



## Pharmacovigilance - Addressing the Challenges through Proactive Risk Management

20 of the top 20 pharmaceutical companies run Oracle applications

Oracle automates adverse event and product complaint management processes from the moment of awareness through reporting, monitoring and resolution. Leveraging open technology standards Oracle provides extensive support across the safety continuum and creates an infrastructure that enables effective risk management and compliance with Good Pharmacovigilance Practices.

### **Siebel Contact Center Integration Pack for Oracle Adverse Event Reporting System**

- Provides a seamless transition from contact to case creation
- Streamlines the adverse event reporting process
- Eliminates need for double entry and improves data quality
- Establishes standard business processes
- Enables compliance to Good Pharmacovigilance Practices

Pharmacovigilance and risk management are activities critical to patients, regulators, care providers, employees and markets. Product safety is growing more complicated, with trial safety and pharmacovigilance becoming more critical in the development and marketed use of medicinal products. Once marketed, a medicinal product is introduced to a larger number of patients. These patients could be undergoing treatment with concomitant medical products and have other co-morbid conditions. These factors increase the demands on pre and post safety data collection and risk assessment consequently, placing additional strain on human, technological, and financial resources of a life science company. These challenges require companies to drive faster event processing to help promptly report accurate adverse event and complaint information to the appropriate safety and regulatory group(s) for further evaluation.

### **Siebel Contact Center Integration Pack for Oracle Adverse Event Reporting System**

To streamline the capture, reporting and management of adverse events and product complaints Oracle has integrated its best in class Siebel Contact Center and Oracle Adverse Event Reporting System (AERS). This new integration pack is being delivered as part of Oracle Application Integration Architecture, a comprehensive set of products that delivers integrated business processes across Oracle, third-party and custom applications.

The Siebel Contact Center Integration Pack for Oracle AERS seamlessly passes customer, product and event or complaint information data from Siebel Contact Center to Oracle AERS, automatically escalating reports, as appropriate. These capabilities drive faster event processing to help pharmaceutical and medical device manufacturers promptly report accurate adverse event and complaint information to the appropriate safety and regulatory group(s) for further evaluation

**Siebel Contact Center**

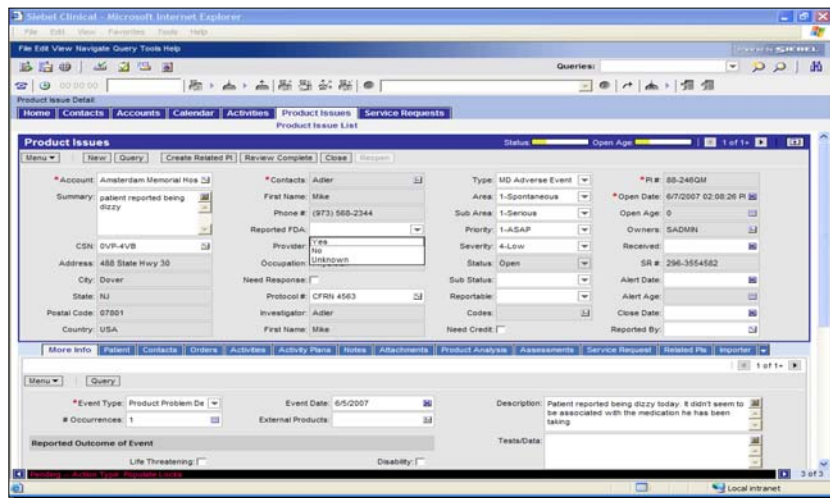
Oracle's Siebel Contact Center transforms a business's call center into an integral part of its total sales, marketing, and service delivery strategy. The application enables agents to handle service, support, and sales interactions seamlessly across all communication channels. As a result, businesses can reduce costs while enhancing service delivery.

- E-mail Response—automatically respond to customer e-mail
- Computer Telephony Integration—provide caller information to agents automatically
- Customer Dashboard—present a comprehensive view of critical information about a customer
- Call Management—provide agents with a complete history of all interactions with a customer
- Contextual Search—retrieve information from anywhere in the application
- Workflow Management—route and track tasks throughout their lifecycles

This closed-loop solution – which automatically loads event-related information from Siebel Contact Center into Oracle AERS and updates it to reflect changes – reduces duplicate data entry and provides life sciences organizations with complete, accurate and synchronized information, helping to reduce costly conflict resolution and reconciliation. As part of the Oracle Application Integration Architecture, the Siebel Contact Center Integration Pack for Oracle AERS provides faster and more efficient implementation through process and data standardization. The Process Integration Pack leverages the Oracle Fusion Middleware Service Oriented Architecture Suite and uses a methodology that should enable quick implementation. In addition, the integrated solution offers you ongoing vendor support, maintenance and upgrades – reducing the total cost of ownership. A vendor-supported integration allows organizations to avoid unknown and unbudgeted support and maintenance costs. Oracle developers worked closely with leading life sciences organizations to create a robust and flexible integration framework utilizing recognized industry specifications and best-practice business processes.

**Streamlined Process**

Using the integration pack a call center representative receiving a product issue enters the required information in Siebel Contact Center. The product issues are created and information entered in the Product Issue screen. Additionally, Siebel Contact Center provides the capability to create targeted questionnaires. These scripts assist agents to ask the right questions and help to ensure that a query can be escalated in the appropriate manner. Once the product complaint or adverse event is determined to be reportable the system triggers an automated workflow, enabled by Oracle Business Process



**Product Issues Entry Screen**

Execution Language (BPEL) Process Manager. Oracle BPEL Process Manager, a member of the Oracle Fusion Middleware family of products, enables enterprises to orchestrate disparate applications and Web services into business processes. Oracle BPEL technology is at the core of the Siebel Contact Center Integration Pack for Oracle AERS. Oracle AERS seamlessly and automatically polls the file, reads it and creates a case report.

**Drug Safety Management**

Oracle Adverse Events Reporting System enables drug safety management through capabilities designed to enable:

- Patient Drug Management
- Data Validation and Query
- Medical Review and Analysis
- Regulatory Reporting

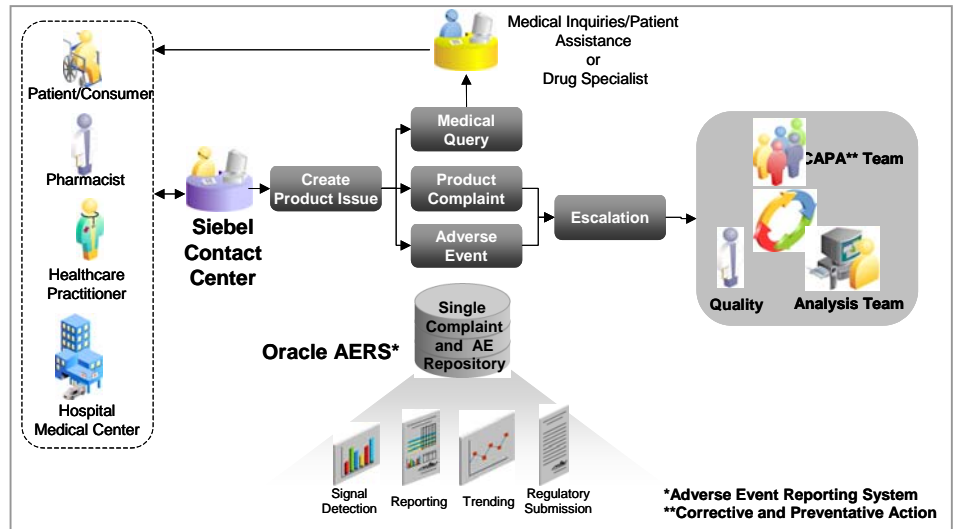
**Developing Good Case Reports**

Siebel Contact Center and Oracle Adverse Events Reporting System provides the information necessary to complete a comprehensive case report. Elements include:

- Description of the adverse events or disease experience
- Suspected and concomitant product therapy
- Patient characteristics and history
- Documentation of the diagnosis of the events
- Clinical course of the event and patient outcomes
- Relevant therapeutic measures and laboratory data
- Information about response to dechallenge and rechallenge

**Oracle Adverse Event Reporting System**

Oracle AERS provides a single global solution with powerful automation and productivity tools to meet the challenges of managing your worldwide safety information. Oracle AERS supports the capture, management, reporting, and analysis of serious adverse event, and product complaint cases, for all medical products (including drugs, medical devices, vaccines, biologics, and gene therapies) from all clinical and spontaneous sources.



Oracle AERS has the most powerful set of case management features in the industry. It is built on a flexible, embedded workflow engine that allows customers to tailor the workflow so that important cases are handled expeditiously. Oracle AERS includes a comprehensive suite of data consistency checks and an online discrepancy management system to manage any data issues identified in your cases, and allows users to create and save queries and case lists for use in ongoing safety surveillance.

Oracle AERS’ powerful query module gives you quick-and-easy answers to complex regulatory and safety questions, provides product surveillance, and protects your products and product pipeline. The query-by-example subsystem is an integral part of the application and eliminates the need to rely on external ad hoc tools to find the cases you need. The query subsystem allows you to build complex queries involving any combination of the more than 800 case data elements stored in Oracle AERS, without any programming. You can also extend queries outside of Oracle AERS data to external sources such as clinical trials data, manufacturing details, lot information, product quality information or other safety repositories. All queries can be saved; documented, parameterized and re-used as necessary allowing you to build a library of frequently used queries that can be run by any authorized user.

### Signal Identification and Safety Surveillance

Pharmacovigilance principally involves the identification and evaluation of safety signals. These signals can arise from post marketing data and other sources. Signals generally indicate the need for further investigation. After a signal is identified, it can be further assessed to determine whether it represents a potential safety risk and whether other action should be taken.

Oracle AERS includes many features for performing safety, surveillance and signal identification. These features include Increased Frequency reporting, which identifies increased frequencies of adverse events for a product over two time periods; Safety Surveillance queries to identify cases requiring surveillance; and powerful, fully integrated visualization and ad hoc reporting tools.

At various stages of risk identification and assessment, systematic examination of the reported adverse events by data mining techniques can provide additional information about the existence of an excess of adverse events reported for a product. By applying data mining techniques, it is possible to identify unusual or unexpected product-event combinations warranting further investigation. Oracle AERS enables data mining through its integration with Qscan®, DrugLogic's workflow-based analytical tool for identifying, analyzing, and resolving drug safety risks in conjunction with public safety data. Oracle AERS pharmacovigilance users can now immediately visualize their case data in Qscan and utilize Qscan's powerful data mining and signal detection capabilities to focus on the cases of most interest. In addition, drug safety teams can establish thresholds for automatic safety signal detection, receive alerts when thresholds are reached or exceeded, and assess their case information using data mining tools for statistical analysis.

### Leveraging the Best-of-Breed Front Office and Adverse Event Applications

As an off-the-shelf integration, Siebel Contact Center Integration Pack for Oracle AERS provides a faster and more efficient implementation through process and data standardization. In addition, the integrated solution offers ongoing vendor support, maintenance, and upgrades – reducing the total cost of ownership. A vendor-supported integration allows you to avoid unknown and unbudgeted support and maintenance costs. Oracle developers worked closely with leading life sciences organizations to create a robust and flexible integration framework utilizing recognized industry specifications and best practice business processes..

### CONTACT US

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