Oracle Argus Safety Japan
Administration Guide

Release 8.4
F51806-01
September 2022

Oracle Argus Safety Japan Administration Guide, Release 8.4

F51806-01

Copyright © 2019, 2022, Oracle and/or its affiliates.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software, software documentation, data (as defined in the Federal Acquisition Regulation), or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs) and Oracle computer documentation or other Oracle data delivered to or accessed by U.S. Government end users are "commercial computer software," "commercial computer software documentation," or "limited rights data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, reproduction, duplication, release, display, disclosure, modification, preparation of derivative works, and/or adaptation of i) Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs), ii) Oracle computer documentation and/or iii) other Oracle data, is subject to the rights and limitations specified in the license contained in the applicable contract. The terms governing the U.S. Government's use of Oracle cloud services are defined by the applicable contract for such services. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle®, Java, and MySQL are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Inside are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Epyc, and the AMD logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

Contents

Preface

Documentation accessibility v
Related resources v
Access to Oracle Support v

1 Business Configuration

Configuring Product Family 1-1
Configuring Products 1-1
Configuring Licenses 1-2
- License Configuration 1-2
- Exclude from Report Candidates option 1-4

Configuring Studies 1-5
Configuring Expedited Reporting Rules 1-7

2 System Configuration

Configuring Common Profile Switches 2-1
- Common Profile Switches for Oracle Argus Safety Japan 2-1
- Common Profile Switches for Reporting 2-3
  - Profile Switch for Incomplete Report Submission - Auto Action item 2-7
  - PMDA Downgrade/nullification Report Scenario when All Events are Non-Reportable 2-8
- Common Profile Switches for Device Report 2-9
- Common Profile Switches for E2B 2-10

Configuring Field Level Validations 2-12
- Field Label Configuration (J Specific) 2-12

Configuring Field Labels 2-12
- User Defined Fields Updates 2-13

Configuring Local Reports - Local Reporting Rule and Local Reports 2-13

3 Code List Configuration

Code Lists 3-1
- General Functionality Changes 3-1
- Device Classification 3-2
- Device Outcome 3-3
- Device Reporting Category 3-4
- Emperor 3-5
- J Reportable Product Keyword 3-6
- License Category 3-7
- Literature Type 3-7
- Reporting Category 3-8
- Literary Citation 3-9
- Reporting Destination 3-10
- Manufacturers 3-11
- Reporter Information 3-12
- Flexible Data Re-Categorization 3-14
  - Reporting Category (LM_RPT_CATEGORY) 3-15
  - License Category (LM_LIC_CATEGORY) 3-16
  - Dev Phase (LM_DEV_PHASE) 3-16
  - Risk Category of OTC Drug (LM_RISK_CATEGORY_OTC) 3-16
  - Route for Acquiring OTC Drug (LM_ROUTE_ACQUIRE_OTC) 3-17
  - Device Reporting Category (LM_DEVICE_RPT_CATEGORY) 3-17
  - Device Classification (LM_PMDA_DEVICE_CLASSIFICATION) 3-18
  - Device Outcome (LM_PMDA_DEVICE_OUTCOME) 3-18

Preface

This preface contains the following sections:

- Documentation accessibility
- 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.

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

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface of Oracle Health Sciences Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs 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.

1

Business Configuration

This chapter lists the Japanese-specific (J-specific) features in the Business Configuration module of Oracle Argus Safety Console.

For more information, see:

- Configuring Product Family
- Configuring Products
- Configuring Licenses
- Configuring Studies
- Configuring Expedited Reporting Rules

Configuring Product Family

The following table displays the Japanese specific fields:

Field	Description
Product Family Name (J)	Enter a new product family name in Japanese.
Comments (J)	Enter the comments.

> **Note:**
>
> These fields are displayed only to an Oracle Argus Safety Japan (Argus J) user when the Japanese module is enabled.

The fields are printed in the Product Family Configuration print PDF and are covered by the back-end PL/SQL APIs for Product Family Configuration data table updates and audit-logging.

Configuring Products

The following table lists the Japanese specific fields in the Product screen:

Field	Description
J-DRUG コード	Captures the J Drug Code for each ingredient of the product. This field is configured from **Argus Console** > **Business Configuration** > **Product and Licenses** > **Product (J Data Entry)** > **Key Ingredients** > **J-Pop-up**. • This is a text field, and is audit logged. • When the product is added to any case, the Ingredients are populated under **Case Form** > **Product** > **Substance Information**. The J Drug Code of the Ingredient is also populated as configured in Oracle Argus Safety Console.
医療機器の一般名 (Device Generic Name)	Provides the Device Generic Name from the JMDN glossary.
JMDN コード (JMDN Code)	Provides the JMDN Code from the JMDN glossary.
使用辞書コード (Terminology Code)	Provides the Terminology Code from the JMDN glossary.
J-DRUG コード for Product (J Drug Code or OTC Code or Temp Code)	Provides the J Drug Code from the Drug Coding dialog box. You can manually configure the OTC Code or Temp Code if the J Drug Code is not available for the product.

Note:

The other fields on this window, such as Product Name (J) or Ingredient Name (J) are equivalent Japanese values to the corresponding English fields.

Configuring Licenses

The following section describes the changes in License Configuration:

- License Configuration
- Exclude from Report Candidates option

License Configuration

The following table displays the Japanese specific fields on the License Configuration window:

Field	Description
PMDA Re-examination Date	The date of the next PMDA examination.

Field	Description
Clinical Compound Number	The number that identifies the specific chemical compound. • You can edit this field when the Authorization Country is Japan and the license type is either Investigational Drug or Investigational Vaccine. • The Clinical Compound field is only available to users to Oracle Argus Safety Japan.
TIKEN	Selecting the TIKEN check box indicates that the customer will not send the investigational report for the other license.
Blind J.10/J2.11 in PMDA AE Paper Report	This check box is disabled by default and shall be enabled only when the License country is Japan.
Medicinal Product Name	This field is to transmit the investigational products for the DC or DD reporting category in G.k.2.2. This configuration could be used in specific use cases as per the PMDA guidance if: • The drug has multiple CCNs (Clinical Compound Numbers). • It is used for different studies due to a different route of administration. • The active ingredient is approved in JP. • It is a foreign CT report.
PMDA Device Classification 1	This field PMDA Device Classification 1 is for configuring Device Classification printed in PMDA Device report.
PMDA Device Classification 2	This field PMDA Device Classification 2 is for configuring Device Classification printed in PMDA Device report.
PMDA Device Classification 3	This field PMDA Device Classification 3 is for configuring Device Classification printed in PMDA Device report.
Status Category of new drugs	This list captures the Status category of new drugs. The data in this list is populated based on the data in the License Category code list.
Risk Category of OTC drugs	This list captures the Risk Category of over-the-counter (OTC) drugs. The data in this list is populated based on the data in the Risk Category of OTC Drug code list. These new fields available in License Configuration print for both **Print** and **Print All** options. They also support the License/Product with Licenses copy functionality. Any changes to these fields value is logged for audit.

These fields are audit-logged.

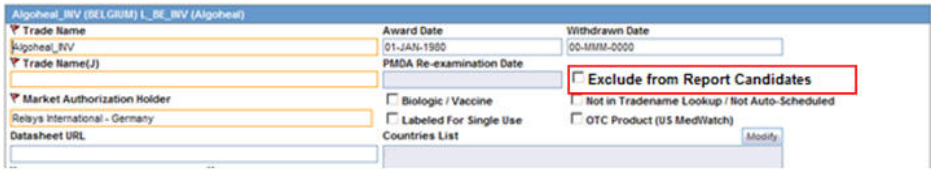
These fields are covered by the back-end PL/SQL APIs for License Configuration data table updates and audit-logging.

The fields available in License Configuration print for both **Print** and **Print All** options. They also support the License/Product with Licenses copy functionality. Any changes to these fields value is logged for audit.

> **Note:**
>
> Other fields, such as Trade Name (J) or Comments (J), are for Japanese data entry equivalent to English fields.

Exclude from Report Candidates option

- The option **Exclude from Report Candidates** has been added to Oracle Argus Safety Console > **Business Configuration** > **License Configuration** as shown below.
  - This check box is displayed to only an Oracle Argus Safety Japan user and when Japanese module is enabled.
  - By default, this field is unchecked.
  - This check box is enabled only when the Authorization Country is Japan.
  - This field value is printed in License Configuration print PDF.
  - Updates to this field value are audit-logged.



- When the product is populated in the case created through J Literature Intake module, it populates only one record in the **Case Form Products** tab for each Product in the matching Product Family. If there are multiple Japanese licenses for a product, then the correct license is picked up based on the following logic:
  - License Authorization Country = Japan
  - Withdrawn date is blank or >= current system date
  - **Hide** check box is not selected for that product license combination
  - **Not in Tradename lookup/Not Autoscheduled** check box is not selected
  - **Exclude from Report Candidates** check box is not selected
  - If multiple licenses exist matching this criteria, then the Earliest awarded date license is considered
  - If multiple licenses still exist matching this criteria, then the license with the lowest internal sequence number is considered.
- Following is the change in logic that is used to populate Japanese licenses on Event Assessment and PMDA tabs. There is no change in logic for other country licenses. Manually Added Products through Bookin or Case Form or Case Intake or Affiliate Event Acceptance:

  - If the user selects a Japanese license during product selection in **Bookin / Case Form / Affiliate Event**, then only that license is considered for Event Assessment and PMDA tabs irrespective of the value of **Exclude from Report Candidates** check box.
  - If the user selects a non-Japanese license during product selection in **Bookin / Case Form / Affiliate Event**, then only the Japanese licenses for which **Exclude from Report Candidates** check box is not selected is considered for populating Japanese licenses in Event Assessment and PMDA tabs.
- Products Added through Literature Intake:
  - Only the Japanese licenses for which **Exclude from Report Candidates** check box is not selected are considered for populating Japanese licenses in Event Assessment and PMDA tabs.
- Products Added through E2B Import:
  - Only the Japanese licenses for which **Exclude from Report Candidates** check box is not selected are considered for populating Japanese licenses in Event Assessment and PMDA tabs.
  - While identifying the product license to be used to populate the Products tab, only those Japanese licenses are used for which **Exclude from Report Candidates** check box is not selected.
  - This is applicable to all the E2B factory profile logic - ICH, FDA, EMEA and PMDA.
- PMDA Event Assessment section on PMDA General tab:
  - Only the Japanese licenses for which **Exclude from Report Candidates** check box is not selected are considered for populating Japanese licenses in Event Assessment and PMDA tabs.
- **Manual Report Scheduling dialog** > **License # drop-down** displays only those Japanese licenses which are available on **Event Assessment** tab.

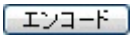
Configuring Studies

The user can now select a particular license that is then used to fetch the CCN and other related data.

The following list displays the Japanese specific fields:

- 治験成分記号 (Clinical Compound Number)
- 対象疾患(使用理由) (Target disease)
- 投薬中の症例の有無 (Are any subjects given this investigational drug?)
- 届出回数 (Notification Number)
- Test Drug Type

> **Note:**
>
> This field can be used to configure the type of drug as required for the PMDA reporting by using this configuration in the advanced condition SQL queries for the reporting rules.

After selecting a J Drug, the user must add it to the product section of the J pop-up. The column called **WHO Encoded?** has been added to the product grid. If the J Drug is not associated with a WHO drug, an  ("Encode") button appears in the column. Clicking this button opens the WHO Drug Browser, so the user can associate the J Drug with the corresponding WHO drug, if it is available. This step is not mandatory. Once the J Drug has been associated with a WHO drug, the button is replaced with the letter **Y**, meaning "Yes".

> **Note:**
>
> Clicking the (**Encode**) button opens the English version of the WHO Drug Browser.

Before closing the J pop-up, the user is reminded to associate the J Drugs with WHO drugs if the association has not been made for all the J Drugs. This is not mandatory.

