GUDID Global Unique Device Identification Database

HL7 SPL Submission Option

March 10, 2016

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Learning Objectives

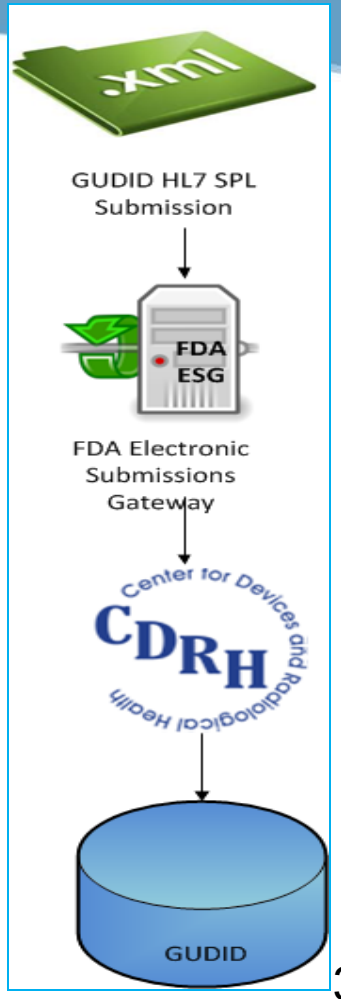
- Obtain an overview of the GUDID HL7 SPL Submission option
- Understand the required testing and process steps
- Learn about the FDA Electronic Submissions Gateway (ESG)
- Identify and understand the three acknowledgements you'll receive
- Learn key pointers regarding editing GUDID HL7 SPL submissions
- Understand who and when to contact for help

GUDID HL7 SPL Submission Option

Definitions:
HL7 = Health Level 7
SPL = Structured Product Labeling

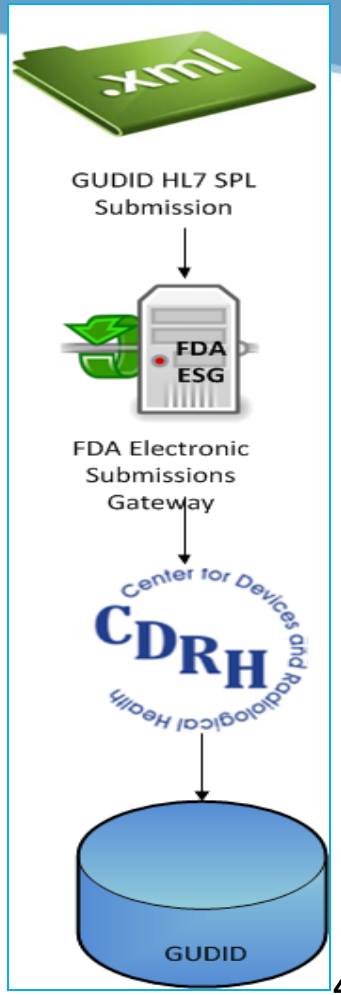
- Submission of medical device information as HL7 SPL XML message file
  - One DI record per XML file

- Technical specifications available on the UDI website



GUDID HL7 SPL Submission Option

- HL7 SPL XML submissions sent via the FDA Electronic Submissions Gateway (ESG)
- Testing required prior to production submission
- Suitable for labelers with large volume of submissions



FDA Electronic Submissions Gateway

- Enables secure receipt and authentication of FDA electronic regulatory submissions
- Routes submissions to the appropriate Center
  - Only one ESG account is needed for all submissions to all Centers

FDA Electronic Submissions Gateway

FDA Electronic Submissions Gateway

- Two Options for submission
  - **WebTrader** - use for Low Volume
  - **AS2** – use for High Volume

- If you choose **WebTrader**:
  - use GUDID Web Interface, instead of HL7 SPL submissions

- GUDID does not use eSubmitter tool used for CDRH eMDR submissions

FDA Electronic Submissions Gateway

FDA Electronic Submissions Gateway

- Acknowledgements for each stage of report transmission
- www.fda.gov/esg
- Note Proper Codes
  - **Center =** CDRH
  - **Submission Type =** GUDID

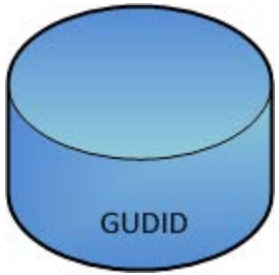
FDA Electronic Submissions Gateway

Acknowledgements (Ack)

Center = CDRH
Submission Type = GUDID

Labelers

ESG



CDRH

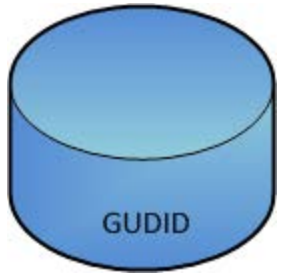
Acknowledgements (Ack)

Center = CDRH
Submission Type = GUDID

Labelers

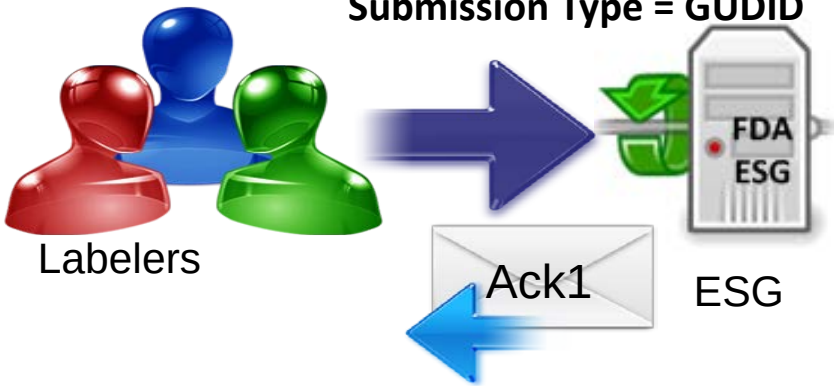
ESG

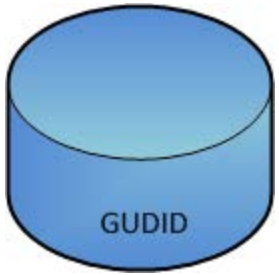
CDRH



Acknowledgements (Ack)

Center = CDRH
Submission Type = GUDID





CDRH

Acknowledgements (Ack)

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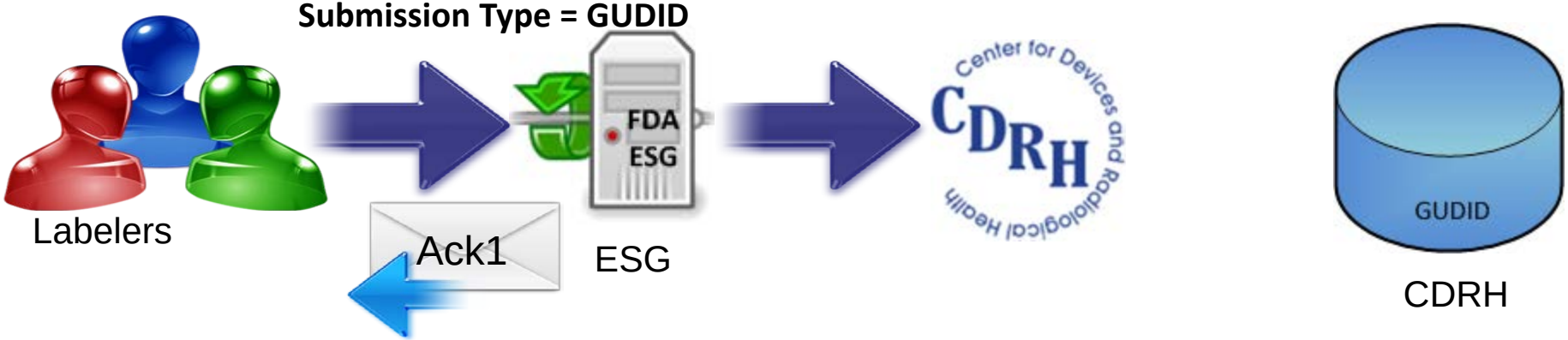
Submission Type = GUDID



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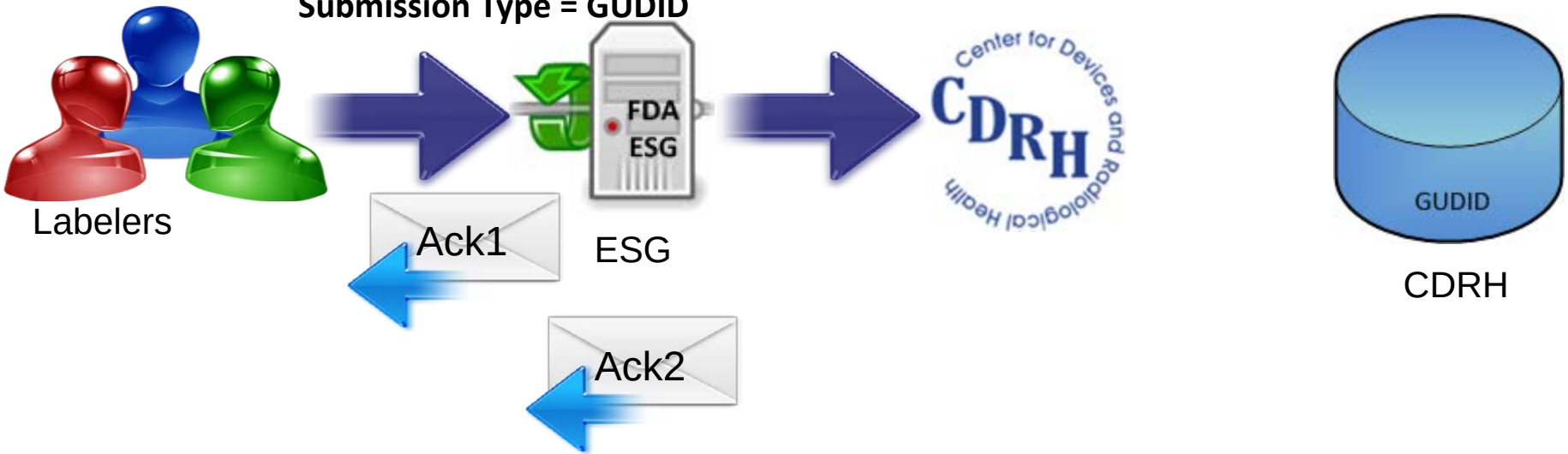
Submission Type = GUDID



