



Oracle Application Integration  
Architecture Release 1.0

# **Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System Implementation Guide**

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# 1

# Introduction to Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System

## Preface

Welcome to the Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System Implementation Guide.

## TTY Access to Oracle Support Services

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## Accessibility of Links to External Web Sites in Documentation

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

## Structure

- 1 [Introduction to Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System](#)
- 2 [Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System Environment](#)
- 3 [Integrations](#)
- 4 [Installation and Configuration](#)
- 5 [Initial Loading](#)
- 6 [Troubleshooting](#)

## Related Documents

For more information, read the following documents:

- [Oracle Adverse Event Reporting System Reports Technical Reference Manual](#)
- [Oracle Adverse Event Reporting System Administrator's Guide](#)
- [Siebel Life Sciences documentation available on the Siebel bookshelf](#)

## Do Not Use Database Tools to Modify Oracle Applications Data

Oracle **STRONGLY RECOMMENDS** that you never use SQL\*Plus, Oracle Data Browser, database triggers, or any other tool to modify Oracle Applications data unless otherwise instructed.

Oracle provides powerful tools you can use to create, store, change, retrieve, and maintain information in an Oracle database. But if you use Oracle tools such as SQL\*Plus to modify Oracle Applications data, you risk destroying the integrity of your data and you lose the ability to audit changes to your data.

Because Oracle Applications tables are interrelated, any change you make using an Oracle Applications form can update many tables at once. But when you modify Oracle Applications data using anything other than Oracle Applications, you may change a row in one table without making corresponding changes in related tables. If your tables get out of synchronization with each other, you risk retrieving erroneous information and you risk unpredictable results throughout Oracle Applications.

When you use Oracle Applications to modify your data, Oracle Applications automatically checks that your changes are valid. Oracle Applications also keeps track of who changes information. If you enter information into database tables using database tools, you may store invalid information. You also lose the ability to track who has changed your information because SQL\*Plus and other database tools do not keep a record of changes.

## Glossary and Abbreviations

**AE.** Adverse Event report or case

**AERS.** Oracle's Adverse Event Reporting System

**Asynchronous Integration.** A type of integration where the initiating application sends a request and proceeds with its own actions without having to wait for the provider application to process in the same thread. The provider application picks up the request and processes the message. For example, in the Call-to-Case process flow, the customer service representative does not have to wait for a case to be created in AERS.

**BPEL.** Business Processes Execution Language, a standards-based extensible language.

**Connector.** Siebel product that supports point-to-point integration.

**DVM.** Domain Value Map.

**E2B / E2B(M).** The ICH guidance E2B Data Elements for Transmission of Individual Case Safety Reports was signed off by the International Conference on Harmonisation (ICH) in July 1997 and issued by the FDA in January 1998. ICH subsequently issued a revised guidance, E2B(M), to provide additional information and clarification. ICH signed off on E2B(M) in November 2001, and the FDA issued the revised guidance in April 2002.

**EAI.** E-Business Application Interface, a Siebel integration technology tool.

**EBS.** Oracle E-Business Suite Applications

**FMW.** Fusion Middleware

**ICSR.** Individual Case Safety Report

**Middleware.** Integration software that is used to connect applications, such as Webmethods.

**Oracle Account.** Definition of a customer used by Oracle Order Management

**OWB.** Oracle Warehouse Builder

**Party.** Oracle party

**Siebel Account.** Siebel name for a customer (Hospital or similar)

**Siebel Contact.** Siebel name for a person (Physician or similar)

**SLS.** Siebel Life Sciences

**SOA.** Service Oriented Architecture

**UAN.** Universal Application Network, Siebel integration product that support hub-spoke environment





# Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System Environment

This chapter contains the following information:

- [About Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System on page 9](#)
- [Software Requirements on page 9](#)
- [Cross-References on page 9](#)
- [Language Support on page 10](#)

## About Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System

The integration of Siebel Life Sciences (SLS) and Oracle Adverse Event Reporting System (AERS) enables customers to avoid costly double data entry, produce greater data integrity and streamline the regulatory processes associated with capturing, tracking, investigating, reporting and managing adverse events and product complaints.

## Software Requirements

The Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System requires the following versions:

- Oracle Adverse Event Reporting System 4.6.1
- Oracle SOA Suite 10.1.3.1 (upgraded to the latest patch)
- Siebel Adverse Event and Complaints 7.8
- Siebel Service 7.8.2.x, Siebel Industry Applications only
- Oracle JDeveloper 10.1.3.1 (upgraded to the latest patch)

## Cross-References

The Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System uses domain value maps (DVM) as static cross-references. The DVMs used are:

- Country DVM
- Error Messages DVM

## Language Support

The Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System exchanges data between Siebel Life Sciences and Oracle Adverse Event Reporting System using text encoded in the UTF-8 character set.

# 3

## Installation and Configuration

This chapter contains the following information:

- [Downloading and Installing Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System Software on page 11](#)
- [Process of Configuring Siebel Life Sciences on page 13](#)
- [Process of Deploying Business Processes Execution Language Processes on page 20](#)
- [Modifying Oracle Adverse Event Reporting System on page 26](#)

### Downloading and Installing Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System Software

Read the following topics to learn how to download and install the software and patches needed for Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System.

- [Downloading Required Software on page 11](#)
- [Installing Fusion Middleware Software on page 12](#)
- [Installing Fusion Middleware and JDeveloper Patches on page 12](#)

### Downloading Required Software

The required software for Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System is available on Oracle E-Delivery.

