SoftwareCPR®
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SoftwareCPR® Job Aid

FDA Guidance:
Global Unique Device Identification Database (GUDID)

Guidance document version: December 17, 2024

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The observations and opinions in the presentation that follows should only be applied in the appropriate context with oversight by regulatory and software professionals with direct knowledge and experience with the topics presented**.** While SoftwareCPR® attempts to ensure the accuracy of information presented, no guarantees are made since regulatory interpretations and enforcement practices are constantly changing and are not entirely uniform in their application.

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Purpose

This document is intended as a summary job aid for applying the FDA guidance. This job aid should only be applied by those who are knowledgeable with the guidance, its proper interpretation, and the implementation domain. To achieve summarization, the job aid does not include full guidance text nor always the exact text in the guidance. There may also be unintended omissions or inaccuracies.

A multi-factor approach can be taken to guidance application:

- Are all recommended processes established?
- Are all recommended tasks and activities performed?
- Are all documentation recommendations met?
- Do tasks and deliverables incorporate all recommended and relevant items?

A group could fully implement one or more factors but not be fully aligned with the guidance. This job aid is intended to assist with evaluation, selection, and implementation rather than just providing a checklist.

Scope

This job aid is based on the *Global Unique Device Identification Database (GUDID) Guidance* for Industry and Food and Drug Administration Staff, issued December 17, 2024.

Medical device manufacturers (referred to as "labelers" in the guidance) should take the recommended actions for submitting device identification information to the GUDID.

These actions apply to manufacturers of devices subject to Unique Device Identification (UDI) requirements under 21 CFR Part 830, including class II, class III, and certain class I devices not otherwise excepted.

Initiation actions

Note: while the actions are shown in a general sequence, there can be some task overlapping depending on priorities and scheduling.

1. Obtain a DUNS Number

- Action: Secure a Data Universal Numbering System (DUNS) number from Dun & Bradstreet (D&B) if the manufacturer does not already have one.
- Details:
    - The DUNS number is a unique nine-digit identifier required for the GUDID account and to identify the labeler organization.
    - If needed, request a free DUNS number from D&B (allow up to 30 business days) or use an expedited option for a fee.
    - Verify and update the company name and address in the D&B database to ensure accuracy, as GUDID pulls this information directly from D&B.

2. Designate GUDID User Roles

- Action: Assign individuals within the organization to the required GUDID user roles.
- Details:
    - Regulatory Contact:
        - Appoint one individual as the point of contact with the FDA for device identification matters.
        - Responsible for ensuring GUDID submission compliance (21 CFR 830.320(a)).
        - Does not require GUDID login credentials unless also serving in another role.
    - Coordinator(s):
        - Designate one or more individuals to manage the GUDID account.
        - Responsibilities include creating Labeler Data Entry (LDE) user accounts and assigning Labeler DUNS numbers.
    - Labeler Data Entry (LDE) Users:
        - Assign one or more individuals to enter, submit, and manage device information in the GUDID.
    - Notes:
        - One person may fulfill multiple roles (e.g., Regulatory Contact and Coordinator).

        - Roles must be clearly defined within the organization.

3. Prepare and Submit a GUDID Account Request

- Action: Compile necessary information and submit a request to the FDA to establish a GUDID account.
- Details:
    - Required Information:
        - Organization DUNS Number: Represents the highest corporate level (e.g., headquarters or parent company).
        - Labeler Organization Name: For verification purposes.
        - Regulatory Contact Information: Name, email, phone, and physical address.
        - Labeler DUNS Numbers: Identify all labelers under the account; ensure the company name matches the device label.
        - Coordinator Information: Name, email, phone, and assigned Labeler DUNS numbers.
        - Third-Party DUNS Numbers: If using a third-party submitter.
        - Preferred Submission Method: Indicate Web Interface, HL7 SPL, or both.
    - Process: Submit the request via the FDA UDI website (http://www.fda.gov/udi).
    - Notes:
        - If a third-party will act as the Regulatory Contact, include a signed letter on company letterhead during the request.

4. Set Up User Accounts

- Action: Once the GUDID account is approved, have the Coordinator establish LDE user accounts.
- Details:
    - The FDA provides the Coordinator with login credentials after account creation.
    - The Coordinator creates LDE user accounts by providing:
        - LDE user details (name, email, phone).
        - Assigned Labeler DUNS numbers.
    - LDE users receive temporary login credentials via email to access the GUDID.

5. Obtain GMDN Term Codes

- Action: Acquire appropriate Global Medical Device Nomenclature (GMDN) Term Codes for each device.
- Details:
    - Access: Join the GMDN Agency (free basic membership available since April 2019) to access the GMDN vocabulary (http://www.gmdnagency.com).
    - Selection:
        - Identify active GMDN Term Codes that accurately describe each device version or model.
        - If a new term is needed, request it from the GMDN Agency (plan for additional time).
    - Validation: Ensure terms are active (not obsolete) before submission; update obsolete terms as needed.

6. Prepare Device Information

- Action: Gather all required device data elements for GUDID submission.
- Details:
    - Refer to the GUDID Data Elements Reference Table (available at www.fda.gov/udi) for the complete list of required attributes.
    - Key elements include:
        - Primary Device Identifier (DI): The main identifier for the base package.
        - Secondary DI: Alternate identifiers from other issuing agencies, if applicable.
        - Unit of Use DI: For individual devices not labeled with a UDI.
        - Direct Marking DI: For devices requiring direct marking (21 CFR 801.45).
        - Package DI: For each package configuration.
        - Production Identifier Flags: Indicate which PIs (e.g., lot number, serial number) appear on the label.
    - Ensure consistency with premarket submissions and other FDA documentation (e.g., registration, adverse event reports).

7. Choose and Prepare for Submission Method

- Action: Select a submission method and prepare accordingly.
- Options:
    - GUDID Web Interface:
        - Suitable for low-volume submitters.
        - Requires manual data entry by LDE users.
    - HL7 SPL Submission:
        - Suitable for high-volume submitters using XML files via the FDA Electronic Submissions Gateway (ESG).
        - Additional steps:
            - Establish an ESG Account: Set up and test an ESG account (www.fda.gov/esg).
            - Complete GUDID Testing: Follow the HL7 SPL Implementation Files (www.fda.gov/udi) for testing before production submissions.

8. Create and Submit DI Records

- Action: Enter and submit Device Identifier (DI) records to the GUDID.
- Details:
    - Creation: Use the chosen method to input device information. (see selected diagrams from Guidance below)
    - Review: Validate each DI record against GUDID business rules.
    - Submission:
        - Set the Publish Date to ensure the record becomes "Published" no later than fifteen calendar days after the device enters commercial distribution (21 CFR 830.330).
        - For Web Interface: Submit manually after passing validation.
        - For HL7 SPL: Submit XML files via the ESG.
    - Status:
        - Draft: For Web Interface only; save incomplete records (purged after 180 days of inactivity).
        - Unpublished: Publish Date is in the future; not yet publicly available.
        - Published: Publish Date is today or past; meets submission requirements.

Flowcharts from the FDA guidance illustrating action #8 activity:

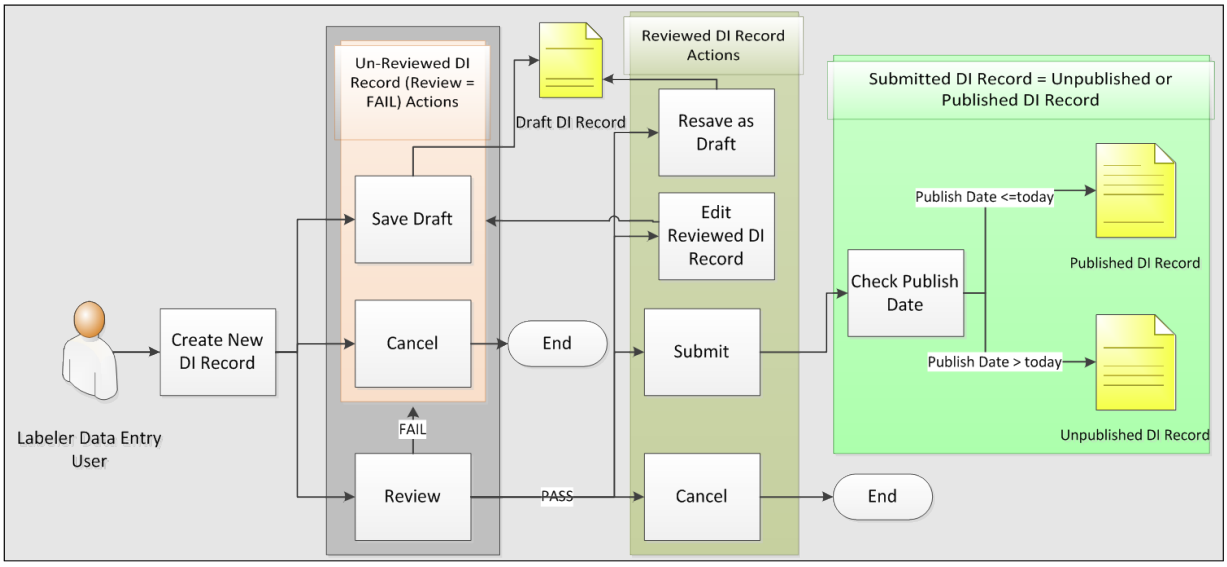
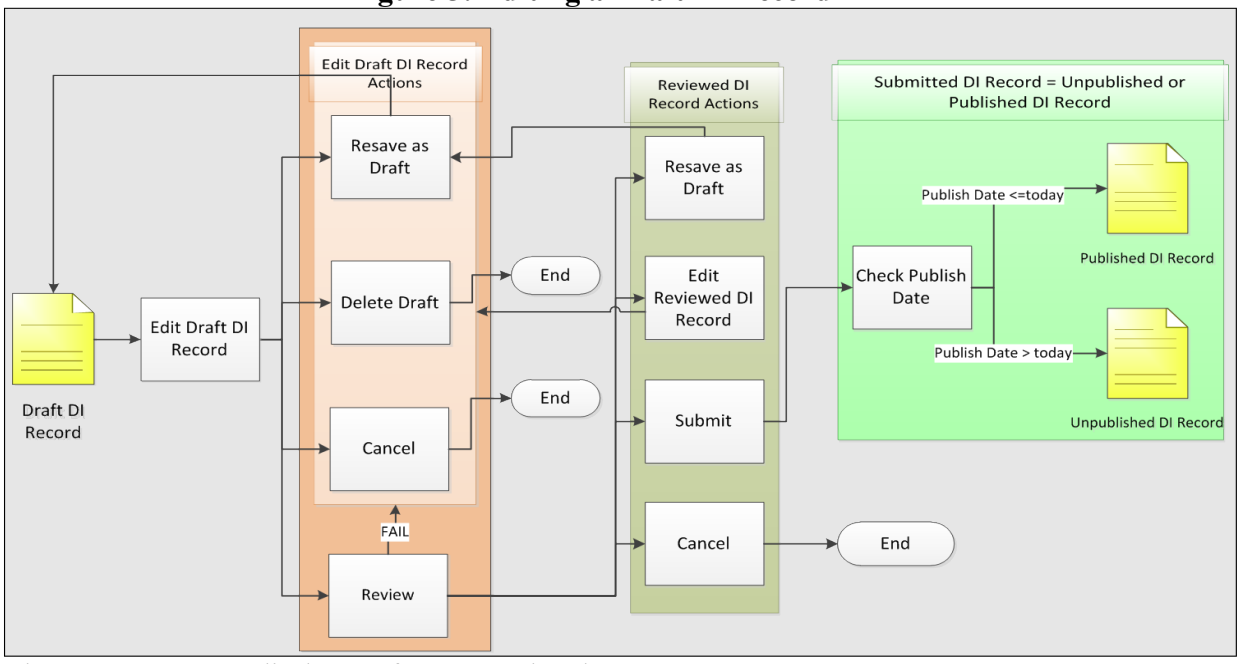


