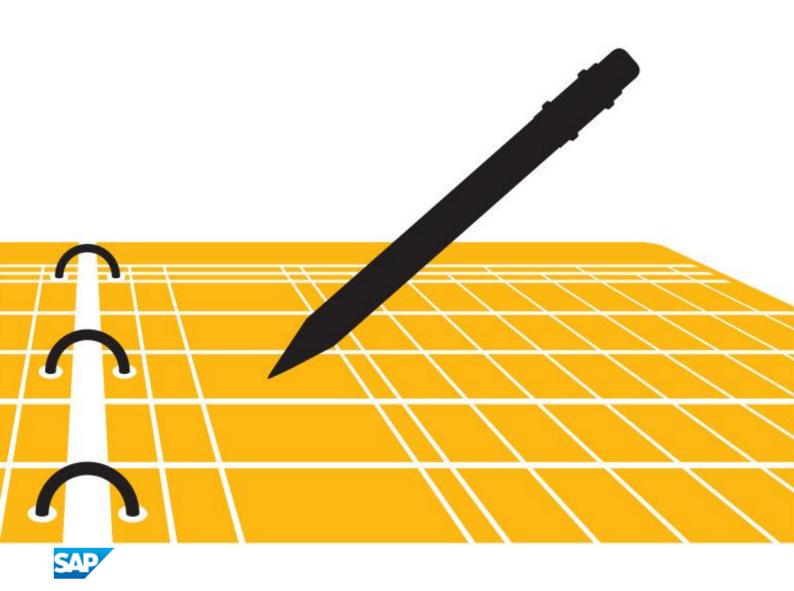
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SAP Advanced Track and Trace for Pharmaceuticals 1.0 SP1

United States of America



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></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. | | | |

Document History

| Version | Status | Date | Change |
|---------|-----------------|------------|--------------------|
| 1.0 | Final Version | 2015-09-15 | All topics updated |
| 1.1 | Updated Version | 2016-04-04 | Updates for SP1 |

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1 About This Document

1.1 Purpose and Scope

This country-specific Configuration Guide is the documentation of steps that are required or optionally possible to configure SAP Advanced Track and Trace for Pharmaceuticals for a specific country usage. It therefore describes the configuration contents and context for country specific features that are included within SAP Advanced Track and Trace for Pharmaceuticals

1.2 Target Audience

This document is intended for the following target audiences:

- Consultants
- Partners
- Customers
- System administrators
- Support specialists

1.3 Related Information

For detailed information about the application refer to the application help in the SAP Help Portal at:

http://help.sap.com/attp

For more information about the general configuration of SAP Advanced Track and Trace for Pharmaceuticals, please refer to the *Configuration Guide - General* provided in the SAP Service Marketplace at:

http://service.sap.com/instguides \rightarrow Focused Business Solutions \rightarrow SAP Advanced Track and Trace for Pharmaceuticals \rightarrow SAP Advanced Track and Trace for Pharmaceuticals 1.0.

2 Solution Overview

SAP Advanced Track and Trace for Pharmaceuticals includes country-specific contents mainly driven by the legislation within the respective country.

This mainly includes country-specific interfaces for communicating with governmental systems or supply chain partners but also may include certain additional master data or event properties including the related customizing settings.

The Drug Supply Chain Security Act (DSCSA) of United States of America has various introduction phases.

The first phase is the Lot level tracking phase and begins 2015 and will last till 2023. Companies participating in the supply chain process have to exchange lot level information in the form of Transaction Information (TI), Transaction History (TH) and Transaction Statement (TS).

November 2017 manufacturers will have to start serializing their pharmaceutical packages but still the data exchange on lot level only is relevant.

Only by November 2023 the members of the supply chain will need to exchange data on serialized item level.

SAP Advanced Track and Trace for Pharmaceuticals plans to support this phased introduction of serialization.

As of today, SAP Advanced Track and Trace for Pharmaceuticals supports the Lot level EPCIS message exchange together with persisting lot like objects and events within the repository system. In addition item based EPCIS message exchange is supported with SP1.

The implementation is done based on GS1 U.S. Healthcare implementation guideline 1.1.

Lot and Item level ASNs are not supported.

For more detailed information about the country-specific functionality, please refer to the application help for SAP Advanced Track and Trace for Pharmaceuticals in the help portal at: http://help.sap.com/attp

3 Setting up the Solution

3.1 General Customizing

There are no specific customizing settings for USA as part of the general customizing.

3.2 AIF Interfaces

The following messages are supported for US Supply Chain Reporting:

SR_INFORM_SUCC Supply Chain Partner: Inform Successor

This message is a part of the core solution which informs subsequent supply chain partners. Based on the settings within the business partner master data the country specific extension for DSCSA are included in composing the XML message.

For this message an according AIF interface is defined.

For more information about the country-specific features, please refer to the application help in the help portal at: http://help.sap.com/attp.

The required customizing for the AIF interfaces is included within the BC set for AIF that is part of the solution. A country-specific BC set is also provided which includes additional customizing within Advanced Track and Trace for Pharmaceuticals for that country.

You may extend the AIF interfaces based on local variants as part of the extensibility concept of AIF.

You may manipulate the data being transmitted or received through the interfaces based on according BAdIs that are part of the country-specific logic within SAP Advanced Track and Trace for Pharmaceuticals.

3.3 Country-specific Parameters and Attributes

3.3.1 Product Properties

The following product properties for USA are included as part of the solution:

SC_US_CONTAINER_SIZE Supply Chain US HC: Container Size
 SC_US_DOSAGE_FORM Supply Chain US HC: Dosage form
 SC_US_DRUG_NAME Supply Chain US HC: Drug name

SC_US_MANUFACT_NAME
 Supply Chain US HC: Manufacturer name

SC_US_STRENGTH
 Supply Chain US HC: Strength

3.3.2 Event Properties

There are no specific event attributes delivered for USA.

3.3.3 Event BLOB

The following tag relevance must be included within the customizing to allow accessing the transaction statements within the customer BAdI (TA: /STTP/DM_MAP_BLB).

USHC_TRANS_STATEMENT gs1ushc:dscsaTransactionStatement

3.3.4 Event Attribute Mapping

No specific attribute mapping contents are required as part of the delivered solution for U.S.A.

3.3.5 Country Content Activation for Inbound Message Processing

For inbound processing of the special US tags the country content for U.S. has to be activated by adding the country us in the customizing Transaction /STTP/C_CTY_DM - Country Content Activation.

4 Data Archiving

All data that is stored within the standard database tables that are part of SAP Advanced Track and Trace for Pharmaceuticals are archived based on the general archiving concept that is part of the solution. There are no country specific database application tables that need to be archived.

5 Volume-based License

Country-specific content is licensed separately and measured based on country functionality used. In other words, the regulatory reporting events are measured per country.

6 Disclaimer

The information stated herein is based on the feature set available in the release that is listed in the beginning of this document. SAP reserves the right to adjust and extend the configuration options of the solution in future releases. Certain options may be extended also as part of future service packs. This especially applies to additional country content that is made available.

The implementation of BAdIs is generally considered custom code and thus a resulting misbehavior of the solution is not covered as part of the general maintenance agreement for this solution. You should generally not change internal attributes that are used by the solution to control the system behavior despite that in some cases such attributes are exposed to the BAdI interfaces.



