
Document History

Version	Date	Status	Change
1.0	5 March 2021	Released to Customer	Initial release

Contents

1	About this Document	5
1.1	Purpose and Scope.....	5
1.2	Assumptions.....	5
1.3	Target Audience.....	5
1.4	Glossary.....	5
1.5	Typographic Conventions.....	6
2	Introduction	7
2.1	Business Scenarios.....	7
2.2	Supported Industries.....	7
3	Service Overview	8
3.1	Key Benefits.....	9
3.2	SAP Message Orchestration.....	9
4	Applicable GxP Requirements	10
5	Main Functions	11
5.1	Connection.....	11
5.2	Service Definitions.....	11
	5.2.1 Communication from SAP ATTP to SNCM.....	11
	5.2.2 Response and Payload to SAP ATTP.....	11
5.3	Technical Framework.....	12
	5.3.1 Communication Patterns.....	12
5.4	Access Management.....	12
5.5	Message Routing.....	12
5.6	Message Validation.....	12
5.7	Performance Requirements.....	13
5.8	App Access.....	13
5.9	Single Sign On.....	13
5.10	Alarms and Alarm Notifications.....	13
	5.10.1 Exception Alarms.....	13
	5.10.2 Alarm Notifications.....	13
5.11	Technical Communication.....	14
	5.11.1 Connectivity.....	14
	5.11.2 Authentication.....	14
6	Important Disclaimers and Legal Information	15
6.1	Coding Samples.....	15
6.2	Accessibility.....	15
6.3	Gender-Neutral Language.....	15
6.4	Internet Hyperlinks.....	15

Legal Disclaimer

The information in this document is confidential and proprietary to SAP and may not be disclosed without the permission of SAP.

1 About this Document

1.1 Purpose and Scope

This document describes the service for Brazil reporting used by manufacturers interacting on the SAP Information Collaboration Hub for Life Sciences reporting to the SNCM reporting system of the Brazilian Health Regulatory Agency (ANVISA). This document describes current processes supported by SAP.

1.2 Assumptions

Basic knowledge of SNCM Regulatory Reporting processes.

1.3 Target Audience

This document is for customers and partners of the SAP Information Collaboration Hub for Life Sciences who use the Regulatory Reporting service, including:

- Integration experts
- Implementation teams
- SAP ATTP Configuration experts and administrators

Related Information

- SAP Information Collaboration Hub for Life Sciences Help Portal
- SAP Information Collaboration Hub for Life Sciences Onboarding Wiki
- SAP Advanced Track and Trace for Pharmaceuticals Help Page

1.4 Glossary

Abbreviation	Definition
ANVISA	Brazilian Health Regulatory Agency
ICH	SAP Information Collaboration Hub for Life Sciences

Abbreviation	Definition
MAH	Marketing Authorization Holder
SAP ATTP	SAP Advanced Track and Trace for Pharmaceuticals
SAP Info Hub	SAP Information Collaboration Hub for Life Sciences
SNCM	Sistema Nacional de Controle de Medicamentos - Brazilian National System of Control of Medications

1.5 Typographic Conventions

Type Style	Description
Example	Words or characters quoted from the screen. These include field names, screen titles, pushbuttons labels, menu names, menu paths, and menu options. Textual cross-references to other documents.
Example	Emphasized words or expressions.
EXAMPLE	Technical names of system objects. These include report names, program names, transaction codes, table names, and key concepts of a programming language when they are surrounded by body text, for example, SELECT and INCLUDE.
Example	Output on the screen. This includes file and directory names and their paths, messages, names of variables and parameters, source text, and names of installation, upgrade and database tools.
Example	Exact user entry. These are words or characters that you enter in the system exactly as they appear in the documentation.
<Example>	Variable user entry. Angle brackets indicate that you replace these words and characters with appropriate entries to make entries in the system.
EXAMPLE	Keys on the keyboard, for example, F2 or ENTER.

2 Introduction

The SAP Information Collaboration Hub for Life Sciences is an innovative on-demand solution that connects pharmaceutical organizations and their supply chain partners on a secure network that is owned and managed by SAP, and supports the transfer and transformation of serialization messages between members of the pharmaceutical supply chain.

SAP Information Collaboration Hub for Life Sciences also supports the transfer of formatted messages to government or institutional databases and systems such as the Brazilian National Pharmaceutical Track and Trace System (SNCM).

