Oracle Argus Safety

Japanese Administrator's Guide

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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 Argus J Safety system for configuring Argus Safety.

Documentation Accessibility

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About This Book

This guide contains the following chapters:

Chapter 1, "Introduction"

Chapter 2, "Business Configuration"

Chapter 3, "System Configuration"

Chapter 4, "Code List Configuration"

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

2.1 Configuring Product Family

The following is the list of changes in Product Family Configuration:

Product Family Configuration: "Comments (J)" text area field has been added right below the English "Comments" text area:

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

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

It is audit-logged and 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 is the list of changes in License Configuration:

2.2.1 PMDA Device Reporting Support in Console

The following is the list of changes for PMDA Device Reporting Support in Console:

1. Three new dropdown fields have been added to Console > Business Configuration > License Configuration.
    a. These dropdowns list fixed dropdown options, as specified below in the same order.

        PMDA Device Classification 1:

        High Level Controlled Medical Device

        Controlled Medical Device

        Generic Medical Device

        PMDA Device Classification 2:

        Biogenous

        Specific Biogenous

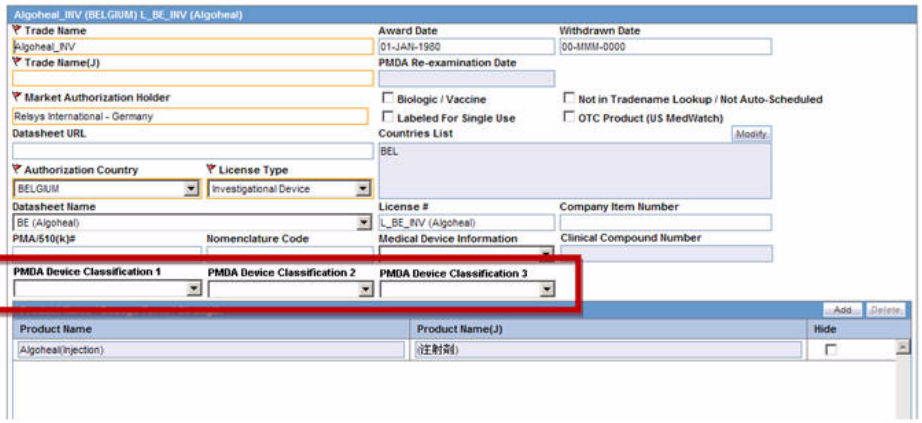
        Other

PMDA Device Classification 3:

Single Use Medical Device

Reiteration Use Medical Device

Figure 2–1 Console License Configuration - PMDA Device Classifications



b. These fields have <Blank> as the default value for these drop-down lists.

c. These fields are displayed to only an Argus J user when Japanese module is enabled.

d. These fields are editable only when Authorization Country is selected as Japan and License Type is selection as either of "Marketed Device " or "Investigational Device". Otherwise, these are displayed as blank and disabled.

e. The dropdown option values are displayed in English even to the Argus J user as this is an English base screen. The Japanese value specified for these dropdowns is used to populate these in PMDA Device Expedited Form 8 and 10.

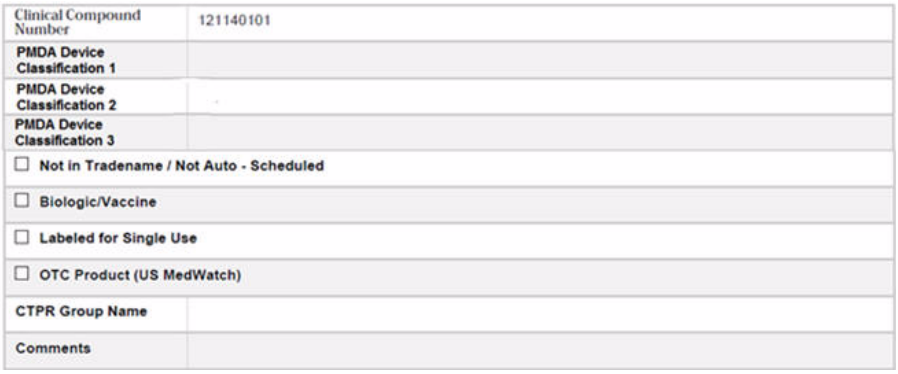
f. Existing fields - "Medical Device Information" and "Clinical Compound Number" have been adjusted in the user interface of the application.

g. These three fields are printed in License Print PDF in three different rows, right below Clinical Compound Number field in alternate-colored rows thereafter.

h. These fields are audit-logged.

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

Figure 2–2 Console License Configuration - Print PDF



2. A separate Japanese Comments field is supported for the following in Console ' Business Configuration.

   - License Configuration: "Comments (J)" text area field has been added right below the English "Comments" textarea:

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

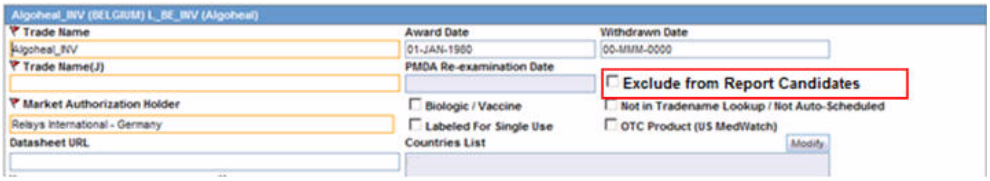
     It is printed in the License Configuration print PDF right after the English Comments field.

