The Global Language of Business

Healthcare

GS1 US Rx EPCIS Conformance Testing Program

Program Guide

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About GS1

GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely-used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

About GS1 US

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely-used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers, and distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US® in the United States.

About GS1 Healthcare US

GS1 Healthcare US® is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to help improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

1 Introduction

The *United States Drug Supply Chain Security Act (DSCSA)* requires pharmaceutical trading partners to share chain-of-ownership data in a manner that allows for serialized item traceability back to the product origin commencing in 2023. In 2014, the U.S. Food and Drug Administration (FDA) designated Electronic Product Code Information Services (EPCIS), as a method that can be used to comply with the data exchange requirements of the DSCSA.[1]

EPCIS is a GS1 Standard that enables supply chain partners to capture event information about supply chain events (e.g., shipped; received; etc.), and to share that information with their trading partners securely and in near real-time. The EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. There are numerous options for how the standard can be implemented in order to accommodate different applications and environments. Nonetheless, there still needs to be a certain level of consistency in terms of how the standards are implemented by individual trading partners in order to support collaborative supply chain solutions like DSCSA serialized item traceability.

Therefore, members of the U.S. pharmaceutical industry have been working in conjunction with GS1 US® to determine how the EPCIS standards can best be applied to support DSCSA serialized item traceability. More than 100 individuals representing nearly fifty organizations from across the U.S. pharmaceutical supply chain have participated in this on-going effort. Leading manufacturers, wholesalers, retail pharmacies, healthcare providers, government agencies and industry associations have all been working together to analyze business processes and business requirements, consider the various options, and decide how the standards could best be applied.

The *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability* ("GS1 US Rx Guideline") records all of the decisions points from that effort, including EPCIS events and data elements. The current guideline (Release 1.2, Nov 07 2016) is based on EPCIS Version 1.2 and Core Business Vocabulary (CBV) Version 1.2.

Members of the U.S. pharmaceutical industry have been preparing their systems and business processes to meet DSCSA requirements. To support their work, industry approached GS1 US about establishing a program to evaluate EPCIS messages for their conformance to the GS1 US Rx Guideline. The goal is to support and streamline trading partner on-boarding with a mechanism to provide a level of confidence about readiness, implementation quality and consistency.

In response, GS1 US launched the *GS1 US Rx EPCIS Conformance Testing Program* ("the Program"). This is a voluntary program offered to support pharmaceutical industry members implementing EPCIS for DSCSA and traceability pursuant to the GS1 US Rx Guideline. The Program is designed to validate that an EPCIS event file follows the format and structure defined in the GS1 US Rx Guideline to support interoperable EPCIS baseline functionality for the purposes of serialized partner exchanges.

Important: As with all GS1 Standards and solutions, this program is voluntary, not mandatory. It should be noted that use of the words "must" and "require" throughout this document relate exclusively to certification and testing.

2 Document Information

2.1 Document Purpose

- Describe the GS1 US Rx EPCIS Conformance Testing Program.
- Describe the conformance testing process.
- Define the requirements for third-party testing services to be certified by GS1 US.

[1] U.S. FDA Guidance for Industry: *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information* (November, 2014).

2.2 Audience

- Pharmaceutical supply chain members who will exchange EPCIS events pursuant to the GS1 US Rx Guideline
- Companies that will generate EPCIS events pursuant to the GS1 US Rx Guideline
- Third-party conformance testing firms

2.3 Scope

This document describes the GS1 US Rx EPCIS Conformance Testing Program in terms of the conformance testing process, and the requirements for third-party testing services to be certified by GS1 US. At this time, GS1 US is finalizing the mechanics of how third-party testing firms will apply for certification (e.g., web page, contact, email address, portal, launch date, etc.). Final details will be available in the coming weeks, and this document will be updated with that information as soon as it is finalized.

Because the pharmaceutical industry has emphasized that time is of the essence, GS1 US has chosen to publish the initial release of this document without that information in order to make the requirements for GS1 US-certified conformance testing services available as soon as possible. This will enable interested third-party testing firms to begin developing their services immediately.

3 Pharmaceutical Supply Chain

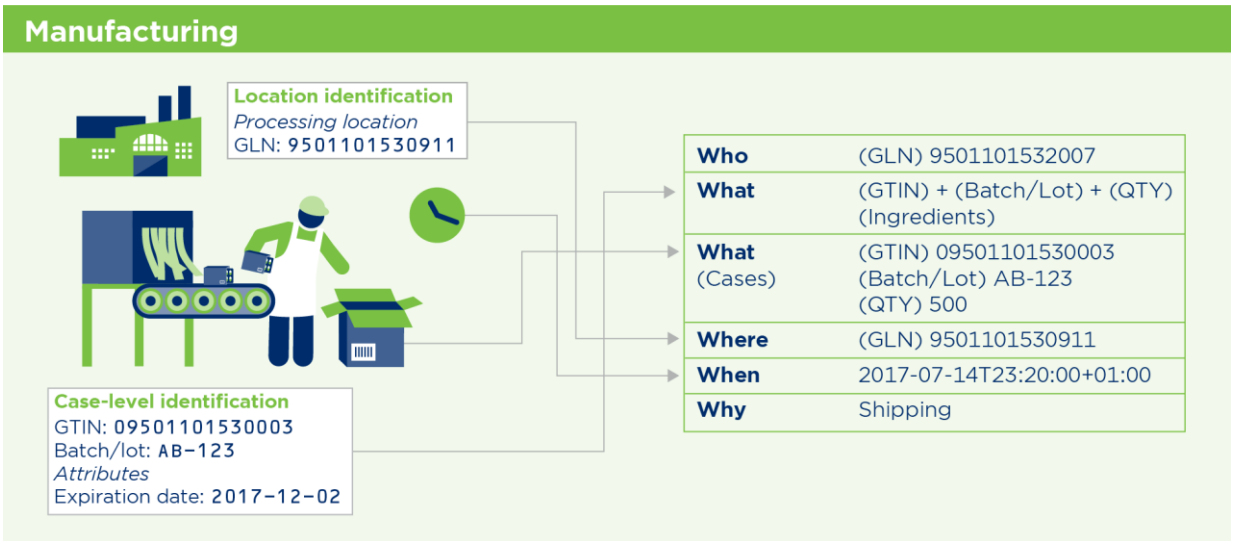
This chapter provides high-level information about the pharmaceutical supply chain to provide background about key business processes, types of EPCIS events available to support those processes, and current industry challenges.

3.1 High-Level Business Process Workflow

3.1.1 Manufacturing

The manufacturer transforms ingredients into final products, and then packs the products into cases. To maintain traceability, the inputs and outputs of the process are recorded on batch/lot and serialized levels.

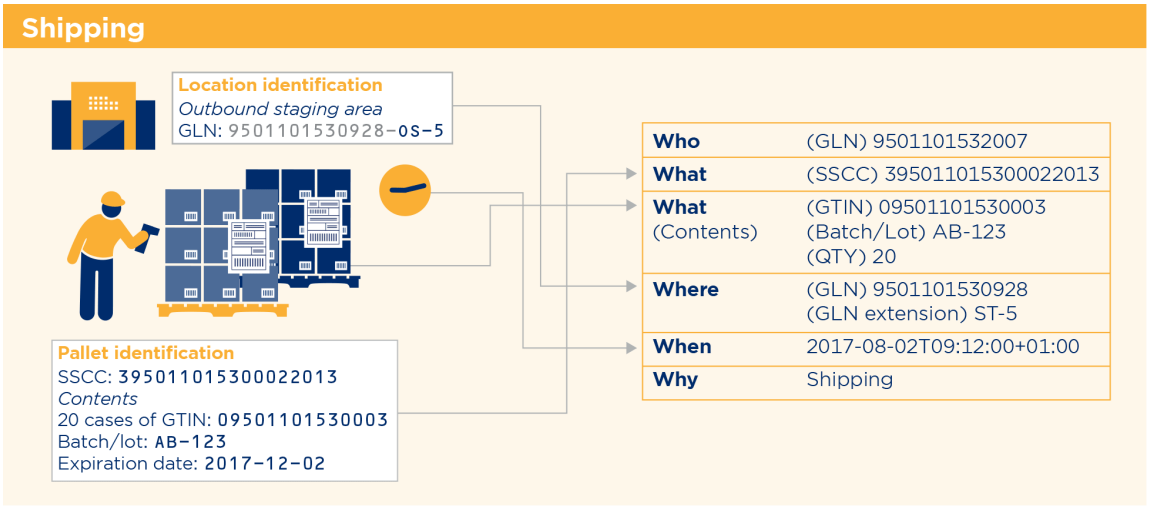
Figure 3-1 Manufacturing Workflow



3.1.2 Shipping

The warehouse department picks the cases and packs them onto pallets. During this process, the warehouse records the link between the product identifiers (i.e., Global Trade Item Number® (GTIN®) + batch/lot + serial number) and pallet identifiers (i.e., Serial Sipping Container Codes (SSCC)) to support traceability. Subsequently, the pallets are moved to the outbound staging area to be collected by the transportation carrier.

