

Overview

This workbook facilitates pharmaceutical companies in managing DSCSA compliance by organizing traceability requests. It contains multiple interconnected worksheets to handle transaction information (TI), requester details, audit references, and lookup tables.

Contents of the Workbook

1. changes

- Logs changes made to the workbook versions.
- Use this sheet to track modifications or updates.
No user input required.

2. Instructions

- Provides detailed guidance on how to use the workbook.
- Review this section before making entries.
No user input required.

3. Audit References

- Contains fields to record essential audit trail information.
- Use this section to reference audits related to requests.
Ensure accurate and complete records for audits.

4. Requester Information

- Collects details about the individual or organization making the trace request.
- Fields include requester name, contact information, and organization.

How to fill:

1. Enter your full name.
2. Provide your contact email and phone number.
3. Enter the requesting organization and role (if applicable).

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5. TI Request Parameters

- Captures parameters for the transaction information (TI) being requested.
- Includes product identification, lot numbers, and transaction dates.

How to fill:

1. Enter the product identifier (e.g., NDC or GTIN).
2. Provide the lot number and expiration date, if available.
3. Specify the transaction dates for which information is needed.

6. TI Request Additional Info

- This sheet contains optional fields for supplemental data to support the TI request.
- Use this section to add comments or context about the trace request.

7. TI Requests

- Main section where detailed TI requests are compiled.
- This includes specific product trace requests and their statuses.

How to fill:

1. Enter each individual TI request on a new row.
2. Provide the requested information based on product and transaction parameters.
3. Track the status (Pending, Completed, etc.).

8. Lookup Tables

- Contains predefined values for easy data entry (e.g., product codes, organization names).
- These tables help ensure consistency across the workbook. *Review the available lookup values to avoid errors in entries.*

How to Use the Workbook

1. **Review Instructions:**
 - Begin with the **Instructions** sheet to familiarize yourself with the workbook's structure and entry requirements.
2. **Enter Requester Information:**
 - Fill out your contact details and organization information in the **Requester Information** sheet.
3. **Add Transaction Parameters:**
 - Input key parameters such as product identifiers and transaction dates in the **TI Request Parameters** sheet.
4. **Provide Additional Information (Optional):**
 - Use the **TI Request Additional Info** sheet for any extra context.
5. **Track Requests:**
 - Enter your TI requests in the **TI Requests** sheet and monitor their progress.
6. **Utilize Lookup Tables:**
 - Use the **Lookup Tables** for predefined values to ensure accurate data input.

Tips for Effective Use

- **Consistency is Key:** Use the **Lookup Tables** whenever possible to avoid typos and ensure uniform data entry.
- **Update Status Regularly:** Keep the status of each request up to date in the **TI Requests** sheet.
- **Track Changes:** Refer to the **changes** sheet for a history of modifications to the workbook.

This guide aims to ensure you use the workbook efficiently and accurately for DSCSA compliance management. If you encounter any issues, refer to the **Instructions** sheet or consult your DSCSA administrator.