guide for PDG DSCSA TI Response Workbook

TI Response Workbook v2.0.0

Contents

Introduction.....	2
Purpose of the Workbook.....	2
Overview of DSCSA Trace Requests and Responses.....	2
Workbook Structure.....	2
Detailed Instructions for Each Sheet.....	3
Common Scenarios and Examples.....	4
Reviewing the Workbook.....	5
Submitting the Response.....	5
Conclusion.....	5

Introduction

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Purpose of the Workbook

The DSCSA Trace Response Workbook is designed to facilitate compliance with the Drug Supply Chain Security Act (DSCSA). It enables trading partners to respond to trace requests by providing necessary data in a standardized format.

Overview of DSCSA Trace Requests and Responses

Under the DSCSA, trading partners must be able to trace pharmaceutical products through the supply chain. This process involves:

1. Sending a **Trace Request** to a known trading partner.
2. Receiving a **Trace Response** with detailed product transaction information.
3. Using the received data to trace the product further, if necessary.

The workbook streamlines the creation of a **Trace Response**, ensuring accuracy and compliance.

Workbook Structure

The workbook comprises the following sheets:

1. **Changes:** Tracks revisions made to the workbook.
2. **Instructions:** Provides general guidance for using the workbook.
3. **Audit References:** Lists references required for audit purposes.
4. **Responder Information:** Collects details about the responding trading partner.
5. **Response Message:** Captures the main content of the Trace Response.

6. **Responder 3911s:** Includes specific 3911-related data.
 7. **TI Response Additional Info:** Allows for additional transaction information or document links.
 8. **Response for Req Line 01:** Used for responding to specific request lines.
 9. **Lookup Tables:** Contains predefined values for consistent data entry.
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Detailed Instructions for Each Sheet

1. Instructions Sheet

- Review the purpose and scope of the workbook.
- Note the version number for audit purposes.

2. Responder Information Sheet

- Fill in the **Responding Party** details, including:
 - Company Name
 - Address
 - Contact Information
- Ensure accuracy as this identifies the source of the response.

3. Response Message Sheet

- Provide the primary response to the Trace Request.
- Include:
 - Request ID
 - Response Type (use the predefined values in the Lookup Tables sheet).

4. Responder 3911s Sheet

- Record all 3911-related data associated with the requested product.
- Use the template provided to ensure compliance.

5. TI Response Additional Info Sheet

- Add supplementary information, such as links to external documents or attachments.
- Use this section to clarify any discrepancies or provide additional audit data.

6. Response for Req Line 01 Sheet

- For each request line, repeat this sheet:
 - Fill in **Request Line Number**.
 - Provide **Product ID** (e.g., GTIN).
 - Complete other required fields based on the request.
- Ensure data matches the originating Trace Request.

7. Lookup Tables Sheet

- Reference this sheet for:
 - Response Type options.
 - Transaction Information formats.
 - Always use predefined values to maintain consistency.
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Common Scenarios and Examples

Scenario 1: Filling a Trace Response for a Single Product

1. Open the **Responder Information** sheet and enter the trading partner details.
2. Navigate to the **Response Message** sheet and select the appropriate response type.
3. Complete the **Response for Req Line 01** sheet with:
 - Request Line Number
 - Product ID
4. Add any supporting documents in the **TI Response Additional Info** sheet.
5. Validate entries against the **Lookup Tables**.

Scenario 2: Adding Additional Information for Audit Compliance

1. Use the **Audit References** sheet to document references related to the request.
 2. Include hyperlinks or attach files in the **TI Response Additional Info** sheet.
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Validation and Submission

Reviewing the Workbook

- Verify that all required fields are complete.
- Cross-check entries with the **Lookup Tables** sheet.
- Ensure data accuracy to avoid rejection by the requesting partner.

Submitting the Response

- Save the workbook as a shared Excel file or PDF.
 - Send it to the trading partner using secure communication methods.
 - Retain a copy for audit purposes.
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Conclusion

This workbook simplifies compliance with DSCSA traceability requirements. Proper training and attention to detail will ensure timely and accurate responses to Trace Requests.