     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

The following is the list of Literature Intake Updates:

- A new checkbox - "Exclude from Report Candidates" field has been added to Console ' Business Configuration ' License Configuration screen 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 will only be enabled when the Authorization Country = Japan. Otherwise, it is unchecked and displayed as disabled.
  - This field value is printed in License Configuration print PDF.
  - The updates to this field value is 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 marked as checked for that product license combination
  - "Not in Tradename lookup/Not Autoscheduled" checkbox is not marked as checked
  - "Exclude from Report Candidates" checkbox is not marked as checked
  - If multiple licenses exist matching this criteria, then Earliest award date license are considered
  - If multiple licenses still exist matching this criteria, then the license with the lowest internal sequence number are considered.
- The following describes 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 marked as checked 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 marked as checked 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 marked as checked 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 marked as checked.
  - 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 marked as checked are considered for populating Japanese licenses in Event Assessment and PMDA tabs.
- Manual Report Scheduling dialog > License # dropdown displays only those Japanese licenses which are available on Event Assessment tab.
- The following change has been made to the system 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, have 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 following is the list of changes in Study Configuration:

Study Configuration: Existing text area field (Comments) in the "J Data Entry" popup for Study Configuration screen does not share the same value with English and is made an independent data field to store the corresponding translation:

It is printed in the Japanese Study Configuration print PDF at the same place but now with the Japanese Comments value.

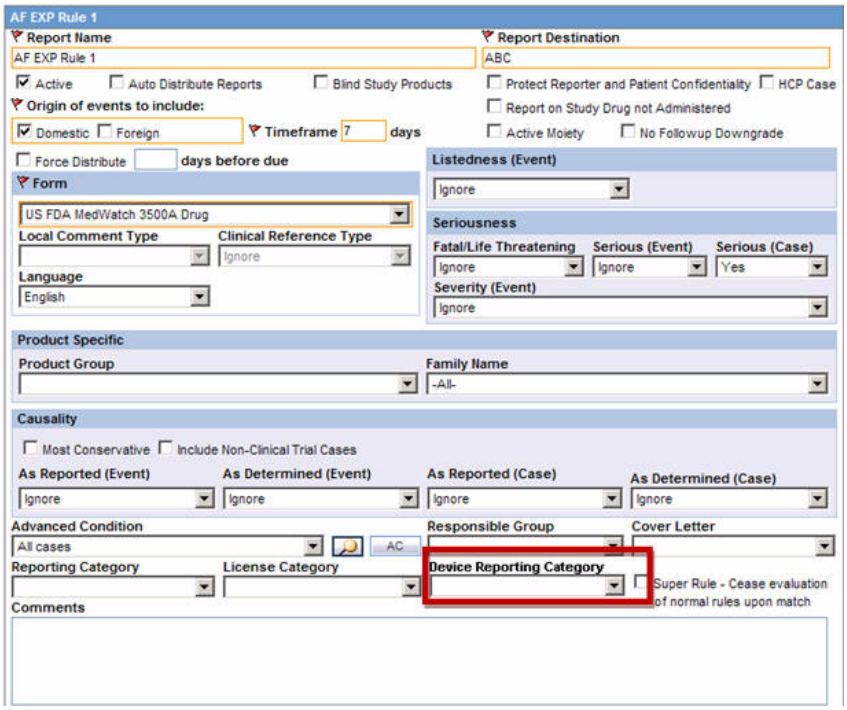
It is audit-logged and is covered by the back-end PL/SQL APIs for Study Configuration data table updates and audit-logging.

2.4 Configuring Expedited Reporting Rules

The following is the list of changes in Expedited Reporting Rules Configuration:

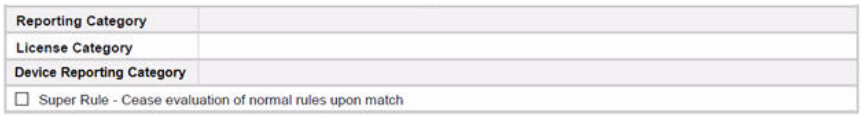
A new dropdown field - "Device Reporting Category" has been added to Console > Business Configuration > Expedited Reporting Rules screen as displayed in the screen mockup below:

Figure 2–3 Console Expedited Reporting Rules Configuration - Device Reporting Category



- This dropdown field is displayed to English as well as Japanese users only when Japanese module is enabled.
- This dropdown displays the English values as specified in the "Device Reporting Category" Code List and marked as "Display".
- It contains <Blank> as the first option also as 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 2–4 Console Expedited Reporting Rules Configuration - Print PDF



