Oracle® Argus Safety Japan

Administrator's Guide

Release 8.1

E75839-01

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Oracle Argus Safety Japan Administrator's Guide, Release 8.1

E75839-01

Contents

Preface

This document describes the steps for installing and configuring the components of the Argus Console (Japanese) application.

Intended Audience

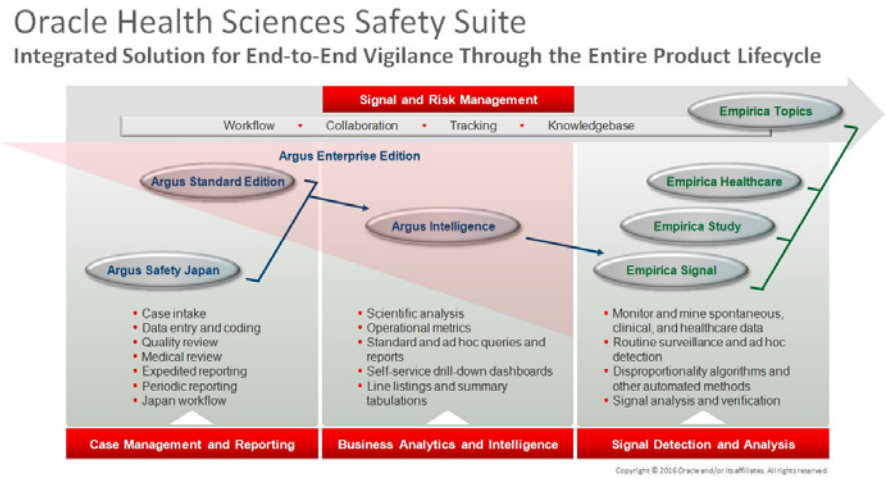
This document is intended for administrators of the Oracle Argus Safety Japan (Argus J) Safety system for configuring Argus Safety.

About This Book

This guide contains the following chapters:

The Oracle Health Sciences Safety Suite

This product is part of the Oracle Health Sciences Safety Suite, an integrated solution for end-to-end vigilance from adverse event management to signal management, through the entire lifecycle of a medicinal product from clinical trials to post-marketing surveillance.



The Oracle Health Sciences Safety Suite consists of the following components:

- Oracle Argus Standard Edition: Manage and report adverse events through a workflow including case intake, data entry, coding, quality review, medical review, expedited reporting, and periodic reporting. Modules include Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, Oracle Argus Unblinding, and the Oracle Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus.
- Oracle Argus Enterprise Edition: In addition to managing the adverse event workflow and reporting, employ a powerful and flexible business analytics and intelligence platform for both scientific analysis and operational metrics. Modules include Oracle Argus Analytics, Oracle Argus Insight, Oracle Argus Mart, Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, Oracle Argus Unblinding, and the Oracle Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus.
- Oracle Argus Safety Japan: Manage and report adverse events in Japan, and connect the global and local workflows using a single database.
- Oracle Health Sciences Empirica Topics: Manage and document safety signals through a workflow including validation, prioritization, assessment, confirmation/refutation, and resulting actions.
- Oracle Health Sciences Empirica Study: Detect and analyze safety signals in clinical trial data including adverse events, clinically significant labs, electrocardiograms, vital signs, and shifts from baseline.
- Oracle Health Sciences Empirica Signal: Detect and analyze safety signals in post-marketing spontaneous adverse reaction data including public health authority databases and/or private inhouse databases such as Oracle Argus.
- Oracle Health Sciences Empirica Healthcare Analysis: Evaluate safety signals in healthcare data including electronic medical records and administrative claims, and support pharmacoepidemiology, comparative effectiveness analysis, and health economics and outcomes research.

For more information on Argus Safety, visit the Oracle Health Sciences Safety suite page at:

http://www.oracle.com/goto/pharmacovigilance.html

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.

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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.

Related Documents

This section lists the manuals for Oracle Argus products. You can order printed manuals from the Oracle iStore.

Oracle Argus Documentation

The *documentation set* includes:

- *Argus Safety Affiliate User Guide*
- *Argus Safety Administrator's User Guide*
- *Argus Safety Dossier User Guide*
- *Argus Safety Interchange User Guide*
- *Argus Safety Installation Guide*
- *Argus Safety Service Administrator Guide*
- *Argus Safety Flexible Aggregate Reporting Extensibility Guide*
- *Argus Safety BIP Aggregate Reporting User's Guide*
- *Argus Safety User's Guide*
- *Argus Safety Unblinding User Guide*
- *Argus Safety Minimum Security Configuration Guide*
- *Argus Safety Japanese Administrator's Guide*
- *Argus Interchange Japanese User's Guide*
- *Argus Safety Japanese User's Guide*

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action such as Buttons, Dialog boxes, Check boxes, Combo boxes, Drop-down lists, Labels, Option (Radio) buttons, Tabs, Text boxes, etc.

Convention	Meaning
"between quotation marks"	Information that may appear as-is on screen, or information provided by the user.
Note	Information that should be noted before proceeding with the instructions.
Important	Important information that must be noted to ensure accurate, reliable, or safe behavior of the system.
Tip	Information that enables easier completion of the current task or helps in completing other tasks.
Bold Underline	Link indicating that additional "pop-down" information is available.
ALL CAPITALS	Keyboard keys
Initial Capitals	Names of user interface elements, modules, applications, proper nouns, etc.

1 Introduction

This guide lists the Japanese-specific (J-specific) features in Argus Console.

These features have been covered as per the modules where they are displayed, in the following chapters:

- Business Configuration
- System Configuration
- Code List Configuration

2

Business Configuration

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

2.1 Configuring Product Family

The following list indicates the changes in Product Family Configuration:

- **Comments (J)** has been added below the English **Comments** area.
- This field is displayed only to an Oracle Argus Safety Japan (Argus J) user when the Japanese module is enabled.
- It is printed in the Product Family Configuration print PDF right after the English Comments field.
- It is covered by the back-end PL/SQL APIs for Product Family Configuration data table updates and audit-logging.

2.2 Configuring Licenses

The following section describes the changes in License Configuration:

2.2.1 License Configuration - Argus J Specific Parameters

The following changes have been made for PMDA Device Reporting Support in Console:

- The following drop-down lists have been added to **Console** > **Business Configuration** > **Products and Licenses**. These drop-down lists have the following options in the same order.
  - **PMDA Device Classification 1**:

    High Level Controlled Medical Device (Class IV)

    High Level Controlled Medical Device (Class III)

    Controlled Medical Device

    Generic Medical Device

    Combination products (Drugs)

    Combination products (Tissue-Engineered Medical Products)

    Stand-alone software (Class IV)

    Stand-alone software (Class III)

Stand-alone software (Class II)

PMDA Device Classification 2:

Biogenous

Specific Biogenous

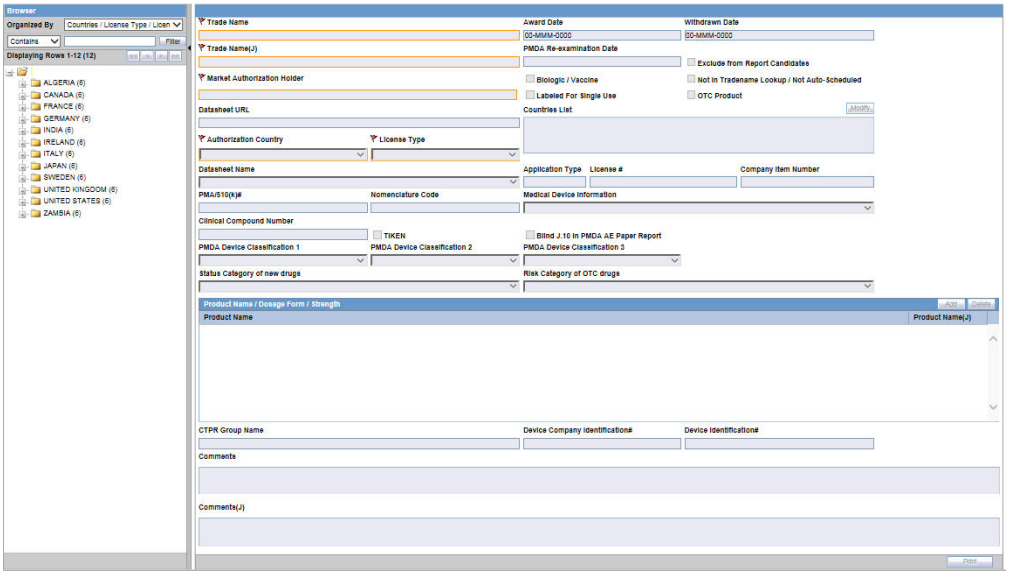
Other

PMDA Device Classification 3:

Single Use Medical Device

Reiteration Use Medical Device

Figure 2–1 Console License Configuration - PMDA Device Classifications



- These drop-down lists have <Blank> as the default value.
- These fields are displayed to only an Argus J user when Japanese module is enabled.
- These fields are editable only when **Authorization Country** is selected as Japan and **License Type** is selected as either Marketed Device or Investigational Device.
- The list options are displayed in English even to the Argus J user as this is an English base screen. The Japanese value specified for these options is used to populate them in PMDA Device Expedited Form 8 and 10.
- **Medical Device Information** and **Clinical Compound Number** have been adjusted in the user interface of the application.
- These three fields are printed in License Print PDF in three different rows, right below **Clinical Compound Number** field in alternate-colored rows thereafter.
- 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.

  - A new checkbox **TIKEN** is available. Any changes to this checkbox value are audit logged.
  - **Blind J.10 in PMDA AE Paper Report**: This checkbox is disabled by default and shall be enabled only when the License country is Japan.
  - **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.

- A separate Japanese Comments field is supported for the following in Console ' Business Configuration.
  - **Comments (J)** field has been added right below the English **Comments** area.

    This field is displayed only to Argus J users when Japanese module is enabled.

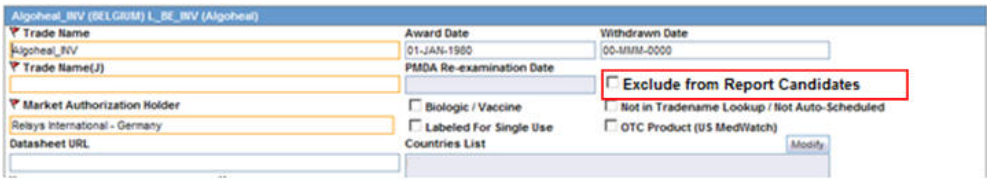
    It is printed in the License Configuration print PDF right after the English Comments field.

    It is audit-logged and is also covered by the back-end PL/SQL APIs for License Configuration data table updates and audit-logging.

2.2.2 Literature Intake Updates

Following is the list of Literature Intake Updates:

- A new option **Exclude from Report Candidates** has been added to Console > Business Configuration > License Configuration as shown below.
  - This checkbox is displayed to only an Argus J user and when Japanese module is enabled.
  - By default, this field is unchecked.
  - This checkbox 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** checkbox is not selected for that product license combination
  - **Not in Tradename lookup/Not Autoscheduled** checkbox is not selected
  - **Exclude from Report Candidates** checkbox 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** checkbox.
  - 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** checkbox 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** checkbox 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** checkbox 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** checkbox 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** checkbox 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.
- The following change has been made while populating product licenses data in Case Form > Analysis tab > PMDA > General as well as Comment sub-tabs.
  - Marketed or Investigational Japanese Device Licenses is not populated, as PMDA General and Comments tab is not relevant for Device Reporting to PMDA.
  - Existing customer case data where Marketed or Investigational Japanese Device Licenses are already populated in PMDA General and Comments tab, has also been removed.

– Removal of Marketed or Investigational Japanese Device Licenses from PMDA tab for existing customer data is audit logged with the "System" user.

2.3 Configuring Studies

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

The following changes have been made in Argus Console > Business Configuration > Study Configuration.

The application has been enhanced such that when user adds 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.

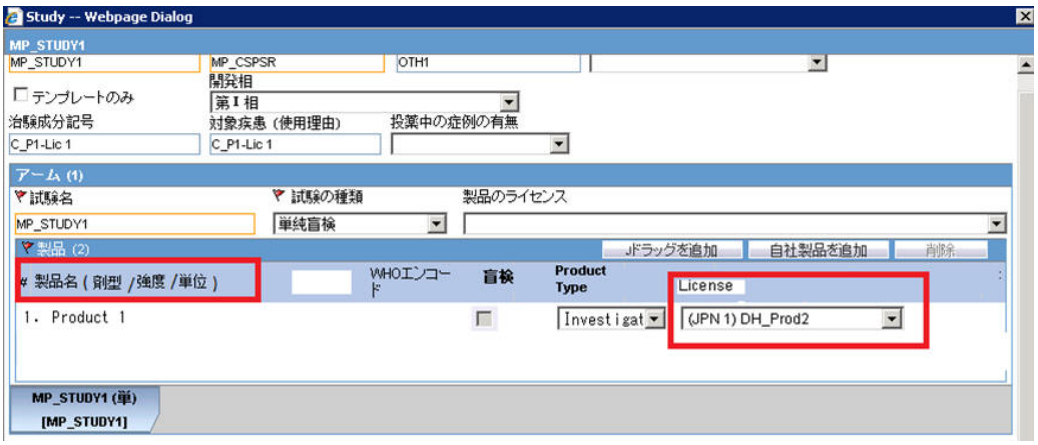
Note: The same English product name is populated in the Case form English Product name (as explained below) when the corresponding study drug is added in the case.

- 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 WHO drug remains intact.When the user tries to associate the WHO drug with the J Drug, by clicking the WHO Drug association button such that English Drug Name is not blank (or default text *J DRUG*) then the WHO Drug Browser opens with pre-populated English Drug Name (Populated from the English sub file) in the Trade Name (text box) of WHO Browser for user to perform a quick search .Also, when the user associates the J Drug to the WHO, 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 with 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)**, as shown below:

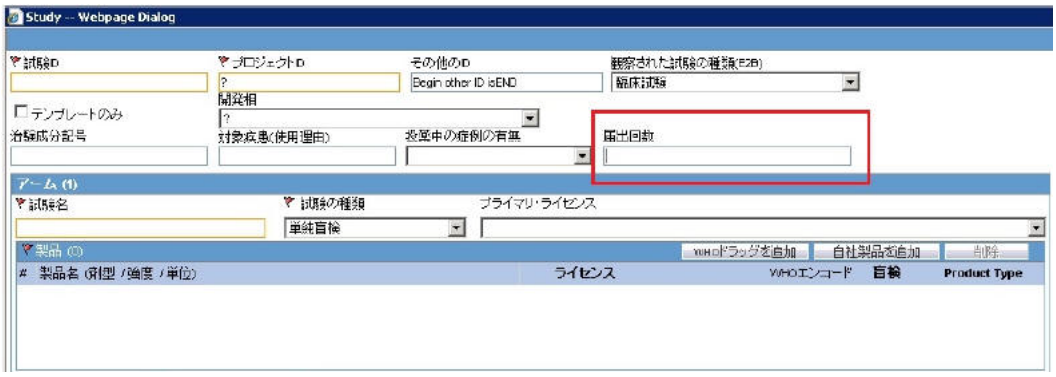


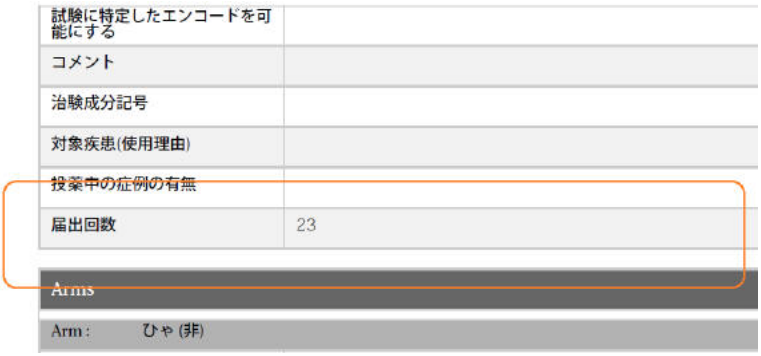
- A new license selection drop-down list, **License**, has been added in the J pop-up Product Selection grid. This list contains all the J Licenses that are present for the respective product.
- This license is used as the primary selected license when you select the product as the study drug in the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