Figure 3-2 Shipping Workflow

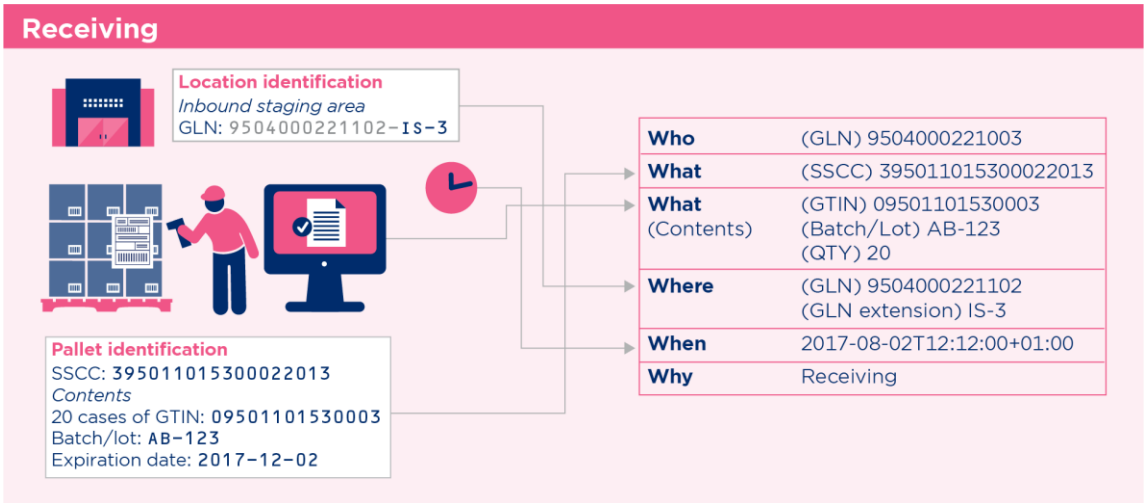


3.1.3 Receiving

The pallets arrive in the downstream trading partner distribution centers. The receiving team inspects the received goods by scanning the SSCCs on the pallet label and comparing physical goods on the pallet to the pre-registered information about the pallet contents in the system. Once validated, the goods are marked as available in the inventory management system.

Note: Receiving is being presented here to support an end-to-end overview of the business processes involved in moving products through the pharmaceutical supply chain. However, it should be noted that Receiving events are not currently part of DSCSA traceability requirements.

Figure 3-3 Receiving Workflow

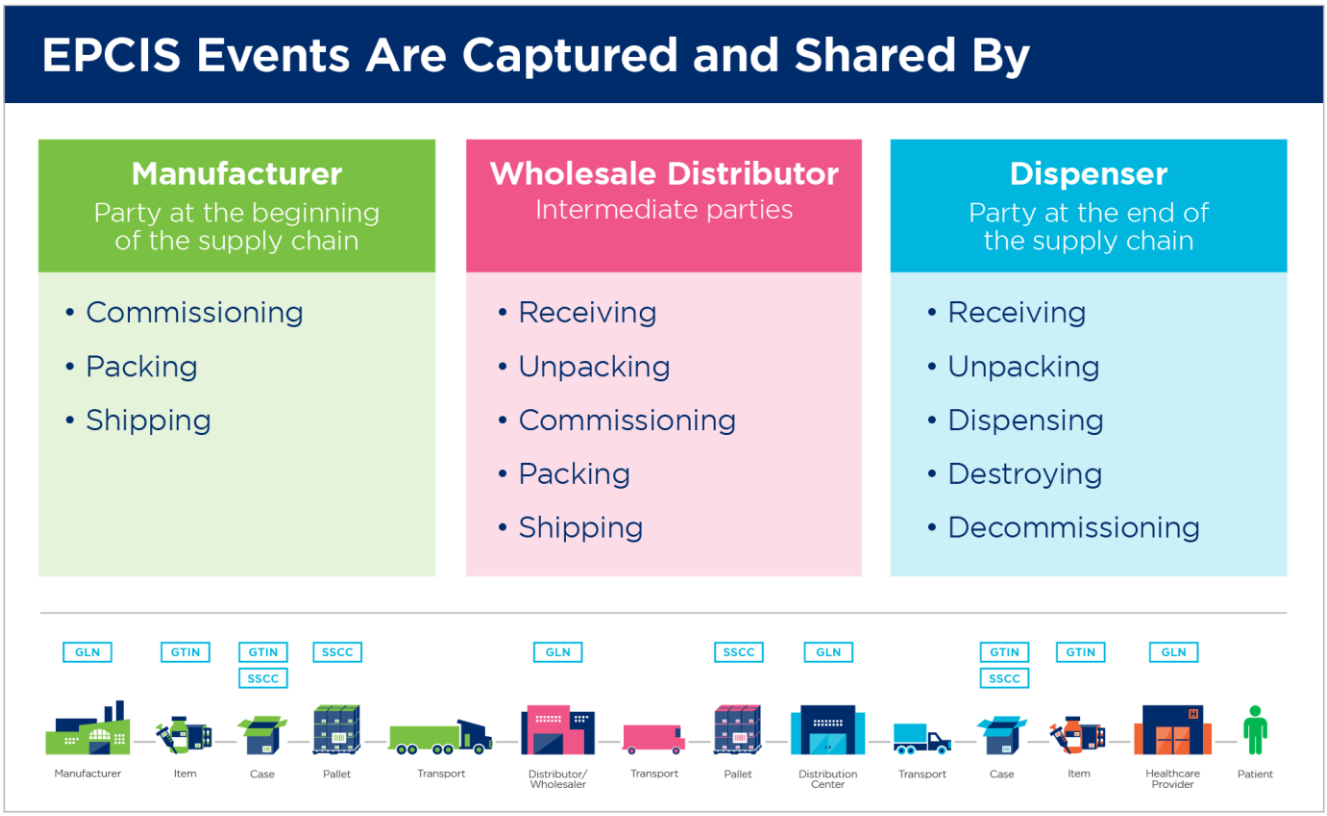


3.2 EPCIS Events for Pharmaceutical Business Processes

EPCIS events are discrete data files that record a pre-defined set of data about the movement and status of objects in the supply chain. Supply chain partners capture EPCIS events at key points in their business processes (e.g., packing, shipping, receiving, etc.). Trading partners can share EPCIS events to gain end-to-end visibility of the path products have taken through the supply chain, from manufacturer through to dispenser.

As shown below, the types of events captured by each supply chain partner depends on their role and the types of business processes they perform.

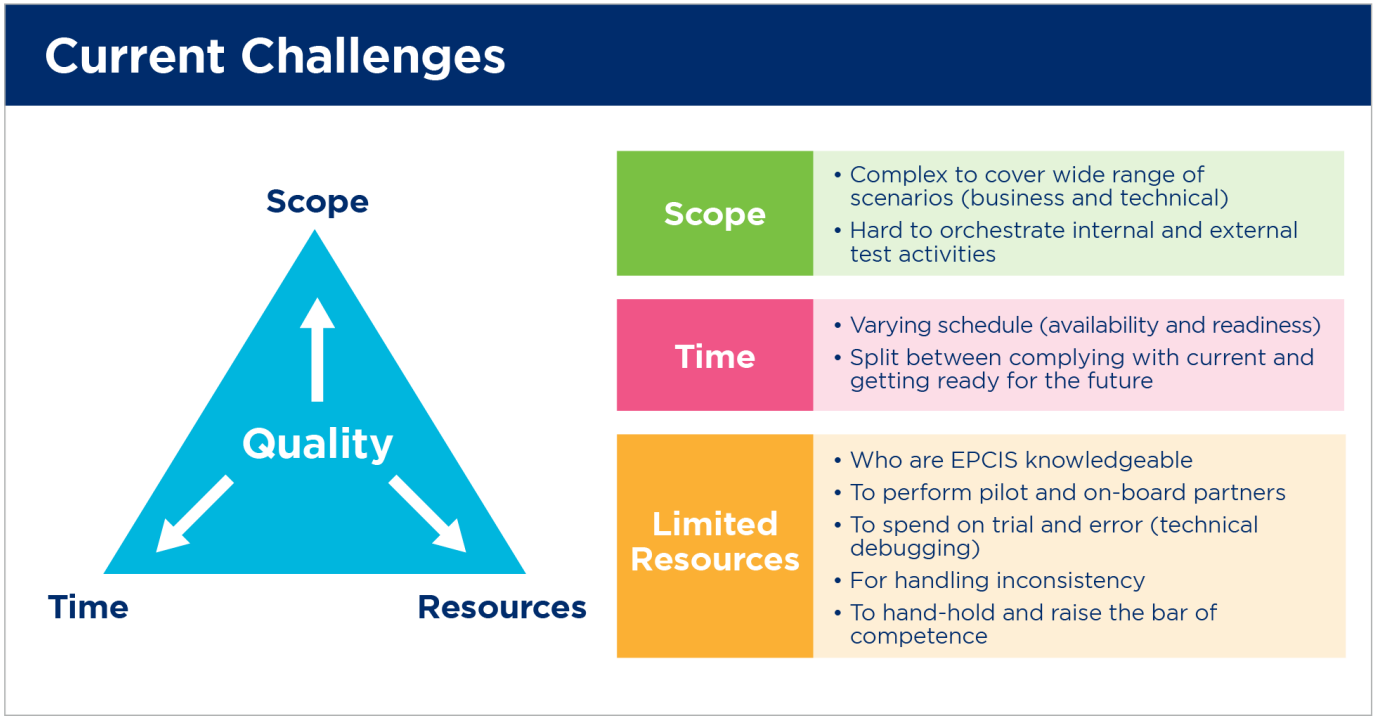
Figure 3-4 Examples of EPCIS Events for the Pharmaceutical Supply Chain



4 Industry Need for Conformance Testing

DSCSA requires pharmaceutical trading partners to share chain-of-ownership data in a manner that allows for serialized item traceability back to the product origin commencing in 2023. Many in the U.S. pharmaceutical industry have chosen to use EPCIS to support their DSCSA data exchange implementation. As they have been preparing their systems and business processes to meet DSCSA requirements, industry has encountered certain challenges related to the scope of the effort, time constraints, and limited resources.