3

System Configuration

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

3.1 Configuring Commmon Profile Switches

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

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

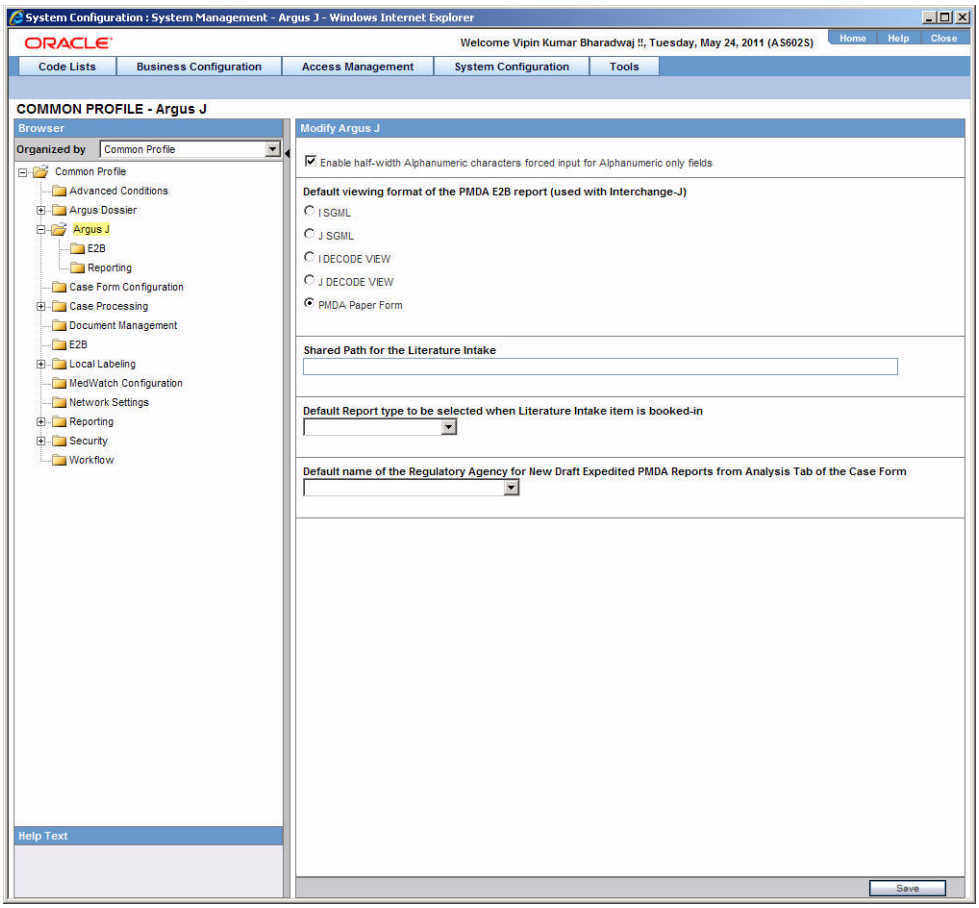
- Company Name: Textbox, Maxlength = 100
- Department: Textbox, Maxlength = 100
- Address: Textbox, Maxlength = 60
- Telephone: Textbox, Maxlength = 50
- Fax: Textbox, Maxlength = 50
- Email: Textbox, Maxlength = 255

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 as well as in addition to E2B.

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:

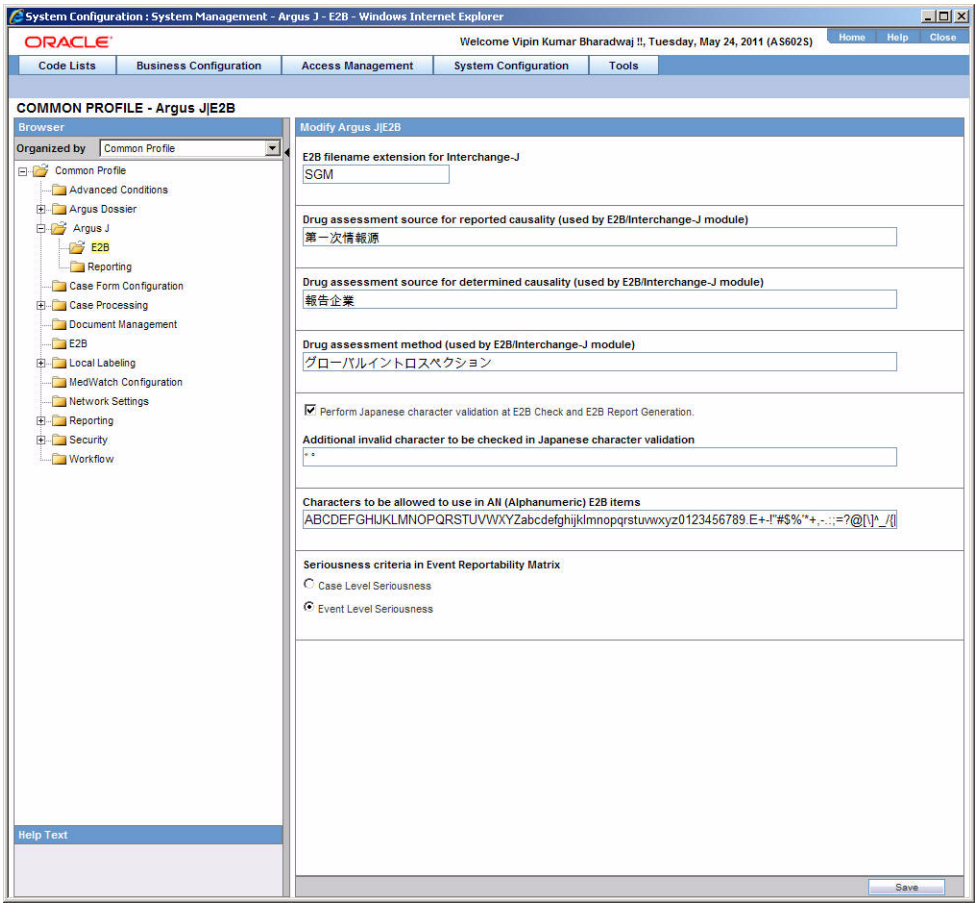
Field Name	Description	Field Options
Default name of the Regulatory Agency for New Draft Expedited PMDA Reports from Analysis Tab of the Case Form		Reporting Destinations configured in the Console J
Default viewing format of the PMDA E2B report (used with Electronic Submission Module (Interchange-J))	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