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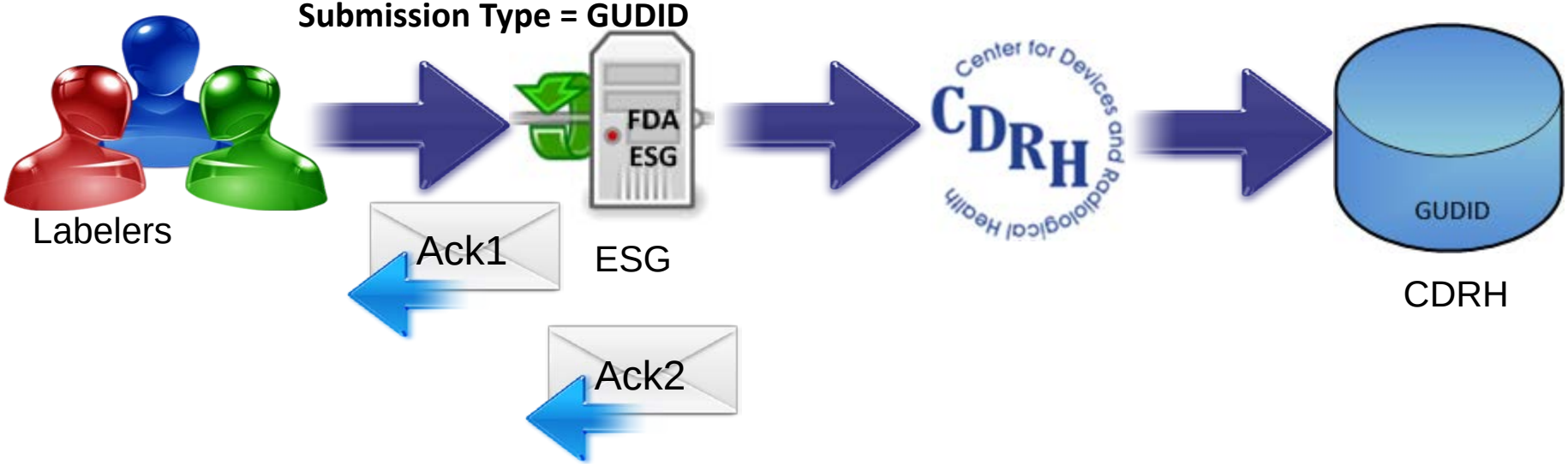

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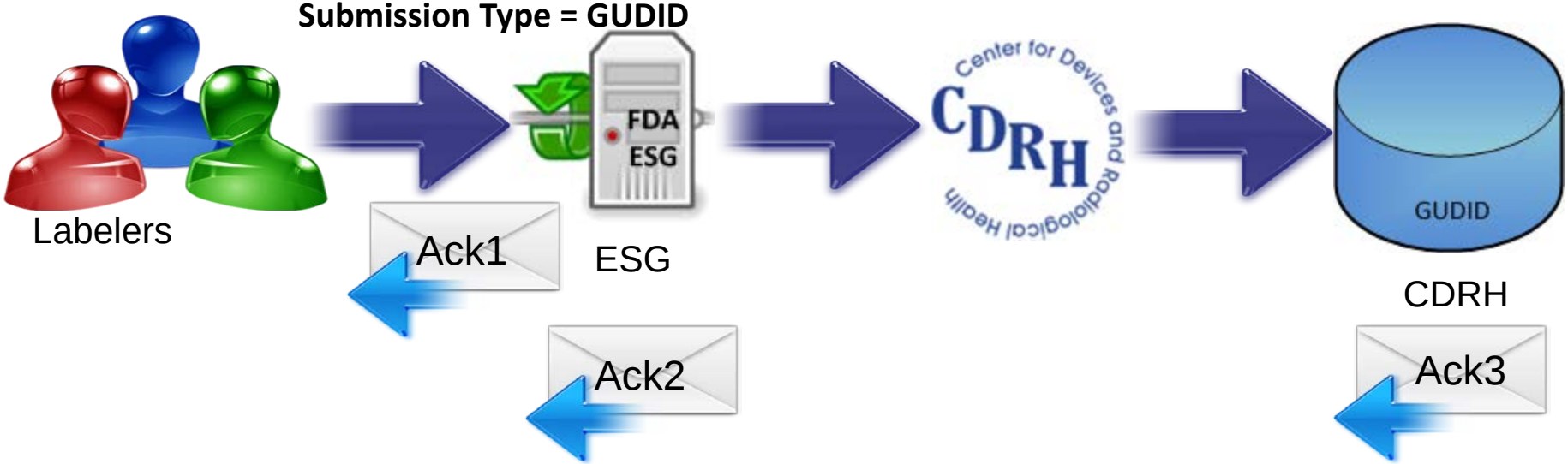