Figure 4-1 Current Challenges



In response to these challenges, members of the U.S. pharmaceutical industry approached GS1 US about establishing a program to evaluate EPCIS event files for conformance to the GS1 US Rx Guideline. They sought technical validation of EPCIS event file structure and syntax in order to raise the baseline quality of messages, reduce upfront technical hurdles, and enhance confidence in trading partner readiness to engage in serialized exchanges. Industry believed that such a program could help them with the current challenges they are facing related to the scope of the effort, time constraints, and limited resources:

- **Optimize resources**
  - Less errors permits pilot testing to focus on more complex scenarios and exception handling
  - Minimize extra cost of iterations due to technical errors
  - Reduce overall implementation cost
  - Support industry efforts to channel resources in pursuit of value-add activities
- **Enhance time management**
  - Streamline trading partner on-boarding
  - Minimize time spent troubleshooting trading partner technical errors
  - Shorten implementation period making it easier to meet compliance milestones
- **Reduce the scope of the effort**
  - Focus pilot testing efforts on business requirements and scenarios
  - Increase time available for designing and exercising more complex use cases, choreographies and exceptions relevant to business operations

5 GS1 US Rx EPCIS Conformance Testing Program

5.1 Overview

The *GS1 US Rx EPCIS Conformance Testing Program* ("the Program") is a voluntary program offered to support pharmaceutical industry members implementing EPCIS for DSCSA and traceability pursuant to the GS1 US Rx Guideline. The Program is designed to validate that an EPCIS event file follows the format and structure defined in the GS1 US Rx Guideline to support interoperable EPCIS baseline functionality for the purposes of DSCSA serialized partner exchanges.

Conformance testing is designed to evaluate a trading partner's ability to produce EPCIS documents that conform to the GS1 US Rx Guideline. Although scoring is pass/fail, the testing results will offer diagnostic information and guidance to help submitters understand the issues that resulted in a failed conformance test. Therefore, the conformance testing program can be leveraged as both a tool to support the implementation process, and a validation of final output conformance. It is anticipated that conformance testing services will offer various pricing models, including subscriptions, to enable industry members to leverage the testing for either or both purposes.

Benefits:

- Offers a level of assurance about technical conformance and readiness to exchange of serialized information with trading partners pursuant to the GS1 US Rx Guideline
- Offers a testing platform with diagnostic information and guidance to help support a trading partner's implementation process

5.2 Program Features

Table 5-1 GS1 US Rx EPCIS Conformance Testing Program

Who will use the program?	▪ The program is designed for the sender of EPCIS events (whether the company themselves, or a solution provider on their behalf), also known as "EPCIS event generators." Specifically:
	  - Manufacturers
	  - Wholesaler/Distributors
	  - Solution Providers (on behalf of a manufacturer, wholesaler or distributor)
	▪ The program is not designed for receivers of events.

What is submitted for testing?	▪ EPCIS event files generated by a system capable of creating EPCIS messages based on the GS1 US Rx Guideline.
What does the Program test for?	▪ Structural and syntactical adherence to the GS1 US Rx Guideline. ▪ Confirmation that generated EPCIS messages are consumable. ▪ Verification of a string of discrete events related to a shipment. ▪ Confirmation that a single electronic EPCIS document covers sequence and events related to shipment.
When would a company use conformance testing?	▪ Throughout development of system to generate of EPCIS messages pursuant to the GS1 US Rx Guideline ▪ At initial Implementation of a system to generate of EPCIS messages pursuant to the GS1 US Rx Guideline ▪ Upon on-boarding a Trade Partner ▪ Upon failure to process an EPCIS message to/from trading partners ▪ When a relevant software module is being developed, updated and/or released

How will the Program be implemented?	▪ GS1 US will certify third party testing services to administer the conformance tests ("certified conformance testing service"). ▪ GS1 US will oversee program and award GS1 US Conformance Trustmarks to EPCIS event generators for each role-based test scenario they pass.
What does a company get for passing a conformance test?	▪ Final Conformance Testing Report for GS1 US Conformance Trustmark ▪ GS1 US Rx EPCIS Trustmark ***The report and Trustmark are awarded for a specific scenario pursuant to a specific version of the GS1 US Rx Guideline.**

Note: The GS1 US Rx EPCIS Conformance Testing Program is NOT the same as GS1 EPCIS certification program, and is NOT a substitute for software validation testing. The GS1 US Rx EPCIS Conformance Testing Program DOES NOT:

- test for DSCSA compliance
- test the accuracy of the data
- address EPCIS transport mechanism
- replace trading partner pilots

5.3 GS1 US Conformance Testing Scenarios

Conformance testing under the Program is based on a set of role-based test scenarios developed by the *GS1 Healthcare US® R1.2 Implementation Guideline Workgroup*. Each scenario presents a unique use case of pre-defined operational considerations (e.g., supply chain role, number of purchase orders in the shipment, drop shipment, direct shipment, etc.). For example:

- Manufacturer: Single Purchase Order with Aggregation
- Manufacturer: Multiple Purchase Orders without Aggregation for Drop Shipment
- Wholesaler: Single Purchase Order with Aggregation and with complete Direct Purchase
- Wholesaler: Multiple Purchase Orders without Aggregation and partial Direct Purchase

EPCIS event generators submit EPCIS event files for the scenario(s) which are applicable to their business operations, and conformance testing will then test the EPCIS event file for technical conformity to the GS1 US Rx Guideline. This scenario-based approach provides flexibility for pharmaceutical manufacturers and wholesalers to undergo conformance testing for scenarios which are applicable to their particular business operations.

To date, 16 conformance testing scenario have been defined. EPCIS event generators can submit EPCIS event files for whichever scenario(s) they choose. Conformance test scenarios are described in the *Conformance Testing chapter* of this Program Guide.

5.4 Program Phases

The Program is being rolled out in three phases:

- Phase 1: Manufacturers to their downstream trading partners
- Phase 2: Wholesalers to Dispensers
- Phase 3: Exceptions and Returns (future phase)

Each phase encompasses a specific set of role-based test scenarios. The *Conformance Testing chapter* below details the Phase 1 and Phase 2 conformance test scenarios. Phase 3 (Exception and Returns) will be covered in a future update to this document.

5.5 Certified Third Party Conformance Testing Services

Conformance testing under this Program will be conducted by third-party testing services certified by GS1 US ("certified conformance testing service"). Certified conformance testing services will be able to conduct conformance testing for all test scenarios. GS1 US will certify third-party testing services that satisfy the *Certification Requirements for Third Party Testing Services* defined in this document.

GS1 US provides this certification as a convenience and this does not constitute or imply an endorsement, recommendation or favoring by GS1 US of any identified companies, products or services. GS1 US does not warrant or guarantee any of the products or services identified, nor does it assume any legal liability or responsibility with respect to them.

5.6 Alignment GS1 US Rx Guideline Versions

The GS1 US Rx EPCIS Conformance Testing Program is based on the GS1 US Rx Guideline. The Program will maintain alignment and keep pace with the guideline:

- Third-party testing services are certified for specific version of the guideline.
- Conformance testing scenarios are based on a specific version of the guideline.
- GS1 US Rx EPCIS Trustmarks are awarded for a specific scenario and version of the guideline.

The Program is being launched on GS1 US Rx Guideline R1.2.

- R1.2 is the current version of the guideline. It is based on EPCIS 1.2 and Core Business Vocabulary (CBV) 1.2.
- Some in industry are still transitioning from EPCIS 1.1 to EPCIS 1.2. Therefore, the initial launch of the Program accommodates a certain level of conformance testing for both implementation environments. Specifically:
  - If an EPCIS 1.2 event file is submitted, the testing will evaluate the EPCIS event file for conformance with GS1 US Rx Guideline R1.2
  - If an EPCIS 1.1 event file is submitted, the testing will be for diagnostic purposes only against the EPCIS 1.1 Standard (and not the GS1 US Rx Guideline)

Going forward, the Program will keep pace with updated releases of the GS1 US Rx Guideline.

- Conformance testing scenarios will be defined for any future version(s) of the guideline.
- Third-party testing services can be updated/supplemented to accommodate future version(s) of the guideline and conformance testing scenarios, and then apply to be certified for that version(s) of the guideline.
- EPCIS event generators can undergo conformance testing based on future scenarios and version(s) of the guideline to obtain additional GS1 US Rx EPCIS Trustmarks for those scenarios and version(s).

6 Conformance Testing

6.1 Overview

GS1 US Rx EPCIS conformance testing is based on a set of role-based test scenarios. Each scenario presents a unique use case of pre-defined operational considerations (e.g., supply chain role, number of purchase orders in the shipment, drop shipment, direct shipment, etc.). Scenarios correspond to a specific version of the GS1 US Rx Guideline. This scenario-based approach provides the necessary

flexibility for pharmaceutical manufacturers and wholesalers to undergo conformance testing for scenarios which are applicable to their particular business operations.

EPCIS event generators submit EPCIS event files for the scenario(s) which are applicable to their business operations, and conformance testing will then test the EPCIS event file for technical conformity to the GS1 US Rx Guideline.

6.2 Conformance Testing Scenarios

Each conformance testing scenario presents a unique use case of pre-defined operational considerations. The associated variables embodied in the scenarios are defined in the table below.

Table 6-1 Variables of Conformance Testing Scenarios

Scenario Variable	Definition	Values
EPCIS Generator	The party generating the EPCIS Event	▪ Manufacturer ▪ Wholesaler ▪ Solution Provider (on behalf of their customer)
PO Qty	Whether the activity is reflects a single purchase order (PO) or multiple PO's	▪ Single PO ▪ Multiple PO
Aggregation	Whether the EPCIS event file contains one or more Aggregation events	▪ No ▪ Yes ▪ Both (mixture of aggregated and non-aggregated products)
Ship Timing	The timing of shipping events relative to the transaction time	▪ Any ▪ GT 24 hrs *(i.e., shipping time is greater than 24 hours after transaction time)*
Other Variables	Other information need to define the scenario	▪ None ▪ Drop Shipment ▪ Complete Direct Purchase[2] ▪ Partial Direct Purchase[3]

All of the GS1 US conformance testing scenarios are provided in a spreadsheet entitled *GS1 US Rx EPCIS Conformance Test Scenarios - Phase 1 + 2*. For each scenario, the spreadsheet provides the Scenario ID#, Scenario Description, and references to the governing sections of the GS1 US Rx Guideline. In addition, the spreadsheet also defines the parameters (i.e., the specific value for the variables shown above) applicable to each scenario.

The GS1 US Rx EPCIS Conformance Testing Program is being rolled out in three phases. Each phase encompasses a specific set of role-based test scenarios, as described in the table below.

Table 6-2 Phases of the GS1 US Rx EPCIS Conformance Testing Program

Phase	Description	Number of Scenarios
Phase 1	Manufacturer to Downstream Trading Partners Test Scenarios	7
Phase 2	Wholesaler to Dispenser Test Scenarios	9
Phase 3	Exception and Return Test Scenarios (future phase)	TBD

This chapter details Phase 1 and Phase 2 conformance test scenarios. Phase 3 (Exception and Returns) will be covered in a future update to this document.

[2] *Direct Purchase* means that products were purchased directly from the manufacturer, from the exclusive distributor of the manufacturer, or from a re-packager that purchased directly from the manufacturer.
[3] *Partial Direct Purchase* means that some of the serialized products in the shipment were directly purchased (see section 14.3.2 of GS1 US Rx Guideline R1.2).

6.3 Phase 1 Test Scenarios

Phase 1 includes seven (7) testing scenarios for EPCIS event files from the manufacturer to downstream trading partners based on R1.2 of the GS1 US Rx Guideline. The Phase 1 scenarios are listed below, and detailed information for each scenario can be found in the companion Excel spreadsheet *GS1 US Rx EPCIS Conformance Test Scenarios - Phase 1 + 2*.

Table 6-3 Phase 1 Conformance Testing Scenarios -- *manufacturer to downstream trading partners*

Scenario ID#	Scenario Description
01	Single Purchase Order without Aggregation
02	Single Purchase Order with Aggregation
03	Multiple Purchase Orders with and without Aggregation
04	Multiple Purchase Orders without Aggregation where shipment date is greater than 24 hours after transaction date
05	Multiple Purchase Orders with Aggregation where shipment date is greater than 24 hours after transaction date
06	Multiple Purchase Orders without Aggregation for Drop Shipment
07	Multiple Purchase Orders with Aggregation for Drop Shipment

6.4 Phase 2 Test Scenarios

Phase 2 includes nine (9) testing scenarios for EPCIS event files from wholesalers to dispensers based on R1.2 of the GS1 US Rx Guideline. The Phase 2 scenarios are listed below, and detailed information for each scenario can be found in the companion Excel spreadsheet *GS1 US Rx EPCIS Conformance Test Scenarios - Phase 1 + 2*.

Table 6-4 Phase 2 Conformance Testing Scenarios – *wholesaler to dispenser*

Scenario ID#	Scenario Description
08	Single Purchase Order without Aggregation
09	Single Purchase Order with Aggregation
10	Single Purchase Order without Aggregation and with complete Direct Purchase
11	Single Purchase Order with Aggregation and with complete Direct Purchase
12	Multiple Purchase Orders with and without Aggregation
13	Multiple Purchase Orders without Aggregation where shipment date is greater than 24 hours after transaction date
14	Multiple Purchase Orders with Aggregation where shipment date is greater than 24 hours after transaction date
15	Multiple Purchase Orders without Aggregation and partial Direct Purchase
16	Multiple Purchase Orders with Aggregation and partial Direct Purchase

6.5 Scoring

- EPCIS event generators submit an EPCIS event file for each scenario for which they would like to undergo conformance testing. Each EPCIS event file is tested and scored individually.
- Conformance test scoring is Pass/Fail.

- A passing score is awarded when an EPCIS event file fully conforms to the GS1 US Rx Guideline for the specific scenario.
- If an EPCIS event file fails conformance testing, diagnostic information and guidance are provided to help submitters understand the issue(s) that resulted in a failed conformance test.
- EPCIS event files can be resubmitted and retested without adverse impact to scoring. Resubmission of EPCIS event files is permitted and encouraged until a passing score is achieved.

6.6 Awarding of a GS1 US Rx EPCIS Trustmark

When an EPCIS event file successfully passes conformance testing, the submitting company will receive a *Final Conformance Testing Report for GS1 US Trustmark* from the third-party testing service, and a GS1 US Rx EPCIS Trustmark from GS1 US.

- GS1 US will issue a GS1 US Rx EPCIS Trustmark when an EPCIS event file successfully passes conformance testing by a GS1 US-certified conformance testing service.
  - GS1 US Rx EPCIS Trustmarks are specific to supply chain role, conformance testing scenario, and GS1 US Rx Guideline version.
  - Companies will receive a GS1 US Rx EPCIS Trustmark for each conformance testing scenario they pass.
- A GS1 US Rx EPCIS Trustmark will only be awarded for conformance testing conducted by a GS1 US-certified conformance testing service.
- Companies awarded a GS1 US Rx EPCIS Trustmark have the opportunity to be listed as such on a GS1 US web-page (with their approval).
- The GS1 US Rx EPCIS Trustmark will be awarded by Supply Chain Role indicating the specific scenarios and guideline version passed. Examples:
  - Manufacturer
    - GS1 US Rx EPCIS Trustmark (Scenario 01 – R1.2): Single Purchase Order without Aggregation
    - GS1 US Rx EPCIS Trustmark (Scenario 02 – R1.2): Single Purchase Order with Aggregation
  - Manufacturer
    - GS1 US Rx EPCIS Trustmark (Scenario 03 – R1.2): Multiple Purchase Orders with and without Aggregation
    - GS1 US Rx EPCIS Trustmark (Scenario 04 – R1.2): Multiple Purchase Orders without Aggregation where shipment date is greater than 24 hours after transaction date
    - GS1 US Rx EPCIS Trustmark (Scenario 05 – R1.2): Multiple Purchase Orders with Aggregation where shipment date is greater than 24 hours after transaction date
  - Wholesaler
    - GS1 US Rx EPCIS Trustmark (Scenario 10 – R1.2): Single Purchase Order without Aggregation and with complete Direct Purchase
    - GS1 US Rx EPCIS Trustmark (Scenario 15 – R1.2): Multiple Purchase Orders without Aggregation and partial Direct Purchase
  - Solution Provider on behalf of Manufacturer
    - GS1 US Rx EPCIS Trustmark (Scenario 01 – R1.2): Single Purchase Order without Aggregation
    - GS1 US Rx EPCIS Trustmark (Scenario 02 – R1.2): Single Purchase Order with Aggregation

- GS1 US Rx EPCIS Trustmark (Scenario 03 – R1.2): Multiple Purchase Orders with and without Aggregation
- GS1 US Rx EPCIS Trustmark (Scenario 04 – R1.2): Multiple Purchase Orders without Aggregation where shipment date is greater than 24 hours after transaction date
- GS1 US Rx EPCIS Trustmark (Scenario 05 – R1.2): Multiple Purchase Orders with Aggregation where shipment date is greater than 24 hours after transaction date
- GS1 US Rx EPCIS Trustmark (Scenario 06 – R1.2): Multiple Purchase Orders without Aggregation for Drop Shipment
- GS1 US Rx EPCIS Trustmark (Scenario 07 – R1.2): Multiple Purchase Orders with Aggregation for Drop Shipment

- Solution Provider on behalf of Wholesaler
  - GS1 US Rx EPCIS Trustmark (Scenario 08 – R1.2): Single Purchase Order without Aggregation
  - GS1 US Rx EPCIS Trustmark (Scenario 09 – R1.2): Single Purchase Order with Aggregation
  - GS1 US Rx EPCIS Trustmark (Scenario 12 – R1.2): Multiple Purchase Orders with and without Aggregation

7 Certification Requirements for Third Party Testing Services

7.1 General

GS1 US will certify third-party testing services to conduct conformance testing for the GS1 US Rx EPCIS Conformance Testing Program. These third-party testing services will be automated systems that evaluate EPCIS messages for conformance to the GS1 US Rx Guideline.

- GS1 US will certify third-party testing services that satisfy the requirements defined in this chapter.
- Certified conformance testing services will be able to conduct conformance testing for all test scenarios.
- Applications for certification that are denied may be resubmitted once the issues causing the denial are resolved.
- Successful certification applications will result in the certified conformance testing service's name being placed on the GS1 US website as a certified partner.

GS1 US provides this certification as a convenience and this does not constitute or imply an endorsement, recommendation or favoring by GS1 US of any identified companies, products or services. GS1 US does not warrant or guarantee any of the products or services identified, nor does it assume any legal liability or responsibility with respect to them.

7.2 GS1 US Rx Guideline

The GS1 US Rx EPCIS Conformance Testing Program is based on the GS1 US Rx Guideline: conformance testing scenarios are based on a specific version of the guideline, and third-party testing services are certified for a specific version of the guideline.

The Program is being launched on GS1 US Rx Guideline R1.2.

- Initial applications for certification are to be based on R1.2.
  - R1.2 is the current version of the guideline. It is based on EPCIS 1.2 and Core Business Vocabulary (CBV) 1.2. Some in industry are still transitioning from EPCIS 1.1 to EPCIS 1.2.

Therefore, the initial launch of the Program is designed to accommodate a certain level of testing for both implementation environments. Specifically:

- If an EPCIS 1.2 event file is submitted, the testing will evaluate the EPCIS event file for conformance with GS1 US Rx Guideline R1.2
- If an EPCIS 1.1 event file is submitted, the testing will be for diagnostic purposes only against the EPCIS 1.1 Standard (and not the GS1 US Rx Guideline)

- Third-party testing services applying for certification must support both of these levels of conformance testing for R1.2.

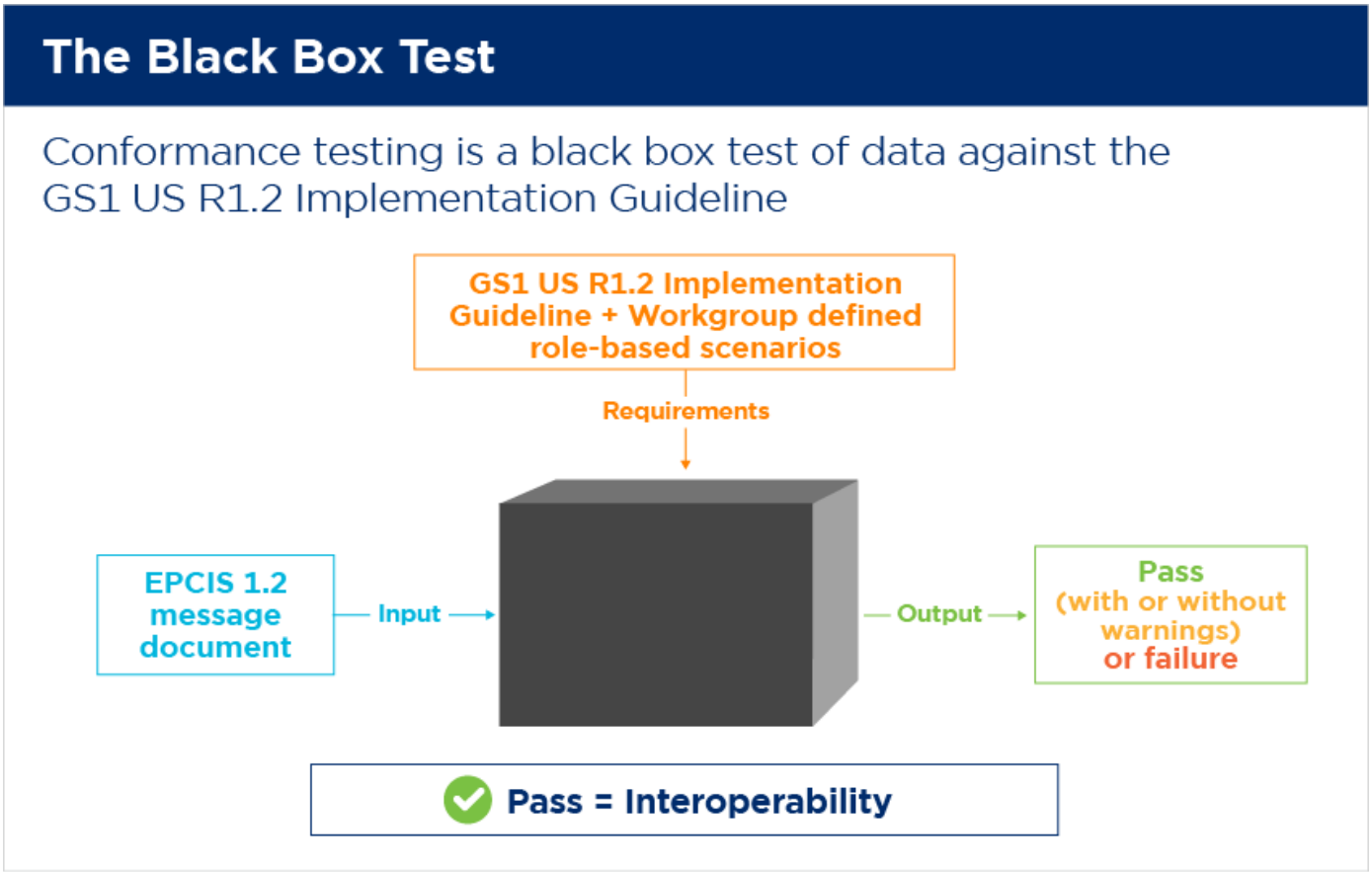
Going forward, the Program will keep pace with updated releases of the GS1 US Rx Guideline.

- Conformance testing scenarios will be updated/supplemented to accommodate future version(s) of the guideline.
- Third-party testing services can be updated/supplemented to accommodate future version(s) of the guideline and conformance testing scenarios, and then apply to be certified for that version(s) of the guideline.

7.3 Conceptual Architecture

The conceptual architecture of a third party conformance testing service is a "Black Box" tool that tests EPCIS event files against the GS1 US Rx Guideline. The architecture would include a web portal, redundancy and scalable components.

Figure 7-1 Conceptual "Black Box" Tool for Conformance Testing



7.4 Technical Requirements

7.4.1 System Requirements

Req. No	Requirement Description
7.4.1.1	The test system shall provide a user friendly graphical user interface access through a web browser.
7.4.1.2	The test system at a minimum provide a graphical user interface (GUI) enabling manufacturers, wholesalers, distributors, and solution providers to perform the following: ▪ Register Company (i.e., enter the company information to create an "account") ▪ Submit EPCIS Event Files for conformance testing ("test files") ▪ Generate Reports
7.4.1.3	The test system shall support the creation and administration of multiple user accounts per company.

7.4.2 Registrant Configuration

Req. No	Requirement Description
7.4.2.1	The test system shall at a minimum capture the following information about the company registering for conformance testing: ▪ Company Name ▪ Company Address ▪ Company Phone ▪ Contact Name ▪ Contact Email ▪ Contact Phone
7.4.2.2	The test system shall at a minimum enable the registering company to specify the various relevant roles that the company performs in its business functions. ▪ Manufacturer ▪ Wholesaler ▪ Solution Provider (acting on behalf of the above roles) For example, a company with distribution and repackaging functions will specify Wholesaler.
7.4.2.3	The test system shall at a minimum capture all of the relevant EPCIS versions that the registering company supports. For example, a company who can only generate events using EPCIS 1.1 will specify EPCIS 1.1. A company who can generate events using EPCIS 1.1 and EPCIS 1.2 will specify both versions.

7.4.3 Conformance Test Initiation and Submission

Req. No	Requirement Description
7.4.3.1	The test system shall enable a registered company to upload EPCIS event files via a portal for automated conformance testing.
7.4.3.2	The test system shall enable unlimited resubmissions of EPCIS event files for testing.
7.4.3.3	The test system shall evaluate each submitted EPCIS event file as a single submission and independently validate the submitted EPCIS event file based on the test case scenario specified by the submitter.

Req. No	Requirement Description

7.4.3.4	The test system shall at a minimum enable the submitter to specify the following submission information:
	▪ Test Scenario ID
	▪ Supply Chain Role (the role generating the test file - e.g., manufacturer, wholesaler, etc.)
	  ▪ Solution providers who are submitting a test file shall indicate which supply chain role they are simulating to generate the test file.
	  ▪ Similarly, companies who perform multiple business functions shall indicate which supply chain role they are simulating to generate the test file.
	▪ Test File Name
	▪ EPCIS Version (1.2 or 1.1)

7.4.3.5	The test system shall at a minimum capture the date and time the EPCIS event file was submitted, and the name of the company and the user who submitted the test file.
7.4.3.6	The test system shall at a minimum generate and assign a unique Submission ID and associate this with the submission information. This system generated Submission ID will be referenced in subsequent reports.
7.4.3.7	The test system shall support the submission of XML test files.

7.4.4 Conformance Test Tracking

Req. No	Requirement Description
7.4.4.1	The test system shall enable participants to track and report progress against scenario requirements.
7.4.4.2	When an EPCIS event file receives a passing score, the system shall notify the participant and GS1 US of the participant's qualification to receive a GS1 US Rx EPCIS Trustmark.

7.4.5 Security Requirements

Req. No	Requirement Description
7.4.5.1	The test system shall validate that user accounts created are associated only with companies that have been authorized to access the test system.
7.4.5.2	The test system shall have the utility to enable users to reset their passwords.
7.4.5.3	The test system shall be designed to assure data confidentiality by segregating data by company.
7.4.5.4	The test system shall assure that only authorized individuals will be permitted to have access to data, files, and the underlying system.

7.4.6 Notifications, Alerts, Communication

Req. No	Requirement Description
7.4.6.1	Upon the completion of conformance testing evaluation, the test system shall notify users via e-mail.
7.4.6.2	The email notification shall include link to the resulting conformance test submission reports.

7.4.7 General Reporting Requirements

Req. No	Requirement Description
7.4.7.1	The test system shall facilitate querying and viewing of conformance test submission information at summary and detail level.
7.4.7.2	The test system shall support interactive viewing of test submission results on the screen.
7.4.7.3	The test system shall enable user to successively drill down summary level result data to more detail data relevant for the type of report requested.
7.4.7.4	The test system shall support the export of report content into PDF or CSV.
7.4.7.5	The test system shall at a minimum support the generation of the following report types: ▪ Submission Test Result Report (conformance testing results by test case and submission) ▪ Summary Progress Report ▪ Final Conformance Testing Report (for GS1 US Rx EPCIS Trustmark)

7.4.8 Submission Test Result Report

Req. No	Requirement Description
7.4.8.1	The test system shall generate a Submission Test Result Report that provides the processing outcome of the test file for a particular conformance test case scenario.
7.4.8.2	The user can access a specific Submission Test Result Report by clicking on the link from the system notification email sent to the user upon the completion of processing of test file submission.

7.4.8.3	The test system shall at a minimum provide the users the option to specify the following report parameters to access specific Submission Test Result Reports:
	▪ Submission Date (Mandatory)
	▪ Optional Filters:
	  ▪ Submission ID
	  ▪ Supply Chain Role
	  ▪ Scenario ID
	Upon entering the submission date, the test system shall at a minimum facilitate narrowing user selection by displaying the submission IDs, supply chain role, scenario level and scenario IDs matching specified submission date.

7.4.8.4	The test system shall validate report parameters entered and inform the user of any issues preventing the generation of requested report.

7.4.8.5	The Submission Test Result Report shall at a minimum include both a summary and detail section.
	▪ The Summary Section shall at a minimum contain two sections:
	  ▪ Submission Information
	  ▪ Test File Content Profile
	▪ The Detail Section shall at a minimum contain two parts:
	  ▪ Listing of Identifiers found in the submitted test file
	  ▪ EPCIS Events in XML in the submitted test file
	(See the appendices for an *example of the Summary Section*, and an *example of the Detail Section*.)

Req. No	Requirement Description
7.4.8.6	The Submission Information in the Summary Section shall at a minimum contain the following information: ▪ Test Scenario Case No. associated with the submission ▪ Supply Chain Role associated with the submission ▪ Submitted Test File Name ▪ EPCIS Version (1.2, 1.1) ▪ Outcome of processing test file against specified test case scenario (either Pass or Fail) ▪ Submission Date and Time ▪ Company who submitted the test file ▪ Name of the specific user who submitted the test file (See the appendix for an *example*.)

7.4.8.7	The Test File Content Profile in the Summary Section shall at a minimum include a breakdown of identifiers and EPCIS events found in the test file. (See the appendix for an *example*.)
	▪ The breakdown of identifiers shall at a minimum list the number of unique GTINs, SSCCs, GLNs and alternate party identifier (i.e., DEA number) found in the field.
	▪ The breakdown of EPCIS events shall at a minimum list:
	  ▪ the number of commissioning, packing, and shipping events found in the file,
	  ▪ the number of commissioning, packing, and shipping events that passed the test validation, and
	  ▪ the number of commissioning, packing and shipping events that failed the test validation.

7.4.8.8	The Listing of Identifiers in the Detail Section shall at a minimum enumerate the unique identifier values represented by the identifier count in the Summary Section that lists the breakdown of identifiers. (See the appendix for an *example*.) ▪ For example, if there were 10 GTINs listed in the Summary Section, the Detail Section shall at a minimum show each GTIN value (GTIN1, GTIN2, GTIN3, GTIN4, GTIN5, GTIN6, GTIN7, GTIN8, GTIN9, and GTIN10). For each identifier found within submitted test file, the Listing of Identifiers in the Detail Section shall show count and provide the ability to easily navigate to each instance of the identifier within the submitted test file XML.
7.4.8.9	The Events in the Detail Section shall at a minimum show the specific XML representation of each event found. (See the appendix for an *example*.)
7.4.8.10	For failed instances of events, the Submission Test Result Report shall at a minimum provide a detailed explanation for the failure referencing the exact location and nature of the failure. ▪ Errors and failed instances shall be highlighted in the report. ▪ Error details shall include references to specific sections of the GS1 US Rx Guideline. ▪ Include recommendations for possible fixes to correct the error
7.4.8.11	The Submission Test Result Report shall flag as a warning, instances where the submitted test file did not follow the recommended references in the GS1 US Rx Guideline to the following guidelines: ▪ *GS1 RFID Bar Code Interoperability Guideline* ▪ *Healthcare Provider GTIN Tool Kit* ▪ *Healthcare Supplier GTIN Tool Kit* ▪ *Healthcare Provider GLN Tool Kit* ▪ *Healthcare Supplier GLN Tool Kit* ▪ *Healthcare Provider GDSN Tool Kit* ▪ *Healthcare Supplier GDSN Tool Kit* ▪ *The Practice of Inference in the U.S. Pharmaceutical Supply Chain*

7.4.9 Summary Progress Report

Req. No	Requirement Description
7.4.9.1	The test system shall generate a Summary Progress Report that provides a cumulative view of test results for all of the test files that a user company has submitted over a specified period.

7.4.9.2	The test system shall at a minimum provide users the option to specify the following report parameters:
	▪ Submission Period (Start & End Date)
	▪ Optional Filters:
	  ▪ Scenario ID
	  ▪ Submission Result (Pass/Fail)
	  ▪ Supply Chain Role
	▪ Order By
	  ▪ Submission Date
	  ▪ Scenario ID
	Upon entering the submission period, the test system shall at a minimum facilitate narrowing user selection by displaying the submission IDs, supply chain role, and scenario IDs matching the specified submission dates.

7.4.9.3	The test system shall validate report parameters entered and inform the user of issues preventing the generation of requested report.
7.4.9.4	The Summary Progress Report shall display: ▪ Submission Period (Start Date and End Date) ▪ Supply Chain Role ▪ Submission List (test scenario submitted during the specified period)
7.4.9.5	For each submitted test scenario in the Submission List, the Summary Progress Report shall show: ▪ Submission ID ▪ Submission Date/Time ▪ Scenario ID and Description ▪ Submission Result
7.4.9.6	The test system shall give the user the ability to drill down to submission details for each submitted test scenario in the Submission List. The submission details accessible from the Summary Progress Report will be identical to the content generated for Submission Test Result Report. ▪ See the appendix for an example of the *Summary section* ▪ See the appendix for an example of the *Listing of Identifiers* ▪ See the appendix for an example of an *Event XML*

7.4.10 Final Conformance Testing Report (for GS1 US Rx EPCIS Trustmark)

Req. No	Requirement Description
7.4.10.1	The test system shall generate a Final Conformance Testing Report (for GS1 US Rx EPCIS Trustmark) for any/all submitted test files that pass conformance testing.
7.4.10.2	The test system shall at a minimum provide users with the option to specify the following report parameters: ▪ Supply Chain Role
7.4.10.3	The test system shall validate report parameters entered and inform the user of issues preventing the generation of requested report.

Req. No	Requirement Description
7.4.10.4	The Final Conformance Testing Report content shall at a minimum include the following: ▪ Submitting Company ▪ Supply Chain Role ▪ Conformance Test Firm ▪ EPCIS Version ▪ GS1 US Guideline Version *.* ▪ GS1 US Rx EPCIS Trustmark Award Date ▪ List of specific test scenario IDs that were successfully passed (See examples in the *appendix*.)