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**	

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.	
Disable MedDRA coding to J non-current term from MedDRA browser when COI is Japan	This field is used to avoid MedDRA encoding with non-current J terms for Japanese cases. Default Value is checked	When profile switch is turned on, COI is Japan and you encode the MedDRA from English MedDRA browser, encoding is not done for the Japan non-current MedDRA term. When Japan non-current term is entered, a pop-up window is displayed after the encoding failure.

Field Name	Description	Field Options
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
Shared Path for the Literature Intake	This field represents the shared path for the Literature Intake Default Value is blank	Maximum Length: 255

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

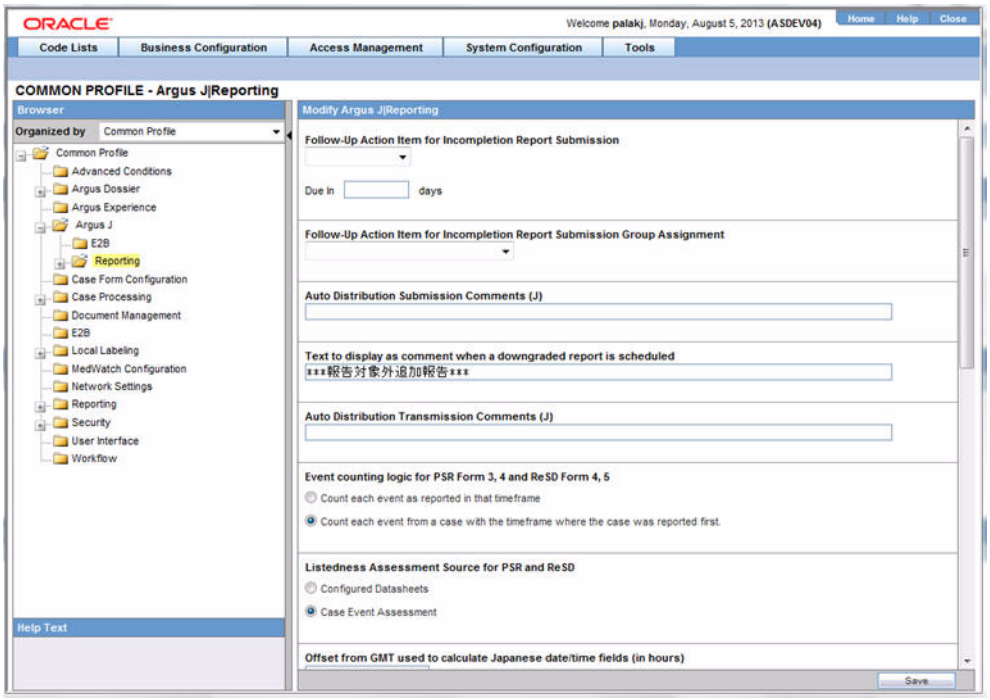


The following table explains the fields used in the screen:

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.
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

Field Name	Description	Field Options
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
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

The following figure 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

Field Name	Description	Field Options
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"		Populated based on Action Type Code list values (not deleted and not hidden)
"Due In ____ days"		
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
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.	

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).
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).

