ADVERSE EVENT AND COMPLAINT MANAGEMENT

Oracle’s Siebel Life Sciences is a world-class customer relationship management solution specifically designed for medical, biotechnology, and pharmaceutical companies. Leading organizations around the globe are standardizing on our comprehensive Adverse Event and Complaint Management functionality to significantly improve regulatory compliance, product quality, and business performance.

Improve Process Quality and Consistency

Siebel Life Sciences enables pharmaceutical, biotechnology, medical device, and supply companies to substantially improve process consistency, cost productivity, and organizational performance. Together with the optional Adverse Event and Complaint Management module, Siebel Life Sciences enables organizations to

- Automate adverse event and complaint handling seamlessly across multiple organizations and stakeholders
- Create a single, closed-loop, standardized, compliant process globally
- Execute timely and high-quality investigations, analyses, and regulatory reports
- Automate assignment of tasks, activities, correspondences, corrective actions, approvals, escalations, and verifications

Accurate Data Capture from the Moment of Awareness

The Adverse Event and Complaint Management module combines a number of sub-processes that enable life sciences companies to

- Create an integrated, traceable, and efficient adverse event and complaint management process with maximum compliance and operational efficiency
- Perform analysis on adverse events and product issues to proactively identify patterns and improve product safety
- Adopt standardized regulatory business processes and best practices globally

You can seamlessly capture and escalate complaints for investigation and regulatory reporting while maintaining a complete audit trail. This approach increases efficiency and helps you comply with stringent regulations, thereby avoiding potential penalties for noncompliance. Features include

- Siebel SmartScript for consistent identification, codification, and recording of adverse events and complaints
• One-button escalation for easy routing of adverse events and complaints sources

• Assignment engine for identifying the appropriate field service and/or quality professional to investigate the adverse event or complaint

• Enhanced security with access restriction based on role, responsibility, group, and organization

Comprehensive Investigation and Analysis
The Adverse Event and Complaint Management module enables you to coordinate investigation among multiple teams. The process allows employees to seamlessly collect adverse event and complaint information, identify the cause of the problem, and effectively assess whether the event has to be reported to the regulatory agency. Features include

• Analytics engine to analyze trends in service requests using prebuilt and easy-to-build ad hoc reports (Siebel Business Analytics)

• Workflow designer to tailor and automate the business process to meet your specific needs while maintaining flexibility and upgradeability

• Secure approval process to electronically capture and verify authorized personnel’s sign-off on company-defined milestones and checkpoints.

• Audit Trail engine to track critical field changes, including lockdown

This functionality enables multiple stakeholders, including regulatory affairs, quality control, customer service, and manufacturing, to effectively and efficiently collaborate in adverse event and product complaint investigations.

Embedded Regulatory Reporting
Siebel’s Adverse Event and Complaint Management module enables you to seamlessly collect adverse event and complaint information and generate regulatory reports for timely submission. The necessary regulatory information can be collected by multiple parties involved in the investigation. The business process unifies this information in one safety file and allows regulatory liaisons to identify the reports that need to be submitted. Regulatory liaisons can easily create reports such as MedWatch initial and supplemental reports, monitor the submission deadlines, and maintain a complete record of the submission to the regulatory agencies. This functionality helps medical companies comply with regulatory guidelines by providing the ability to efficiently collect the necessary information and generate appropriate regulatory reports. Key features include

• Auto-population of regulatory report forms based on report type

• Auto-generation of MedWatch and Vigilance Reports

• Auto-management of regulatory report numbers

Closed-Loop Corrective and Preventive Actions
The Siebel Adverse Event and Complaint Management module from Oracle allows companies to create, assign, investigate, and monitor corrective and preventative actions (CAPA). Corrective actions can be generated from a complaint investigation
or from any internal product issue findings. The CAPA team can easily manage the resolution and implementation, as well as monitor the effectiveness of corrective actions through approval, confirmation, and closure.

**Contact Us**

For more information about Oracle’s Siebel Adverse Event and Complaint Management functionality, please visit [http://www.oracle.com/us/industries/health-sciences/index.htm](http://www.oracle.com/us/industries/health-sciences/index.htm) or call +1.800.ORACLE1 to speak with an Oracle representative.