7.4.11 Performance

Req. No	Requirement Description
7.4.11.1	The test system shall complete conformance test evaluation of submitted test file within 10 minutes.

7.4.12 Availability

Req. No	Requirement Description
7.4.12.1	The test system shall provide 24/7/365 availability except for planned downtimes related to hardware and/or software maintenance.
7.4.12.2	The test system shall be designed with failover capability to assure high system availability.
7.4.12.3	The test system shall perform regularly scheduled maintenance during fixed and published time windows.
7.4.12.4	The test system shall communicate planned maintenance 24 hours in advance of system in availability.

7.4.13 Reliability

Req. No	Requirement Description
7.4.13.1	In case of communication or network failure, the test system shall assure that received submissions are maintained and are accessible upon communication or network reconnection.
7.4.13.2	The test system shall be designed for durability such that the system can tolerate loss of server without negatively impacting previously received test data and previously recorded test evaluations.

7.4.14 Scalability

Req. No	Requirement Description
7.4.14.1	The test system shall accept and process concurrent submissions of test files.
7.4.14.2	The test system shall have the capability to accept and process multiple concurrent conformance test report requests.

7.4.15 Retention Policy

Req. No	Requirement Description
7.4.15.1	The test system shall maintain data within one year from conformance test submission in an online storage device optimized for access.
7.4.15.2	After the first year, test data submissions and results will be archived with the testing firm for up to six years.

7.4.16 Usability

Req. No	Requirement Description
7.4.16.1	The test system shall enable the user to navigate the system with no training required.
7.4.16.2	The test system shall provide online help and user documentation.

7.4.17 Support

Req. No	Requirement Description
7.4.17.1	Service Level Agreements (SLA) between the Third Party Conformance Testing Firm and participating companies shall be established with processes that measure and monitor adherence to SLA.
7.4.17.2	Key Performance Indicators (KPIs) for the SLA shall include but not be limited to system availability, system performance, and help desk support.

7.5 Applying for Certification

GS1 US is currently finalizing the mechanics of how third-party testing firms will apply for certification (e.g., web page, contact, email address, portal, launch date, etc.). Final details will be available in the coming weeks, and this document will be updated with that information as soon as it is finalized.

Appendix A. Submission Test Result Report - Example

A.1 Summary Section

REPORT DATE	April 15, 2019		
SUBMISSION INFORMATION			
Submitting Company	XYZ Pharmaceutical Company		
Submitting User Name	Mary Smith		
Submission Date and Time	2018-03-01T15:10:16Z		
Submitted Test File Name	ABCTESTFILE - SMITH		
Submission ID	100		
Test Scenario	ID # 01-Single Purchase Order without Aggregation		
Supply Chain Role in Submission	Manufacturer		
EPCIS Version	1.2		
Submission Result	Pass		
TEST FILE CONTENT PROFILE			
IDENTIFIERS	Usage / Total Count		
GTIN			
SSCC			
GLN			
Alternate Party Identifier: DEA Number			
EVENTS	Total Count	**# Passed**	**# Failed**
Commissioning	12	10	2
Packing	6	1	5
Shipping	26	20	6

A.2 Detail Section

A.2.1 Listing of Identifiers

Identifiers	Instance Values*	Total Usage / Count
GTIN	GTIN1	4
	GTIN2	3
	GTIN3	3
	GTIN4	5
	GTIN5	4
SSCC	SSCC1	2
	SSCC2	2
GLN	GLN1	3
	GLN2	4
	GLN3	3
Alternate Party Identifier: DEA Number	DEA1	2

**plus ability to easily navigate to each instance of the identifier within submitted XML*

A.2.2 Event XML (with Highlighted Failed Instances)

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- XML Examples for Conformance Testing -->
<!-- Identifiers:
SGTIN: 030001.0012345, 030001.1012345
SGLN: 030001.111111.0, 039999.999999.0,
SSCC: 030001.1234567890
PO: 0399999999991:XYZ567, 0399999999991:XYZ444
Delivery: 0300011111116:DL123

Count of Event BizSteps:
Commissioning 2
Packing 3
Shipping 2 (1 transaction event and 1 object event)

Errors (3)
Commissioning (SSCC) event time is greater than Packing
Packing (SSCC) event time is less than Commissioning
Shipping (SSCC) invalid URN in source and invalid sGLN in destination

-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-
1_2.xsd" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2017-11-
27T17:10:16Z">
      <EPCISHeader>
            <sbdh:StandardBusinessDocumentHeader>
                  <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
```

```
                  <sbdh:Sender>
                        <sbdh:Identifier
Authority="SGLN">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
                  </sbdh:Sender>
                  <sbdh:Receiver>
                        <sbdh:Identifier
Authority="SGLN">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
                  </sbdh:Receiver>
                  <sbdh:DocumentIdentification>
                        <sbdh:Standard>EPCglobal</sbdh:Standard>
                        <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                        <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
                        <sbdh:Type>Events</sbdh:Type>
                        <sbdh:CreationDateAndTime>2017-11-
27T17:10:16Z</sbdh:CreationDateAndTime>
                  </sbdh:DocumentIdentification>
            </sbdh:StandardBusinessDocumentHeader>
            <extension>
                  <EPCISMasterData>
                        <VocabularyList>
                              <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                                    <VocabularyElementList>
                                          <!-- master data for lowest saleable unit --
>
                                          <VocabularyElement
id="urn:epc:idpat:sgtin:030001.0012345.*">
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">00001012345</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">FDA_NDC_11</attri
bute>
                                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
                                          </VocabularyElement>
                                          <!-- master data for case -->
                                          <VocabularyElement
id="urn:epc:idpat:sgtin:030001.1012345.*">
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">00001012345</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">FDA_NDC_11</attri
bute>
                                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
```

```
                                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
                                          </VocabularyElement>
                                    </VocabularyElementList>
                              </Vocabulary>
                              <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                                    <VocabularyElementList>
                                          <!-- Seller -->
                                          <VocabularyElement
id="urn:epc:id:sgln:030001.111111.0">
                                                <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George Ave</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">12345-6789</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                          </VocabularyElement>
                                          <!-- Buyer -->
                                          <VocabularyElement
id="urn:epc:id:sgln:039999.999999.0">
                                                <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro LLC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">10003-1502</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                          </VocabularyElement>
                                    </VocabularyElementList>
                              </Vocabulary>
                        </VocabularyList>
                  </EPCISMasterData>
            </extension>
            <gs1ushc:dscsaTransactionStatement>

      <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
```

```
                <gs1ushc:legalNotice>Seller has complied with each applicable
subsection of FDCA Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
            </gs1ushc:dscsaTransactionStatement>
      </EPCISHeader>
      <EPCISBody>
            <EventList>
                  <!-- E1: Commissioning events (case SNs 123, 456 including relevant
lowest saleable unit SNs) -->
                  <ObjectEvent>
                        <eventTime>2017-11-25T17:10:16Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <epcList>
                              <epc>urn:epc:id:sgtin:030001.0012345.11</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.12</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.13</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.21</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.22</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.23</epc>
                              <epc>urn:epc:id:sgtin:030001.1012345.123</epc>
                              <epc>urn:epc:id:sgtin:030001.1012345.456</epc>
                        </epcList>
                        <action>ADD</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:active</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:030001.111111.0</id>
                        </readPoint>
                        <bizLocation>
                              <id>urn:epc:id:sgln:030001.111111.0</id>
                        </bizLocation>
                        <extension>
                              <ilmd>
                                    <cbvmda:lotNumber>A123</cbvmda:lotNumber>
                                    <cbvmda:itemExpirationDate>2019-03-
31</cbvmda:itemExpirationDate>
                              </ilmd>
                        </extension>
                  </ObjectEvent>
                  <!-- E2: Packing event (for case SN 123) -->
                  <AggregationEvent>
                        <eventTime>2017-11-25T17:10:18Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <parentID>urn:epc:id:sgtin:030001.1012345.123</parentID>
                        <childEPCs>
                              <epc>urn:epc:id:sgtin:030001.0012345.11</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.12</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.13</epc>
                        </childEPCs>
                        <action>ADD</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:packing</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:030001.111111.0</id>
                        </readPoint>
                        <bizLocation>
```