2.1 Business Scenarios

The SAP Information Collaboration Hub for Life Sciences allows communication to the SNCM System for the following scenarios in various Variants as described in the SAP ATTP Configuration Guide for Brazil Regulatory Reporting:

- Activation (not imported)
- Activation (imported)
- Receive (verified payload)
- Receive (unverified payload)
- Dispatch (verified payload)
- Dispatch (unverified payload)
- Finalization (dispensation)
- Finalization (delisting)
- Finalization (exportation)
- Finalization (disposal)
- Finalization (uncontrolled)

2.2 Supported Industries

The following industries are supported for connection and data exchange:

- Pharma

3 Service Overview

The Brazil Regulatory Reporting service of the SAP Information Collaboration Hub for Life Sciences is available to customers who wish to connect:

- An SAP backend system, namely SAP Advanced Track and Trace for Pharmaceuticals (ATTP)

The following figure summarizes connection possibilities:



The SAP Information Collaboration Hub for Life Sciences routes messages to SNCM hosted by the Brazilian Health Regulatory Agency including the following:

- Connection to secure HTTPS endpoints for production and test environments
- Error handling and monitoring

Requirement

You must send messages that comply with the generic reporting message format described in the SAP Information Collaboration Hub for Life Sciences ATTP Configuration Guide for Brazil Regulatory Reporting available on the [Regulatory Reporting Help page](#).

3.1 Key Benefits

The key benefits are as follows:

- Onboarding to Regulatory Services:
 - Fast onboarding to SNCM based on SAP ATTP core capabilities
 - No System upgrades necessary for Generic Reporting services starting with SAP ATTP 3.0
 - Reduced testing effort based on qualified gateway functionality
 - Service managed by SAP
- Simplified Connectivity to SNCM System:
 - Communication secured by NFe certificate
 - Landscape harmonization
- Integration with SAP ATTP out-of-the-box

3.2 SAP Message Orchestration

The SAP Information Collaboration Hub for Life Sciences (SAP Info Hub) handles messages that are sent synchronously to SNCM.

Messages sent from SAP ATTP to SAP Info Hub and responses returned are synchronous due to the design of the SAP Info Hub Adapter Interface, but from a process point of view, exchange is asynchronous. When a customer sends a message to SAP Info Hub, the customer receives a technical acknowledgment for the SAP Info Hub confirming the correct syntax of the message.

Additionally, customers receive the final payload sent to SNCM as well as SNCM response messages using the Generic Reporting Response channel, also based on the SAP Info Hub Adapter Interface.



4 Applicable GxP Requirements

The SAP Information Collaboration Hub for Life Sciences is not a system of record, and therefore, can be regarded as a system with low risk with regards to GxP. Nevertheless, data transmitted may be GxP relevant so basic GxP principles for developing and operating the system are applied.

GxP Factor	Status
Audit trail	n/a, data is not changed, logging is available for 30 days
Electronic Signatures	n/a
Security Requirements	For Routing: certificates expiring
Development	SAP Quality Management System applies
Operations	SAP Cloud Platform is SOC1, SOC2 and ISO 27001 certified.

5 Main Functions

5.1 Connection

To establish a successful connection to SNCM services the following parameters are mandatory for the service managed connection:

- NFe certificate used to connect to SNCM

5.2 Service Definitions

5.2.1 Communication from SAP ATTP to SNCM

SAP Information Collaboration Hub for Life Sciences receives messages in the Generic Reporting Format from a customer's SAP ATTP backend system. See SAP ATTP Configuration Guide for Brazil Regulatory Reporting on the [Regulatory Reporting Help page](#).

Generic Reporting Notifications are transformed to the SNCM format. The message is signed according to SNCM requirements, and sent to the "evtIn" Web Service used for sending all event types to SNCM.

SAP Information Collaboration Hub for Life Sciences sends the final payload sent to SNCM to a customer's ATTP using the Generic Reporting Response channel. Additionally, the functional or technical response message from SNCM is provided.

5.2.2 Response and Payload to SAP ATTP

The following number of response messages is expected for each SNCM notification type:

Notification Type	Number of expected responses	Comment
Activation, all Variants	2	One response with status "PAYLOAD", one with functional response status.
Shipment, all Variants	2	One response with status "PAYLOAD", one with functional response status.

Notification Type	Number of expected responses	Comment
Receive, all Variants	2	One response with status "PAYLOAD", one with functional response status.
Finalization, all Variants	2	One response with status "PAYLOAD", one with functional response status.