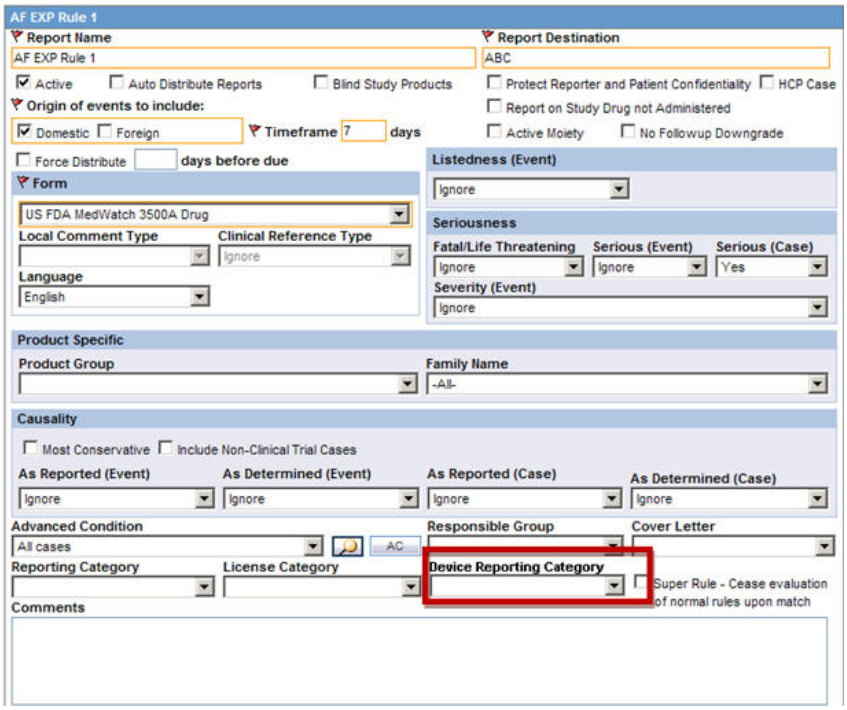
This new field is available in Study Configuration print for both **Print** and **Print All** options. It also supports the Study copy functionality. Any change to this field value is logged for audit.

2.4 Configuring Expedited Reporting Rules

Following is the list of changes in Expedited Reporting Rules Configuration:

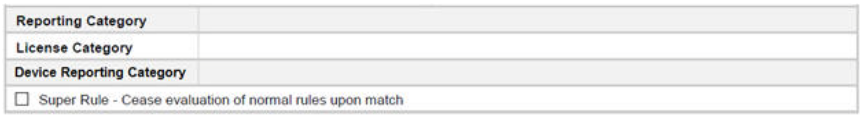
- A new drop-down list **Device Reporting Category** has been added to Console > Business Configuration > Expedited Reporting Rules screen as follows:

Figure 2–2 Console Expedited Reporting Rules Configuration - Device Reporting Category

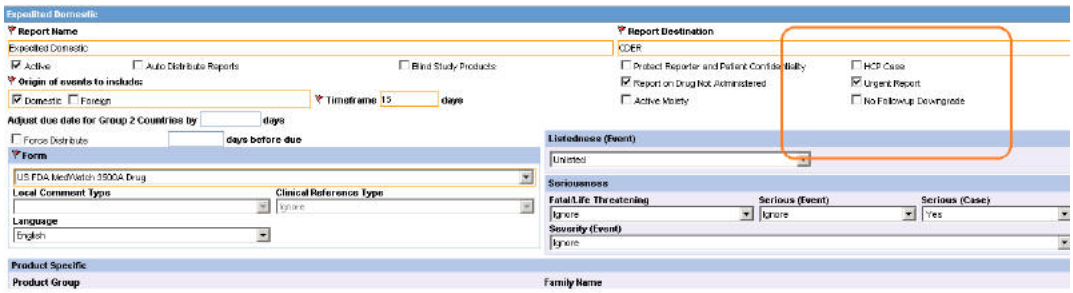


- This field is displayed to English as well as Japanese users only when Japanese module is enabled.
- This drop-down displays the English values as specified in the Device Reporting Category Code List and are marked as Display.
- It contains <Blank> as the first option and it is also the default value.
- 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 2–3 Console Expedited Reporting Rules Configuration - Print PDF



- A new option **Urgent Report** is available in the Reporting Rule Print. Selecting this checkbox will mark a report as urgent. The new option supports the copy functionality and changes to it will be logged for audit.


Expedited Domestic
Report Name
Expedited Domestic
Report Destination
CDER
Active
Auto Distribute Reports
Blind Study Products
Protect Reporter and Patient Confidentiality
HCP Case
Origin of events to include:
Report on Drug Not Administered
Urgent Report
Domestic
Foreign
Timeframe 15 days
Active Moiety
No Followup Downgrade
Adjust due date for Group 2 Countries by days
Forces Distribute
days before due
Listedness (Event)
Form
Unlisted
US FDA MedWatch 3500A Drug
Local Comment Type
Clinical Reference Type
Seriousness
Fatal/Life Threatening
Serious (Event)
Serious (Case)
Language
Ignore
Ignore
Yes
English
Severity (Event)
Ignore
Product Specific
Product Group
Family Name

3

System Configuration

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

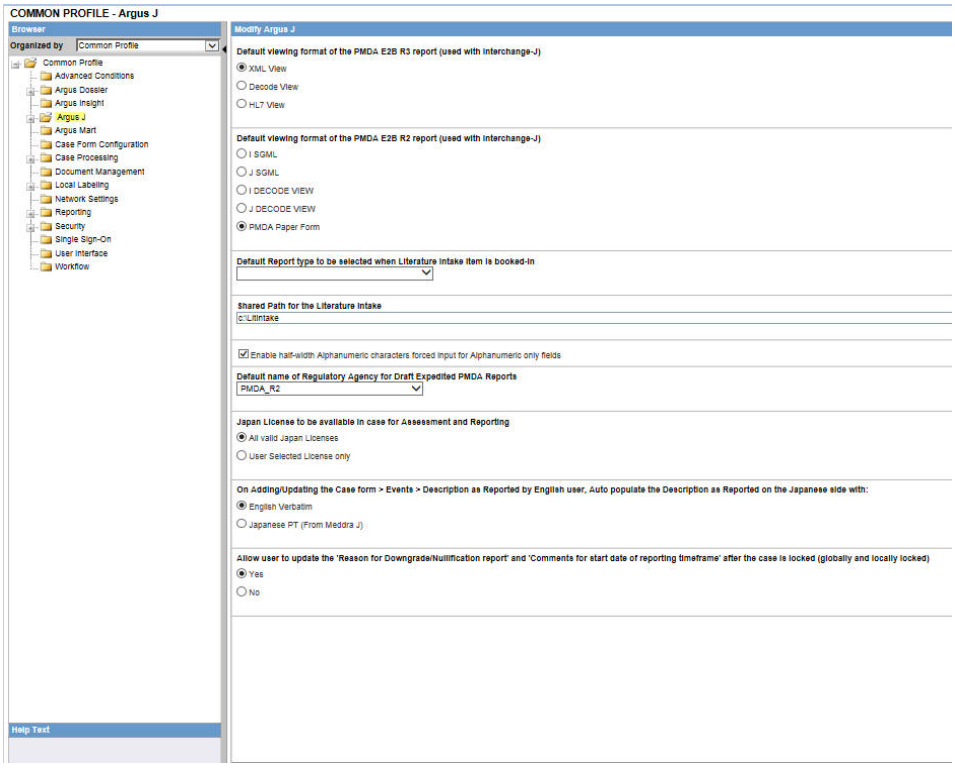
3.1 Configuring Common Profile Switches

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

3.1.1 Common Profile Switches

This section explains the Common Profile Switches for Argus J.

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



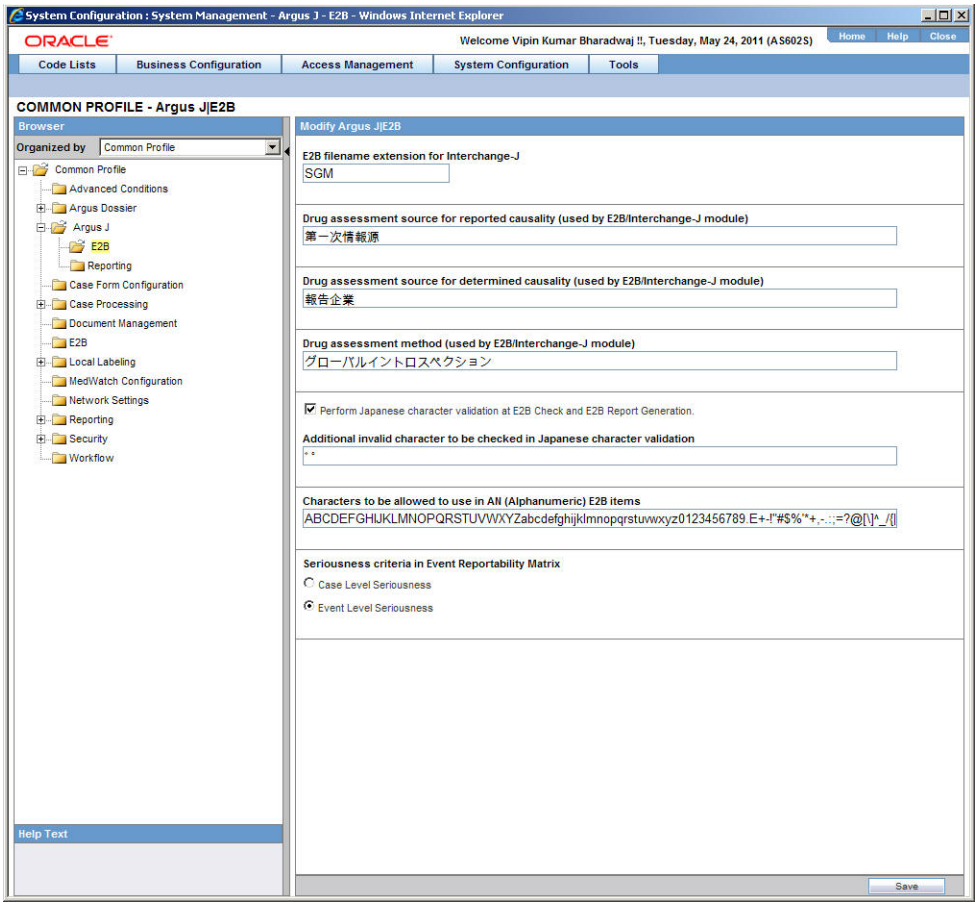
The following table explains the fields used in the screen:

Field Name	Description	Field Options
Enable half-width Alphanumeric characters forced input for Alphanumeric only fields	In the Argus J application, if this Profile Switch is on, the system automatically forces the input method to fixed half-width English when you enter data in the Alphanumeric only fields. For example, J user sets Japanese as input method on the client system, and without changing the input method, they can work through Argus J. Case Form: The following items are always alphanumeric input only regardless of the profile switch: All the fields in English UI are forced to enter half-width alphanumeric characters. Login fields are forced to enter half-width alphanumeric characters. All non-Japanese fields in the multi-language pop- up. The following items are forced to input Alphanumeric characters by profile switch: All global fields PMDA tab **General** > **Japan first information received date** **General** > **Japan follow-up received date**	
Default viewing format of the PMDA E2B report (used with Electronic Submission Module (Interchange-J))	This field represents the default viewing format of the PMDA E2B 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
Shared Path for the Literature Intake	This field represents the shared path for the Literature Intake. Default Value is blank.	Maximum Length: 255

Field Name	Description	Field Options
	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 Console J: 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 Console J SRS **Population Rule** section. All the regular fields that have A (Alphanumeric only) in Input Lang Type classification of Console J SRS. Default Value is checked.	
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 Console J
Default name of the Regulatory Agency for New Draft Expedited PMDA Reports from Analysis Tab of the Case Form	This field represents the default name of the regulatory agency for new draft expedited PMDA reports.	Reporting Destinations configured in the Console J

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
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

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



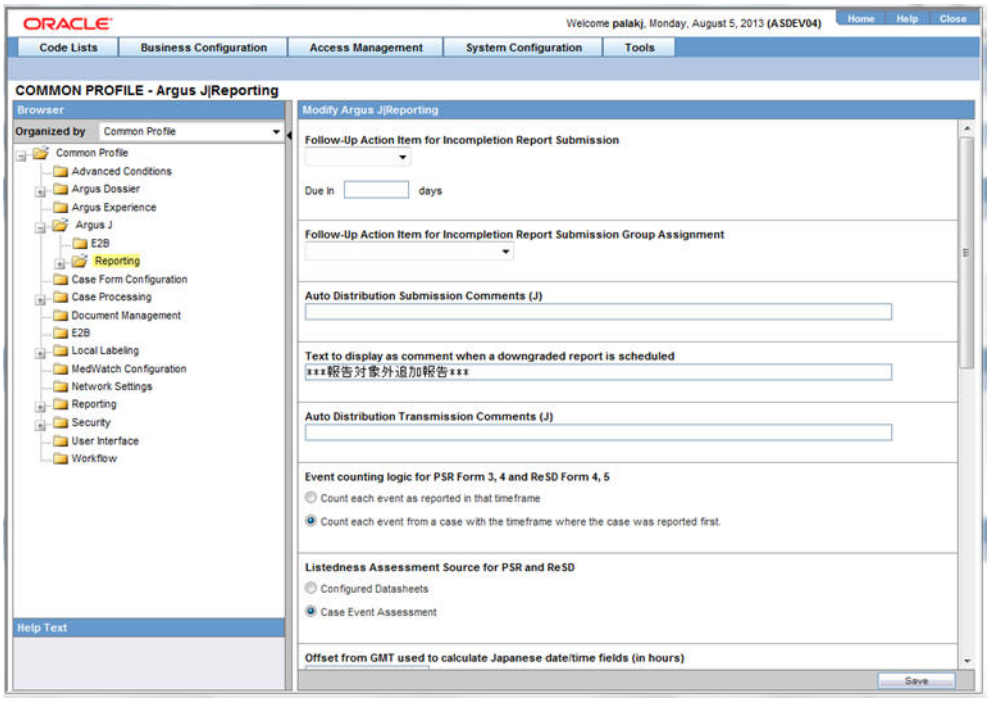
The following table explains the fields used in the screen:

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
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.**
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.

Field Name	Description	Field Options
Characters to be allowed to use in AN (Alphanumeric) E2B items	In this field, you can enter English characters allowed in Argus J. 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: ABCDEFGHIJKLMNOPQRSTUVWXYZabcdefghijklmnopqrstuvwxyz0123456789.E+- !"#$%'()*+,-.:;=?@[\]^_/{|}~	
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: 120J Audit 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: 120J Audit Log: Yes
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: 70J Audit Log: Yes

Field Name	Description	Field Options
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
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
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

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
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
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
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-J Default Value: 7	
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.	
"Follow-Up Action Item for Incompletion Report Submission" "Due In ____ days"		Populated based on Action Type Code list values (not deleted and not hidden)
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.
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

Field Name	Description	Field Options
Count each event as reported in that timeframe	Enables you to count each event as reported in the specified timeframe.	
Count each event from a case with the timeframe where the case was reported first	Enables you to count each event from a case with the timeframe where the case was reported first.	
Configured Datasheets	Enables you to configure datasheets as per your requirements.	
Case Event Assessment	Enables you to assess the case event.	

PIP PMDA Profile Integration for No Reportable Events

The existing Argus Safety application checks for reportable events for PMDA E2B generation for transmission and import process. Due to this check, cases with un-encoded events or missing causality cannot be accepted successfully during follow up import process as reportable events scenario is not met for such follow ups. The Inform-Argus PIP profile has removed the check of reportable events from their profile SQLs. However, because of the 'No reportable' events check during E2B generation for follow up import, it is not possible to accept any follow-up report.

This scenario is encountered during Inform when other system sends un-encoded events to Argus.

This problem has been fixed only for custom PMDA profile. Argus Safety now has an option of excluding 'No Reportable' events check during PMDA E2B generation for transmission and import process based on a common profile switch 'PIP PMDA PROFILE'':

1. Argus Safety now excludes the 'No Reportable' events check for a PMDA E2B report for custom PMDA profile configured in the 'PIP PMDA PROFILE' switch. This will allow a follow up report for a configured custom profile to be imported even though there are no reportable events in the case.
2. No Reportable events check is excluded for E2B generation both for transmission and import scenarios.

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 existing common profile switch, **Offset from GMT used to calculate Japanese date/time fields for Interchange-J (in hours)**, under Console > System Configuration > System Management (Common Profile Switches) > Argus J > Reporting has been

renamed to **Offset from GMT used to calculate Japanese date/time fields (in hours)** to remove the reference of Interchange-J and use it for device reports and E2B.

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)
- 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)

The following table explains the fields used in the screen **Common Profile** > **Argus J** > **Reporting** > **Device Report**:

Field Name	Description	Field Options
Event counting logic for PSR Form 3, 4 and ReSD Form 4, 5	Default option is radio button option #1. If this option is selected, then PSR form 3,4 and ReSD Form 4,5 shall count all events from the timeframe reported. If radio option # 2 is selected, then the PSR Form 3, 4 and ReSD Form 4, 5 shall be updated to count / print all the events from 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 / Paper Report to PMDA in the current reporting period, still it shall be counted / printed under the original timeframe.	Count each event as reported in that timeframe Count each event from a case with the timeframe where the case was reported first.
Event counting logic for PSR Form 3, 4 and ReSD Form 4, 5	If this common profile switch is set to "Yes", then when the case is locked from any point in Argus Safety application, it shall trigger the fresh calculation of the PMDA Event Reportability data.	Yes, No (Default).

Field Name	Description	Field Options
Listedness Assessment Source for PSR and ReSD	When switch is set to "Configured Datasheet", the listedness shall be determined based on the configured Datasheets. When the switch is set to "Case Event Assessment", the listedness is considered from the Case Event Assessment data in the following sections of the report: a.PSR Form 3 (and ReSD Form 4) b.PSR Form 4 (and ReSD Form 5) c.ReSD Tabulations i.Tabulation for UnListed Events ii.Tabulation for Listed Events.	Configured Datasheets, Case Event Assessment (Default).
Blinded text for PMDA AE Paper reports	Enables you to enter blinded text for PMDA AE Paper reports.	

3.1.1.1 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.

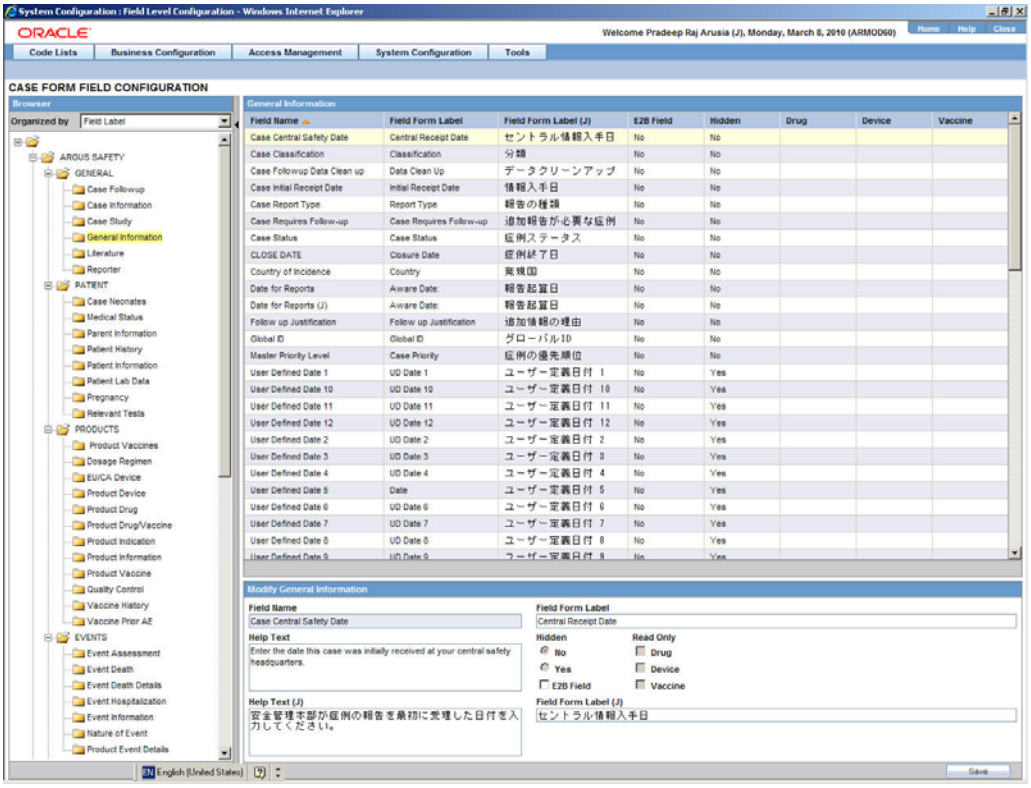
- If the report is nullified (Nullification Report is sent), the Action Item is closed.
- When there are multiple incompletion reports from one case, the system creates the action items, which are same in number as that of the reports generated.
- The system appends a default text in front of description (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.

3.2 Configuring Field Level Validations

This section lists the configuration of fields in Argus Console.

3.2.1 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 Argus J user, when Argus J 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.

3.2.1.1 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.

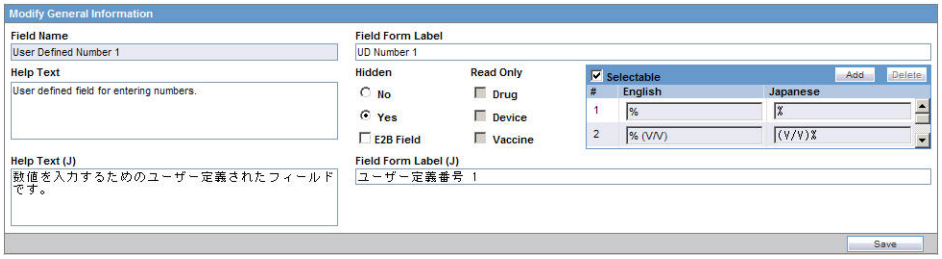
This enhancement is applicable for PMDA E2B Downgrade/nullification reports.