```
                        <id>urn:epc:id:sgln:030001.111111.0</id>
                  </bizLocation>
            </AggregationEvent>
            <!-- E2:Packing event (for case SN 456) -->
            <AggregationEvent>
                  <eventTime>2017-11-25T17:10:19Z</eventTime>
                  <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                  <parentID>urn:epc:id:sgtin:030001.1012345.456</parentID>
                  <childEPCs>
                        <epc>urn:epc:id:sgtin:030001.0012345.21</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.22</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.23</epc>
                  </childEPCs>
                  <action>ADD</action>
                  <bizStep>urn:epcglobal:cbv:bizstep:packing</bizStep>
                  <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                  <readPoint>
                        <id>urn:epc:id:sgln:030001.111111.0</id>
                  </readPoint>
                  <bizLocation>
                        <id>urn:epc:id:sgln:030001.111111.0</id>
                  </bizLocation>
            </AggregationEvent>
            <!-- E3: Commissioning events (for SSCC) -->
            <ObjectEvent>
                  <!-- Error: SSCC Commissioning event time is greater than
Packing event for SSCC.  Reference GS1 US Rx Guideline R1.2 Section 8.2.1 -->
                  <eventTime>2017-11-26T17:10:20Z</eventTime>
                  <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                  <epcList>
                        <epc>urn:epc:id:sscc:030001.1234567890</epc>
                  </epcList>
                  <action>ADD</action>
                  <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
                  <disposition>urn:epcglobal:cbv:disp:active</disposition>
                  <readPoint>
                        <id>urn:epc:id:sgln:030001.111111.0</id>
                  </readPoint>
                  <bizLocation>
                        <id>urn:epc:id:sgln:030001.111111.0</id>
                  </bizLocation>
            </ObjectEvent>
            <!-- E4:Packing event (for SSCC) -->
            <AggregationEvent>
                  <!-- Error: SSCC Packing event time is less than Commissioning
event for SSCC.  Reference GS1 US Rx Guideline R1.2 Section 8.2.1 -->
                  <eventTime>2017-11-26T17:10:19Z</eventTime>
                  <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                  <parentID>urn:epc:id:sscc:030001.1234567890</parentID>
                  <childEPCs>
                        <epc>urn:epc:id:sgtin:030001.1012345.123</epc>
                        <epc>urn:epc:id:sgtin:030001.1012345.456</epc>
                  </childEPCs>
                  <action>ADD</action>
                  <bizStep>urn:epcglobal:cbv:bizstep:packing</bizStep>
```

```
                        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:030001.111111.0</id>
                        </readPoint>
                        <bizLocation>
                              <id>urn:epc:id:sgln:030001.111111.0</id>
                        </bizLocation>
                  </AggregationEvent>
                  <!-- Using a Transaction Event, record the shipping contents
specifically associated with PO# XYZ567 -->
                  <TransactionEvent>
                        <!-- Set eventTime in the transaction event to be prior to
eventTime of shipping event -->
                        <eventTime>2017-11-27T17:10:14Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <bizTransactionList>
                              <!-- Associate PO# XYZ567 to the EPCs in the business
transaction -->
                              <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:XYZ567</bizTransact
ion>
                        </bizTransactionList>
                        <epcList>
                              <epc>urn:epc:id:sgtin:030001.1012345.123</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.21</epc>
                        </epcList>
                        <action>ADD</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:030001.111111.0</id>
                        </readPoint>
                  </TransactionEvent>
                  <!-- E5: Using a Transaction Event, record the shipping contents
specifically associated with PO# XYZ444 -->
                  <TransactionEvent>
                        <!-- Set eventTime in the transaction event to be prior to
eventTime of shipping event  -->
                        <eventTime>2017-11-27T17:10:15Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <bizTransactionList>
                              <!-- Associate PO# XYZ444 to the EPCs in the business
transaction -->
                              <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:XYZ444</bizTransact
ion>
                        </bizTransactionList>
                        <epcList>
                              <epc>urn:epc:id:sgtin:030001.0012345.22</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.23</epc>
                        </epcList>
                        <action>ADD</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
                        <readPoint>
```

```
                              <id>urn:epc:id:sgln:030001.111111.0</id>
                        </readPoint>
                  </TransactionEvent>
                  <!-- E6: Shipping event (for SSCC)-->
                  <ObjectEvent>
                        <eventTime>2017-11-27T17:15:14Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <epcList>
                              <epc>urn:epc:id:sscc:030001.1234567890</epc>
                        </epcList>
                        <action>OBSERVE</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:030001.111111.0</id>
                        </readPoint>
                        <bizTransactionList>
                              <bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0300011111116:DL123</bizTrans
action>
                              <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:XYZ567</bizTransact
ion>
                              <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:XYZ444</bizTransact
ion>
                        </bizTransactionList>
                        <extension>
                              <sourceList>
                                    <!-- Error: instead of urn:epc:id:sgln, cause an
error by using ur:epc:id:gln.  Reference GS1 US Rx Guideline R1.2 Section 5.3.4-->
                                    <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:gln:030001.111111.0</source>
                              </sourceList>
                              <destinationList>
                                  <!-- Error: instead of giving SGLN, include a GLN
value -->
                                    <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:0399999999991</destination>
                              </destinationList>
                        </extension>
                  </ObjectEvent>
            </EventList>
      </EPCISBody>
</epcis:EPCISDocument>
```

Appendix B. Summary Progress Report - Example

Submission Period

- **Start Date:** March 1, 2018
- **End Date:** March 30, 2018

Supply Chain Role:

- Manufacturer or Wholesaler

Submission List:

Submission ID * *(hyperlink to submission instance details)*	Submission Date/Time	Scenario ID and Description	Submission Result
100	2018-03-01T15:10:16Z	ID # 01-Single Purchase Order without Aggregation	Fail
101	2018-03-02T12:15:16Z	ID # 02- Single Purchase Order without Aggregation	Fail
102	2018-03-05T16:11:16Z	ID # 04-Single Purchase Order without Aggregation, shipping GT 24 hrs.	Pass
103	2018-03-07T10:12:16Z	ID # 12 -Multiple Purchase Orders with & w/o Aggregation	Pass
104	2018-03-15T12:15:16Z	ID# 10 -Multiple Purchase Orders without Aggregation and with Complete Direct Purchase	Pass
105	2018-03-30T12:15:16Z	ID# 11-Multiple Purchase Orders with Aggregation and with Complete Direct Purchase	Fail

**The test system shall at a minimum enable the user to click on the hyperlink for each Submission ID, which will at a minimum display the content details for a specific submission. The content for each specific submission will be identical to the content generated for Conformance Testing Result by test case and submission.*

Appendix C. Final Conformance Testing Report for GS1 US Rx EPCIS Trustmark - Examples

C.1 Example 1: Manufacturer with initial set test scenarios

Submitting Company:	GS1 Pharma LLC
Supply Chain Role:	Manufacturer
Conformance Test Firm:	Test Firm XYZ
EPCIS Version:	1.2
GS1 US Rx Guideline Version:	1.2
GS1 US Rx EPCIS Trustmark Award Date:	March 5, 2018
Passed:	ID# 02 – Single PO with Aggregation

C.2 Example 2: Manufacturer with second set of test scenarios

Submitting Company:	GS1 Pharma LLC
Supply Chain Role:	Manufacturer
Conformance Test Firm:	Test Firm XYZ
EPCIS Version:	1.2
GS1 US Rx Guideline Version:	1.2
GS1 US Rx EPCIS Trustmark Award Date:	March 30, 2018
Passed:	ID# 06 – Multiple PO with Aggregation Drop Ship

C.3 Example 3: Solution Provider – submitting for manufacturer

Solution Provider:	SolutionProviderXYZ
Supply Chain Role:	Manufacturer
Conformance Test Firm:	Test Firm ABC
EPCIS Version:	1.2
GS1 US Rx Guideline Version:	1.2
GS1 US Rx EPCIS Trustmark Award Date:	March 16, 2018
Passed:	ID# 04 – Multiple PO, no Aggregation, and shipping GT 24 Hrs.

C.4 Example 4: Wholesaler

Submitting Company:	Wholesaler XYZ
Supply Chain Role:	Wholesaler
Conformance Test Firm:	Test Firm XYZ
EPCIS Version:	1.2
GS1 US Rx Guideline Version:	1.2
GS1 US Rx EPCIS Trustmark Award Date:	May 1, 2018
Passed:	ID# 15 – Multiple PO, no Aggregation, Partial Direct Purchase

C.5 Example 5: Solution Provider Submitting for Wholesaler

Submitting Company:	SolutionProviderXYZ
Supply Chain Role:	Wholesaler
Conformance Test Firm:	Test Firm XYZ
EPCIS Version:	1.2
GS1 US Rx Guideline Version:	1.2
GS1 US Rx EPCIS Trustmark Award Date:	June 10, 2018
Passed:	ID# 12 – Multiple PO with and w/o Aggregation,

C.6 Example 6: Manufacturer who is also a wholesaler

Submitting Company:	GS1 Pharma LLC
Supply Chain Role:	Wholesaler
Conformance Test Firm:	Test Firm XYZ
EPCIS Version:	1.2
GS1 US Rx Guideline Version:	1.2
GS1 US Rx EPCIS Trustmark Award Date:	May 30, 2018
Passed:	ID# 14 – Multiple PO with Aggregation, ship time GT 24 Hrs.

Appendix D. Acronyms

CBV	Core Business Vocabulary
DEA	U.S. Drug Enforcement Agency
DSCSA	Drug Supply Chain Security Act
EPCIS	Electronic Product Code Information Services
FDA	U.S. Food and Drug Administration
GLN	Global Location Number
GTIN	Global Trade Item Number
GUI	Graphical User Interface
NDC	National Drug Code
PO	Purchase Order
SSCC	Serial Shipping Container Code
URI	Uniform Resource Identifier
URN	Uniform Resource Name
XML	eXtensible Markup Language

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