GUDID Account Request: Preparation and Process

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The GUDID

- Data submission required by UDI System Final Rule
- Submission must be made to the Global Unique Device Identification Database (GUDID)
- Data submission requires establishing a GUDID Account
- Request account at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416113.htm

Learning Objectives

- Understand the GUDID Account Request Process
- Prepare the necessary information to open your account
- Evaluate your GUDID submission options
- Understand the functions of the FDA UDI Help Desk

GUDID Roles - Entities

- Organization
  - Highest corporate level of company
  - Account is registered to this entity
  - Entity responsible for meeting data submission requirements
- Labeler
  - Name of company on the label
  - Entity responsible for submitting the data to the GUDID
- Third Party Data Submitter
  - May submit records on behalf of the labeler

GUDID Roles - Users

- Regulatory Contact
  - Responsible for GUDID submission requirements
  - May be a third party
- Coordinator
  - Manages GUDID labeler accounts
- Labeler Data Entry (LDE) User
  - Submits required information for each device to the GUDID

The GUDID Account Request

- Editable PDF document
- Seven Sections
  - Labeler Organization
  - Regulatory Contact
  - GUDID Submission Option
  - Premarket Application Number
  - Labeler DUNS
  - Coordinator
  - Third Party Submitter (optional)

Labeler Organization Information

- Represents highest corporate level of the organization
- Includes
  - Organization's Dun & Bradstreet Numbering System (DUNS) number (http://www.dnb.com/government/duns-request.html)
  - Name
  - Address
- GUDID pulls information from DUNS database
  - Contact Help Desk if information changes

Regulatory Contact Information

- Individual responsible for GUDID submission requirements
- May be an employee of the Organization or an authorized third party
- Designating a third party requires letter from your Organization stating:
  - which devices the third party will serve as contact
  - how long the third party will serve as contact
  - who will notify the FDA if the third party is modified or removed

GUDID Submission Option

- Two options:
  - Web Interface
  - Health Level 7 Structured Product Labeling (HL7 SPL) submission
- Web Interface option
  - Goes directly to production environment. Published records will be publicly visible.
- HL7 SPL option
  - Requires testing in pre-production environment. Pre-production records will not be publicly visible and do not satisfy UDI requirements.
  - Production access will be granted once testing is completed.
  - HL7 SPL accounts include web interface access

Web Interface

- Offers a form-based method for entering required device identification information
- Limited to one record per entry
- Requires less technical expertise
- Best option for users with small quantities of records

HL7 SPL

- Uses Extensible Markup Language (XML) schema to submit records
- Can publish multiple records simultaneously
- Must submit completed test results with production account request
- Requires separate account through FDA Electronic Submissions Gateway (ESG). http://www.fda.gov/esg
- Requires more technical expertise
- Best option for users with large quantities of records
- Labelers may use a third party to submit on their behalf

FDA Premarket Application Number

- Method for validating labeler eligibility to open an account
- May provide: Premarket Approval (PMA), Premarket notification [510(k)], *de novo* classification, Humanitarian Device Exemption
- Do not provide FDA listing number
- Only one valid number is necessary to approve an account.

Labeler DUNS Number

- DUNS number of labeler who is responsible for submitting GUDID entries
- Used to identify the labeler for a version or model of a device
- Each device record must be associated with a labeler DUNS
- Labeler company name in DUNS should match what is listed on the device label

Coordinator Information

- Responsible for management of the GUDID account for a specified labeler DUNS
- Creates the Labeler Data Entry (LDE) user accounts in the GUDID that create and edit DI records
- Coordinator may also be an LDE user
- May be a member of the organization or a third party representative

Third Party Submitter Information

- Entities authorized to submit to the GUDID on behalf of a labeler
- Third parties may request pre-production accounts to test their services prior to submitting for clients
- Labeler organizations retain all data access capabilities
- Labeler organizations remain responsible for meeting data submission requirements

Steps for Success

- Ensure that all sections are completed
  - Third Party Submitter conditionally required
- Confirm accuracy of information in DUNS database for all labeler and organization DUNS numbers
- Identify individuals for each GUDID user role
- Verify that your device is part of one of the Classes open to GUDID entry
- Configure email accounts to accept responses from “@salesforce.com”

Help Desk

- Located at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm
- Primary method to interact with UDI team
- Questions are submitted via website. Submission establishes an email correspondence with an assigned case number.

Help Desk Best Practices

- Complete contact information
- Submit a Help Desk inquiry for a single question
- Keep follow-up questions related to the original in the same email thread
- Submit a new Help Desk inquiry for new questions
- Use system generated auto response email to send attachments, if necessary
  - Ex: use to submit HL7 SPL test results

Summary

- Data must be submitted to the GUDID to comply with UDI rule requirements
- Establish an account to submit data, following defined procedures
- Choose best submission method for your needs
- Use the Help Desk for communicating with the UDI team
- All resources can be accessed at: http://www.fda.gov/udi

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   - **Web Homepage:** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm