Oracle Argus Safety
CDRH eMDR Best Practices

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Preface

This preface contains the following sections:

- Documentation accessibility
- Diversity and Inclusion
- Related resources
- Access to Oracle Support

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Related resources

For information about Oracle Argus patches, see My Oracle Support.

All documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.

Cloud customers receive support assistance through Support Cloud

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- Japanese interface of Oracle Life Sciences Support Cloud へようこそ (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit Life Sciences Support | Oracle or visit Oracle Accessibility Learning and Support if you are hearing impaired.

On-premises customers receive support assistance through My Oracle Support

Oracle customers that have purchased support have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

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Revision History

Argus Version	Description
8.4.1	First release

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Introduction

This document lists best practices and recommendations for generating electronic medical device reports (eMDR).

In July 2019, the Food and Drug Administration (FDA) published guidelines on Post-Marketing Safety Reporting (PMSR) for combination products. These guidelines refer to the reporting of combination products marketed in the United States. FDA has also published a technical specification document for preparing and submitting electronic ICSRs and ICSR attachments in February 2020, which covered the following requirement on similar devices reporting:

Combination Product Applicants for combination products containing device constituent parts should submit Malfunction reports to FDA for otherwise reportable malfunctions, for both devices and device constituent parts of combination products marketed outside the U.S. by that applicant that are the same as, or similar to, the device constituent part of the applicant's U.S.-marketed combination product if the malfunction is likely to occur in the U.S. marketed combination product.

As per FDA, Combination Product Applicants should submit PMSRs consistent with the requirements for combination products with the compliance date set as July 31, 2020 when reporting:

- ICSRs to FDA Adverse Event Reporting System (FAERS);
- ICSRs reported with Electronic Medical Device Reporting System (eMDR).

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How to configure Device Products

Best practices for configuring device products from the Business Configuration screen.

1. In Argus Console, navigate to the **Business Configuration** tab from the main menu bar and select **Products and Licenses**.

2. On the Products and Licenses screen, at the bottom of the left pane, click the **Add New Family** button.

3. Enter the required data and then click **Save**.

4. Click **Add New Product** on the bottom of the left pane and then enter the required data in the right pane.

5. **Save** the product. Make sure that you entered the three-character **Device Code and Manufacturer**.

6. Click **Add New License** on the bottom of the left pane and then enter the data required for creating a device license, as seen in the examples below:

   a. Authorization country = UNITED STATES

   b. License Type = Marketed Device

   c. PMA/510(k)# = <PMA number>

7. **Save** the license.

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How to set up reporting destinations

Recommendations for creating the reporting destination required to send eMDR to the Center for Devices and Radiological Health (CDRH), if the submitter is a Manufacturer.

On the Agency Information tab

Enter the name and address information, as applicable.

The CDRH technical specifications recommends using **CDRH_ESUBS** as Agency Identifier.

Select the **Manufacturer** check box for the Contract Type field.

On the Local Company tab

Enter the name and address information of the Local Company Contract that is responsible for eMDR submission.

Other than the mandatory fields displayed, the following data is required for eMDR submission:

- Sender Type
- Department
- Contact Name information:
    - Title
    - First Name
    - Last Name
    - Address
    - City
    - State
    - Postal Code
    - Country
    - Phone
    - Fax
    - Email Address

On the EDI tab

The CDRH technical specifications recommends using CDRH_ESUBS as Agency Identifier.

For the Message Profile field, select **CDRH EMDR V1.0 MESSAGE TEMPLATE**. This is the standard profile.

The **ACK Profile** option is disabled for eMDR.

Mark the **Transmit ICSR Attachments** option.

For **Attachment Classification**, mark one or more attachment classifications, depending on what is required for submission along with the eMDR.

The supported attachment file size is 15 MB and 50 MB for the report size.

Make sure to specify the outgoing folder location. Example: `C:\ESM\CDRH\OUT\`.

Select the **E2B EDI gateway** Method.

> **✎ Note:**
>
> If the eMDR submitter is an Importer or a Distributor, then follow the same steps as described above for Manufacturer. However, make sure that the **Importer** or **Distributor** check box is selected instead of the **Manufacturer** check box.

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How to set up reporting rules

The recommended reporting rules that are needed when you enable eMDR report scheduling.

Country	License type	Agency	Rule Name	Time frame	Report Form	Condition
United States	Marketed Device	CDRH	5-day	5	eMDR	A criteria that uses Advance conditions with Remedial Action. Any other condition as per your company's business process.
United States	Marketed Device	CDRH	30-day	30	eMDR	Case Serious = NO Criteria using Advance conditions with Malfunction = Yes Any other condition as per your company's business process.

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How to create and process cases with Device Products

Steps for creating and processing cases with Device Products

Follow these steps to create and process cases with Device Products when generating an eMDR:

1. Book-in a case with the information received as per the source documents.

    > ✎ **Note:**
    >
    > When you select the product from the **Product** browser, the **Device** tabs are enabled if the suspect product involved is a device product.

2. Enter Device data. You can also enter additional device information in the MedWatch information pop-up window within the **Device** tab.

3. You can select:

    *   IMDRF Codes that refer to the Device Problem code, evaluation Codes from the **Device** tab.

    *   IMDRF Codes pertaining to Patient Problem codes from the **Events** tab > Clinical Signs IMDRF Code.

4. If the administered product was a Combination Product, enter the Drug information as a separate product in the case and then enter data in the **Drug** tab.

5. Save the case. Make sure all mandatory information required for CDRH submission is entered.

6. Perform auto-scheduling. The system schedules an eMDR to the CDRH agency by using the eMDR Profile.

7. Click the **Draft** link to preview the report in XML view.

8. The Device data is embedded within the `<suspectdevice>` block as seen below:

    ```
     <suspectdevice>
      <brandname>PaceM</brandname>
      <typeofdevicename>Heart Pacemaker</typeofdevicename>
      <typeofdevicecode>OSR</typeofdevicecode>
      <singleusereprocorreuse>true</singleusereprocorreuse>
     <devicemfrinfo>
      <mfrname>Aster Inc</mfrname>
      <mfraddressline1>#4, Presto Avenue</mfraddressline1>
      <mftcity>Irvine</mftcity>
      <mfrcountry>USA</mfrcountry>
      <mfrpostalcode>787938794</mfrpostalcode>
      <mfremail>mailto:Test@test.com</mfremail>
    ```

```
    </devicemfrinfo>
    </suspectdevice>
```

9. The Drug data is embedded within the `<suspectproducts>` block as seen below:

```xml
<suspectproducts>
  <drugseqnum>1</drugseqnum>
  <drugname>Drug-A </drugname>
  <manufacturername>Aster Inc</manufacturername>
  <drugbatchnumb>B30475</drugbatchnumb>
  <drugstructuredosagenumb>3</drugstructuredosagenumb>
  <drugstructuredosageunit>012</drugstructuredosageunit>
  <drugadministrationroutetext>003</drugadministrationroutetext>
  <drugstartdate>20200420</drugstartdate>
  <diagnosisuse>Injection(Injection)</diagnosisuse>
  <compoundedproduct>false</compoundedproduct>
  <otcproduct>false</otcproduct>
</suspectproducts>
```

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Frequently asked questions

The most frequently asked questions about generating electronic medical device reports (eMDR).

In this chapter:

- Do you require an acknowledgment profile for eMDR?
- Does eMDR print multiple suspect devices?
- Is the Allowed Value Check validation rule performed for IMDRF codes during eMDR generation?
- Are date validation checks handled in eMDR report generation checks?

Do you require an acknowledgment profile for eMDR?

No, you don't. eMDR acknowledgments (ACKs) are read by Interchange without using the profile. Interchange recognizes specific tags within the ACK file that is received by the agency and it is able to determine if submission was accepted or rejected.

Argus does not create ACK files for eMDR, as an import feature is not supported.

Does eMDR print multiple suspect devices?

For device reports such as a MedWatch device, eMDR prints only the suspected device in the scheduled report. If there are multiple suspect devices, then multiple reports are scheduled, namely one report for each suspected device.

Is the Allowed Value Check validation rule performed for IMDRF codes during eMDR generation?

No, Allowed value check is not performed for eMDR during generation. It is recommended that you update the IMDRF repository to the latest version to avoid any rejections due to obsolete codes.

Are date validation checks handled in eMDR report generation checks?

Date validation checks such as Explanted Date (D6b) must be equal to or greater than the Implanted Date (D6a) and it is not provided as Out-of-the-box validation during eMDR generation. Checks on incorrect dates can be performed during data entry by creating field validations in Argus Console.

For more information on field validations, see the *Oracle Argus Safety Administration* guide.