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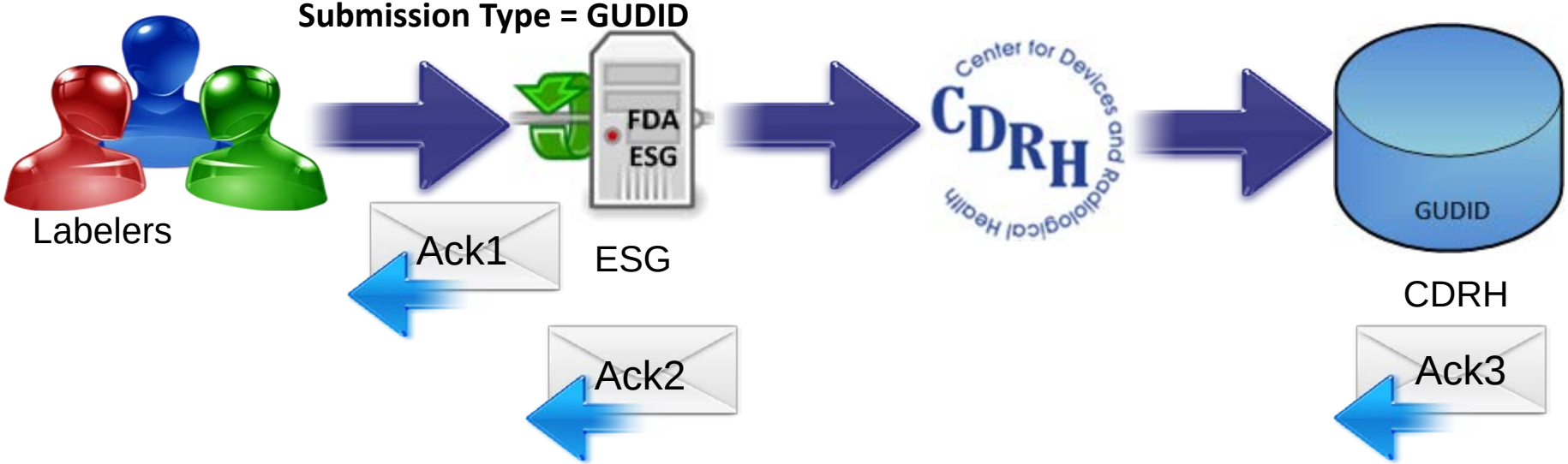
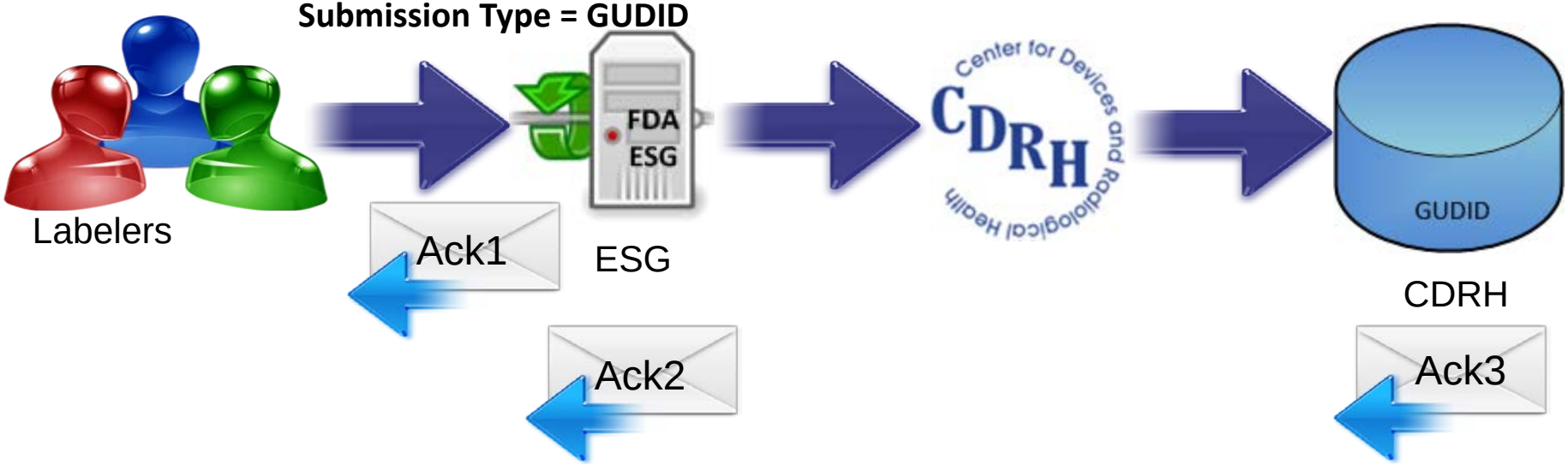


for Ack1 and Ack2 Issues: contact **FDA ESG Help Desk**, esghelpdesk@fda.hhs.gov

Acknowledgements (Ack)

Center = CDRH
Submission Type = GUDID



for Ack1 and Ack2 Issues: contact **FDA ESG Help Desk**, esghelpdesk@fda.hhs.gov

for Ack3 Issues: **contact FDA UDI Help Desk**, gudidsupport@fda.hhs.gov

Acknowledgement Types: Ack1

Ack1/Receipt/MDN

```
This MDN (Message Disposition Notification) was automatically built on
Tue, 25 Mar 2014 23:36:26 GMT in response to a
message with id <20425118.41395790583689 JavaMail.John.ADAMS@ABC1234567> received from
ZZFDATST on Tue, 25 Mar 2014 23:36:25 GMT.
Unless stated otherwise, the message to which this MDN applies
was successfully processed.
```

