ORACLE E-RECORDS

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INCLUDES:

- E-Signatures for Oracle Application Framework Forms
- One-step e-signature with optional e-record view
- Parallel approvers
- First responder wins functionality
- Redlining capability
- E-Signatures for Mobile Supply Chain applications (MSCA)
- Tailorable E-Record formatting—ASCII or PDF
- Controlled E-Record printing with optional collation
- UI setup validation

Oracle® E-Records is a configurable framework for secure capture, storage, inquiry, and printing of electronic records and electronic signatures (ERES) in compliance with government regulations, such as the United States Food and Drug Administration (US FDA) 21 CFR Part 11. Oracle E-Records is part of the Oracle E-Business Suite, an integrated set of applications that are engineered to work together.

Oracle E-Business Suite Has Built-in Compliance

The Oracle E-Business Suite provides a complete set of tools for managing electronic records. These tools comply with the technical requirements presented in the US FDA 21 CFR Part 11, including strong security, audit trails, archiving, and operational system checks built into GxP-critical business flows and electronic signatures.

Configuration options are extensive, and include choices of events that trigger the required electronic signatures, the number and type of signatures required, the sequence in which signatures must occur, the designated individuals who are authorized to sign, signature deferral rules (with deferral history tracked in the e-record), and flexible XML-based e-record output formats.

E-Signatures for Oracle Application Framework Forms

Product teams who are part of the Oracle E-Business Suite use the e-records and e-signatures framework to take snapshots of transactions and obtain electronic signatures prior to committing the transaction. Oracle E-records framework provided this capability for business transactions in Oracle forms-based applications with minimal intrusion to the forms code. The E-records framework also supports Oracle Applications built using the Oracle Applications Framework (OAF). The OAF is a Java-based J2EE architecture using the Model View Controller (MVC) design pattern.

Validate Setup UI functionality allows you to validate the setup for business events, approval rules, approvers, and e-record format prior to deploying it to the production environment.

Support for Approvals Management Features

Sequential Approver functionality was required to sign sequentially during the e-signature approval process. This meant that each approver had to sign in a predefined succession.

Parallel Approver functionality is introduced to allow multiple users or groups of

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same sequence to authenticate simultaneously.

Using the **First Responder Wins** feature permits voting functionality. The first individual to approve a transaction "wins" the approval of all others. Other signatures are not required; the transaction is approved. If a transaction has parallel approvers, then at the time of signing any member of the approval group can sign the transaction. In case of a deferred approval, all parallel notifications are canceled after the first responder approves or rejects the notification.

E-Record Features

Oracle E-Records can be used to manage critical information related to production orders, quality records, or other information key to conformance with FDA Good Manufacturing Practices (cGMP). Hardcopy documents must be accounted for to ensure that production operators are working only from certified document versions as they perform their jobs. Companies that want to utilize electronic recordkeeping in a hybrid mode—to maintain records electronically, but then print them for manual signatures—need the capability to produce controlled documents and track the number of printouts made. This has driven the requirement to provide the option to tightly control the printing of electronic records. Enforced accountability by allowing only specified individuals to print, and then the tracking of who submitted and approved the print requests is an additional benefit. Oracle E-Records offers the printing of one or many e-records in a single print job. Optionally, add e-record and e-signature control to the submission of print jobs to verify that printing is appropriate and reviewed. This is auditable if e-records are turned on for the print process.

You can select e-record formats in **ASCII or PDF.** Using **Redlining**, product teams can now provide evidence of exactly what changed during the approval process.

Figure 1: Redlining can show users, exactly what is changed in current transaction e-record

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RELATED PRODUCTS

Oracle E-Records is part of E-Business Suite—designed to perform with the following products:

- Oracle Workflow
- Oracle Approval Management
- Oracle XML Gateway
- Oracle XML Publisher
- Mobile Supply Chain Application (MSCA) Architecture

RELATED SERVICES

The following services are available from Oracle Support Services:

- Oracle E-Business Suite Accelerators
- Oracle Application Solution Centers
- Oracle University
- Oracle Consulting

One-step E-signature with Optional E-record View

The one-step single-check e-signature us more user friendly than the previous three-step procedure. All the required information for an approval process is shown in a single page with the optional e-record. This is more suited for transaction approval where all the relevant data for the approval is visible on the form. For example statuses change Approval, lot expiry approval.

For more complex transactions such as recipe and batch creation, where data spans multiple forms, it is better to use traditional three-step signature process. All relevant data required to review prior to approval, can be summarized in the e-record. The one-step signature supports all the features provided by three-step e-signature including: Online and deferred approvals, signers list modifications, AME approvers, serial and parallel signing processes, overriding approvers, attachment support.

E-Signatures for Mobile Supply Chain Applications (MSCA)

The e-record and e-signature framework now provides e-signatures for mobile supply chain transactions. The underlying technology is available for future uptake by the E-Business Suite applications. Custom extensions to the EBS MSCA framework can leverage this capability.

Conclusion

Oracle is committed to providing software tools and applications to help Life Sciences companies run their businesses in an efficient manner and in compliance with federal regulations. Understanding that validating operating environments in accordance with the FDA 21 CFR Part 11 is of high importance in the industry, Oracle provides an unmatched set of tools to achieve the goal of maintaining cGMP critical records electronically. The Oracle E-Business Suite provides a comprehensive set of tools—strong system security, audit trails, electronic signatures, and a secure evidence store from which these records can be queried—to address the technical and governmental requirements of electronic recordkeeping.

Oracle E-Business Suite—The Complete Solution

Oracle E-Business Suite enables companies to efficiently manage customer processes, manufacture products, ship orders, collect payments, and more—all from applications that are built on unified information architecture. This information architecture provides a single definition of your customers, suppliers, employees, and products—all important aspects of your business. Whether you implement one module or the entire Suite, Oracle E-Business Suite enables you to share unified information across the enterprise so you can make smarter decisions with better information.

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