

# Oracle Life Sciences Safety One Intake Cloud Service

## Release Notes



Release 24.1

F81452-05

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The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

ORACLE®

Oracle Life Sciences Safety One Intake Cloud Service Release Notes, Release 24.1

F81452-05

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# Preface

This preface contains the following sections:

## Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

## Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Oracle Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <https://www.oracle.com/life-sciences/support/> or visit <https://www.oracle.com/corporate/accessibility/learning-support.html#support-tab> if you are hearing impaired.

## Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

# 1

## Introduction

Oracle Safety One Intake provides advanced intake capabilities for processing adverse event data from various sources. It automatically analyzes structured and unstructured documents and converts them into cases for use in Oracle Argus Safety.

Please note that Oracle Safety One Intake must be purchased separately from Oracle Argus Safety.

# 2

## What's new in Oracle Safety One Intake

This release introduces support for ingesting email content into Oracle Safety One Intake so it can be processed and transmitted to Oracle Argus Safety. It also adds support for multiple enterprises and enhancements to the audit log for improved transparency and regulatory compliance.

### Topics:

- [Email intake](#)
- [Support for CROs or multiple enterprises](#)
- [Enhancements to the audit log](#)

## Email intake

Oracle Safety One Intake now provides automatic intake of email content directly from specified inboxes.

Automatic email intake helps you work more efficiently by allowing you to view entire emails within Oracle Safety One Intake, eliminating the need to monitor messages in a separate email account.

Each email triggers the creation of a single intake record within Oracle Safety One Intake. The system auto-processes email attachments according to the rules you define, similar to the way it processes documents uploaded manually or through the REST API. Any email intake records that need additional processing by the user are available in the worklist.

### Configuration

Oracle Safety One Intake provides flexible configuration and setup for email intake features. You or your system administrator can do the following:

- Specify and validate the email accounts your organization uses for adverse event reporting
- Identify the folders in those accounts that you want Oracle Safety One Intake to monitor
- Create rules for processing adverse event information ingested from emails. You can set up rules to handle manual validation, grouping, and the use of email header information to create adverse event report details, such as using the sender and receipt date from the header as reporter details and initial event receipt date.
- Define email account details for outgoing emails, which helps ensure a standardized and reliable process for sending emails such as acknowledgments from within Oracle Safety One Intake.

### Automated acknowledgments

You can configure Oracle Safety One Intake to send an acknowledgment automatically to the email sender (the adverse event reporter) after the intake record is accepted. Acknowledgment status appears in the Processed dashboard.

## Support for CROs or multiple enterprises

Oracle Safety One Intake now supports multiple enterprises, allowing it to be used by CROs (Contract Research Organizations).

Enterprise users can now access the Oracle Safety One Intake application for a specific enterprise from the Global Homepage. Users can easily switch between enterprises, accessing one at a time, from the Oracle Safety One Intake application itself.

Intake processors can manage intake records for their respective enterprises. In addition, workflow managers overseeing dedicated or multiple enterprises can monitor the intake process for their enterprise. This feature enables efficient navigation and control, allowing managers to focus on one enterprise at a time for optimal workflow supervision.

## Enhancements to the audit log

The audit log now provides detailed information about CRUD (Create, Read, Update, Delete) operations.

These updates to the audit log make it easy to identify the users responsible for specific changes, as well as the time the changes occurred. This information helps ensure transparency, traceability, and compliance with FDA 21 CFR Part 11 requirements.

Audit log information is now available for intake configurations as well as intake records.

## Features added in earlier releases

For information about enhancements in earlier versions of Oracle Safety One Intake, please refer to the releases notes for that version.

- [Oracle Safety One Intake 23.4 Release Notes](#)
- [Oracle Safety One Intake 23.3 Release Notes](#)

# 3

## Interoperability with Oracle Argus Safety

This release of Oracle Safety One Intake includes some enhancements to support interoperability with Oracle Argus Safety.

### **Email intake and Oracle Argus Safety**

If the reporter's email address exists in the intake record, the address appears in the Oracle Argus Safety case form.

Any email that results in the creation of an intake record and is subsequently transmitted to Oracle Argus Safety is available in the case attachments section, both for traceability and to maintain integrity. The email is provided in PDF format for better readability and compliance with regulatory standards for attachments.

### **Audit log changes in Oracle Argus Safety**

New categories have been added to the Oracle Argus Safety audit log so you can view information related to intake configuration in Oracle Safety One Intake.



# 4

## Enhancements to the Global Homepage

You can add, modify, or remove access to one or more enterprises for individual users through the Global Homepage application.

As described in [Support for CROs or multiple enterprises](#), Oracle Safety One Intake introduces support for multiple enterprises. The Global Homepage has been enhanced for this release so that users with the Global Admin role can take advantage of its comprehensive access control features to manage enterprise access for individual Oracle Safety One Intake users.

In addition, Global Admin users can manage intake processing configurations across multiple enterprises from the Global Enterprise Management tab in the Global Homepage, ensuring a centralized and streamlined approach to adapting intake processing settings according to the specific needs of each enterprise.

For more information on the Global Homepage application, refer to the Oracle Argus Safety documentation.

# 5

## Compatibility and browser requirements

Oracle Safety One Intake 24.1 is a companion release for Oracle Argus Safety 8.4.3.

### Compatibility with Oracle Argus Safety

Oracle Safety One Intake version	Compatible versions of Oracle Argus Safety
Oracle Safety One Intake 24.1	<ul style="list-style-type: none"><li>• Oracle Argus Safety 8.4.3 (Cloud)</li><li>• Oracle Argus Safety 8.4.3 (Licensed)</li></ul>

### Browser requirements

Browser	Resolution
<ul style="list-style-type: none"><li>• Google Chrome version 121.0.3865.90 or later</li><li>• Microsoft Edge version 122.0.2365.38 or later</li></ul>	Make sure the resolution display of your computer is above 1280 x 1024.

# 6

## Known issues

For information about known issues in this release, please see the article [Oracle Safety One Intake Documentation \(Doc ID 3024370.1\)](#) on [My Oracle Support](#). Workarounds are provided where available.

# 7

## Product Verification Pack (PVP)

The Product Verification Pack (PVP) is a collection of product release documents designed to help with your validation efforts.

The PVP is used by Oracle for certification purposes, and Oracle makes the pack available to customers with every release (except patches). You can use the PVP as a blueprint for acceptance testing.

The PVP for Oracle Safety One Intake is available on [My Oracle Support](#). For information on how to download a PVP, follow the instructions in [Oracle Argus Product Verification Pack](#). The patch containing the PVP for Oracle Safety One Intake is **35790103**. Please note that the product name appears as Oracle Safety One Argus in the patch listing.