Acknowledgement Types: Ack1, Ack2

Ack1/Receipt/MDN

```
This MDN (Message Disposition Notification) was automatically built on
Tue, 25 Mar 2014 23:36:26 GMT in response to a
message with id <20425118.413957905836 89 JavaMail.John.ADAMS@ABC1234567> received from
ZZFDATST on Tue, 25 Mar 2014 23:36:25 GMT.
Unless stated otherwise, the message to which this MDN applies
was successfully processed.
```

Ack2

```
MessageId:<20425118.413957905836 89 JavaMail.John.ADAMS@ABC1234567>
CoreId: ci1395790584826.2538@fdsul05622_te2
DateTime Receipt Generated: 03-25-2014, 19:36:52
File Count: 1Directory Count: 2

CDRH has received your submission
```

Acknowledgement Types: Ack1, Ack2

Ack1/Receipt/MDN

```
This MDN (Message Disposition Notification) was automatically built on
Tue, 25 Mar 2014 23:36:26 GMT in response to a
message with id <20425118.413957905836 89 JavaMail.John.ADAMS@ABC1234567> received from
ZZFDATST on Tue, 25 Mar 2014 23:36:25 GMT.
Unless stated otherwise, the message to which this MDN applies
was successfully processed.
```

Ack2

```
MessageId:<20425118.413957905836 89 JavaMail.John.ADAMS@ABC1234567>
CoreId: ci1395790584826.2538@fdsul05622_te2
DateTime Receipt Generated: 03-25-2014, 19:36:52
File Count: 1Directory Count: 2
CDRH has received your submission
```

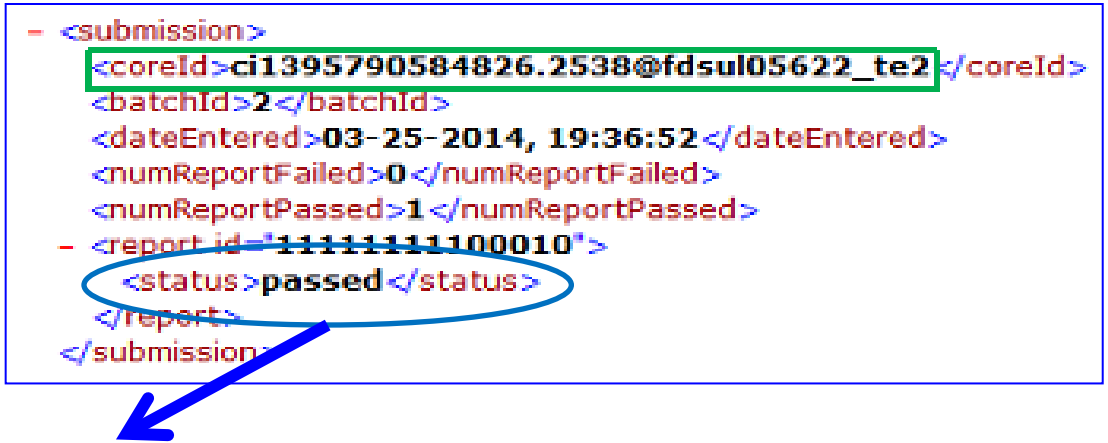
Acknowledgement Types: Ack3

Ack3

```
- <submission>
    <coreId>ci1395790584826.2538@fdsul05622_te2</coreId>
    <batchId>2</batchId>
    <dateEntered>03-25-2014, 19:36:52</dateEntered>
    <numReportFailed>0</numReportFailed>
    <numReportPassed>1</numReportPassed>
  - <report id="11111111100010">
      <status>passed</status>
    </report>
  </submission>
```

Acknowledgement Types: Ack3

Ack3



If Ack3 shows <status>**failed**</status>

<html><body> Unidentified or unparseable submission type [CoreID] </body></html>

Acknowledgement Types: Ack3

Ack3

```
- <submission>
    <coreId>ci1395790584826.2538@fdsul05622_te2</coreId>
    <batchId>2</batchId>
    <dateEntered>03-25-2014, 19:36:52</dateEntered>
    <numReportFailed>0</numReportFailed>
    <numReportPassed>1</numReportPassed>
  - <report id="11111111100010">
      <status>passed</status>
    </report>
  </submission>
```

Unidentified: we do not know where to route it
Unparseable: fails validation against the schema

If Ack3 shows <status>**failed**</status>

```
<html><body><p>Unidentified or unparseable submission type [CoreID]</p></body></html>
```

Acknowledgements (Ack)