3.1.1.1 Profile Switch for Incompletion Report Submission - Auto Action item

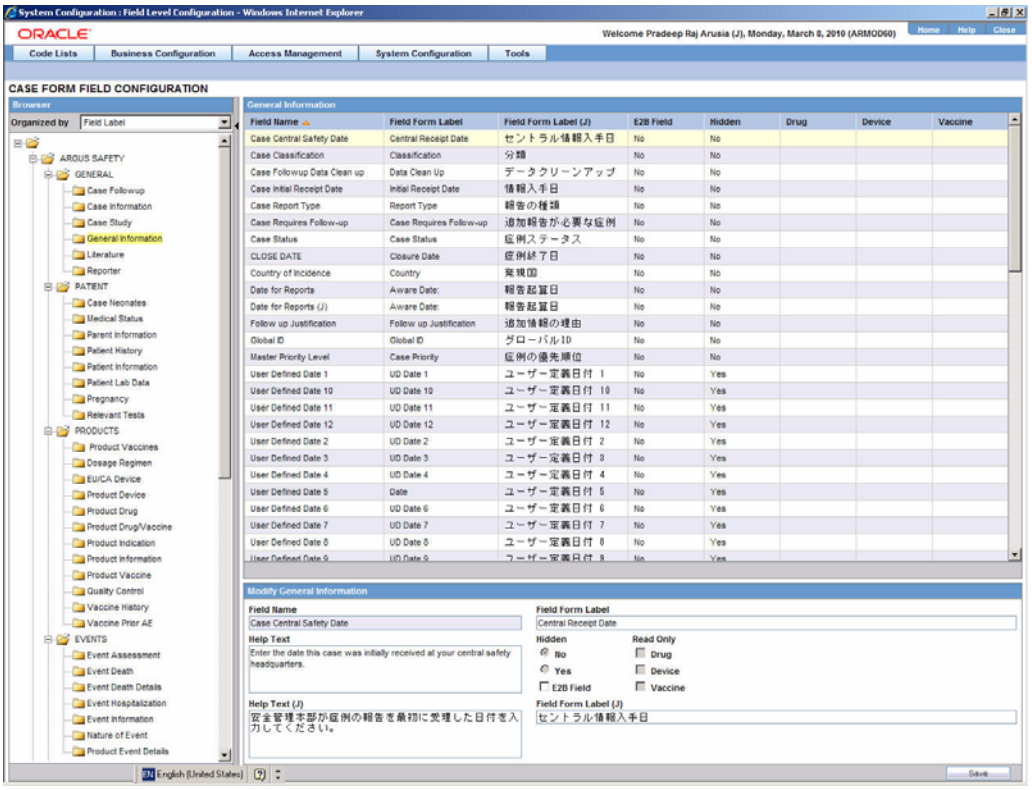
- When this action item is configured, the system creates an action item automatically when **Incompletion** report is submitted. (Mhlwadmicsrcompleteclass, 1=Incomplete, 2=Complete, Case Form/Analysis/PMDA/PMDA General/Incompletion checkbox)
- **Blank (Default)**: if this option is present in the **Action 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 prepends 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:

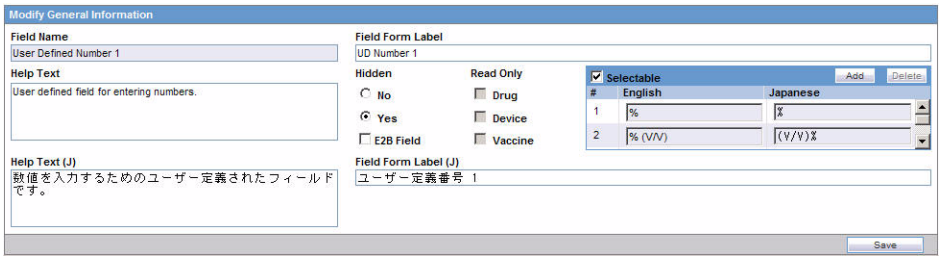
Field Name	Description
Field Form Label (J)	This field allows you to edit the field labels. It is valid only for the labels where label change is allowed. This is an optional field.
Help Text (J)	You can enter the help text here for a selected field. This is an optional field.

3.3 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.

4

Code List Configuration

This chapter lists 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:

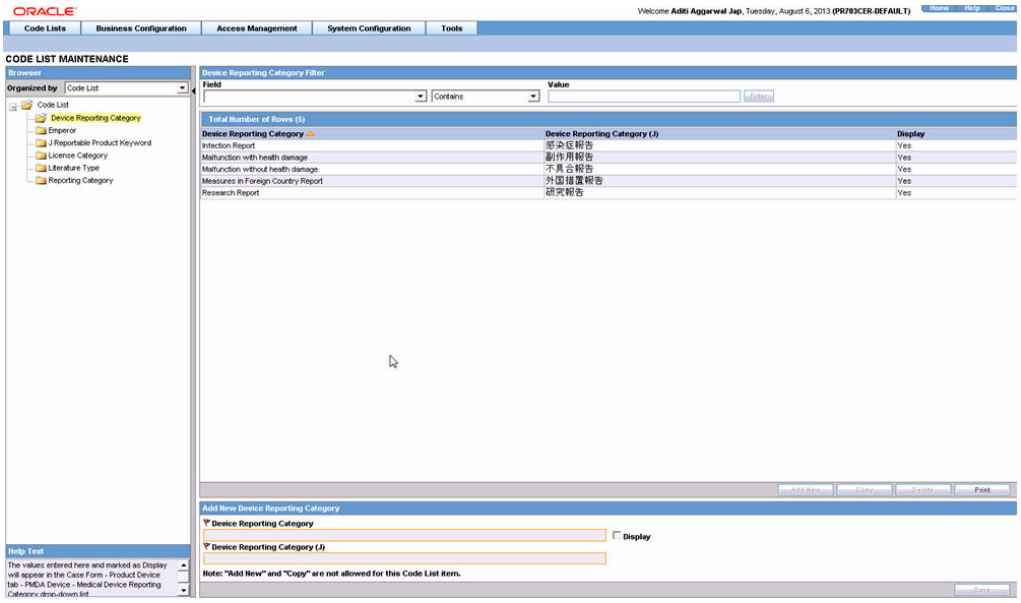
1. **Sort Order**: The sort order for display of the elements in the Code Listing is based upon English element as default. If the element is only Japanese, Japanese is the priority sort language.
2. **Print**: The PRINT functionality is modified to display all the Japanese fields also.
3. If Japanese 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.
4. 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.
5. 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 Case Form - Product Device tab - PMDA Device - Medical Device Reporting Category drop-down list."