#### *To download the files*

- 1 Log in to Oracle E-Delivery (<http://edelivery.oracle.com>).
- 2 From the Product Pack menu, choose Oracle Application Integration Architecture.
- 3 From the Platform menu, choose your platform, and click Go.
- 4 Download the following files:
  - Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System, v1.0 Implementation Guide (Documentation\_LSIPv1.0.zip)
  - Oracle SOA Suite 10g (10.1.3.1.0) (file name(s) and count vary by platform)

- Oracle Fusion Middleware 10.1.3.1 Patches (FMW\_Patches\_AIAv1.0.zip)
- Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System, v1.0 (SEBLCallCntIntegPkLSv1.0.zip)

## Installing Fusion Middleware Software

Install the following Fusion Middleware components:

- 1** Oracle Database 10g Release 2 (10.2.0.1) Enterprise Edition.  
Download and install the database only if you do not already have an Oracle 10.2.0.2 (or higher) database instance available for the SOA Suite to access. For information on installing Oracle Database, refer to the Oracle Technology Network. Oracle Technology Network link has the following URL:  
<http://www.oracle.com/technology/documentation/index.html>  
After installation, apply the appropriate patch from DB\_Patches\_AIAv1.0.zip (choose the patch appropriate to the operating system that your database is installed on.) This patch brings the database up to required version 10.2.0.2.
- 2** SOA Suite 10g10.1.3.1  
For information on installing Oracle SOA Suite, refer to the Oracle Application Server Documentation Library. The library is available on the Oracle Technology Network. Oracle Technology Network link has the following URL:  
<http://www.oracle.com/technology/documentation/index.html>.  
Click Oracle Application Server 10g Release 3 (10.1.3.1)  
Make sure to install the full SOA suite using the Advanced Installation Mode.
- 3** Oracle JDeveloper 10.1.3.1 (Studio Version)  
Download Oracle JDeveloper from:  
<http://www.oracle.com/technology/software/products/jdev/archives.html>.  
This is a free download. Support for JDeveloper is not included. If desired, support for JDeveloper can be purchased separately. For information on installing Oracle JDeveloper, refer to the Oracle Technology Network. Oracle Technology Network link has the following URL:  
<http://www.oracle.com/technology/documentation/index.html>

## Installing Fusion Middleware and JDeveloper Patches

Install all Fusion Middleware and JDeveloper patches described in this section. If any particular patch has already been installed, there is no need to reinstall it. The latest version of each patch can be downloaded from <http://metalink.oracle.com>.

### *To install SOA Suite patches*

- 1** Download the Fusion Middleware and JDeveloper patches. The file name is:  
FMW\_Patches\_AIAv1.0.zip

- 2 Unzip the file to yield the mandatory bug-fix patches listed in the following table.

Patch Number	Comments
5473225	Fixes problems that involve catching an exception during a transform.
5596476	Fixes problems that involve the XSLT map not rendering in the user interface.
5609537	Fixes issues with commit in child processes.
5917910	Fixes problems that involve: <ul style="list-style-type: none"> <li>■ Creating &lt;XSL:variable&gt; with value "&amp;#0;"</li> <li>■ Java heap error on Service Oriented Architecture Suite, V10.1.3.1 release on Linux.</li> <li>■ Invoking PL/SQL procedure with a large output parameter.</li> </ul>
5931554	Fixes problems that involve: <ul style="list-style-type: none"> <li>■ Cross-reference feature</li> <li>■ XPATH function, LOOKUP-DVM, but does not work in assign activity of Business Processes Execution Language.</li> </ul>

- 3 Apply each of these patches to your installation.
- 4 Refer to the ReadMe.txt in each patch for guidance on how to apply the patch.

## Process of Configuring Siebel Life Sciences

To configure Siebel Life Sciences, complete the following tasks:

- [Preparing to Configure Siebel Life Sciences on page 14](#)
- [Configuring the Error Handler Service on page 14](#)
- [Importing SIF Files on page 14](#)
- [Configuring Business Components on page 15](#)
- [Importing Web Service Definitions on page 17](#)
- [Importing Workflow Definitions on page 17](#)
- [Activating Workflow Definitions on page 18](#)
- [Adding an LOV Entry for MD Adverse Event on page 18](#)
- [Changing LOV Entries for Route on page 19](#)

## Preparing to Configure Siebel Life Sciences

This is a step in the [Process of Configuring Siebel Life Sciences on page 13](#).

### *To prepare for configuring*

- 1 Locate the following file that you downloaded as instructed in [Downloading Required Software on page 11](#):

SEBLCallCntrlIntegPKLSv1.0.zip

- 2 Expand the file into a folder on your Siebel Server.

This folder holds the files you need to complete the remaining configuration steps. In those steps this folder is referred to as <Siebel Download Folder>.

## Configuring the Error Handler Service

This is a step in the [Process of Configuring Siebel Life Sciences on page 13](#).

### *To configure the Error Handler service*

- 1 Log in to Siebel Tools.
- 2 Navigate to Tools > Import from Archive.
- 3 Select the following file:  
<Siebel Download Folder>/ApplicationChanges/Siebel/7.8.2/Errorhandling/GenesisErrorHandler.sif
- 4 Click Import.
- 5 From Tools > Business Service, find Genesis Error Handler.
- 6 Stop Siebel-related services such as Siebel Enterprise and Gateway Name Server.
- 7 Compile to the repository file used by your Siebel server.
- 8 Restart the stopped services.

## Importing SIF Files

This is a step in the [Process of Configuring Siebel Life Sciences on page 13](#).

### *To import SIF files*

- 1 Log in to Siebel Tools.
- 2 If the LS Medical Product Issue – AERS Sync project exists, lock it.
- 3 Navigate to Tools > Import from Archive.

- 4 Browse to the folders that contain the SIF files:  
 <Siebel Download Folder>/ApplicationChanges/Siebel /7. 8. 2/Product/BusinessServices  
 and  
 <Siebel Download Folder>/ApplicationChanges/Siebel /7. 8. 2/Product/  
 IntegrationObjects
- 5 Import the following files:
  - CRMIntegSEBLALSCLinicalFaultMessage.sif
  - CRMIntegSEBLALSCLinicalProductIssueInterface.sif
  - SiebelClinicalProductIssue.sif
  - CRMIntegClinicalCreatePISEBL782ToAERS46Sync.sif
- 6 Navigate to Tools > Compile Projects.
- 7 Find the LS Medical Product Issue – AERS Sync project and compile the SRF files for server and clients.

## Configuring Business Components

This is a step in the [Process of Configuring Siebel Life Sciences on page 13](#).

### *To configure business components*

- 1 Modify the Contact business component Field information as follows:

Name	Calculated	Calculated Value	Immediate Post Change	Type	New/Modify
Country LIC	Y	LookupName("COUNTRY", [Country])		DTYPE_TEXT	New

- 2 Modify the LS Medical Product Issue business component Field information as follows:

Name	Calculated	Calculated Value	Immediate Post Change	Type	New/Modify
Area LIC	Y	LookupName("SR_AREA", [Area])		DTYPE_TEXT	New
FDA Reportable			Y		Modify  See Note below.

Name	Calculated	Calculated Value	Immediate Post Change	Type	New/Modify
Patient Sex LIC	Y	LookupName("FIN_GENDE R", [Patient Sex])		DTYPE_TEXT	New
Sub-Area LIC	Y	LookupName("SR_AREA", [Sub-Area])		DTYPE_TEXT	New
Type			Y		Modify  See Note below.

**3** Modify the LS Medical Product Issue business component User Property information as follows:

Name	Value	New/Modify
Named Method 8	"TransmitToAERS", "INVOKESVC", "LS Medical Product Issue", "Workflow Process Manager", "RunProcess", "'ProcessName'", "LS CRMIntegSEBLSIAProductIssueInsertOutboundFlow", "'RowId'", "[Id]"	New (if 8 is already there, create last + 1)
On Field Update Invoke 1 See NOTE below.	"Type", "LS Medical Product Issue", "TransmitToAERS", "[Type]=LookupValue('SR_AREA', 'MD Adverse Event') AND ([FDA Reportable] = LookupValue('LS_MED_FDA_REPORTABLE_TYPE', 'Yes') OR [FDA Reportable] = LookupValue('LS_MED_FDA_REPORTABLE_TYPE', 'Potential'))"	New (if 1 is already there, create last + 1)
On Field Update Invoke 2 See NOTE below.	"FDA Reportable", "LS Medical Product Issue", "TransmitToAERS", "[Type]=LookupValue('SR_AREA', 'MD Adverse Event') AND ([FDA Reportable] = LookupValue('LS_MED_FDA_REPORTABLE_TYPE', 'Yes') OR [FDA Reportable] = LookupValue('LS_MED_FDA_REPORTABLE_TYPE', 'Potential'))"	New (if 1 is already there, create last + 2)

**NOTE:** If you set up synchronization to trigger on the values of the On Field Update Invoke fields, you may encounter errors. For more information on the errors and the solution, read ["Error Messages"](#) on page 36.

- 4** Select both Business components.
- 5** Navigate to Tools > Compile Selected Objects.
- 6** Compile the SRF files for server and clients.



## Importing Web Service Definitions

This is a step in the [Process of Configuring Siebel Life Sciences on page 13](#).

### *To import web services definitions*

- 1 Log in to Siebel Call Center.
- 2 Navigate to the Administration – Web Services > Outbound Web Services view.
- 3 Import the following file:  
`<Siebel Download Folder>\ApplicationChanges\  
 Siebel CRMSIA\7.8.2\Product\WebServices\CRMIntegCreateClinicalProductIssueSEBL782To  
 AERS46Sync.XML`
- 4 Query for the following web service:  
`CRMIntegCreatePI SEBL782ToAERSSync`
- 5 In the Service Port applet, update the address to point to your BPEL server location. For example:  
`http://localhost:8888/orabpel/default/CRMIntegCreatePI SEBL782ToAERSSync/1.0`
- 6 Change the localhost to the SOA host name, change 8888 to proper port number.
- 7 Set the status to Active.
- 8 Click Clear Cache.

## Importing Workflow Definitions

This is a step in the [Process of Configuring Siebel Life Sciences on page 13](#).

### *To import workflow definitions*

- 1 Log in to Siebel Tools and make sure it connects to the same database as the Siebel application server.
- 2 If the LS Medical Product Issue – AERS Sync project exists, lock it.
- 3 From Object Explorer, navigate to Workflow Process.
- 4 From the list applet, right-click and choose Import Workflow Process.
- 5 Browse to <Siebel Download Folder>\ApplicationChanges\SiebelCRMSIA\7.8.2\ Product\ Workflows, and select  
`[Workflow]CRMIntegSEBLSIAClinicalProductIssueInsertOutboundFlow.xml`.
- 6 Click Import.
- 7 Query for the workflow process LS CRMIntegSEBLSIAProductIssueInsertOutboundFlow.
- 8 Select the LS CRMIntegSEBLSIAProductIssueInsertOutboundFlow process and click Deploy.

## Activating Workflow Definitions

This is a step in the [Process of Configuring Siebel Life Sciences on page 13](#).

### *To activate the workflow definitions*

- 1 Log in to Siebel Call Center.
- 2 Navigate to Administration – Business Process > Workflow Deployment view
- 3 In the Repository Workflow Processes applet, query for the LS CRMIntegSEBLSIAProductIssueInsertOutboundFlow workflow.
- 4 Select the LS CRMIntegSEBLSIAProductIssueInsertOutboundFlow workflow and click Activate.

## Adding an LOV Entry for MD Adverse Event

This is a step in the [Process of Configuring Siebel Life Sciences on page 13](#).

### *To add LOV entries*

- 1 Log in to the Siebel Call Center Application.
- 2 Navigate to Data Administration > List Of Values.
- 3 Query in Language-Independent Code for MD Adverse Event and in Type for SR\_AREA.
- 4 If the record is not available, add a new record with following details:

Type	Display Value	Language-Independent Code	Language Name	Order	Active	Translate
SR_AREA	MD Adverse Event	MD Adverse Event	English-American	Get existing Max Order number for Type 'SR_AREA' and add + 1	Y	Y

- 5 Add the following LOV values for Area and Sub-Area fields for MD Adverse Event type.

Type	Display Value	Language-Independent code	Language Name	Parent LIC)	Active	Translate
SR_AREA	Spontaneous	Spontaneous	English-American	MD Adverse Event	Y	Y
SR_AREA	Study	Study	English-American	MD Adverse Event	Y	Y

Type	Display Value	Language-Independent code	Language Name	Parent LIC)	Active	Translate
SR_AREA	Serious	Serious	English-American	MD Adverse Event Spontaneous	Y	Y
SR_AREA	Non Serious	Non Serious	English-American	MD Adverse Event Spontaneous	Y	Y
SR_AREA	Non Serious	Non Serious	English-American	MD Adverse Event Study	Y	Y
SR_AREA	Serious	Serious	English-American	MD Adverse Event Study	Y	Y

## Changing LOV Entries for Route

This is a step in the [Process of Configuring Siebel Life Sciences on page 13](#).

The values used for the route field in Siebel Life Sciences differ from the values used by Oracle Adverse Event Reporting System. To synchronize properly, the values must be the same. You need to edit Siebel Life Sciences's LOV values to match the ones used in Oracle Adverse Event Reporting System.

### *To change Route LOV entries*

- 1 Log in to the Siebel Call Center Application.
- 2 Navigate to Data Administration > List Of Values.
- 3 Query in the Type column for LS\_MED\_ROUTE\_USED\_TYPE.
- 4 Using the data in the following table, modify the LOV values in the Display Value column.

Original Value	New Value
Oral	PO
Intravenous	IV
Epidural	ED
Intramuscular	IM
Unknown	UNK
N/A	UNK

# Process of Deploying Business Processes Execution Language Processes

Business Processes Execution Language (BPEL) is an essential component in Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System integration. This integration uses BPEL processes to transform the data. To complete this configuration, use these topics:

- 1 [Locating the Business Processes Execution Language Files on page 20](#)
- 2 [Setting Up Domain Value Maps on page 21](#)
- 3 [Setting Up Canonical Objects on page 21](#)
- 4 [Configuring Business Processes Execution Language Processes on page 22](#)
- 5 [Setting Up an Application Workspace on page 23](#)
- 6 [Implementing the WriteE2BFile Process on page 24](#)
- 7 [Deploying Business Processes Execution Language Processes on page 25](#)

## Locating the Business Processes Execution Language Files

This is a step in [Process of Deploying Business Processes Execution Language Processes on page 20](#).

### *To locate the BPEL files*

- 1 In the files you downloaded and expanded, find the following directory:  
SEBLClinicalIntegPkORCLClinical
- 2 Move this directory to a location where Jdeveloper has access to deploy into it.
- 3 Locate the following files and move them to a directory that has a short path name, such as D:\SLS:
  - SEBLClinicalIntegPkORCLClinical\BusinessProcesses\Product\CRMIntegCreatePISEBL782ToAERSSync
  - SEBLClinicalIntegPkORCLClinical\BusinessProcesses\Product\WriteE2BFile

These files have long names and are moved to avoid possible problems with truncation of path names, which can cause a deployment error.

The SEBLClinicalIntegPkORCLClinical directory has the following structure:

- **SEBLClinicalIntegPkORCLClinical\ApplicationChanges.** Contains the Siebel application changes.
- **SEBLClinicalIntegPkORCLClinical\BusinessProcesses.** Contains the integration BPEL processes.

- **SEBLClinicalIntegPkORCLClinical\SetUp.** Contains setup content for BPEL Processes.
- **SEBLClinicalIntegPkORCLClinical\SharedComponents.** Contains the cross-reference patch and DVM maps.

## Setting Up Domain Value Maps

This is a step in [Process of Deploying Business Processes Execution Language Processes on page 20](#).

### *To set up domain value maps*

- 1 Locate the following directory:  
`SEBLClinicalIntegPkORCLClinical\Utility\DVM\Maps`
- 2 Within that folder, locate the following files:
  - COUNTRY.XML
  - ErrorMessage.xml
- 3 Connect to `http://SOAHost:port/esb` and then log in.
- 4 Click the maps icon on the top right.
- 5 Click Create > Import a new map
- 6 Browse to each of the xml files mentioned above and import them.

## Setting Up Canonical Objects

This is a step in [Process of Deploying Business Processes Execution Language Processes on page 20](#).

### *To set up canonical objects*

- 1 Copy the following file:  
`\SEBLClinicalIntegPkORCLClinical\BusinessProcesses\xml\lib`  
and put it into the xml\lib folder for your SOA installation, such as:  
`<SOA_HOME>\bpel\system\xml\lib`
- 2 Verify that the schema can be accessed by open a browser and typing in the following URL:  
`http://<SOA Host Name: BPEL Console port number>/orabpel/xml/lib/SEBLClinicalIntegPkORCLClinical/CanonicalObjects/coCommon.xsd`  
For example:

`http://127.0.0.1:8888/orabpel/xmllib/SEBLCIiniCalIntegPkORCLCIiniCal/CanonicalObjects/coCommon.xsd`

The CoCommon schema should be able to open correctly. If there is a problem in opening the file, restart the SOA suite.

## Configuring Business Processes Execution Language Processes

This is a step in [Process of Deploying Business Processes Execution Language Processes](#) on page 20.

### *To configure BPEL processes*

- 1 Open the following file for editing:

`SEBLCIiniCalIntegPkORCLCIiniCal\SetUp\CRMIIntegProcessParameters.xml`

- 2 Modify its content until it matches the following:

**TIP:** Look for lines that begin with "`<property name="PARAMNAME">http://127.0.0.1:8888/orabpel/xmllib</property>`".

```
<?xml version="1.0" encoding="UTF-8"?>
<LISTOFBUILDAPPARAMETERS xmlns="http://www.siebel.com/uan/SiebelBIAs/SharedComponents/CRMIIntegProcessProperties">

    <!--Start SEBLAcctOrigIntegPklFLEXUBS section-->
    <BUILDAPPARAMETER>
        <property name="PARAMNAME">http://PARTNERLINKDOMAIN/orabpel/xmllib</property>
        <property name="PARAMVALUE">http://oracleappsrvrhost:port/orabpel/xmllib</property>
        <property name="DESC">This Parameter is to capture BPEL domain URL information. Specify your environment specific value for "PARAMVALUE" property. Here "http://oracleappsrvrhost:port" should be replaced with the HOST, PORT where the BPEL PM is running. "orabpel" should stay same. "default" is the name of domain where the bpel processes are to be deployed.</property>
    </BUILDAPPARAMETER>

    <BUILDAPPARAMETER>
        <property name="PARAMNAME">http://PARTNERLINKDOMAIN/orabpel/default</property>
        <property name="PARAMVALUE">http://oracleappsrvrhost:port/orabpel/default</property>
        <property name="DESC">This Parameter is to capture BPEL domain URL information. Specify your environment specific value for "PARAMVALUE" property. Here "http://oracleappsrvrhost:port" should be replaced with the HOST, PORT where the BPEL PM is running. "orabpel" should stay same. "default" is the name of domain where the bpel processes are to be deployed.</property>
    </BUILDAPPARAMETER>
```

```

<BUI LDPARAMETER>
  <property name="PARAMNAME">http://127.0.0.1:8080/eai_enu/
start.swe?SWEExtSource=WebService& amp; SWEExtCmd=Execute& amp; UserName=SADMI
N& amp; Password=MSSQL"</property>
  <property name="PARAMVALUE">http://siebwebsrvrhost:port/eai_enu/
start.swe?SWEExtSource=WebService& amp; SWEExtCmd=Execute& amp; UserName=userN
ame& amp; Password=password"</property>
  <property name="DESC">This Parameter is to capture the Siebel Web Server URL
and the user name and password for siebel authentication. Speci fy your envi ronment
speci fic value for "PARAMVALUE" property. Here "http://locahost:8080" should be
replaced with the HOST, PORT where the Siebel web server is running.</property>
</BUI LDPARAMETER>

<BUI LDPARAMETER>
  <property name="PARAMNAME">C:\BPELProj ects\DummyOutput</property>
  <property name="PARAMVALUE">DummyOutput Folder Name</property>
  <property name="DESC">This Parameter is to speci fy where the output of the
input into the dummy processes should be put. Please change it to your envi ronment
speci fic value</property>
</BUI LDPARAMETER>
<!--End SEBLAcctOri gl ntegPkl FLEXUBS secti on-->

</LI STOFBUI LDPARAMETERS>

```

- 3 Run this command for the BPEL projects under \SEBLClinicalIntegPkORCLClinical\BusinessProcesses:

```

java -jar EditParam.jar -i d:\BPELProj ects\ SEBLCl i ni cal IntegPkORCLCl i ni cal
\Busi nessProcesses -f d:\BPELProj ects\ SEBLCl i ni cal IntegPkORCLCl i ni cal
\Setup\CRMI ntegProcessParameters.xml -verbose -t D:\temp

```

- 4 Open the following file:

\CRMI ntegCreatePI SEBL782ToAERSSync\bpel \ CRMI ntegCreatePI SEBL782ToAERSSync.wsdl  
under CRMI ntegCreatePI SEBL782ToAERSSync\Busi nessProcesses

- 5 Verify that in the file the address for RuntimeFault.wsdl has changed from:

```

"<import namespace="http://schemas.oracle.com/bpel/extension" location="http://
PARTNERLINKDOMAIN/orabpel/xml/lib/RuntimeFault.wsdl"/>

```

to:

```

"<import namespace="http://schemas.oracle.com/bpel/extension" location="http://
<Your SOA Host Name>:<port number>/orabpel/xml/lib/RuntimeFault.wsdl"/>"

```

## Setting Up an Application Workspace

This is a step in [Process of Deploying Business Processes Execution Language Processes on page 20](#).

Make sure the SOA Suite has been installed and the cross-reference patch has been applied. Make sure JDeveloper has been installed and the cross-reference patch has been applied and the application server and integration server connection have been configured.

### *Setting up an application workspace*

- 1 Start the Oracle JDeveloper
- 2 Click the Applications Navigator tab.
- 3 Right-click the Applications icon.
- 4 Choose New and specify the type as Application.
- 5 Specify this name for the application:  
SEBLClinicalIntegPkORCLClinical
- 6 Specify a directory name where the dummy processes are stored. For example:  
d:\BPJELProjects\ SEBLClinicalIntegPkORCLClinical
- 7 In the Create Project popup click Cancel.
- 8 Repeat the following steps for each of the following JPR files:
  - WriteE2BFile.jpr
  - CRMIntegCreatePISEBL782ToAERSSync.jpr
  - a Select the SEBLClinicalIntegPkORCLClinical application.
  - b Right-click and choose Add to SEBLClinicalIntegPkORCLClinical.jws.
  - c Select a JPR file and click Open.

This imports the process code into the application.

## **Implementing the WriteE2BFile Process**

This is a step in [Process of Deploying Business Processes Execution Language Processes on page 20](#).

The WriteE2BFile BPEL process communicates Siebel Life Sciences's product issue data (in a common format: E2B) with Oracle Adverse Event Reporting System. This process writes the E2B message to a file and returns a success signal to Siebel Life Sciences. Later, Oracle Adverse Event Reporting System may pick up the E2B file and process it. No signal from Oracle Adverse Event Reporting System is sent back to Siebel Life Sciences or to the BPEL process.

The CRMIntegCreatePISEBL782ToAERSSync BPEL process invokes the WriteE2BFile BPEL process and passes on the E2B compliant message. The WriteE2BFile process then writes the message into a file. Later, Oracle Adverse Event Reporting System may pick up the file to process the message. If there is an error while writing the file, BPEL catches the error message and a BPEL fault message constructed based on this error message is returned to the CRMIntegCreatePISEBL782ToAERSSync process. Oracle Adverse Event Reporting System does not return any error messages.

### *To configure the processes*

- 1 Using JDeveloper, double-click on the PartnerLink (CallWriteFileSEBL782ToAERSSync).  
The Edit Partner Link window opens.



- 2 Click the Define Adapter Service icon.

This invokes the Adapter Configuration Wizard.

- 3 Click File Adapter and then click Next.

- 4 Click Next until you the File Configuration page displays.

The destination directory name has been configured as a logical name in this adapter. The logical name provided in the BPEL process is OutputFileDir. In the BPEL partner link binding tag in the bpel.xml file, you can specify an outbound partner link binding property through the property tab of the partner link. This resolves the mapping between the logical directory name and the actual physical directory name.

- 5 If desired, change the logical name for the directory.

- 6 Specify a naming convention for the files.

Outbound files cannot have a static name, as having one would mean the files would be overwritten each time the BPEL process is executed. The file name needs to have a static part and a dynamic part. The dynamic part can be a sequence number or a timestamp. In the BPEL process, the output filename has been provided as E2B\_%yyMMddHHmmss%.xml to create a file with a time stamp.

- 7 Click Next, and then click Finish.

- 8 Open the bpel.xml file for editing.

- 9 Locate the following block and change the directory to point to a physical directory where your account has read and write access.

```
<partnerLinkBinding name="CallWriteFileE2BToAERSSync">
  <property name="wsdlLocation">WriteE2BFiletoDisk.wsdl </property>
  <property name="retryInterval">60</property>
  <property name="OutputFileDir" type="LogicalDirectory">/tmp/bpel </property>
</partnerLinkBinding>
```

- 10 Save and deploy the BPEL process for the changes to take effect.

## Deploying Business Processes Execution Language Processes

This is a step in [Process of Deploying Business Processes Execution Language Processes on page 20](#).

Make sure the SOA Suite has been installed and the cross-reference patch has been applied. Make sure JDeveloper has been installed and the cross-reference patch has been applied and the application server and integration server connection have been configured.

### *To deploy BPEL processes*

- 1 Make sure the SOA Suite has been started.
- 2 From Oracle JDeveloper, select the WriteE2BFile project.

- 3 Right-click on the project name and choose Deploy > IntegrationServerName > Deploy to default domain.
- 4 Ignore the warnings listed on the build output window.
- 5 Select the CRMIntegCreatePISEBL782ToAERSSync project.
- 6 Right-click on the project name and choose Deploy > IntegrationServerName > Deploy to default domain.
- 7 Ignore the warnings listed on the build output window.

This compiles the SRC code and then deploys the BPEL process to the SOA Instance.

## Modifying Oracle Adverse Event Reporting System

You need to set up an Oracle Adverse Event Reporting System E2B Import Automation Job. For the exact procedure, refer to the E2B section of *Oracle Adverse Event Reporting System Reports Technical Reference Manual*.

The high level steps are:

- 1 In global maintenance set up an E2B sender.
- 2 Set the Sender ID to the value sent in m.1.5. field of the e2b message. The default is:  
Siebel Life Sciences 7.8.2
- 3 Set up an e2b automation database job.

The Oracle Adverse Event Reporting System database processes needs to be able to read and delete the e2b files sent from Siebel Life Sciences. There are several ways to accomplish this:

- Have the BPEL output files written to a directory (networked or on the same server) accessible to AERS.
  - Set up an automated FTP process to transfer the BPEL output files to a location where AERS can read the files.
- 4 Optional: Configure a workflow step that Oracle Adverse Event Reporting System users use to process incoming cases.

# 4 Integrations

This chapter contains the following sections:

- [Integration Assumptions on page 27](#)
- [Call-to-Case Integration Point on page 27](#)

## Integration Assumptions

The following are assumed to be in place:

- The integration is based on Siebel Life Sciences 7.8 and Oracle Adverse Event Reporting System 4.6.
- Siebel Life Sciences 7.8 and Oracle Adverse Event Reporting System 4.6 are installed and configured according to their documentation.
- Oracle's BPEL engine transforms the data between the two applications.
- The data is transformed according to the industry standard E2B format.
- Oracle Adverse Event Reporting System does not accept updates from Siebel Life Sciences when a case report is created based on a Siebel product issue. You should not permit updating a product issue record after it has been synchronized.

## Call-to-Case Integration Point

The Siebel Call Center Integration Pack for Oracle Adverse Event Reporting System consists of one integration point: the Call-to-Case integration point. This integration point passes a record from Siebel Life Sciences to Oracle Adverse Event Reporting System.

This integration point provides the ability to pass service request and product issue information from Siebel Life Sciences to Oracle Adverse Event Reporting System. This includes deletions, edits, and inserts.

This Call-to-Case integration point consists of:

- [Integration Sequence on page 28](#)
- [Integration Specifics on page 29](#)

## Integration Sequence

Table 1 shows the sequence of events that occur during the integration.

Table 1. Call-to-Case Integration Point Sequence

Activity	Comments
Agent using Siebel Life Sciences creates a new service request record.	
(Optional) Agent creates a related product issue record in Siebel Life Sciences and enters additional product complaint information.	
Application checks the record for trigger conditions	For information on trigger conditions, read <a href="#">“Synchronization Triggers” on page 28</a> .
Issue record sent to Siebel Integration Object	
Data set transformed into E2B Standard and written to an XML file in a shared location.	
Oracle Adverse Event Reporting System picks up the XML file from the shared location.	
Oracle Adverse Event Reporting System stores the imported raw file in Portal and executes an e2b import.	
If successful, Oracle Adverse Event Reporting System creates a new case, with the Siebel IDs saved for cross reference.	
The Oracle Adverse Event Reporting System user can choose to save the new case with a permanent case id or to logically delete the case.	

### Synchronization Triggers

No synchronizations occur unless the Siebel Life Sciences Integration user preference value is set to PI. Siebel Life Sciences checks for specific conditions in new product issue records. If the conditions match for a product issue, the data is sent to Oracle Adverse Event Reporting System. This is a one-way synchronization from Siebel Life Sciences to Oracle Adverse Event Reporting System.

Product Issue records are synchronized if the associated product issue record exists and it meets all of these conditions:

- Type= MD Adverse Event
- FDA Reportable = Yes or Potential

The above conditions are the default configuration and can be modified to match your specific needs. For example, you can modify the Type picklist to trigger on a different value.

**NOTE:** Users should make sure they have selected values in the Area and Sub-Area fields before they set the FDA Reportable field.

## Integration Specifics

The following is a list of the specifics of the Call-to-Case integration point.

- [Synchronized Entities on page 29](#)
- [BPEL Processes on page 30](#)
- [Domain Value Map Templates on page 31](#)
- [Siebel Life Sciences Repository Changes on page 31](#)
- [Siebel Life Sciences Product Issue Mappings on page 33](#)

### Synchronized Entities

[Table 2](#) lists the entities synchronized from Siebel Life Sciences to Oracle Adverse Event Reporting System.

Table 2. Entities Synchronized from Siebel Life Sciences to Oracle Adverse Event Reporting System

Siebel Life Sciences	Oracle Adverse Event Reporting System
SR & PI Number	Safety Id & Ref Num
Area	Report Type
Description	Reporter Comment
Seriousness	Seriousness
Reporter Name & Addr	Reporter Name & Addr
Patient Data	Patient Data
Study Info	Clinical Info
Product Info	Drug Info
Tests/Results	Tests/Results
Narrative	Narrative

**BPEL Processes**

The Call-to-Case integration point uses two BPEL processes to transform the data. [Table 3](#) lists the data for the CRMIntegCreatePISEBL782ToAERSSync BPEL Process.

Table 3. CRMIntegCreatePISEBL782ToAERSSync BPEL Process

Element	Comments
Process Name	CRMIntegCreatePISEBL782ToAERSSync
Description	This is the main process to send Siebel Life Sciences product issue data to Oracle Adverse Event Reporting System. The Siebel Life Sciences product issue format is transformed to the E2B format.
Calls To	WriteE2BFile.
Calls From	None.
Inputs	Siebel Life Sciences product issue data.
Outputs	Transformed Product Issue data.
Synch/Asynch	Synchronous
Exceptions/Errors	Runtime Faults, "No Product Issue Number", "No Description", "No Contact Name", "No Product Name".

[Table 3](#) lists the data for the WriteE2BFile BPEL Process.

Table 4. WriteE2BFile BPEL Process

Element	Comments
Process Name	WriteE2BFile
Description	Process used to take E2B formatted message and write it out to a text file. The file location is specified in the WriteE2BFile Service Link. The WriteE2BFile is a BPEL file adapter.
Calls To	None.
Calls From	CRMIntegCreatePISEBL782ToAERSSync.
Inputs	Siebel Life Sciences product issue data in E2B format
Outputs	Text file
Synch/Asynch	Synchronous
Exceptions/Errors	Runtime Faults.

## Domain Value Map Templates

Domain Value Map templates are XML files conforming to the Oracle SOA Suite DVM schema. You import these XML file and then modify according them to meet your implementation needs. Only add additional rows and do not change the DVM name or Column names or number of columns. There are two domain value map files.

COUNTRY.xml maps country names between Siebel Life Sciences and Oracle Adverse Event Reporting System. Because Siebel Life Sciences and Oracle Adverse Event Reporting System use different country codes, this mapping file is used to lookup the corresponding Oracle Adverse Event Reporting System country code when synchronizing product issue records. The DVM name is: County Code Mapping between Siebel and AERS

If the country names in Siebel Life Sciences do not match the expected values in Oracle Adverse Event Reporting System, the values either can be added or modified in the XML file. This can be done before or after importing into ESB.

ErrorMessages.xml maps error messages between Siebel Life Sciences and Oracle Adverse Event Reporting System. If validation errors are detected in BPEL process from Siebel Life Sciences input, this mapping file is used to lookup the corresponding Error code to display the error message in Siebel Life Sciences. The DVM name is: Error Message Mapping between BPEL and Siebel

## Siebel Life Sciences Repository Changes

To implement the Call-to-Case integration point, some changes are made to Siebel Life Sciences repository objects.

Table 5 lists changes to business components.

Table 5. Business Component Changes

Business Component	Project	Comments
Contact	LS Medical Product Issue	Added a new field for fetching a contact's Country Language Independent Value
LS Medical Product Issue	LS Medical Product Issue	<p>The Business Component whose user properties is used to control the invocation of the Oracle Adverse Event Reporting System from Siebel Life Sciences. When the Type is set to MD Adverse Event and FDA Reportable is set to Yes or Potential while creating or updating a new Product Issue record, then the LS CRMIntegSEBLSIAProductIssueOutboundFlow workflow is invoked to submit to Oracle Adverse Event Reporting System.</p> <p>Added new fields for fetching Area and Sub-Area Language Independent Values</p>

Table 6 lists changes to business processes and workflows.

Table 6. Business Processes and Workflows Changes

Workflow	Project	Integration Server Flow	Comments
LS CRMIntegSEBLSIAProductIssueInsertOutboundFlow	LS Medical Product Issue – AERS Sync	CRMIntegCreatePISEBL782ToAERSSync	Used to perform initial sending of Siebel Life Sciences Product Issue data to Oracle Adverse Event Reporting System

Table 7 lists changes to business services.

Table 7. Business Services Changes

Business Service	Display Name	Project	Comments
LS Siebel Product Issue	LS Siebel Product Issue	LS Medical Product Issue – AERS Sync	Service for manipulating LS Product Issue business component records using an integration object.
CRMIntegSyncPISEBL782ToAERSSync	CSSWSOutboundDispatcher	LS Medical Product Issue – AERS Sync	Web service interface for sending and receiving product issues.  Note: This service needs to be created during setup as it is generated from the WSDL published by the integration middleware (BPEL).
Genesis Error Handler	CUIF Error Handler	LS Medical Product Issue – AERS Sync	Genesis Error Handler Business Service encompasses the following error handling functionalities that can be used inside the workflow <ul style="list-style-type: none"> <li>■ Error detection</li> <li>■ Translation of BPEL Fault Messages to Siebel-specific fault messages.</li> <li>■ Displaying the translated error messages on screen.</li> </ul>



Table 8 lists changes to integration objects.

Table 8. Integration Object Changes

Integration Object	Project	Comments
CRMIntegSEBLSIALSP roductIssueInterface	LS Medical Product Issue – AERS Sync	This integration object needs to read from the LS Product Issue business component in Siebel Life Sciences. No writing to this integration object is supported.
CRMIntegSEBLSIALSC linicalFaultMessage	LS Medical Product Issue – AERS Sync	This integration object with the base object type as xml is used for error handling in Siebel Life Sciences.