Ack1/2 Issues

- esghelpdesk@fda.hhs.gov
- Ack1 – Provide info
- Ack2 – Provide messageID

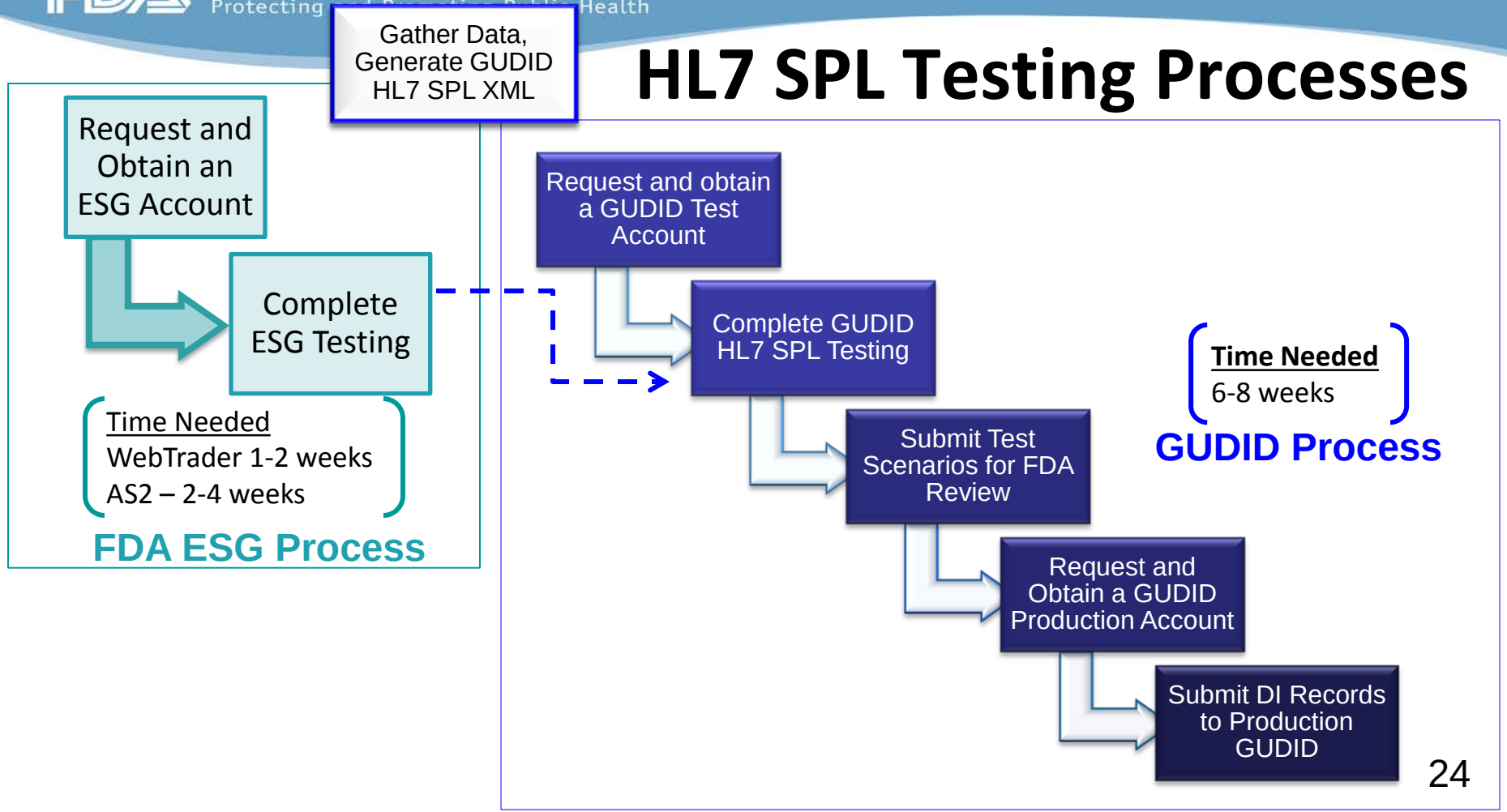
GUDID Global Unique Device Identification Database

Ack3 Issues

- gudidsupport@fda.hhs.gov
- Provide coreID

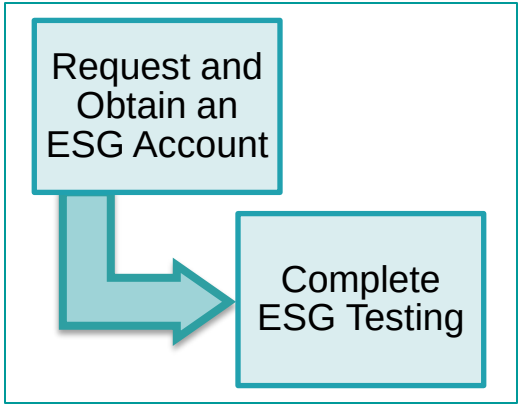
Contact appropriate Helpdesk regarding issues prior to retransmitting

HL7 SPL Testing Processes



ESG Testing Process

- **Request and Obtain a test ESG account**
  - Obtain a digital certificate
  - Send letter of non-repudiation
- **Complete ESG testing**
  - Connectivity test
  - Load test
- **Allocate 2-4 weeks for the above**
- **May Use Existing ESG test accounts**
- **For all GUDID submissions, be sure to specify:**
  - Center = **CDRH**
  - Submission Type = **GUDID**