The application has been enhanced such that when you add a J Drug to the **Argus Console** > **Business Configuration** > **Study Configuration (J pop-up)**, the corresponding English Drug name is populated in the English Product name.

> **Note:**
>
> The same English product name is populated in the Case form English Product name (as explained below) when the corresponding study drug is added in the case.

- The application lists the above added J drugs in the study for which the English product name is not blank (or not default text *J DRUG* in DB) in the corresponding English Study configuration screen. These products are listed in the existing Products grid of the corresponding English Study configuration screen.
- The functionality of associating the J Drug in the study configuration with the corresponding WHO drug remains intact. When the user tries to associate the J Drug with the WHO drug, by clicking the WHO Drug association button such that English Drug name is not blank (or default text *J DRUG*), the WHO Drug Browser opens with the pre-populated English Drug Name (populated from the English sub file) in the Trade Name (text box) of the WHO Drug Browser, for the user to perform a quick search. Also, when the user associates the J Drug to the WHO drug, the English Product Name is updated with the Product name returned from the WHO dictionary.

When the user adds a JDrug from J Drug Browser for which the English drug name is blank, the existing behavior of populating *J DRUG* in the English product name has been retained.

The Product Grid in both the English and J Study Configuration pop-up screens has been updated as follows:

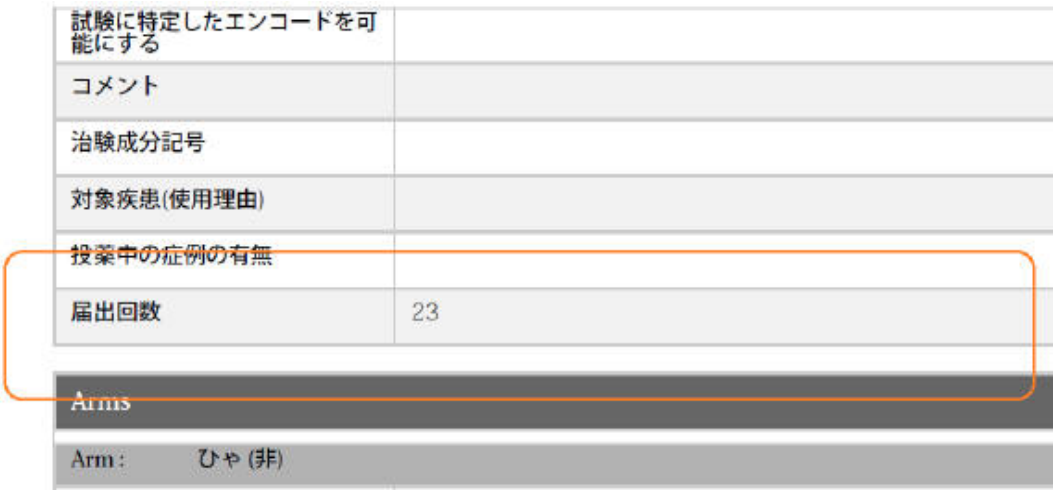
- Product, Dosage, Unit, and Formulation have been merged into one column called **Product Name (Dosage Form / Strength / Unit)**.

- The license selection drop-down list, **License**, has been added in the J pop-up Product Selection grid. This list contains all the J Licenses that are present for the respective product.
- This license is used as the primary selected license when you select the product as the study drug in the Case Form, in the following format:

  Trade name<space>(License Type)<space>Clinical compound Number or License Number

  The License Type is printed as *MKT* for **Marketed Drug/Device/Vaccine** and *INV* for **Investigational Drug/Device/Vaccine**.

  This license should be used as Primary license if the case is accepted as Initial/Follow-up from E2B, Literature Intake or Case Intake.
- The study configuration field, **Notification number**, has been added in the J pop-up Product Selection grid to capture the notification number. The notification number is the unique number allocated by PMDA to each study for a particular Clinical compound number.



  You must enter numeric data in this field.

  This new field is available in Study Configuration print for both **Print** and **Print All** options. It also supports the Study copy functionality. Any change to this field value is logged for audit.

Configuring Expedited Reporting Rules

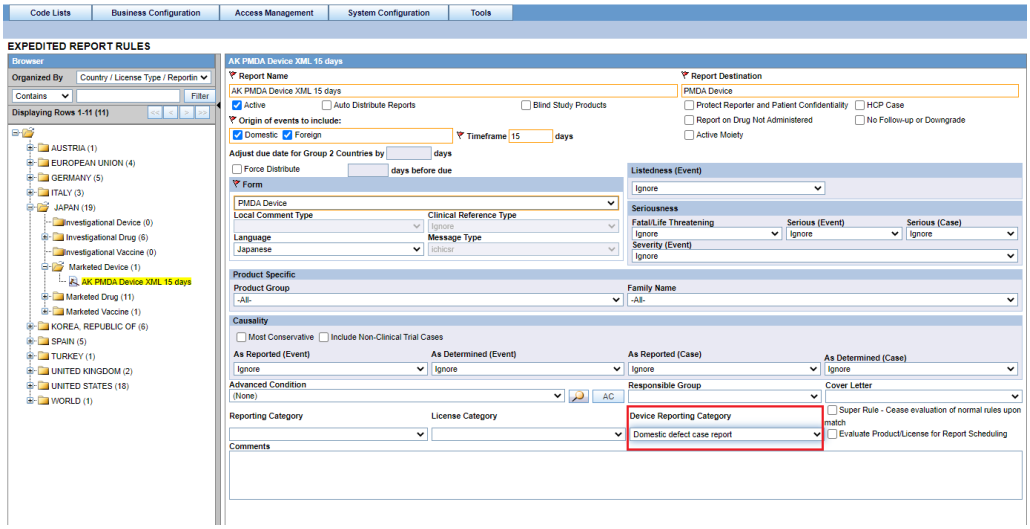
When you configure a reporting rule report from Console > Business Configuration > Expedited Reporting Rules and if you select PMDA Device Report in the Form drop-down menu, then the application populates ichicsr in the Message Type drop-down field and disables it.

The following list displays the Japanese specific fields and information:

- Reporting Category
- License Category

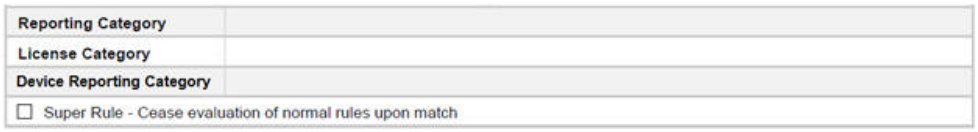
- Device Reporting Category

The drop-down list **Device Reporting Category** has been added to Oracle Argus Safety Console > **Business Configuration** > **Expedited Reporting Rules** screen as follows:



- This field is displayed to English as well as Japanese users only when Japanese module is enabled.
- This drop-down displays the English values as specified in the **Device Reporting Category Code List** and are marked as **Display**.
- It contains <Blank> as the first option and it is also the default value.
- This field is printed in **Expedited Report Rules Print PDF** right below **License Category** field in alternating colored row.
- This field is audit-logged.
- It is covered by the back-end PL/SQL APIs for Expedited Reporting Rules data table updates and audit-logging.

Figure 1-1 Figure 1-3 Console Expedited Reporting Rules Configuration - Print PDF



2

System Configuration

This chapter lists the Japanese-specific (J-specific) features in the System Configuration module of Oracle Argus Safety Console:

- Configuring Common Profile Switches
- Configuring Field Level Validations
- Configuring Field Labels
- Configuring Local Reports - Local Reporting Rule and Local Reports

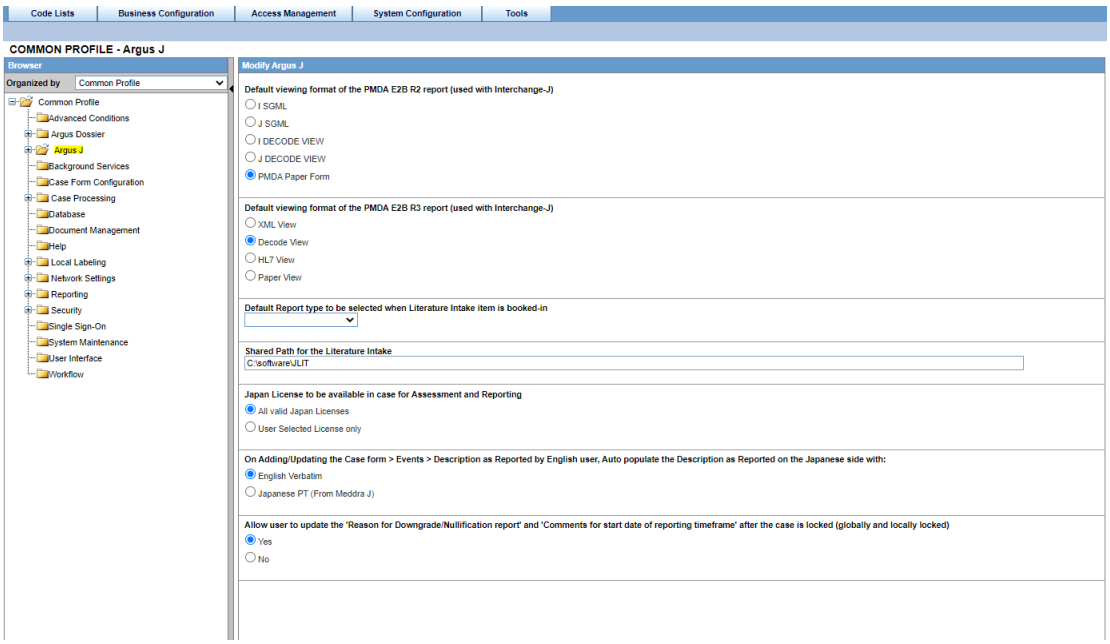
Configuring Common Profile Switches

This section describes the functionality for the J-specific Common Profile switches:

- Common Profile Switches for Oracle Argus Safety Japan
- Common Profile Switches for Reporting
- Common Profile Switches for Device Report
- Common Profile Switches for E2B

Common Profile Switches for Oracle Argus Safety Japan

The following figure is displayed when you navigate to **Common Profile** > **Argus J**:



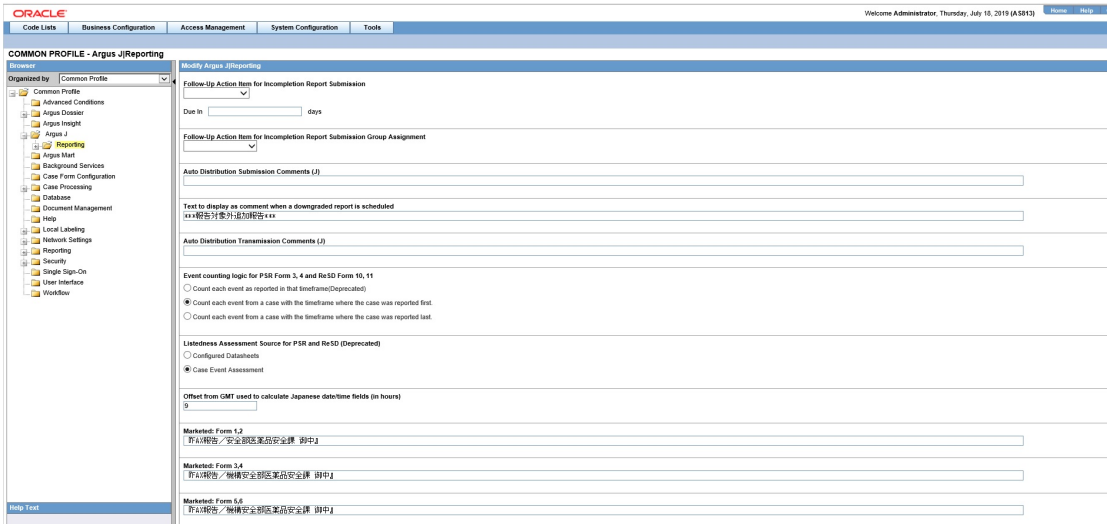
The following table explains the fields used in the screen:

Field Name	Description	Field Options
Default viewing format of the PMDA E2B R3 report (used with Interchange-J)	The field represents the formats for viewing the PMDA E2B R3 report (used with Interchange-J) Default Value is Decoded.	XML Decoded HL7 Paper View
Default viewing format of the PMDA E2B R2 report (used with Electronic Submission Module (Interchange-J))	This field represents the default viewing format of the PMDA E2B R2 report (used with Electronic Submission Module (ESM)). When **PMDA Paper Form** is selected, the system determines the correct paper format from the **Reporting Category** E2B item and creates paper draft image. Default Value: 1	I SGML J SGML I Decoded View J Decoded View PMDA Paper Form
Default Report type to be selected when Literature Intake item is booked-in	This field represents the default report type value for **Book-in** screen for cases booked-in through Literature Cases. Default Value is blank.	Report Type configured in Oracle Argus Safety Japan Console
Shared Path for the Literature Intake	This field represents the shared path for the Literature Intake. Default Value is blank. PSR configuration UI Subject of Report/Report Number Investigation Timeframe/Assigned Date Investigation Timeframe/International Birthdate Investigation Timeframe/Japanese Aware Date Investigation Timeframe/Report is due ___days after specified end date Investigation Timeframe/Start Date Investigation Timeframe/End Date Report Batch Printing popup / Run at Report Batch Printing popup / Due Date Oracle Argus Safety Japan Console: The following items are forced to input Alphanumeric characters by profile switch: All the J pop-up fields marked as S (Share same value as English one. So there is same database field for both) in Oracle Argus Safety Japan Console SRS **Population Rule** section. All the regular fields that have A (Alphanumeric only) in Input Lang Type classification of Oracle Argus Safety Japan Console SRS. Default Value is checked.	Maximum Length: 255

Field Name	Description	Field Options
Japan License to be available in case for Assessment and reporting	The field represents the selection for Japan licenses to be available for Assessment and reporting.	All valid Japan Licenses User Selected License only
On Adding/Updating the Case form > Events > Description as Reported by English user, Auto populate the Description as Reported on the Japanese side with:	The field represents the auto-population options for Description as Reported on the Japanese side on adding or updating the case form. Default Value is English Verbatim.	English Verbatim Japanese PT (From Meddra J)
Allow user to update the “Reason for Downgrade/ Nullification report" and “Comments for start date of reporting timeframe" after the case is locked (globally and locally locked).	The field represents the options available after the case is globally locked. Default Value is Yes.	Yes No

Common Profile Switches for Reporting

The following screen is displayed when you navigate to **Common Profile** > **Argus J** > **Reporting**:



The following table explains the fields used in the screen:

Field Name	Description	Field Options
Follow-Up Action Item for Incompletion Report Submission"Due In ____ days"	--	Populated based on Action Type Code list values (not deleted and not hidden) For more information, see Profile Switch for Incomplete Report Submission - Auto Action item .
Follow-up Action Item for Incompletion Report Submission Group Assignment	This field represents the user group to which the Incompletion Report Submission Action Item is assigned. Default value is blank.	User Groups from Console For more information, see Profile Switch for Incomplete Report Submission - Auto Action item .
Auto Distribution Submission Comments (J)	This field allows you to enter the Japanese Submission comments used for Expedited Reports Transmission, which are auto-distributed by the system based on Expedited Reporting Rules or Reporting Destinations. These comments are used in the same way as **Auto Submission Comments**, but when J user is on the system.	Field Length: 1000 Audit Log: Yes
Text to display as comment when a downgrade report is scheduled	The field length is 2000 J. The text appears in the **Report Detail** > **Comment** tab.	--
Auto Distribution Transmission Comments (J)	This field allows you to enter the Japanese Transmission comments used for Expedited Reports Transmission, which are auto-distributed by the system based on Expedited Reporting Rules or Reporting Destinations. These comments are used in the same way as **Auto Distribution Comments**, but when J user is on the system.	Field Length: 1000 Audit Log: Yes

Field Name	Description	Field Options
Event counting logic for PSR Form 3, 4 and ReSD Form 10, 11	Option 1 is deprecated. Option 2 - If this option is selected, then the PSR Form 3, 4 and ReSD Form 10, 11 is be updated to count or print all the events from the case only under the timeframe where that case was reported first. Even if a new event (new event_seq_num) from a case has been reported in an E2B or Paper Report to PMDA in the current reporting period, it must be counted or printed under the original timeframe. Option 3 - If this option is selected, then the PSR Form 3, 4 and ReSD Form 10,11 are updated to count or print the events from the latest submitted E2B or Paper Report in the latest timeframe where it was reported across all the timeframes for which the report is executed.	1. Count each event as reported in that timeframe (Deprecated)) 2. Count each event from a case with the timeframe where the case was reported first. 3. Count each event from a case with the timeframe where the case was reported last.
Listedness Assessment Source for PSR and ReSD (Deprecated)	The common profile switch “Listedness Assessment Source for PSR and ReSD" is marked as deprecated. Instead a new report level parameter is added “Listedness Assessed on" in PSR/ReSD configuration window.	Configured Datasheets Case Event Assessment
Offset from GMT used to calculate Japanese date/ time fields for Interchange-J (in hours)	This field represents the offset from GMT that is used to calculate Japanese date/time fields. ESM-JDefault Value: 7	--
Blinded text for PMDA AE Paper reports	Enables you to enter blinded text for PMDA AE Paper reports.	--
Major Developed Countries for Approval Status in J-DSUR	This field lists the countries to be considered as major developed countries for J-DSURs.	Text box with 1000 characters limit, without any default value. Users can also configure comma-separated A2 country codes.
Perform Japanese character validation at E2B Check and E2B Report Generation.	If this is checked, the Japanese language check is performed during E2B Report Generation. Default value is checked.	This option is in the same section as **Additional invalid characters to be checked in Japanese character validation.**

Field Name	Description	Field Options
Additional invalid characters to be checked in Japanese character validation	This field allows you to add invalid Japanese characters to be checked in Japanese Language check in the profile switch.	This option is in the same section as **Perform Japanese character validation at E2B Check and E2B Report Generation** When the **Perform Japanese character validation at E2B Check and E2B Report Generation** checkbox is unchecked, this field is disabled.
Characters to be allowed to use in AN (Alphanumeric) E2B items	In this field, you can enter English characters allowed in Oracle Argus Safety Japan. When this is entered, the English characters E2B check validates if AN fields (Allow Japanese Characters=No) has undefined characters in the Profile Switch. The E2B check displays following error message when invalid character(s) (characters not configured in the Profile switch) are found in the E2B item: Value of element [element tag] has invalid English character(s). Default Value: ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz0123456789.E+- !"#$%'()*+,-.:;=?@[\]^_/{|}~	--
Perform PMDA Event Reportability calculation on each Case Lock	If this common profile switch is set to "Yes", then when the case is locked from any point in the Oracle Argus Safety application, it triggers fresh calculation of the PMDA Event Reportability data.	Yes, No (Default).
PMDA E2B Nullification Reason Text for No Valid Event Scenario	--	No For more information, see PMDA Downgrade/ nullification Report Scenario when All Events are Non-Reportable

Field Name	Description	Field Options
Product details printing format in PSR NUPR - Word format	When you select Option 1 (**Print Trade Name, Formulation, Strength, Drug code as available**), the application prints data in the format <Trade Name (J)> (<Formulation (J)>space<Strength> <Unit (J)>) (Drug Code (J)). If the Formulation or Strength fields (or both) do not contain value, then prescribed text is printed to indicate that they are unknown. When you select Option 2 (**Print Trade Name unknown when Formulation or Strength not available**) the application prints data in the format: <Trade Name (J)> (<Formulation (J)>space<Strength> <Unit (J)>) (Drug Code (J)). If the Formulation or Strength fields (or both) do not contain value, then the application prints only the J Drug Code.	--

For more information, see:

- Profile Switch for Incomplete Report Submission - Auto Action item
- PMDA Downgrade/nullification Report Scenario when All Events are Non-Reportable

Profile Switch for Incomplete Report Submission - Auto Action item

- When this action item is configured, the system creates an action item automatically when **Incompletion** report is submitted. (Mhlwadmicsrcompleteclass, 1=Incomplete, 2=Complete, Case Form/Analysis/PMDA/PMDA General/Incompletion checkbox)
- **Blank (Default)**: if this option is present in the **Action Item** drop-down, the system does not create any Action Items for the Incompletion Report Submission (current functionality).
- Action Item drop-down (Codelist):
  - This option displays all the Action Items configured within the Code List Action type which are not deleted or allowed to be viewed.
  - If there is a value selected, the system creates an Action Item which would be Due in, as defined by you.
  - The **Due in** field allows you to enter up to 99 days.
  - The group assigned to the Action Item is **Unassigned**.
  - The Action Item is created as soon as the status of the Incompletion Report is changed to **Submitted**.
- The Audit Log tracks the updates made to this field.
- Once the Follow-up Completion Report is submitted, the Action Item associated to the report is **Closed** with the Close Date as the System Date (Server date).
- If the Follow-up report is still an incompletion report, the Action Item remains open.
- If the report is nullified (Nullification Report is sent), the Action Item is closed.

- When there are multiple incompletion reports from one case, the system creates the action items, which are same in number as that of the reports generated.
- The system appends a default text in front of description (J): `Incompletion Report: XXX` where `XXX` refers to the text entered in the **Description (J)** field.
- The Group can be assigned using the **Follow-up Action Item for Incompletion Report Submission Group Assignment** profile switch.

PMDA Downgrade/nullification Report Scenario when All Events are Non-Reportable

When reportable event is deleted from a Case Form by significant follow-up change, downgrade report against E2B to PMDA cannot be sent. Also, user is not able to send the nullification report when all the reportable events are deleted.

As per MHLW notification for investigational drugs, if reportable events disappears (becomes invalid events) by follow-up information and if there are no "reportable event" as result, it is necessary to report as nullification report. If reportable event(s) become non-reportable by follow-up information then a downgrade report is sent.

For Marketed drugs, when events in the case are updated in such a manner that none of the events in the case is valid then only nullification report is sent. If the reportable event becomes non-reportable by the follow-up information then a downgrade report shall be sent.

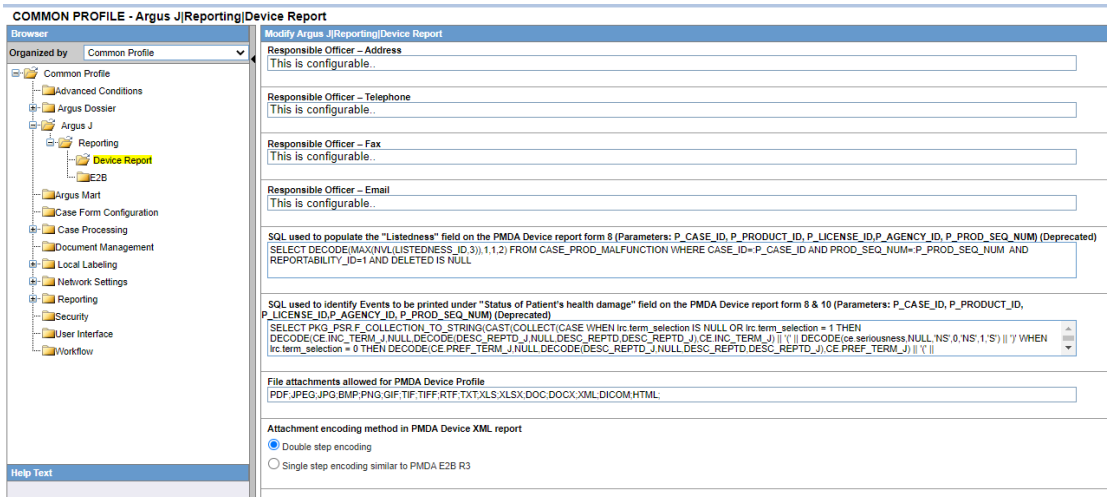
- Definition of "Non-Reportable" and "Invalid" events:
  - Non-Reportable events - same as it exists today.
  - Invalid events are:
    - Deleted events and
    - Those events for which the "Not include for the report in Japan" (available in the Case Form | Japan Event tab) checkbox is checked
- The PMDA E2B follow-up Downgrade report is generated when all the valid events in the case became "non-reportable". A downgrade report shall:
  - Include all the latest valid events that exist in the case.
  - Ignore non-coded events as it has already been implemented in the current functionality.
  - Not reference previously submitted report's data.
- For Marketed reports (reporting categories (1, 2, 3 and 4), In a scenario when events in the case are updated in such a manner that none of the events in the case remains valid (as described in the point # 1b above) then the PMDA E2B Nullification report is generated.
- For investigational reports (reporting categories (8, 9, 10, and 11), if all the reportable events w.r.t. previously submitted report becomes invalid (as described in the point # 1b above) by the follow-up information then the PMDA E2B Nullification report is generated.
- As per the existing implementation, the nullification E2B report will get its data (including the REACTION section) from the previous submitted E2B XML.
- When the nullification E2b reports is auto-scheduled for the above mentioned scenarios:

- A new common profile switch "PMDA E2B Nullification Reason Text for No Valid Event Scenario" is created in console under Argus J > Reporting with default value in Japanese - (There is no valid event available in the case). The profile switch is a text box having a maxlength of 200 characters. It support English as well as Japanese data entry.
- The value specified in the common profile switch "PMDA E2B Nullification Reason Text for No Valid Event Scenario" is used for the value of E2B element A.1.13.1 NULLIFICATIONREASON in PMDA E2B.

This enhancement is applicable for PMDA E2B Downgrade/nullification reports.

Common Profile Switches for Device Report

The following screen is displayed when you navigate to **Common Profile** > **Argus J** > **Reporting** > **Device Report**:



Device Report Responsible Officer

A new tree-node, **Device Report Responsible Officer**, has been added under Console > System Configuration > System Management (Common Profile Switches) >Argus J > Reporting. It has the following new switches in the same order as specified below:

- Responsible Officer – Company Name: Textbox, Maxlength = 100
- Responsible Officer – Department: Textbox, Maxlength = 100
- Responsible Officer – Address: Textbox, Maxlength = 60
- Responsible Officer – Telephone: Textbox, Maxlength = 50
- Responsible Officer – Fax: Textbox, Maxlength = 50
- Responsible Officer – Email: Textbox, Maxlength = 255

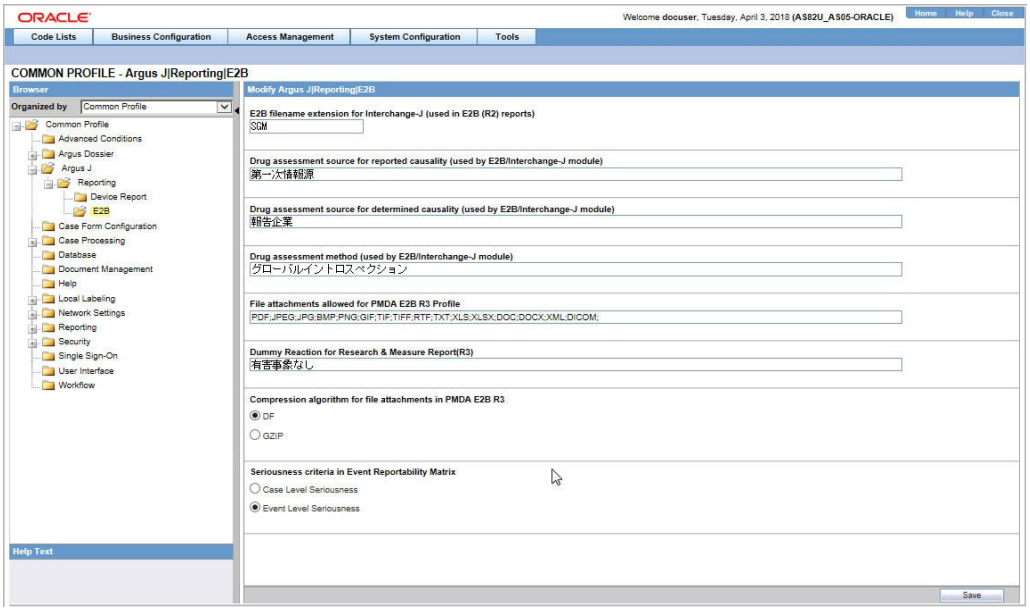
The following common profile switches are available under Common Profile > Argus J > Reporting > Device Report:

- SQL used to populate the **Listedness** field on the PMDA Device report form 8 (parameters: P_CASE_ID, P_PRODUCT_ID, P_LICENSE_ID, P_AGENCY_ID, P_PROD_SEQ_NUM) (Deprecated)
- SQL used to identify Events to be printed under **Status of Patient's health damage** field on the PMDA Device report form 8 and 10 (Parameters: P_CASE_ID, P_PRODUCT_ID, P_LICENSE_ID, P_AGENCY_ID, P_PROD_SEQ_NUM) (Deprecated)

- File attachments allowed for PMDA Device Profile: it is populated by default with **PDF;JPEG;JPG;BMP;PNG;GIF;TIF;TIFF;RTF;TXT;XLS;XLSX;DOC;DOCX;XML;DICOM;HTML;**
- Attachment encoding method in PMDA Device XML report: it has the Double step encoding and Single step encoding similar to PMDA E2B R3 options. For PMDA Device XML, the Double step encoding default value has to be set.

Common Profile Switches for E2B

The following screen is displayed when you navigate to **Common Profile** > **Argus J** > **E2B**:



The following table explains the fields used in the screen:

Field Name	Description	Field Options
E2B filename extension for Interchange -J	This field represents the E2B filename extension for ESM-J Default Value: SGM	SGM
Drug assessment source for reported causality (used by E2B/Interchange-J module)	This function for the B.4.k.18.2 is different from EMEA rule, as in EMEA these values are hardcoded in the application while in PMDA they come from the **CMN_Profile** switch.	Field Length: 120JAudit Log: Yes
Drug assessment source for determined causality (used by E2B/Interchange-J module)	This function for the B.4.k.18.2 is different from EMEA rule, as in EMEA these values are hardcoded in the application while in PMDA they come from the **CMN_Profile** switch.	Field Length: 120JAudit Log: Yes

Field Name	Description	Field Options
Drug assessment method (used by E2B/Interchange-J module)	The field value chosen in the **Case Form > Event Assessment** tab is populated for **B.4.k.18.3 DRUGASSESSMENTMETHOD** field for the Product Event combination selection for E2B report mapping. If you have the **Drug Assessment Method** field hidden for the Case Form, the value for **B.4.k.18.3 DRUGASSESSMENTMETHOD** is set to the value in this field by default.	Field Length: 70JAudit Log: Yes
File attachments allowed for PMDA E2B R3 Profile	This Common Profile Switch checks the allowed files that can be attached in the E2B (R3) report generated using PMDA profile.	Pdf, jpeg, jpg, bmp, png, gif, tif, tiff, rtf, txt, xls, xlsx, doc, docx, xml, html, and dicom
Dummy Reaction for Research & Measure Report (R3)	New Enterprise level profile switch is added in the Oracle Argus Safety Console to configure the Dummy Reaction. A dummy event is created in the case. If the event exits in the report use that event. Else if no event exists then use this dummy event of a PMDA R3 report of research and measure category ('E', 'F', 'G', 'L', 'M', 'N', 'O', 'P'). Also the exclusions for the same are done in the Minimum case validation for these reporting categories. **Note:** If E.i.1.2 is available and E.i.2.1b is not available in the E2B element then encode the Reaction using E.i.1.2 Tag value (Primary Source Path). Refer to the Mapping Document for details. This dummy event is visible in the Pending screen and also listed in the Difference Report Viewer. **Note:** PMDA E2B R3 import logic is implemented based on the Import framework to support EMA R3 import. Hence all the framework level concepts applies to PMDA E2B R3 import as well. Refer *Oracle Argus Interchange User's Guide* for details of the framework.	Text: 255(max length) Default value: 有害事象なし
Compression algorithm for file attachments in PMDA E2B R3	This Common Profile Switch specifies the compression algorithm for the attachments in E2B (R3) report generated using PMDA profile.	DF (default selected) GZIP
Seriousness criteria in Event Reportability Matrix	The Event Reportability algorithm used by the PMDA E2B and Paper Reports considers seriousness criteria value as Case Level or Event Level seriousness based on the value set for this common profile switch. Default Value: Event Level Seriousness	Case Level Seriousness Event Level Seriousness

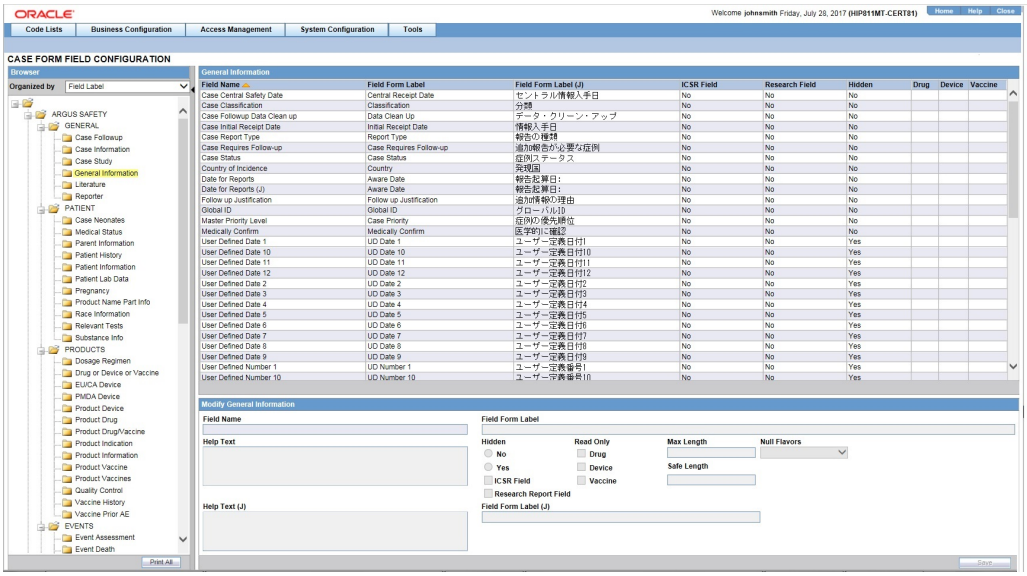
Configuring Field Level Validations

This section lists the configuration of fields in Oracle Argus Safety Console:

- Field Label Configuration (J Specific)

Field Label Configuration (J Specific)

In order to change the field labels, to hide and unhide fields in Case Form, navigate to **System Configuration** > **Field Validation**. This displays the following screen:



> **Note:**
>
> The Field Form Label (J) and Help Text (J) are visible on this screen (grid, data entry, and print) only to Oracle Argus Safety Japan user, when Oracle Argus Safety Japan module/license is enabled.

The following table explains the J specific labels on the screen mentioned above:

Field Name	Description
Field Form Label (J)	This field allows you to edit the field labels. It is valid only for the labels where label change is allowed. This is an optional field.
Help Text (J)	You can enter the help text here for a selected field. This is an optional field.

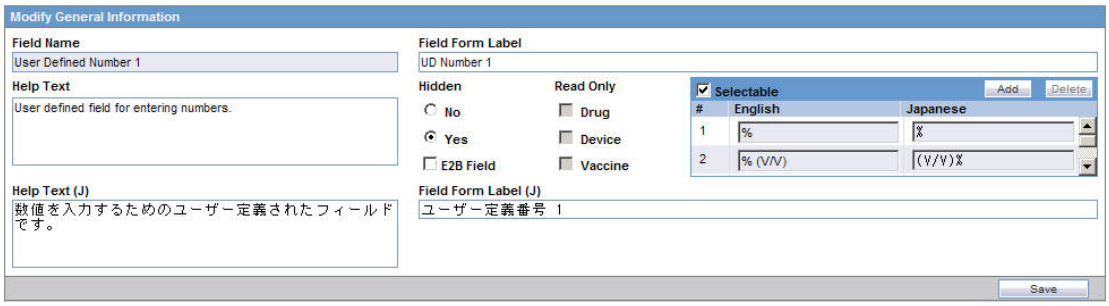
Configuring Field Labels

This section displays the updates made to the user-defined fields:

- User Defined Fields Updates

User Defined Fields Updates

The Oracle Argus Safety Japan system has the following:



- Oracle Argus Safety Japan allows you to enter Japanese drop-down items as well as English.
- Only the English drop-down is a mandatory field. When the English drop-down value is not present, an error message, **User Defined Dropdown English values can not be blank** is displayed.

Configuring Local Reports - Local Reporting Rule and Local Reports

In order to control which reports need to be generated only after Local data entry is done, the application maintains a list of Report forms that are considered as Local Reports, by storing the following data fields:

- Country - This is typically the country of license of the suspect product in a case for which there is a local reporting obligation. This could also be the local country expecting an active moiety reporting.
- Reporting Destination - This is the reporting destination receiving the local report. This shall be populated based on user input during post upgrade script.
- Report Forms - This is the local report. This is stored with the following reports for this release, as displayed in the image below:

i. 医薬品　症例報告書　別紙様式１・２（Mktd 1,２）

ii. 医薬品　研究報告調査報告書　別紙様式３・４（Mktd 3, 4）

iii. 医薬品　外国での措置報告　別紙様式５・６（Mktd 5, 6）

iv. 治験薬　症例報告書　別紙様式１・２（Inv 1, 2）

v. 治験薬　研究報告調査報告書　別紙様式３・４（Inv 3, 4）

vi. 治験薬　外国での措置報告　別紙様式５・６（Inv 5, 6）

vii. 報告様式8：医療機器不具合・感染症症例報告書

viii. 報告様式10：医療機器の研究報告調査報告書／外国措置調査報告書

ix. E2B

A reporting rule that is for the Country + Reporting Destination + Report Form is the Local Reporting Rule.

Any reporting rule that is for the country + reporting destination + report form configured in the above table and in addition satisfies the Truly Local Case system criteria for the case from which these rules are triggered (i.e., the SQL or PL/SQL block or the database function configured in the 2.3.0 returns a value > 0) is referred to as **Local reporting rules**.

Any report that is scheduled by a Local reporting rule is considered a Local report (note that this would have already satisfied the Truly Local case switch as described above).

This configuration data is maintained via backend procedures and no maintenance facility needs to be provided via UI.

Note that to utilize the local locking feature, the customer is expected to maintain the proper **Reporting Destination** value in this table.

Expedited Reports generated as part of Periodic Reports are not considered local reports for this release.

3

Code List Configuration

This chapter lists the Japanese-specific (J-specific) features in the Code List Configuration module of Oracle Argus Safety Japan Console:

- Code Lists

Code Lists

This section describes the functionality for the J specific Code List features:

- General Functionality Changes
- Device Classification
- Device Outcome
- Device Reporting Category
- Emperor
- J Reportable Product Keyword
- License Category
- Literature Type
- Reporting Category
- Literary Citation
- Reporting Destination
- Manufacturers
- Reporter Information
- Flexible Data Re-Categorization

General Functionality Changes

This section lists the Oracle Argus Safety Japan general functionality Code List changes:

- **Sort Order**: The sort order for display of the elements in the Code Listing is based upon English element as default. For Japanese-only elements, the priority sort language is Japanese.
- **Print**: The PRINT functionality is modified to display all the Japanese fields also.
- If Japanese translation is not available for any drop-down (Code list/Factory Data), corresponding J values are shown on the UI in the drop-down but database values remain blank.
- J Fields Display:
  - All the J translation fields end with (J).
  - All the J specific fields are available only if J license is enabled.

  - All the J specific fields are available only for Oracle Argus Safety Japan users. For English users, it is hidden.

- The following functionality is provided when the **Copy** function is used. Unless it is mentioned in each **CodeList** section, the following are the general rules for the copy function of Code List items:
  - When an Oracle Argus Safety Japan user copies the data, the equivalent Japanese data is not copied.
  - When an Oracle Argus Safety Japan user copies the data:
    * **Copy of** is appended in front of the data in the English field (First mandatory textbox field) which is same as current Oracle Argus Safety Japan.
    * コピー〜 is appended in front of the data in the (J) field (First mandatory J textbox field).
  - If the either English name (first mandatory English field unless specified) or Japanese name (first mandatory Japanese field unless specified) is not unique in the existing data table, and you click the **Save** button, the pop-up with a message `A duplicate <field name> already exists!` is displayed to change the duplicate field value.

Device Classification

The following is the screenshot of the Japan specific **Device Classification** code list is available under **Argus Console** > **Code Lists** > **Argus J** menu option.

The values in this code list are referred from the LM_PMDA_DEVICE_CLASSIFICATION table for device license for fields PMDA Device Classification 1, PMDA Device Classification 2, and PMDA Device Classification 3 under **Argus Console**, and then **Products and Licenses**, and then **Product**, and then **License**.

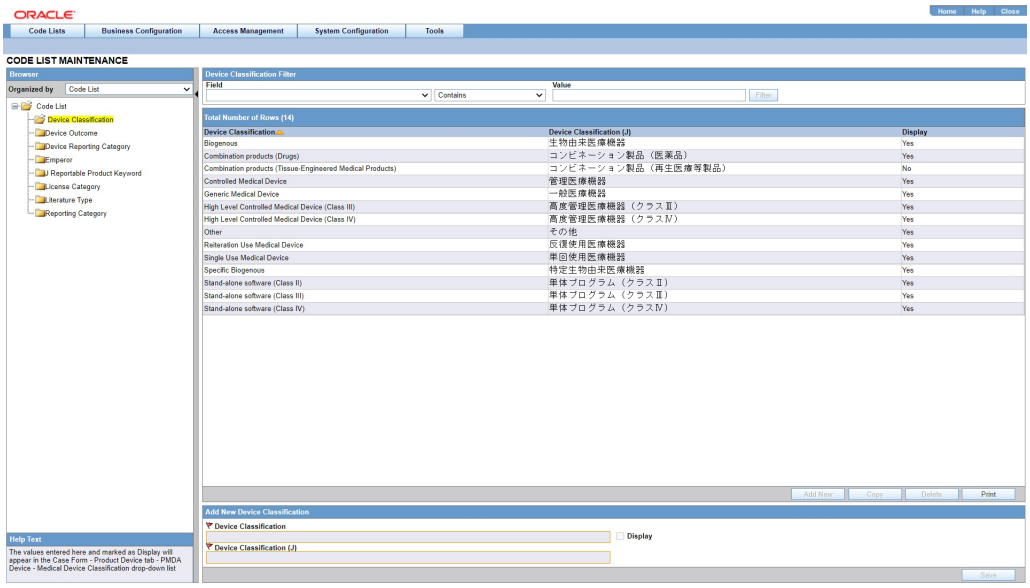


Table 3-1 Device Classification code list - Field Description

Field Name	Description
Device Classification	Allows user to enter device classification value in English.
Display	Allows user to display or hide a device classification in Oracle Argus Safety.
Device Classification (J)	Allows user to enter device classification value in Japanese.

> **Note:**
>
> The Combination products (Tissue- Engineered Medical Products) device classification's **Display** is set to **No**. Hence, this record appears in the flex-code list with **Display** checkbox as unchecked.

Device Outcome

The following is the screenshot of the Japan specific **Device Outcome** code list available under **Argus Console** > **Code Lists** > **Argus J** menu option.

These code list values are used to select the outcome for a device in the case form under **Product**, and then **Device**, and then **Device Information**, and then **Device Outcome**.

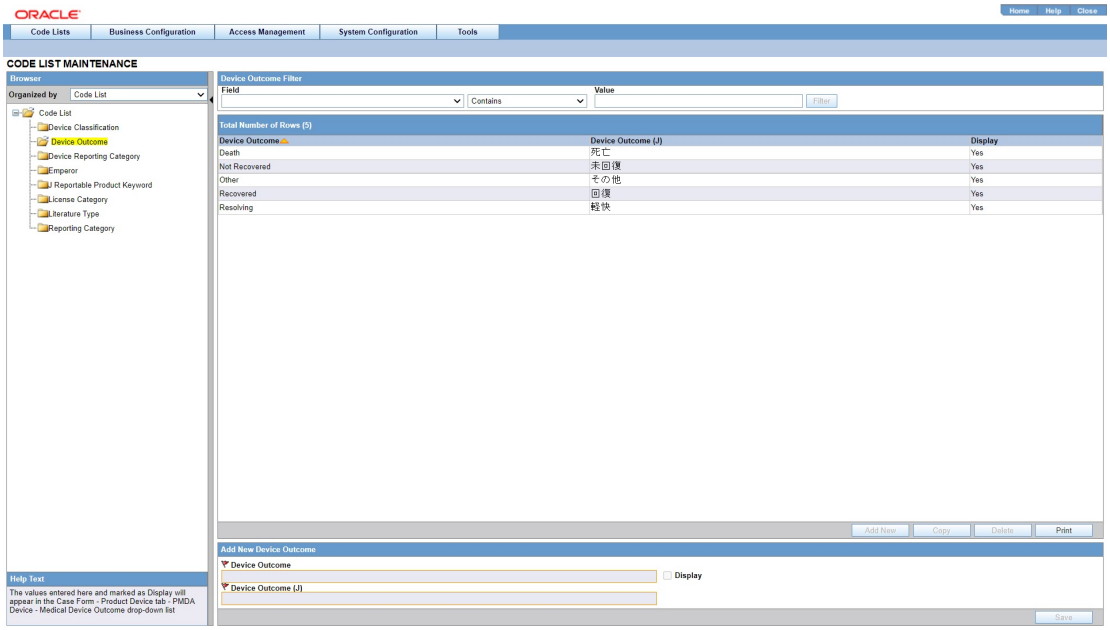


Table 3-2 Device Outcome code list - Field Description

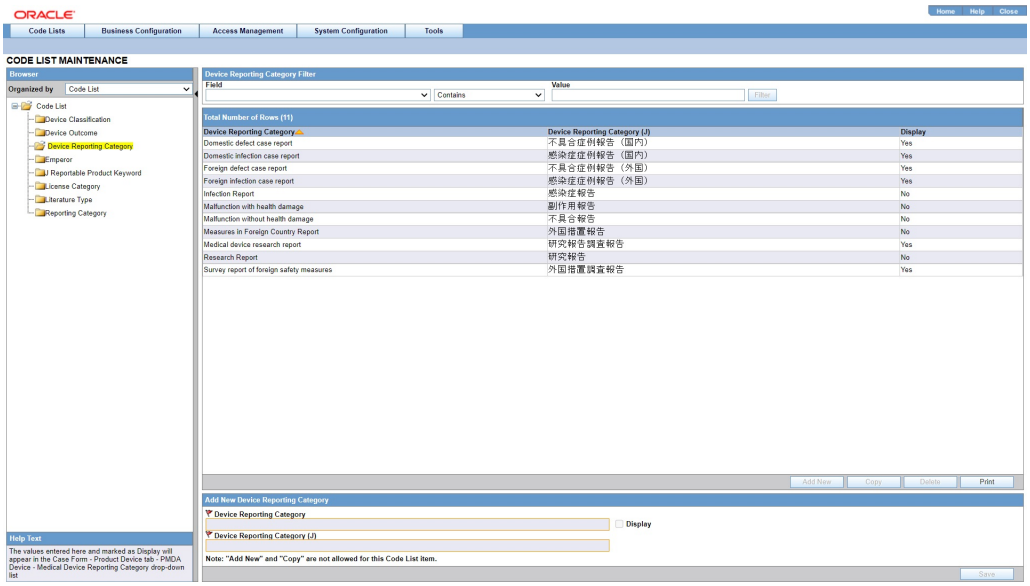
Field Name	Description
Device Outcome	Allows user to enter device outcome value in English.
Display	Allows user to display or hide a device outcome in Oracle Argus Safety.

Table 3-2 (Cont.) Device Outcome code list - Field Description

Field Name	Description
Device Outcome (J)	Allows user to enter device outcome value in Japanese.

Device Reporting Category

The following is the screenshot of the Japan specific **Device Reporting Category** code list available under **Argus Console** > **Code Lists** > **Argus J** menu option.



The values entered here and marked as **Display** appears in the **Case Form > Product Device tab > PMDA Device > Medical Device Reporting Category** drop-down list.

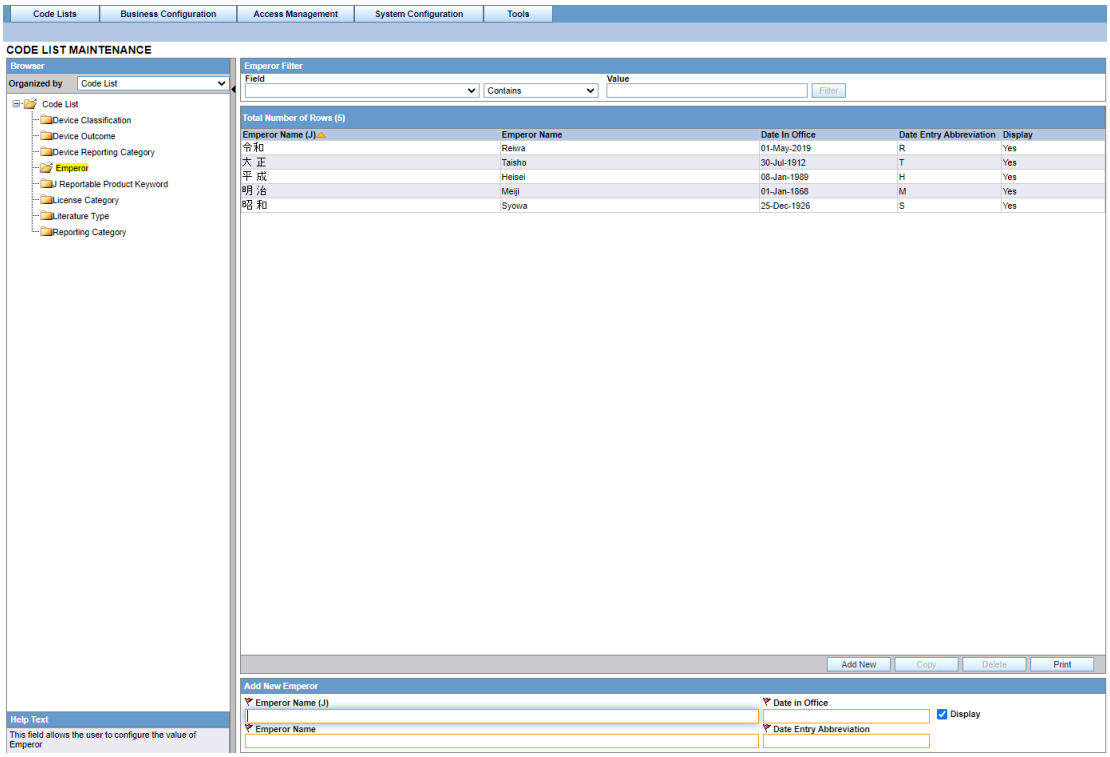
It is covered by the back-end PL/SQL APIs for Device Reporting Category data table updates and audit-logging.

Table 3-3 Device Reporting Category code list - Field Description

Field Name	Description
Device Reporting Category	Allows user to enter Device Reporting Category value in English.
Display	Allows user to display/hide a device reporting category in Oracle Argus Safety.
Dev Report Category	Displays the abbreviation of the reporting category.
Device Reporting Category (J)	Allows user to enter Device Reporting Category value in Japanese.

Emperor

This dialog box allows you to add and configure various Japanese Emperor Data/Era.



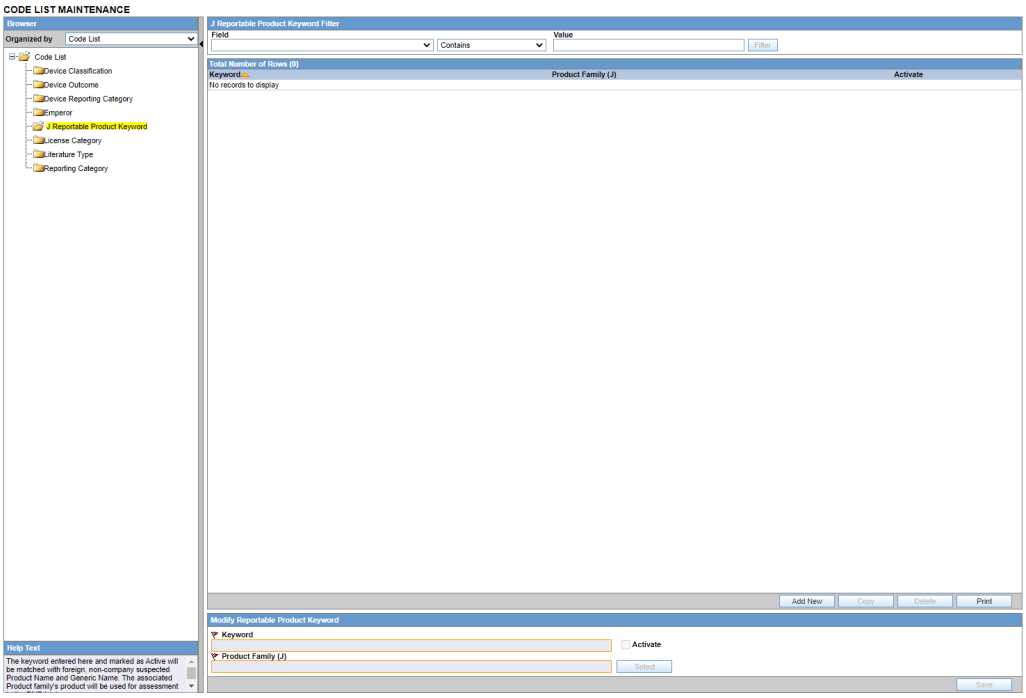
The following table lists the fields used in the dialog box and their description:

Field Name	Description
Emperor Name (J)	This represents the label for the column of text boxes for entering the names of the Japanese Emperors.
Date in Office	This represents the label for column of text boxes for entering dates when the Japanese Emperors assumed their officesDate format DD-MON-YYYY
Display	You can select to display the record in Administrator route in the **Products** screen
Emperor Name	This represents the label for column of text boxes for entering the names of the Japanese Emperors.
Date Entry Abbreviation	This abbreviation is used as shortcut in **Argus Safety** and **Console Date** field to Japanese UI screens while entering year value.This Abbreviation is unique, and duplicate characters are not saved. When you try to enter a character that is already in use and save, a pop-up error message : `A duplicate Date Entry Abbreviation already exists!` is displayed, and the save operation is canceled.
PROTECTED	Internal Only - Protected Field

J Reportable Product Keyword

This code list allows you to associate keywords to Product Families. This is a J specific code list.

Help text: `The keyword entered here and marked Active is matched with foreign, non-company suspected Product Name, and Generic Name. The associated Product Family's product is used for assessment in the PMDA tab.`

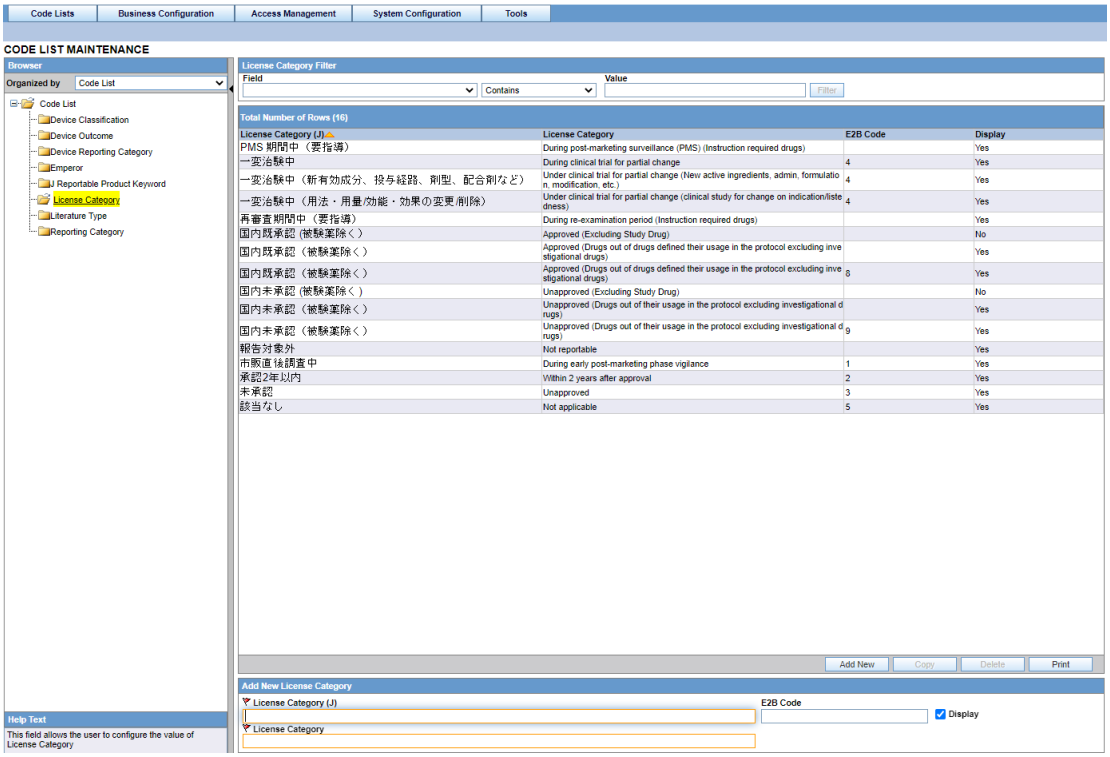


The following lists the fields used in the dialog box and their description:

Field Name	Description
Keyword	This field is used to enter keywords to search related company Product Family from foreign non-company suspected drugs.
Activate	By clicking this, you can decide if you want to include the keyword in the search.
Product Family (J)	If the keyword matches the foreign non-company suspected drug Trade Name or generic name, this Product Family is the target for assessment in Japan (in PMDA tab).
Select	When you click the **Select** button next to the Product Family, the Argus Product Browser is displayed to select the Product Family.If you type any text in the Product Family textbox, and click **Select**, the entered text is transferred to the Product Brower when you navigate away from the Product Family textbox.Once a Product Family is selected in the Product Browser, the Product Family name is transferred to the Product family textbox.

License Category

This dialog box allows you to add and configure various Japanese License categories. This is a J-specific code list.



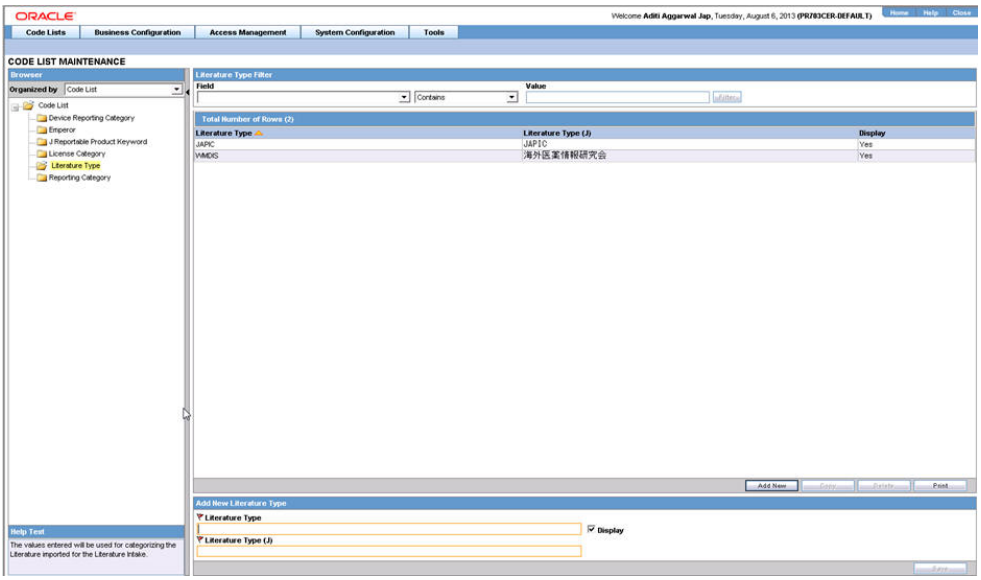
The following table lists the fields used in the dialog box and their description:

Field Name	Description
License Category (J)	This represents the label for entering PMDA License Category in Japanese.
E2B Code	This represents the label to enter the E2B value corresponding to the License Category Name.
Display	You can select to display the record in Administrator route in **Products** screen.
License Category	This represents the label for column of text boxes for entering the License Category in English.
PROTECTED	Internal Field - Protected

Literature Type

Use the following procedure to configure action taken:

1. From the Oracle Argus Safety Console, select **Code Lists** > **Argus J** > **Literature Type**.
2. When the system opens the Code List Maintenance screen, click **Literature Type** in the Code List in the left pane.
3. The system puts the corresponding data for the selected item in the right pane.

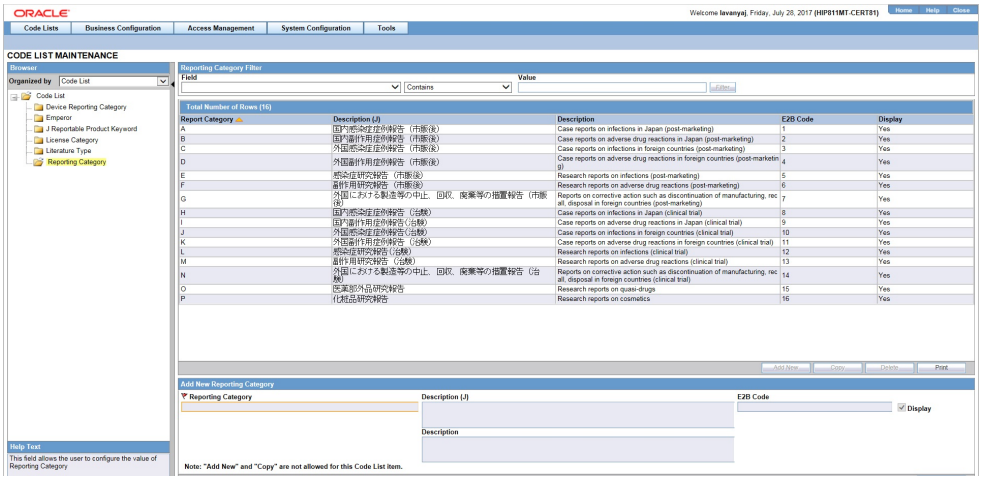


4. This screen enables you to view the English and Japanese names of the configured categories. You can also set the display preferences for these code lists.
5. Click **Add** to add a entry in the code list after filling the required information in the mandatory fields.
6. Click **Save** to save any changes.

Reporting Category

Use the following procedure to configure action taken:

1. From the Oracle Argus Safety Console, select **Code Lists** > **Argus J** > **Reporting Category**.
2. When the system opens the Code List Maintenance screen, click **Reporting Categor**y in the Code List in the left pane.
3. The system puts the corresponding data for the selected item in the right pane.



4. This screen enables you to view the English and Japanese names of the configured categories. You can also set the display preferences for these code lists.
5. Click **Save** to save any changes.

Literary Citation

The following is the list of the J Specific Literary Citation functionality changes:

- There is a note (only for J users) right at the end before the user action buttons displaying:
  `Note: Clicking the SAVE button will reflect the changes made on this English screen to the Japanese pop-up.`
- The main English screen has a **J Data Entry** button, which is available only to J users.
- Clicking on the **J Data Entry** button displays a message to enter the data in the mandatory fields (Name) in English screen before opening the Japanese Translation Window.
- Clicking on the **J Data Entry** button displays a pop-up window as a resizable modal dialog with Japanese equivalent content where you are able to enter Japanese equivalent text for the corresponding field.
- The mandatory fields need to be filled in before displaying the Japanese pop-up, else the **J Data Entry** button displays a warning message: .
  `Enter data in all the mandatory fields!`
- The Japanese pop-up contains all the fields and all of them are editable.
- There is a note above the **Save and Cancel** button

The following functionality is provided while navigating from English screen to J pop-up for Existing Literature:

- On clicking of the **J Data Entry** button, you are prompted to save the data on the English screen before opening the J screen. The following is the prompt message:

  `Do you want to save the changes before opening the Japanese screen?`
- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the changes made on the English screen are not reflected on the J Screen .

The following functionality is provided while navigating from English screen to J pop-up for New Literature:

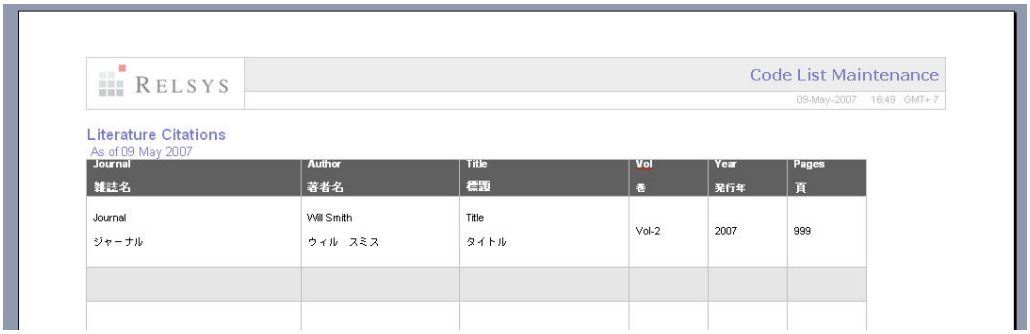
- On clicking of the **J Data Entry** button, you are prompted to save the data on the English screen before opening the J screen. The following is the prompt message:

  `Data must be saved before opening the Japanese screen. Do you want to save?`
- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the J screen does not open.

The following functionality is provided when the **Copy** function is used:

- When the Oracle Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When Oracle Argus Safety Japan user copies the data:
  - **Copy of** is appended in front of the data in the **Journal** field of English UI.
  - **コピー～** is appended in front of the data in the **Journal** field of Japanese UI.
- If the English Literary Citation (all fields in the **English** section) is not unique in the existing data table, and you click the **Save** button or **J Data Entry** button, the pop-up with a message `A duplicate Literary Citation already exists!` is displayed to change the duplicate name.
- If the Japanese Literary Citation (all fields on **Japanese** section) is not unique in the existing data table, and you click the **Save** button in the J data entry pop-up, the pop-up with a message `A duplicate Literary Citation (J) already exists!` is displayed to change the duplicate name in the **J Data Entry** field.

The following is the Print template of the Literature Citations:



Reporting Destination

The following is the list of the J Specific Reporting Destination functionality changes:

The **Argus Console** > **Code list** > **Reporting Destination** > **EDI (tab)** has been enhanced:

- The PMDA-DEVICE MESSAGE TEMPLATE standard device profile uses similar framework as E2B R3. This profile has elements related to both Form 8 and Form 10 XML report.
- In the Message Profile drop-down list, the PMDA E2B R3 profile (*ICH-ICSR V3.0 MESSAGE TEMPLATE - PMDA*) is made available to the users for configuration.
- In the ACK profile, users can select the PMDA E2B R3 Ack Profile.
- The following fields in Reporting destination are populated with default values and displayed in the read-only for the PMDA E2B R3 profile (similar to the ICH E2B (R3) profile):
  - Encoding - UTF-8
  - XML Version - 1.0
  - Maximum # of reports to include in the msg-1

  - SGML (Disabled) / XML (Selected)
  - Identification Code (Agency Information and Local company contact Information)
  - Code Qualifier (Agency Information and Local company contact Information)
  - EDI header Required
  - URL for Message Schema and URL for Ack Schema
- The **EDI** > **Message Profile 2** drop-down list has been blanked and disabled for all the R3 Profiles including PMDA E2B R3 profile. (This drop-down list is only visible to a J user).

The **Argus Console** > **Code list** > **Reporting Destination** > **Agency Information (tab)** has been enhanced:

- Check **Agency Information** > **Authorized Representative**, if you are an authorized representative.
- **Attachments** under **Report Transmissions** is set as Single(default) and disabled.

To print these fields, go to **Reporting Destination** > **Local Company Contact**.

Manufacturers

The following is the list of the J Specific Manufacturers functionality changes:

- There is a note (only for J users) right at the end before the user action buttons displaying:
  `Note: Clicking the SAVE button will reflect the changes made on this English screen to the Japanese pop-up.`
- The main English screen has a **J Data Entry** button, which is available only to J users.
- Clicking on the **J Data Entry** button displays a message to enter the data in mandatory fields (Name) in the English screen before opening the Japanese Translation Window.
- Clicking on the **J Data Entry** button displays a pop-up window as a resizable modal dialog with Japanese equivalent content where you are able to enter Japanese equivalent text for the corresponding field.
- The mandatory fields need to be filled in before opening the Japanese pop-up, else the **J Data Entry** button displays a warning message:

  `Enter data in all the mandatory fields!`
- The Japanese pop-up contains all the fields and all of them are editable.
- There is a note above **Save and Cancel** button.

The following functionality is provided while navigating from English screen to J pop-up for Existing Manufacture:

- On clicking the **J Data Entry** button, you are prompted to save the data on English screen before opening the J screen. The following is the prompt message:
  `Do you want to save the changes before opening the Japanese screen?`
- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the changes made on the English screen are not reflected on the J screen .

The following functionality is provided while navigating from English screen to J pop-up for New Manufacture:

- On clicking the **J Data Entry** button, you are prompted to save the data on the English screen before opening the J screen. The following is the Prompt message: `Data must be saved before opening the Japanese screen. Do you want to save?`
- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the J screen does not open.

The following functionality is provided when the **Copy** function is used:

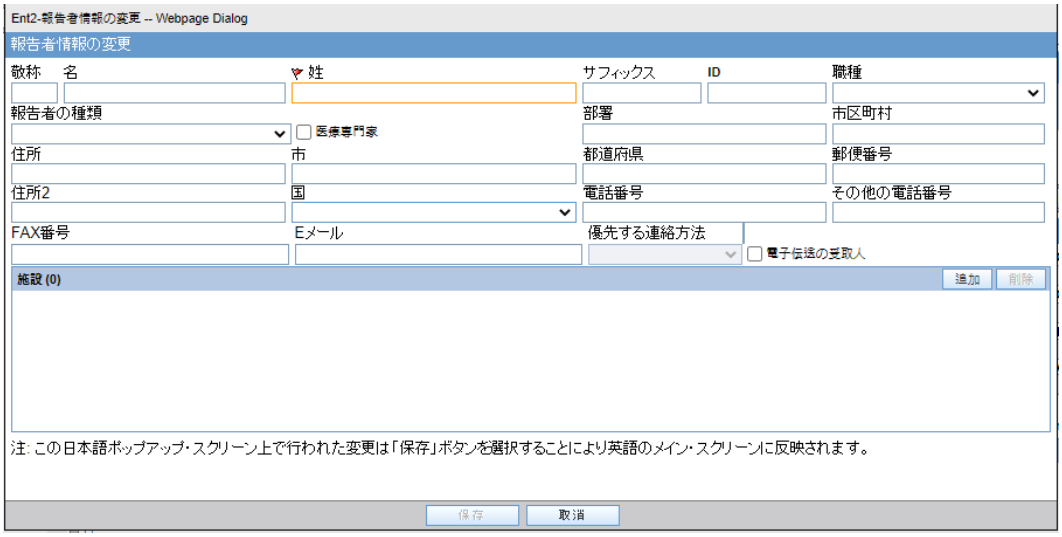
- When the Oracle Argus Safety Japan user copies the data, the equivalent Japanese data is not copied.
- When the Oracle Argus Safety Japan user copies the data:
  - **Copy of** is appended in front of the data in the **Name** field of the English UI.
  - コピー～ is appended in front of the data in the **Name** field of Japanese UI.
- If the English name is not unique in the existing data table, and you click the **Save** button or **J Data Entry** button, the pop-up with a message `A duplicate Name already exists!` is displayed to change the duplicate name.
- If the Japanese name is not unique in the existing data table, and you click the **Save** button in the **J Data Entry** pop-up, the pop-up with a message `A duplicate Name (J) already exists!` is displayed to change the duplicate name in the **J Data Entry** field.

Reporter Information

The following is the list of the J Specific Reporter Information functionality changes:

- There is a note (only for J users) right at the end before the user action buttons displaying:
  `Note: Clicking the SAVE button will reflect the changes made on this English screen to the Japanese pop-up.`
- The upper grid does not have **Phone, Alt.Phone, Fax** column (for Both English and Japanese users), and has a new 2nd column for **First Name (J), Last Name (J), and ID (J)** for Japanese user only.
- The main English screen has a **J Data Entry** button, which is available only to J users.
- Clicking on the **J Data Entry** button displays a message to enter the data in mandatory fields (Name) in English screen before opening the Japanese Translation Window.
- Clicking on the **J Data Entry** button displays a pop-up window as a resizable modal dialog with Japanese equivalent content where you are able to enter Japanese equivalent text for the corresponding field. The Japanese screen looks

like this:



- The mandatory fields need to be filled in before opening up the Japanese pop-up else the **J Data Entry** button displays a warning message:`Enter data in all the mandatory fields!`
- The Japanese pop-up contains all the fields and all of them are editable.
- There is a note above **Save and Cancel** button.

The following functionality is provided while navigating from English screen to the J pop-up for Existing Reporter:

- On clicking the **J Data Entry** button, you are prompted to save the data on English screen before opening the J screen. The following is the prompt message:`Do you want to save the changes before opening the Japanese screen?`
- If you choose to save the data, the data is saved and the changes are reflected on the J Screen.
- If you choose not to save the data, the changes made on the English screen are not reflected on the J Screen .

The following functionality is provided while navigating from English screen to the J pop-up for New Reporter:

- On clicking the **J Data Entry** button, you are prompted to save the data on the English screen before opening the J screen. The following is the prompt message: `Data must be saved before opening the Japanese screen. Do you want to save?`
- If you choose to save the data, the data is saved and the changes are reflected on the J screen.
- If you choose not to save the data, the J screen does not open.

The following functionality is provided when the **Copy** function is used:

- When the Oracle Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When the Oracle Argus Safety Japan user copies the data:
  - **Copy of** is appended in front of the data in the **Name** field of the English UI.
  - **コピー～** is appended in front of the data in the **Name** field of the Japanese UI.

- The Duplicate last name can be saved. If the English ID is not unique in the existing data table, and you click the **Save** button or the **J Data Entry** button, the pop-up with a message `A duplicate ID already exists!` is displayed to change the duplicate value.
- If the Japanese ID is not unique in the existing data table, and you click the **Save** button in the **J Data Entry** pop-up, the pop-up with a message `A duplicate ID already exists!` is displayed to change the Duplicate ID in the **J Data Entry** field.

The following is the Print template of the Reporter Information:

RELSYS

Code List Maintenance

09-May-2007 16:49 GMT+7

Reporters

As of 09 May 2007

Name Reporter ID Occupation 名前 報告者 ID 職種	Health Prof Reporter Type Department 医療専門家 報告者の種類 部署	Institution 施設	Address City, State, Postal Code Country 国 住所	Phone Alt. Phone Fax 電話番号 その他の電話番号 Fax	Email Electronic Transmission Receipt Preferred Method E メール 電子伝送の受取人 優先する連絡方法
Dr First Last 121 Investigator Dr. 野村　雅男 121 調査員	No Company Representative Safety Division いいえ 会社代表 安全性部門	Kaiser Hospital Tokyo University Hospital Yokohama University Hospital カイザー ホスピタル 慶台病院 横浜医学大学病院	123 Main Street City, CA 8976 UNITED STATES 米国 8976 カリフォルニア州メイン市 メインストリート 123	341-908-9087 453-908-9087 564-786-9087	abc@yahoo.com

- The Japanese print out of **Name** section consists of:
  - Title
  - Last Name
  - First Name
  - Suffix
- The Japanese print out of **Address** section consists of:
  - ZipCode
  - State
  - City
  - Street Address
- The Institutions are printed with line feed.

Flexible Data Re-Categorization

The flexible data re-categorization feature allows Oracle Argus Safety Japan and its associated applications, such as Oracle Argus Mart and Oracle Argus Insight, to handle the code list values with more flexibility.

This feature allows applications and customers to store and maintain all types of code list values in a single flat database table structure which is easier to maintain. This code list data storage design can be leveraged to easily add new and custom code lists or values without adding new database tables and columns.

The Flexible Data Re-Categorization feature allows administrators to manage and display the existing and new code list items. You can edit the custom language attribute E2B_R3 and its values.

The following code lists are available under Oracle Argus Safety Console > **Code List** > **Flex Data Re-Categorization**.

For more information on Flexible Data Re-Categorization, see the *Oracle Argus Safety Administrator's Guide* and the following:

- Reporting Category (LM_RPT_CATEGORY)
- License Category (LM_LIC_CATEGORY)
- Dev Phase (LM_DEV_PHASE)
- Risk Category of OTC Drug (LM_RISK_CATEGORY_OTC)
- Route for Acquiring OTC Drug (LM_ROUTE_ACQUIRE_OTC)
- Device Reporting Category (LM_DEVICE_RPT_CATEGORY)
- Device Classification (LM_PMDA_DEVICE_CLASSIFICATION)
- Device Outcome (LM_PMDA_DEVICE_OUTCOME)

Reporting Category (LM_RPT_CATEGORY)

Code listed data in the following table has been added and is synchronized with the Reporting Category flex bucketing code list as indicated in the following table. New language attribute E2B_R3 has been added to flex bucketing code list ID, REPORTING_CATEGORY.

Description	E2B_R3
Case reports on infections in Japan (post-marketing)	AA
Case reports on adverse drug reactions in Japan (post-marketing)	AB
Case reports on infections in foreign countries (post-marketing)	AC
Case reports on adverse drug reactions in foreign countries (post-marketing)	AD
Research reports on infections (post-marketing)	AE
Research reports on adverse drug reactions (post-marketing)	AF
Reports on corrective action such as discontinuation of manufacturing, recall, disposal in foreign countries (post-marketing)	AG
Case reports on infections in Japan (clinical trial)	DA
Case reports on adverse drug reactions in Japan (clinical trial)	DB
Case reports on infections in foreign countries (clinical trial)	DC
Case reports on adverse drug reactions in foreign countries (clinical trial)	DD
Research reports on infections (clinical trial)	DE
Research reports on adverse drug reactions (clinical trial)	DF
Reports on corrective action such as discontinuation of manufacturing, recall, disposal in foreign countries (clinical trial)	DG
Research reports on quasi-drugs	BC
Research reports on cosmetics	BD

License Category (LM_LIC_CATEGORY)

Code listed data in the following table has been added and is synchronized with the License Category flex bucketing code list as indicated in the following table. New language attribute E2B_R3 has been added to flex bucketing code list ID, LICENSE_CATEGORY.

Category	E2B_R3
During early post-marketing phase vigilance	1
Within 2 years after approval	2
Unapproved	3
During clinical trial for partial change	4
Not applicable	5
During re-examination period (Instruction required drugs)	6
During post-marketing surveillance (PMS) (Instruction required drugs)	7

Dev Phase (LM_DEV_PHASE)

Code listed data in the following table has been added and is synchronized with the Dev Phase flex bucketing code list as indicated in the following table. New language attribute E2B_R3 has been added to flex bucketing code list ID, DEV_PHASE.

DEV_PHASE	E2B_R3
Microdose study	0
Phase I	1
Phase II	2
Phase III	3
Phase I/II	4
Phase II/III	5
Under application	7
Others	8

Risk Category of OTC Drug (LM_RISK_CATEGORY_OTC)

Code listed data in the following table has been added and is synchronized with the Dev Phase flex bucketing code list as indicated in the following table. New language attribute E2B_R3 has been added to flex bucketing code list ID, DEV_PHASE.

RISK_CATEGORY	E2B_R3
Class 1 OTC drugs	01
Class 2 OTC drugs	02
Designated second-class OTC drugs	2S
Class 3 OTC drugs	03
Instruction required drugs	04

RISK_CATEGORY	E2B_R3
Pharmacy-compounded drugs	05

Route for Acquiring OTC Drug (LM_ROUTE_ACQUIRE_OTC)

A new list Route for acquiring OTC Drug has been added and is available for editing only through the Flexible Data Re-categorization. The language attribute E2B_R3 has been added to flex bucketing code list ID, ROUTE_ACQUIRE_OTC.

Route	E2B_R3
Mail-order sales through the Internet	I
Household distribution	H
Other mail-order sales (telephone, etc.)	T
Over-the-counter sales at pharmacies	S
Information could not be obtained despite confirmation	ASKU This denotes a Null flavor value.
Unclear because of unconfirmability due to unavoidable reasons	UNK This denotes a Null flavor value.

Device Reporting Category (LM_DEVICE_RPT_CATEGORY)

The Device Reporting Category codelist is available in the Flexible Data Re-Categorization menu option.

The values of the Device Reporting Category flexible codelist are displayed for the Case Form field under the PMDA Device Information section, in the Medical Device Reporting Category drop-down list.

Device Reporting Category	Dev Report Category
Domestic infection case report	DA
Domestic defect case report	DB
Foreign infection case report	DC
Foreign defect case report	DD
Medical device research /survey report	DF
Survey report of foreign safety measures	DG
Infection Report	-
Malfunction with health damage	-
Malfunction without health damage	-
Measures in Foreign Country Report	-
Research Report	-

Device Classification (LM_PMDA_DEVICE_CLASSIFICATION)

The Device Classification codelist is available in the Flexible Data Re-Categorization menu option.

The values are referred from the LM_PMDA_DEVICE_CLASSIFICATION table for the device license for the PMDA Device Classification 1, PMDA Device CLassification 2 and PMDA Device Classification 3 fields.

Device Classification	Display
High Level Controlled Medical Device (Class IV)	Yes
High Level Controlled Medical Device (Class III)	Yes
Controlled Medical Device	Yes
Generic Medical Device	Yes
Combination products (Drugs)	Yes
Stand-alone software (Class IV)	Yes
Stand-alone software (Class III)	Yes
Stand-alone software (Class II)	Yes
Combination products (Tissue-Engineered Medical Products)	No
Biogenous	Yes
Specific Biogenous	Yes
Other	Yes
Single Use Medical Device	Yes
Reiteration Use Medical Device	Yes

Device Outcome (LM_PMDA_DEVICE_OUTCOME)

The Device Outcome codelist is available in the Flexible Data Re-Categorization menu option.

These codelist values are used to select the outcome for a device in the Case Form under Product > Device > Device Information > Device Outcome.

Device Outcome	Display
Death	Yes
Not Recovered	Yes
Resolving	Yes
Recovered	Yes
Other	Yes