Figure 4: Creating a New DI Record

Figure 5: Editing a Draft DI Record



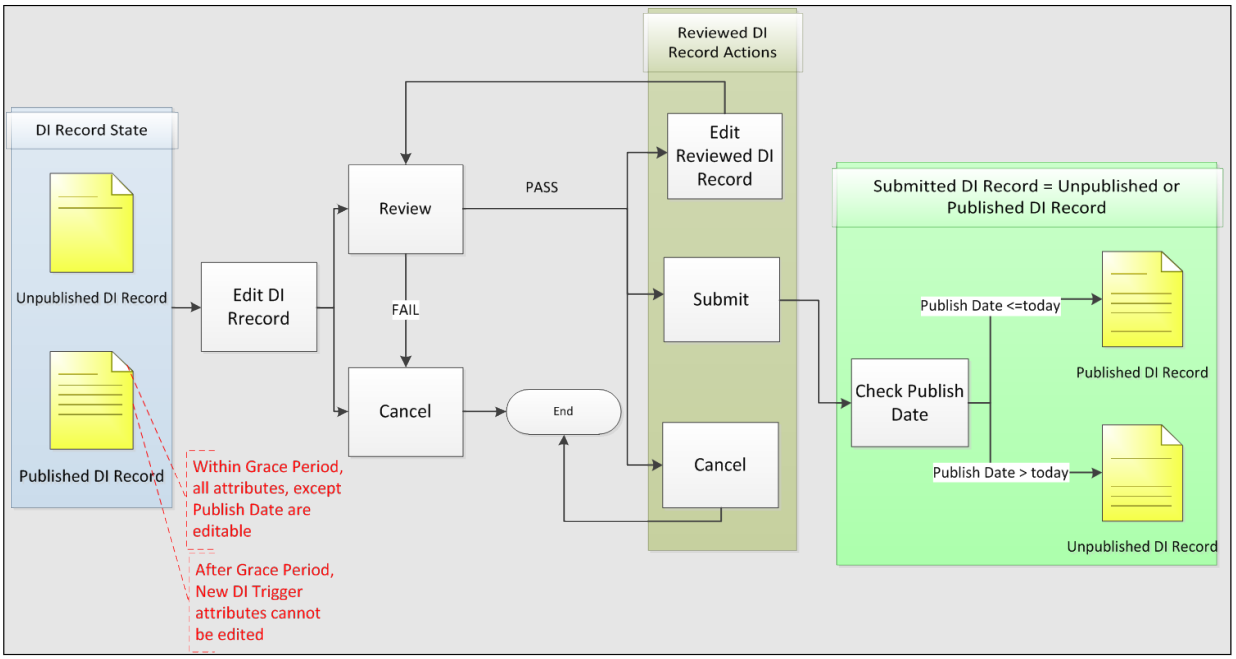


Figure 6: Editing an Unpublished or a Published DI Record

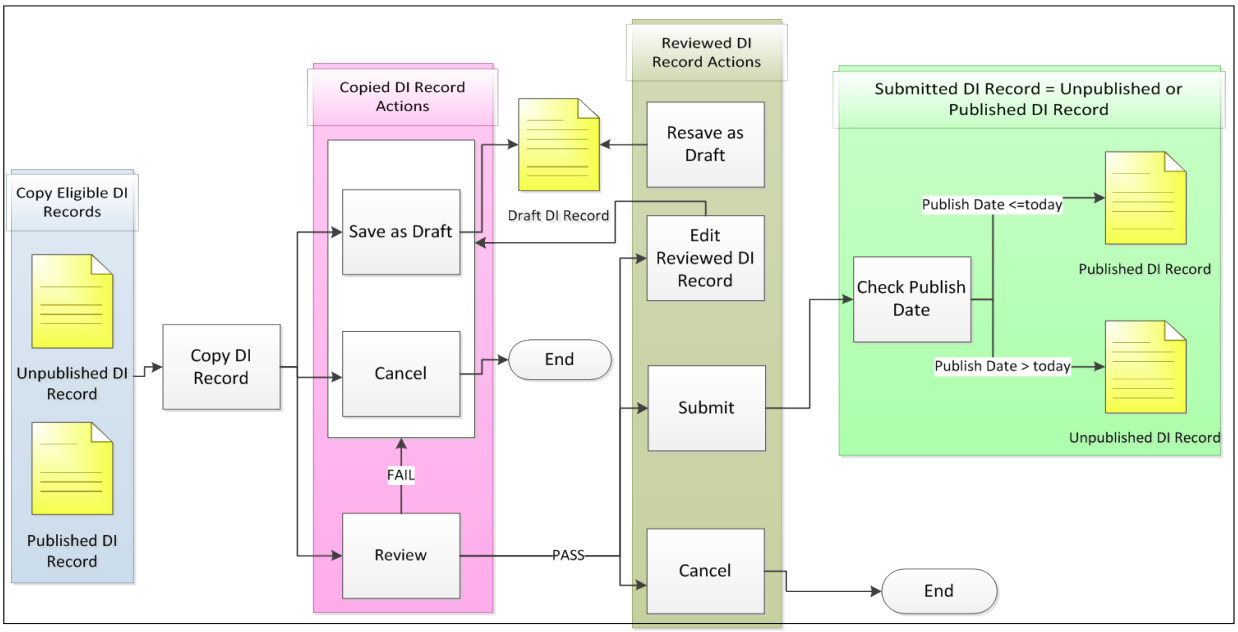


Figure 7: Copying DI Records

Continuing/maintenance actions

The following actions may be needed at any time to maintain or delete DI records and any relevant record requirements.

Comply with Record Retention and Electronic Record Requirements

- Action: Maintain records as required by FDA regulations.
- Details:
    - Retain records per 21 CFR 830.360.
    - If stored electronically, comply with 21 CFR Part 11 (electronic records requirements).
    - Develop standard operating procedures (SOPs) for data quality and integrity.

Maintain and Update DI Records

- Action: Regularly monitor and update DI records to ensure accuracy.
- Details:
    - Grace Period: Edit most attributes within 7 calendar days after publication.
    - Post-Grace Period: Limited editing; "New DI trigger attributes" (e.g., changes requiring a new DI under 21 CFR 830.50) cannot be modified.
    - GMDN Updates: Replace obsolete terms within 10 business days of a change (21 CFR 830.330(b)).
    - Consistency: Use the same submission method for edits as for initial submission to avoid discrepancies.

Handle Devices No Longer in Commercial Distribution

- Action: Update the status of discontinued devices.
- Details:
    - Enter the Commercial Distribution End Date in the DI record.
    - System auto-updates status:
        - End Date > today or blank: "In Commercial Distribution."
        - End Date ≤ today: "Not in Commercial Distribution."
    - Records remain in the GUDID and are publicly searchable.

Manage Third-Party Submitters (if Applicable)

- Action: Authorize and oversee third-party submitters, if used.
- Details:
    - Provide the third-party's DUNS number during the GUDID account request.
    - For Web Interface: Assign Coordinator or LDE roles to the third-party.
    - For HL7 SPL: Ensure the third-party is linked to the GUDID account and completes testing.
    - Responsibility: The labeler remains accountable for data accuracy and compliance.

Monitor for Changes Requiring a New DI

- Action: Identify and address device changes that necessitate a new DI.
- Details:
    - "New DI trigger attributes" (e.g., changes to version or model under 21 CFR 830.50) require a new DI and a new DI record.
    - Create and submit a new DI record when such changes occur.

Address Organizational Changes

- Action: Contact the FDA regarding mergers, acquisitions, or other changes affecting DI records.
- Details:
    - Notify the FDA UDI Help Desk proactively to manage impacts on existing DI records.
    - Follow FDA guidance to update or transfer records as needed.

Additional assistance/questions

This job aid was prepared by Amy Sellers and Mike Russell, Partners at SoftwareCPR.
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