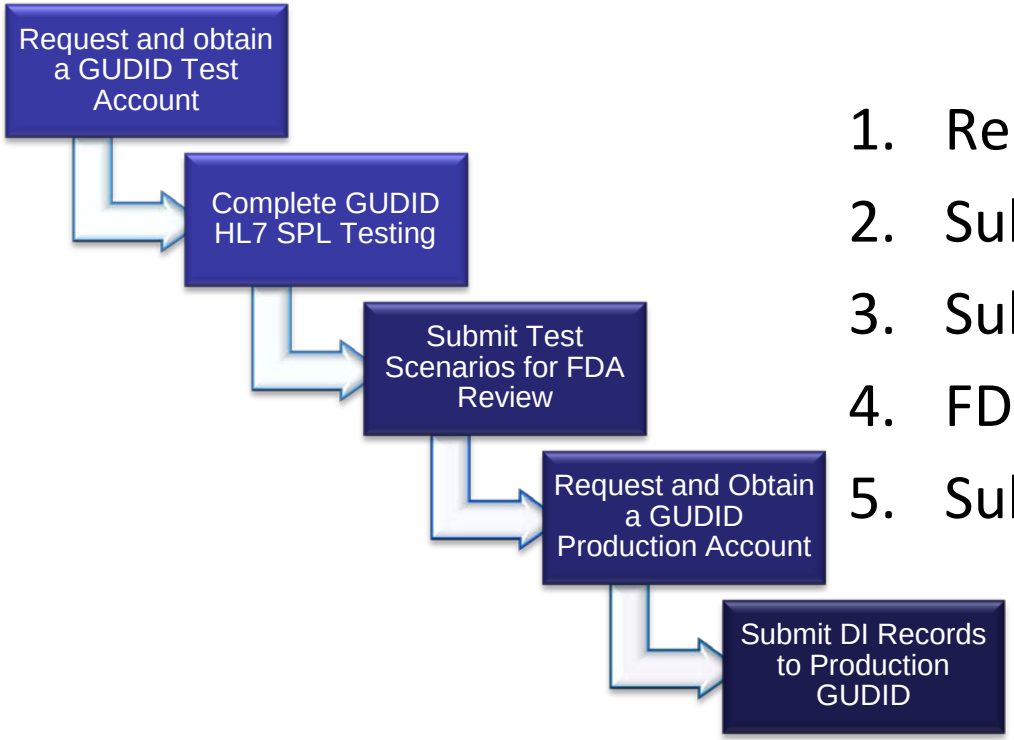


Generate XML Files

- **Build and generate GUDID HL7 SPL XML files**
  - One file for each DI record
  - Validate files against the GUDID schema

- **Unparseable error**
  - Most common error during GUDID testing from users
  - Validating files against the GUDID schema will save you time

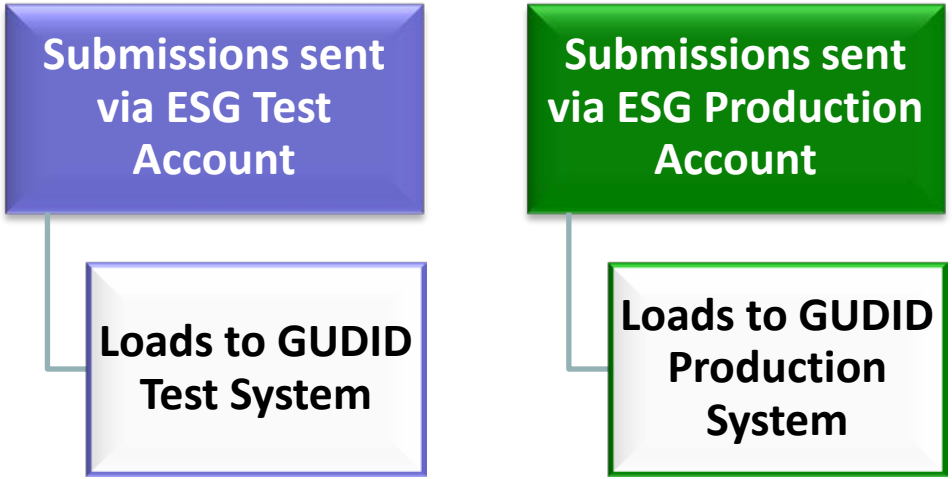
GUDID Testing Process



1. Request a GUDID test account
2. Submit XML files with test scenarios
3. Submit test results to UDI Helpdesk
4. FDA reviews and provides feedback
5. Submit to Production

ESG and GUDID

- ESG serves the entire FDA (all FDA Centers and Programs)
- ESG and GUDID have Test and Production areas



Labelers Using Third-Party Submitters

- **Provide Third-Party information during GUDID account request**
  - If third party is not associated to labeler's GUDID account, submission from third party will be rejected
- **Third Parties may:**
  - Provide software solution/tool to labeler to generate HL7 SPL XML files, and then labeler sends submission via ESG
    - Labeler obtains ESG account
  - Provide end-to-end solution: use labeler data to generate GUDID HL7 SPL XML files AND send submissions via ESG on behalf of labeler
    - Third-party has the ESG account

Labelers and Third-Party Submitters

- Labelers who intend to use the HL7 SPL submission option:
  - must complete GUDID testing
  - even if using a third-party submitter

- Labelers are responsible for fulfilling GUDID submission requirements:
  - Ensure submissions received and processed by FDA.
  - Login to GUDID and review your submissions
  - Report within the required timeframe
  - Maintain proper record keeping

Third-Party Solution Providers

- **May test GUDID HL7 SPL submission solution independently of Labelers**
  - Request a GUDID test Account: indicate it is for HL7 SPL testing
  - Dummy data for certain required attributes provided for testing purposes ONLY, upon request
  - GUDID Web Interface and Production Accounts NOT provided

- **Must complete GUDID HL7 SPL testing with each labeler**
  - Labelers must establish their own separate test GUDID account