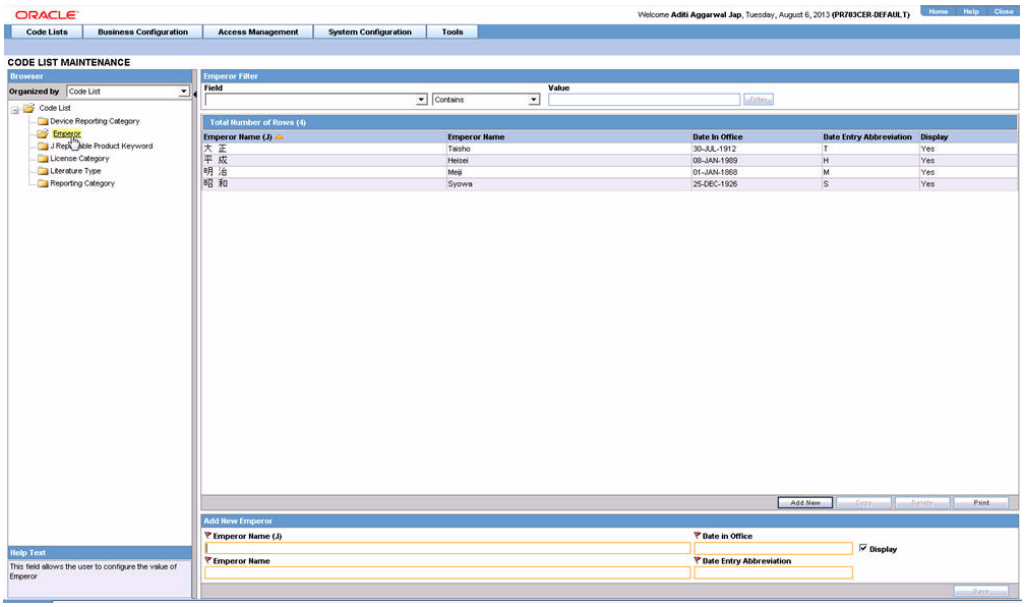


Field Name	Description
Device Reporting Category	Allows user to enter Device Reporting Category value in Japanese
Display	Allows user to display/hide a device reporting category in Argus Safety Case Form
Device Reporting Category (J)	Allows user to enter Device Reporting Category value in English

- 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.



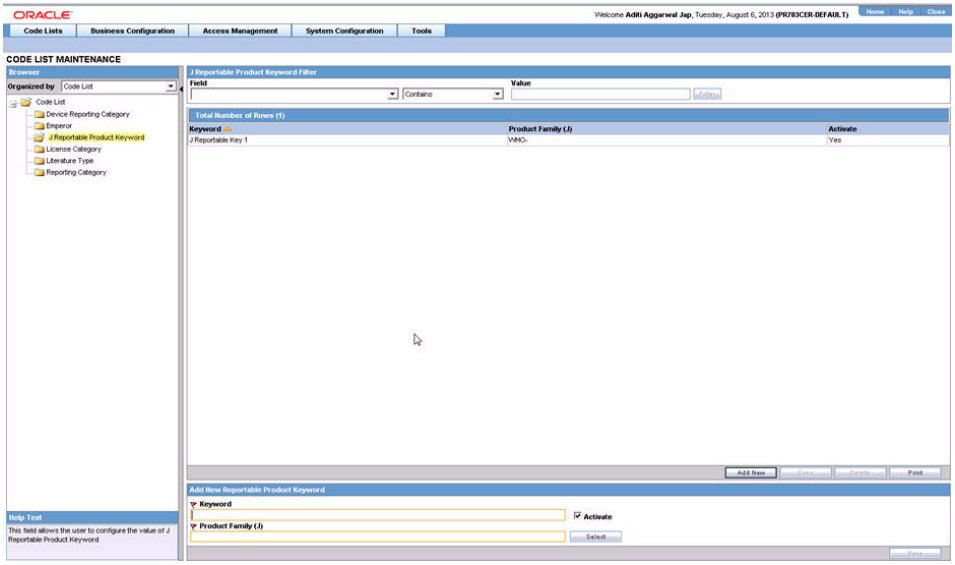
The following table lists the fields used in the dialog box and their description:

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.