5.3 Technical Framework

5.3.1 Communication Patterns

The service communicates with the SNCM synchronously. Connection to SAP Information Collaboration Hub for Life Sciences uses the SAP ATTP Generic Reporting Framework through the synchronous SAP ICH Adapter SOAP Interface.

5.4 Access Management

The service can be used by users who have an active connection with SAP Information Collaboration Hub for Life Sciences. These users can send SNCM related Generic Reporting Notifications to the SAP endpoint provided using a B2B connection from SAP ATTP. These users have no other authorizations.

5.5 Message Routing

The service supports routing of SNCM related Generic Reporting Notifications, after transformation to the correct SNCM service endpoint.

5.6 Message Validation

The service accepts messages that are generated in the correct Generic Reporting format, as specified by SAP. There is no validation of message content. All required checks are in SAP ATTP.

5.7 Performance Requirements

The service processes files according to SNCM specification requirements.

5.8 App Access

The current version of the Brazil Regulatory Reporting service contains no applications. The process of creating Generic Reporting Notifications, monitoring connectivity and responses is managed from SAP ATTP.

5.9 Single Sign On

The service supports Single Sign On (SSO).

5.10 Alarms and Alarm Notifications

5.10.1 Exception Alarms

The service sends a response in case of failed events within SAP Information Collaboration Hub for Life Sciences. In case of technical errors returned by SNCM, users see the result in SAP ATTP. This also applies for functional errors.

Technical errors are investigated by the SAP Support team. Functional errors are investigated solely by customers.

5.10.2 Alarm Notifications

The SAP Support team receives notifications in the event of technical exception events.

5.11 Technical Communication

5.11.1 Connectivity

Customers can connect their SAP ATTP system to the SAP Information Collaboration Hub for Life Sciences Brazil Regulatory Reporting service only by using the SOAP SAP ICH Adapter Interface. Other protocols are not supported to guarantee intended user experience and transparency during the message exchange.

5.11.2 Authentication

SAP Information Collaboration Hub for Life Sciences enables you to authenticate user access from your SAP ATTP system using X.509 certificates.

6 Important Disclaimers and Legal Information

6.1 Coding Samples

Any software coding and/or code lines/strings ("Code") included in this documentation are only examples and are not intended to be used in a productive system environment. The Code is only intended to better explain and visualize the syntax and phrasing rules of certain coding. SAP does not warrant the correctness and completeness of the Code given herein, and SAP shall not be liable for errors or damages caused by the usage of the Code, unless damages were caused by SAP intentionally or by SAP's gross negligence.

6.2 Accessibility

The information contained in the SAP documentation represents SAP's current view of accessibility criteria as of the date of publication; it is in no way intended to be a binding guideline on how to ensure accessibility of software products. SAP in particular disclaims any liability in relation to this document. This disclaimer, however, does not apply in cases of willful misconduct or gross negligence of SAP. Furthermore, this document does not result in any direct or indirect contractual obligations of SAP.

6.3 Gender-Neutral Language

As far as possible, SAP documentation is gender neutral. Depending on the context, the reader is addressed directly with "you", or a gender-neutral noun (such as "sales person" or "working days") is used. If when referring to members of both sexes, however, the third-person singular cannot be avoided or a gender-neutral noun does not exist, SAP reserves the right to use the masculine form of the noun and pronoun. This is to ensure that the documentation remains comprehensible.

6.4 Internet Hyperlinks

The SAP documentation may contain hyperlinks to the Internet. These hyperlinks are intended to serve as a hint about where to find related information. SAP does not warrant the availability and correctness of this related information or the ability of this information to serve a particular purpose. SAP shall not be liable for any damages caused by the use of related information unless damages have been caused by SAP's gross negligence or willful misconduct. All links are categorized for transparency (see: <http://help.sap.com/disclaimer>).

www.sap.com/contactsap



© 2021 SAP SE or an SAP affiliate company. All rights reserved.
No part of this publication may be reproduced or transmitted in any form or for any purpose without the express permission of SAP SE or an SAP affiliate company.
SAP and other SAP products and services mentioned herein as well as their respective logos are trademarks or registered trademarks of SAP SE (or an SAP affiliate company) in Germany and other countries. All other product and service names mentioned are the trademarks of their respective companies. Please see <http://www.sap.com/corporate-en/legal/copyright/index.epx#trademark> for additional trademark information and notices.