3.3 Configuring Field Labels

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

3.3.1 User Defined Fields Updates

The Argus J system has the following:



- Argus J 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.

3.4 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).

For the purpose of this release, 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.

4

Code List Configuration

This chapter lists the Japanese-specific (J-specific) features in the Code List Configuration module of Argus Console.

4.1 Code Lists

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

4.1.1 General Functionality Changes

This section lists the Argus J general functionality Code List changes:

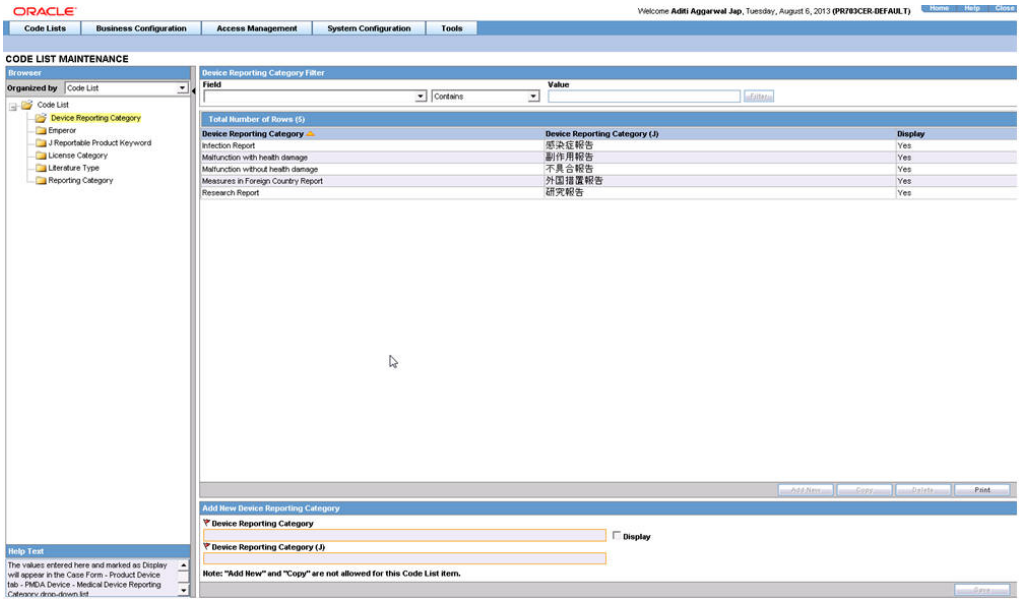
- **Sort Order**: The sort order for display of the elements in the Code Listing is based upon English element as default. For Japanese-only elements, the priority sort language is Japanese.
- **Print**: The PRINT functionality is modified to display all the Japanese fields also.
- If Japanese translation 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 Argus J 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 Argus Safety user copies the data, the equivalent Japanese data is not copied.
  - When Argus J 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 Argus Safety.
    - "TBD" 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.

4.1.2 Device Reporting Category

A new Japan specific code list has been added under Console ' Code Lists ' Argus J menu option as "Device Reporting Category".

- Screen Mockup: The help text for this code list is - "The values entered here and marked as "Display" will appear in the - Product Device tab - PMDA Device - Medical Device Reporting Category drop-down list."

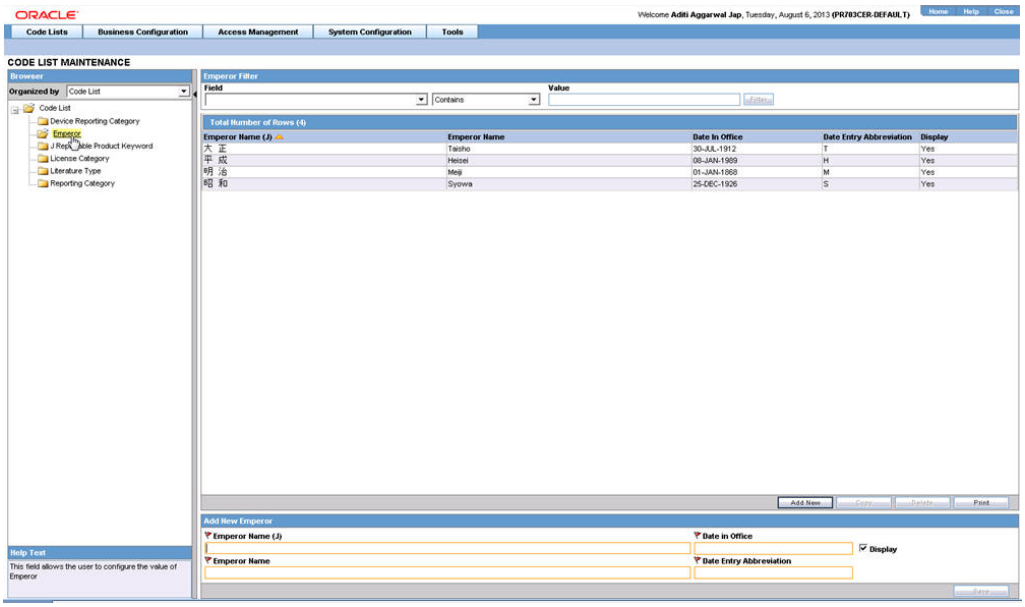


Field Name	Description
Device Reporting Category	Allows user to enter Device Reporting Category value in English.
Display	Allows user to display/hide a device reporting category in Argus Safety .
Device Reporting Category (J)	Allows user to enter Device Reporting Category value in Japanese.

- This code list now opens up by default in place of Emperor code list, when user selects Console > Code Lists > Argus J menu option.
- It is covered by the back-end PL/SQL APIs for Device Reporting Category data table updates and audit-logging.

4.1.3 Emperor

This dialog box allows you to add and configure various Japanese Emperor Data/Era. This is a J specific LM.



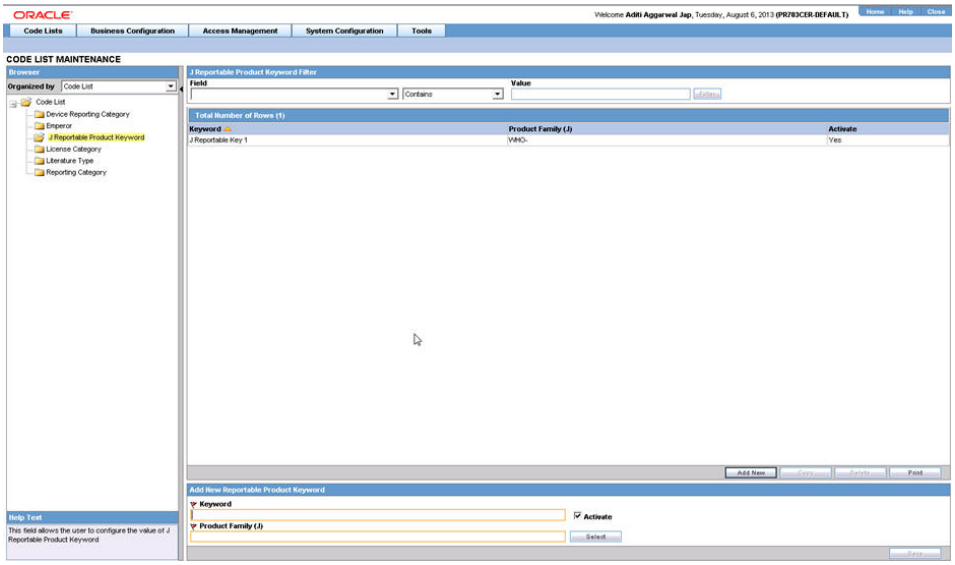
The following table lists the fields used in the dialog box and their description:

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 offices Date 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

4.1.4 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.

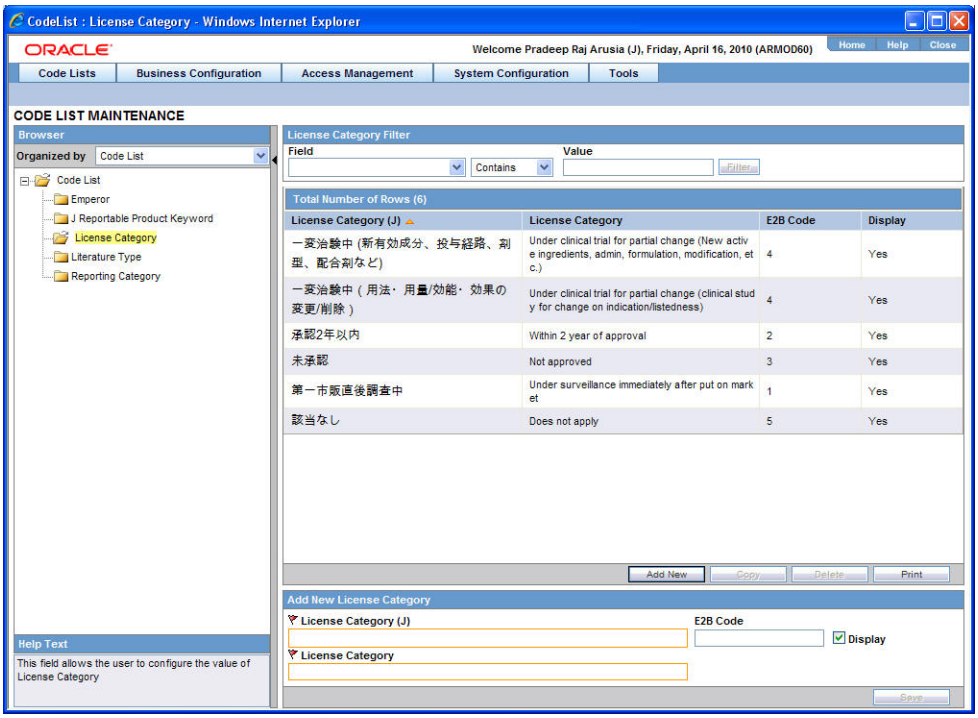


The following lists the fields used in the dialog box and their description:

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.

4.1.5 License Category

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



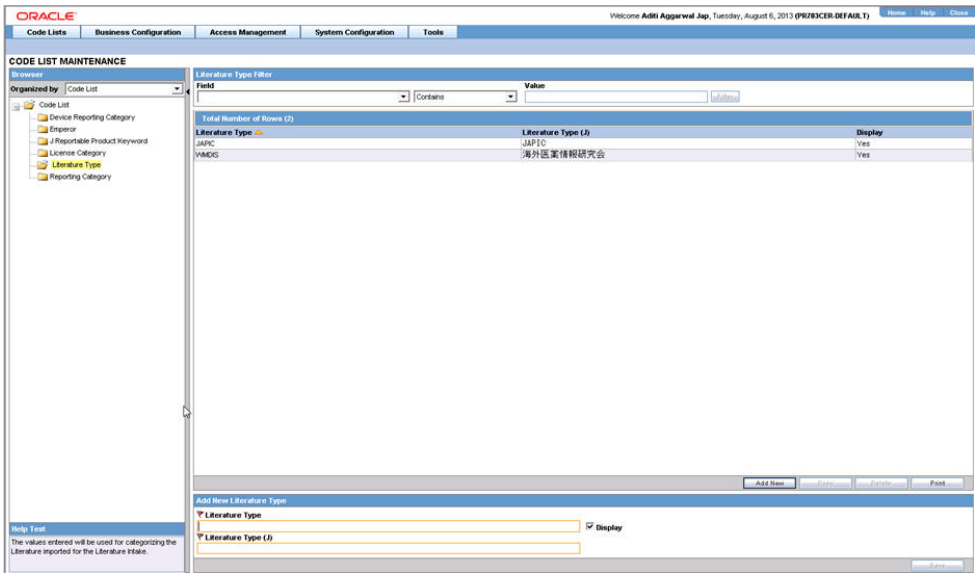
The following table lists the fields used in the dialog box and their description:

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

4.1.6 Literature Type

Use the following procedure to configure action taken:

1. From the Argus 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.

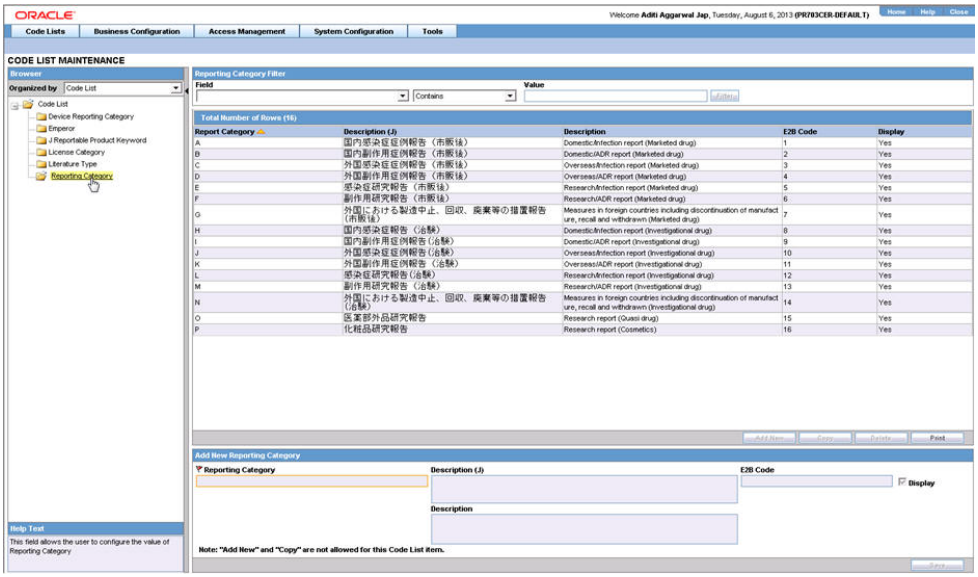


4. This screen enables you to view the English and Japanese names of the configured categories. You can also set the display preferences for these code lists.
5. Click Add to add a entry in the code list after filling the required information in the mandatory fields.
6. Click Save to save any changes.

4.1.7 Reporting Category

Use the following procedure to configure action taken:

1. From the Argus Console, select Code Lists -> Argus J -> Reporting Category.
2. When the system opens the Code List Maintenance screen, click Reporting Category 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.

Note:

When the nullification E2b reports is auto-scheduled for the No valid event scenarios, a new common profile switch called **PMDA E2B Nullification Reason Text for No Valid Event Scenario** has now been made available in Argus Console under the Argus J > Reporting menu.

The default value of this switch in Japanese is 'There is no valid event available in the case'. This switch can contain up to 200 characters and it supports English as well as Japanese data entry.

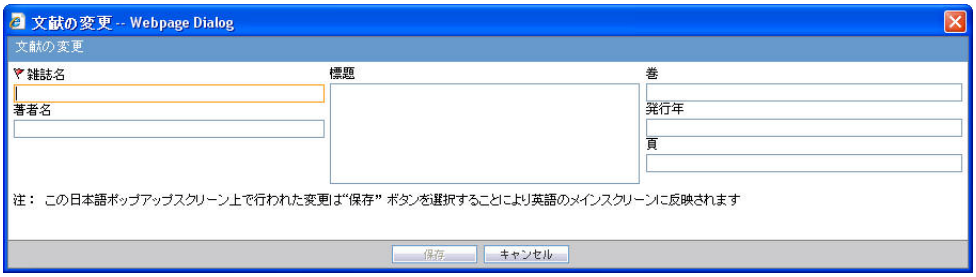
The value entered in this switch is used as the value of the E2B element A.1.13.1 NULLIFICATIONREASON in PMDA E2B.

The reason for nullification is populated when a nullification report is generated.

4.1.8 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 Japanese screen looks like this:



- 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:

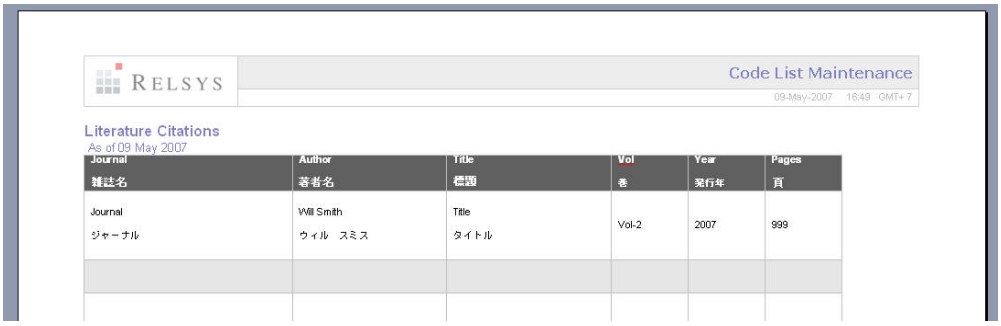
  Data must be saved before opening the Japanese screen. Do you want to save?

- 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 Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When Argus J user copies the data:
  - **Copy of** is appended in front of the data in the **Journal** field of English UI.
  - TBD 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:



4.1.9 Reporting Destination

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

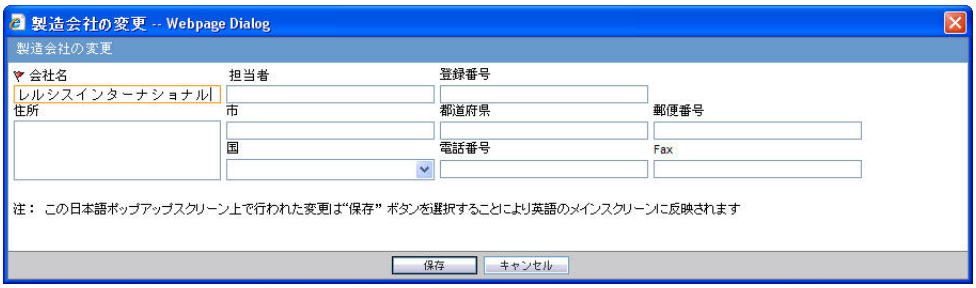
The *Argus Console -> Code list -> Reporting Destination-> EDI* (tab) has been enhanced:

- In the Message Profile drop-down list, the PMDA E2B R3 profile (*ICH-ICSR V3.0 MESSAGE TEMPLATE - PMDA*) is available to users for configuration.
- In the ACK profile, users can select the PMDA E2B R2 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).

4.1.10 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 Japanese screen looks like this:



- 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:

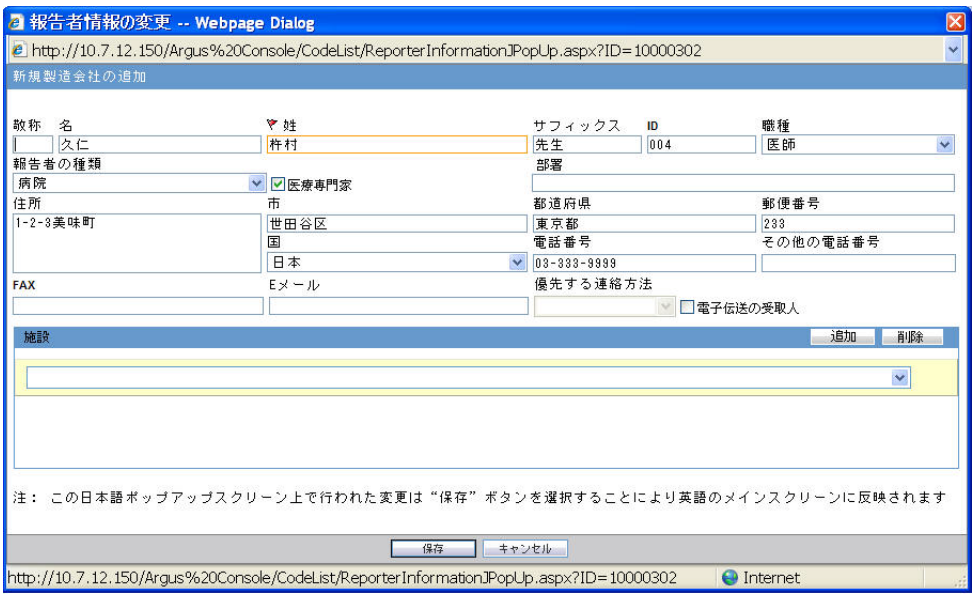
- When the Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When the Argus J user copies the data:
  - **Copy of** is appended in front of the data in the **Name** field of the English UI.
  - "TBD" is appended in front of the data in the **Name** field of Japanese UI.
- 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.

4.1.11 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 Argus Safety user copies the data, the equivalent Japanese data is not copied.
- When the Argus J user copies the data:
  - **Copy of** is appended in front of the data in the **Name** field of the English UI.
  - "TBD" 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　義男 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 帝台病院 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.

4.1.12 Flexible Data Re-Categorization

The flexible data re-categorization feature allows Argus Safety and its associated applications, such as Argus Mart and 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 Console > Code List > Flex Data Re-Categorization.

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

4.1.12.1 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
Domestic/Infection report (Marketed drug)	AA
Domestic/ADR report (Marketed drug)	AB
Overseas/Infection report (Marketed drug)	AC
Overseas/ADR report (Marketed drug)	AD
Research/Infection report (Marketed drug)	AE
Research/ADR report (Marketed drug)	AF
Measures in foreign countries including discontinuation of manufacture, recall and withdrawn (Marketed drug)	AG
Domestic/Infection report (Investigational drug)	DA
Domestic/ADR report (Investigational drug)	DB
Overseas/Infection report (Investigational drug)	DC
Overseas/ADR report (Investigational drug)	DD
Research/Infection report (Investigational drug)	DE
Research/ADR report (Investigational drug)	DF
Measures in foreign countries including discontinuation of manufacture, recall and withdrawn (Investigational drug)	DG
Research report (Quasi drug)	BC
Research report (Cosmetics)	BD

4.1.12.2 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
Under surveillance immediately after put on market	1
Within 2 year of approval	2
Not approved	3
Under clinical trial for partial change (clinical study for change on indication/listedness)	4
Under clinical trial for partial change (New active ingredients, admin, formulation, modification and so on)	4
Partial change during clinical trial	4
Does not apply	5
During the re-review period (Medicines that Require Pharmacist Intervention)	6
During the PMS period (Medicines that Require Pharmacist Intervention)	7

4.1.12.3 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 tests and so on	0
Phase I	1
Phase II	2
Phase III	3
Phase I/II Trial)	4
Phase II/III Trial	5
Biological equivalence study	8
Clinical pharmacology study	8
Preparation NDA submission	8
NDA submitted	7
Other	8

4.1.12.4 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 I OTC drugs	01
Class II OTC drugs	02
Designated Class II OTC drugs	2S
Class III OTC drugs	03
Medications manufactured and marketed by pharmacies	04
Medicines that Require Pharmacist Intervention	05

4.1.12.5 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
Sold over the counter at pharmacies, and so on	S
Household distribution	H
Mail order via the internet	I
Other mail order (telephone, and so on)	T
Checked but unable to obtain information	ASKU This denotes a Null flavor value.
Unable to confirm for unavoidable reasons, unknown	UNK This denotes a Null flavor value.