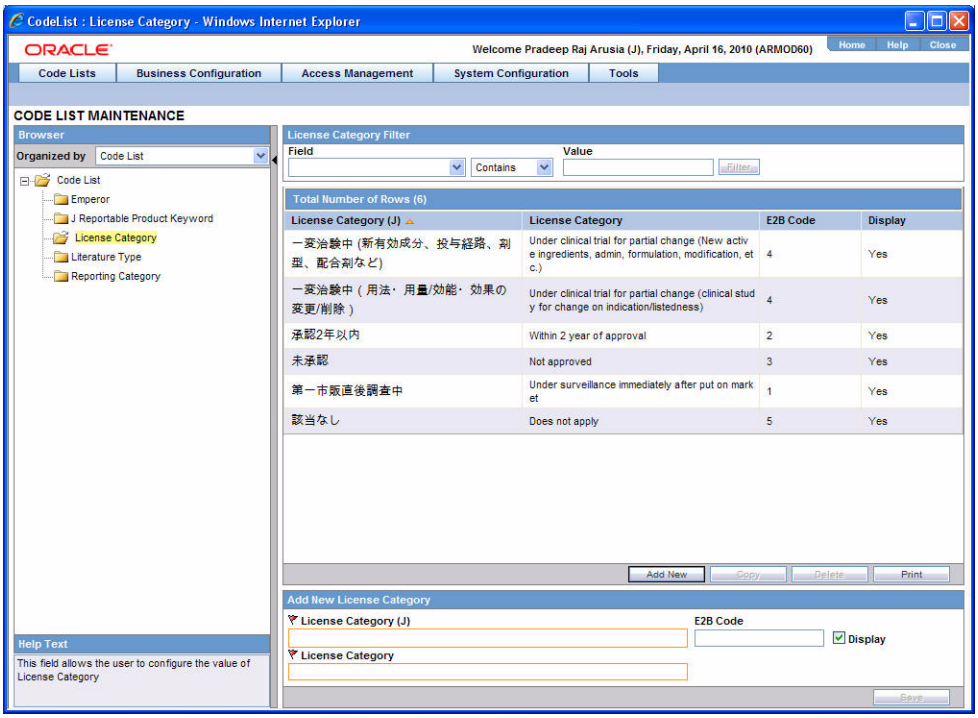


The following lists the fields used in the dialog box and their description:

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.



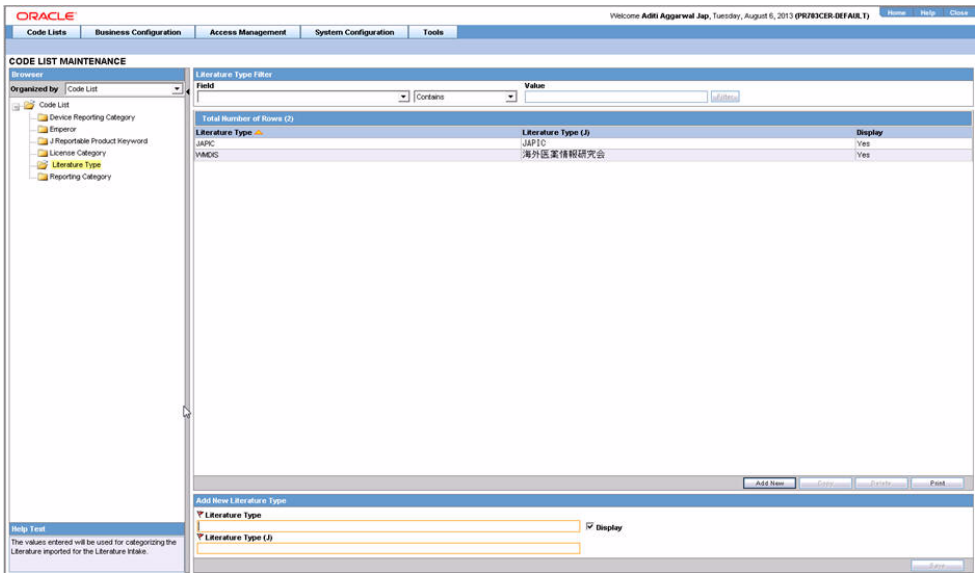
The following table lists the fields used in the dialog box and their description:

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.

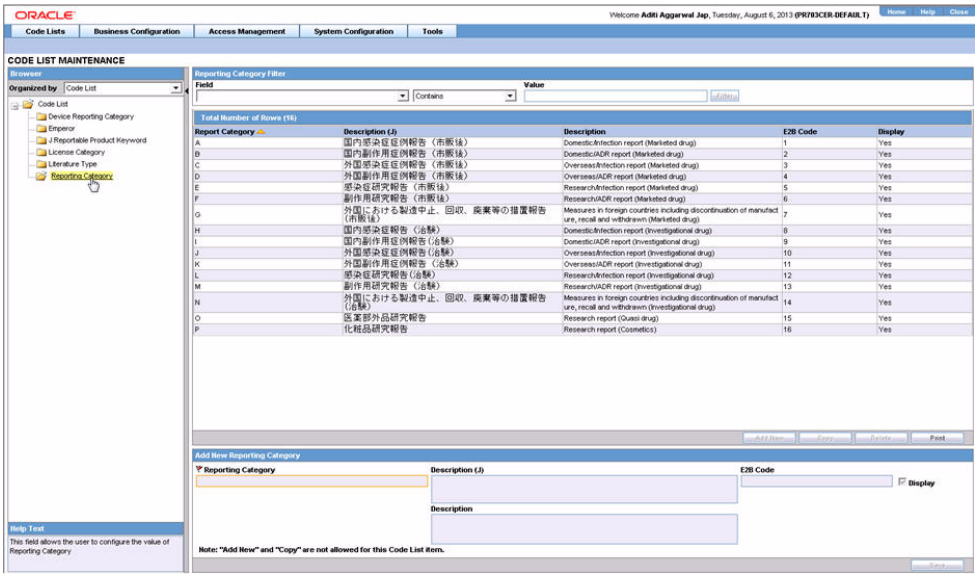


4. This screen enables you to view the English and Japanese names of the configured categories. You can also set the display preferences for these code lists.
5. Click Add to add a entry in the code list after filling the required information in the mandatory fields.
6. Click Save to save any changes.

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.

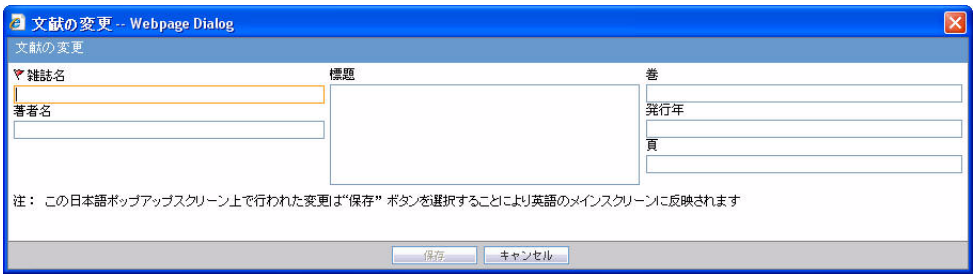


4. This screen enables you to view the English and Japanese names of the configured categories. You can also set the display preferences for these code lists.
5. Click Save to save any changes.

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:

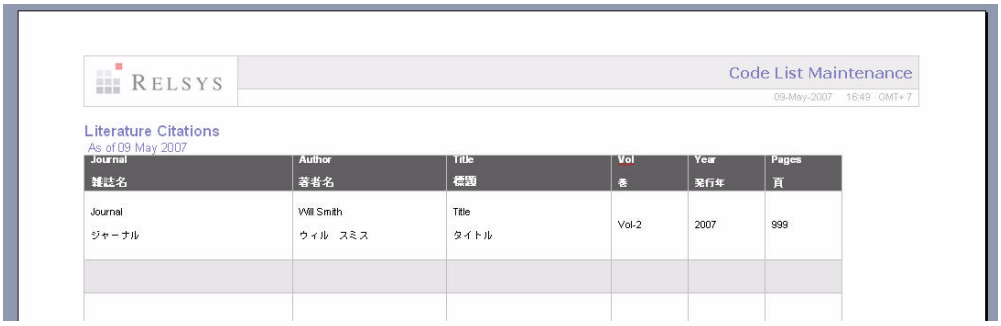
  Data must be saved before opening the Japanese screen. Do you want to save?

- 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.

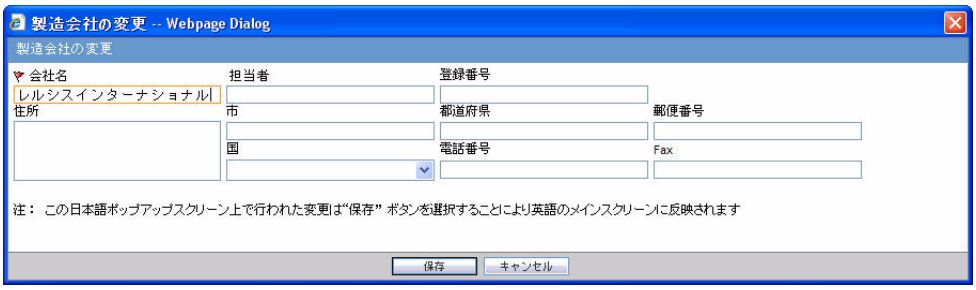
The following is the Print template of the Literature Citations:



4.1.9 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.

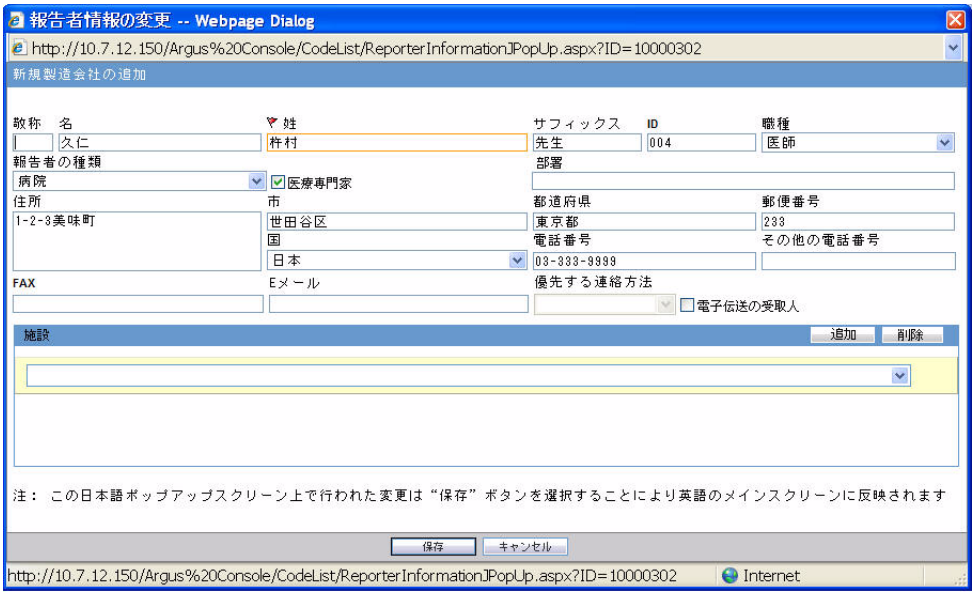
The following functionality is provided when the **Copy** function is used:

- 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.

4.1.10 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　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.