### Siebel Life Sciences Product Issue Mappings

Included with this documentation is a mapping file for product issues. The mapping file is provided in HTML format and is named Mapping-ICH\_ICSR.htm.



# 5

## Troubleshooting

This chapter contains the following information:

- [Error Logs on page 35](#)
- [Error Messages on page 36](#)
- [Troubleshooting Techniques on page 38](#)

### Error Logs

When importing the synchronized data, Oracle Adverse Event Reporting System uses the E2B import automation. The E2B Log contains the results of each attempted import. If you encounter importing errors, check the E2B log to see if any errors are reported. Oracle Adverse Event Reporting System stores an import record in Portal for each successful import. You can check the Portal import records against the E2B log for discrepancies. An attempted synchronization in E2B that does not appear in Portal would indicate that the data did not successfully import.

The Oracle Adverse Event Reporting System Error log contains system errors encountered such as file system security problems accessing the E2B files.

For Siebel Life Sciences, refer to the Object Manager Log file for error details and description.

The WriteE2BFile BPEL Process logs its error to the BPEL console. Check the BPEL Process instance Flow, Audit, and Debug screens for detailed error information. Tab lists BPEL error messages you may encounter.

Table 9. BPEL Error Messages

Error Number	Error Message	Likely Causes
ORABPEL-11058	Error in opening file for writing.	1. The destination directory does not have sufficient write permission. 2. The disk has run out of space. 3. The output filename has exceeded the maximum characters allowed by the operating system.
ORABPEL-11054	Directory cannot be created successfully.	The destination directory does not exist.

Data is passed from Siebel Life Sciences to Oracle Adverse Event Reporting System using XML messages. The following errors may occur:

- The E2B xml message passed by Siebel Life Sciences to Oracle Adverse Event Reporting System is not well formed.

Sample Error Message:

Could not initiate the BPEL process because the input xml is not well formed, the reason is:

Error parsing envelope: (13, 39) End tag does not match start tag 'ns1:ichi csrmessageheader123'. Please correct the input xml.

- Schema validation is turned on to validate E2B message passed by Siebel Life Sciences to Oracle Adverse Event Reporting System BPEL process and the E2B message fails schema validation.

Sample Error Message:

Invalid xml document. According to the xml schemas, the xml document is invalid. The reason is: Error::cvc-complex-type.2.4.a: Invalid content was found starting with element 'ns1:ichi csrmessageheader123'. One of '{"http://www.oracle.com/genes/s/SharedComponents/ApplicationInterfaces/AERS46E2B":ichi csrmessageheader}' is expected.

Error::cvc-complex-type.4: Attribute 'lang' must appear on element 'ns1:reportercountry'.

.  
.  
.

Error::cvc-complex-type.2.4.b: The content of element 'ns1:patient' is not complete. One of '{"http://www.oracle.com/genes/s/SharedComponents/ApplicationInterfaces/AERS46E2B":patientinitial}' is expected.

Please make sure that the xml document is valid against your schemas.

</summary>

</part>

</invalidVariables>

## Error Messages

In Siebel Life Sciences the following error conditions may trigger error messages:

- Transformation faults
- Runtime faults
- Missing values for required fields (such as Product....) when creating a Product Issue record (such as Product Name, Description, Contact Name, and so on). The error message resembles  
{0} is a required field. Please enter a value for the field. (GENESIS-CLM-00101)

Where {0} is the name of the missing field (Contact Last Name, Description, Product Issue number, or Product Name).

In this situation, the integration fails and the trigger value for FDA Reported remains Yes or Potential. To revert the FDA Reported field to the previous value, use the following procedure.

### *To configure the optional information*

- 1 Modify the LS Medical Product Issue business component.

- 2 Disable the On Field Update Invoke 1 and On Field Update Invoke 2 business component user properties.
- 3 Edit the server script and add the following script in Function BusComp\_PreSetFieldValue (FieldName, FieldValue):

```
function BusComp_PreSetFieldValue (FieldName, FieldValue)
{
    var AdverseType = TheApplication().InvokeMethod("LookupValue", "SR_AREA", "MD
Adverse Event");
    var RepYes =
TheApplication().InvokeMethod("LookupValue", "LS_MED_FDA_REPORTABLE_TYPE", "Yes");
    var RepPotent =
TheApplication().InvokeMethod("LookupValue", "LS_MED_FDA_REPORTABLE_TYPE", "Potenti a
l");
    var SyncAERS = "FALSE";
    var currentValue = "test";

    if (FieldName == "Type")
    {
        if (FieldValue == AdverseType)
        {
            currentValue = this.GetFieldValue("FDA Reportable");
            if (currentValue == RepYes || currentValue == RepPotent)
            {
                SyncAERS = "TRUE";
            }
        }
    }

    if (FieldName == "FDA Reportable")
    {
        if (FieldValue == RepYes || FieldValue == RepPotent)
        {
            currentValue = this.GetFieldValue("Type");
            if (currentValue == AdverseType )
            {
                SyncAERS = "TRUE";
            }
        }
    }

    if (SyncAERS == "TRUE")
    {
        try
        {
            this.InvokeMethod("TransmitToAERS");
        }
        catch (e)
        {
            throw e;
            return (Cancel Operation);
        }
    }
}
```

```
    }  
    return (ContinueOperation);  
}
```

## Troubleshooting Techniques

The most common problems on the Oracle Adverse Event Reporting System side are:

- File system and database security problems accessing the E2B files. Such error messages are reported in the Oracle Adverse Event Reporting System E2B and error logs.
- The message sender identifier does not match the entry in the E2B senders table.

For Siebel Life Sciences, check the following possible issues:

- Verify that the workflow is successfully deployed and activated.
- Verify that the Outbound Web Service is successfully imported and activated.
- Verify whether the following URL is working on a Siebel server (after modifying localhost with SOA server name and 8888 with BPEL console Port number):

`http://localhost:8888/orabpel/default/CRMIIntegCreatePISEBL782ToAERSSync/1.0`

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