GUDID HL7 SPL Pointers

- **Read FDA Guidance on GUDID**
  - www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf
- **Allow adequate time for testing – ESG and GUDID**
- **GUDID testing completion criteria is the bare minimum**
  - Do thorough internal testing to ensure the scenarios appropriate for your products are accounted for

GUDID HL7 SPL Pointers

- Validate submissions against the GUDID HL7 SPL schema
- Do not submit sample message in the HL7 SPL implementation package as a test submission – it is not validated
- Specify Proper Fields
  - Center = CDRH
  - Submission Type = GUDID

GUDID HL7 SPL Pointers

- **Submission folder structure must be followed**
  - Top level folder must be uniquely named
  - Lower level folder must always be named “spl”; only 1 “spl” folder
  - GUDID HL7 SPL xml submission file must be named “submission.xml”
  - Do not include any other files in the “spl” folder
- **Only one submission (one DI record) in each folder structure**

GUDID HL7 SPL Pointers

- **Draft DI record state not available in HL7 SPL submission option**
- **Records can be submitted as**
  - **Unpublished** = DI Record Publish Date is in the future
  - **Published** = DI Record Publish Date is today
  - **Review your submission via the Web Interface**
  - Login as a Labeler Data Entry (LDE) user
  - Labeler DUNS number for that DI record should be assigned to you

Device Identifier Record History

Last Modified Date	Time	DI #	Modified By
Mar 21, 2014	5:03 PM	10020030050373	SPL USER

Data Quality

- **Before you move to production**
  - Complete adequate internal testing
  - Verify test records are loaded correctly to GUDID by logging in

- **After you move to production**
  - Continue to monitor, review and correct records during grace period
  - Review information during Grace Period and make edits as needed
  - Use “export” feature to export all records in GUDID as XML files
  - Remember records go to ***AccessGUDID*** after Grace Period

Data Quality

- **Labeler is ultimately responsible for information submitted to GUDID**
  - it does not matter if third party generates or submits

Editing HL7 SPL Submissions

- **Submit the entire DI record, i.e., include changed and unchanged attributes**
  - DI record will be over-written with the most recent file
  - document.setID – links all related submissions
  - document.versionNumber – tracks versions; increment by 1 for each edit, even for failed submissions
    - First time submission, **versionNumber** = 1, Ack3 = Fail
    - Increment **versionNumber** = 2 before resubmitting

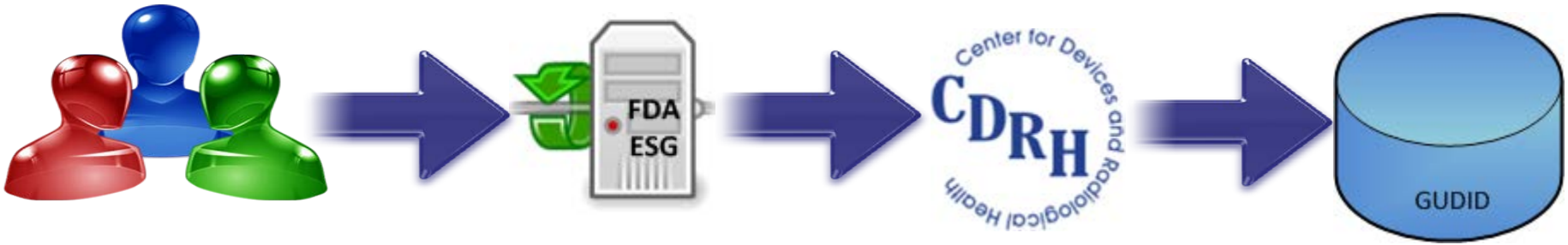
Editing DI Records

- **DI Records submitted using Web Interface**
  - Draft, Unpublished, Published during Grace Period → **must** edit via **Web Interface**
  - Published and past Grace Period → **may** edit via **Web Interface** or **HL7 SPL**

- **DI Records submitted using HL7 SPL**
  - Any state, any time → **may** edit via **Web Interface** or **HL7 SPL**

Submitting Batches in Production

- Start submissions in small batches and slowly ramp up
- Limit submissions to no more than 500 at one time
- If you do not receive Acknowledgements, do not automatically "resend", contact us first



GUDID System Status

- **Scheduled Downtimes**
  - will be posted on www.fda.gov/udi
  - look for GUDID System Status
- **Unscheduled Downtimes**
  - visit www.fda.gov/udi for information
  - if no information, report issue via Help Desk
- **Subscribe to GUDID Email Alerts**

Summary

- Understand the HL7 SPL Submission Process
- Understand the Testing Requirements for ESG and GUDID
- Understand the edit rules to manage your records correctly and accurately
- Understand whom to contact and when for help

Providing Industry Education

1. CDRH Learn – Multi-Media Industry Education

- over 80 modules - videos, audio recordings, power point presentations, software-based "how to" modules
- accessible on your portable devices: http://www.fda.gov/Training/CDRHLearn

2. Device Advice – Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

3. Division of Industry and Consumer Education (DICE)

- If you have a question - Email: DICE@fda.hhs.gov
- Phone: 1(800) 638-2041 or (301) 796-7100 (Live Agents 9am – 12:30 pm; 1-4:30 pm EST)
- **Web Homepage:** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm