GS1 Third Party Data Exchange in Healthcare

Implementation Guide

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Change Log

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1.0	17 Jan 2014	Laura Kinerk	Initial Draft
1.1	27 Jan 2014	L. Kinerk	Updates from comments from Jan 21 meeting.
1.2	3 Feb 2014	L. Kinerk	Structured formatting for Pre-requisites. Added a draft procedure diagram for discussion. Added definitions section.
1.3	4 Feb 2014	L. Kinerk, Janice Kite	Updates based on discussions on weekly work group conference call.
1.4	22 May – 3rd June 2014	L. Kinerk, J Kite	Updates based on discussions on weekly work group conference calls.
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1.7	23rd July 2014	J Kite	Updates based on eBallot review and comment process.
1.8	19 November 2014	John Ryu	Editorial update for GS1 community review
1.9	22 December 2014	John Ryu	Resolved community review comments and posted for eBallot
1.9.1	22 January 2015	John Ryu	eBallot completed
2.0.1	23 February 2015	D. Buckley	Ratified version editorial

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Table of Contents

1. Introduction

Many companies utilise Contract Manufacturing Organisations (CMOs) to enhance their ability to produce products in the global market.

CMOs are typically involved with the manufacturing and packaging of products for more than a single subscriber. Based on GS1 Standards, creation and publication of an implementation guide incorporating common operating practices will facilitate harmonised electronic communication with these providers that will lead to more efficient and cost effective use of their services.

1.1. Purpose of this document

In order to more effectively implement serialization among Third Party Manufactures, CMOs, contract packagers (collectively referred to as CMO throughout this document) and the manufacturers who use them, an electronic data exchange guide is required.

This electronic-data exchange guide will provide a consistent framework for how these service providers (CMOs) should for example: implement quality standards, capture and exchange data, serialize products, aggregate them, report these activities, and conduct business with each other in alignment with GS1 Standards and/or the specific regulations of the destination countries.

1.1.1. Scope

In Scope:

- Serial Number management; process and method including:
  - □ reconciliation
  - □ linking serial numbers to lot/batch numbers
- Product Aggregation (when required)
- Data transfer between two organisations
  - □ Triggers, events
- Data Exchange Protocol(s)
- IT system interfaces

Out of Scope:

- Global Trade Item Number (GTIN) and Lot/Batch Number assignment management; process and method
- What is printed and encoded on the package, package changes
- Products; Product Quality
- Financial terms; Anti-Trust
- Barcode quality, testing, rejection rates etc.
- The manufacturing process of the organisation(s)
- Installation of line equipment and site systems

Out of Scope but planned content for future versions of the guide:

- Non-serialised data management; process and method

- Data transfer to regulatory organisations / governments

- Market requirements that are contrary to GS1 Standards (example: China)

- De-aggregation, re-aggregation

- Human Readable Interpretation

- Other Stakeholders (e.g. Third Party Logistics Providers (3PLs), Regulators)

1.2. Who will use this document

Marketing/Manufacturing Authorization Holders (MAH, Brand Owners) can use this document to prepare their own traceability systems for data communication and system interfaces with multiple CMOs that manufacture/package products for them. CMOs can use this document to prepare their own traceability systems for data communication and system interfaces with the multiple customers to whom they supply product and serialization data.

Solution Providers can use this document to design and build the technical solutions to enable this process.

2. Implementation Procedures

A solution should encompass the following topics:

- Pre-Requisites (see section *2.1*)

- Process Verification/Validation Testing: Connectivity, message structures, end-to-end pilot batch runs

- Quality System for Serial Number integrity

- Serial Number Request: Method, verification, quantity, frequency, trigger

- Serial Number Allocation: transfer method, quantity allocated, range vs. list, random vs. non-randomised

- Serialized Shipping Data: Method, content, aggregation, product receipt processes

- Serialized Data reporting: Method, content, Commissioned, unused, aggregation, data receipt acknowledgement, verification.

- Serial Number Management by CMO

  - □ Randomization

  - □ Aggregation

  - □ Commissioning

  - □ Reconciliation of Decommissioned or Unused numbers (process and method)

  - □ Reconciliation of serial numbers to lot/batch

  - □ CMO maintenance and archiving of MAH data?

- Exceptions processing

2.1. Pre-requisites

Additional activities that must be accomplished by a MAH or a CMO or both.

1. The CMO is able to exchange electronic messages with MAH. Any necessary authorized access or logins are previously set up.

2. It is anticipated existing processes already in place for managing GTIN and/or Lot/Batch numbers and/or expiry date will be leveraged for serial number management processes.

3. If Serial numbers are supplied by a regulator (e.g. China) the MAH manages this process as prerequisite to providing Serial numbers to CMOs

4. All communication methods (e.g. for serial number request and serial number response) should be agreed to in advance and configured as part of the GTIN setup.

5. Reporting triggered by defined business events as defined by country specific reporting requirements. For example, in China, business event triggers include goods receipt, goods issue, scrapping etc.

6. Agreement to make GS1 company prefix and GLN available whenever there's changes to legal, functional or physical entities

2.1.1. Contract between CMO and MAH is in place

It is assumed that a contract will be established between the MAH and the CMO. This contract (or Quality Agreement) will include agreements to ensure products are manufactured, packaged and serialized according to applicable market regulations and MAH requirements. Also, it is recommended that the MAH issue guidance for validation of operational and performance requirements which will include test cases/scenarios that are required to validate packaging lines for coding, serialization and aggregation and for in-process checks that must be performed during each packaging run. Below are current industry best practices, contracts may include the following topics, although this list may not be an exhaustive and MAH or CMO may decide to include other topics/agreements:

1. Adherence to pre-defined barcode quality standards

2. Adherence to pre-defined traceability event standards

3. Adherence to Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and/or ISO Standards as applicable.

4. Meets data quality measurement for accuracy of data content

5. Meets Service Level Agreement (SLA) to ensure timeliness and consistency when data is submitted to MAH

6. Meets SLA for inquiry requests and time to resolve exceptions especially as it relates to data discrepancies

Validation of operational and performance requirements (test cases/scenarios):

The following are tests that could be undertaken when implementing a contract with a CMO:

1. Data Exchange Tests

2. Packaging Tests

3. Serialization Tests

4. Unique Identifiers

5. Aggregation

6. Readability

7. Accuracy

8. End to End Testing

9. Pilot lots

In-process checks

The following would be activities that could take place during a contract period between an MAH and CMO:

1. Defect Classifications and related acceptable quality levels need to be updated to define possible Serialization related defects.

2. Acceptance and rejection criteria for in-process checks must be established.

3. Corrective action or exception procedures related to serialization defects must be

   defined, including any applicable re-inspection, rework or reprocessing procedures and exception reporting.

4. Standard Operating Procedures should be updated to include any additional procedures introduced by the need for serialization and tracking.

5. Certificates of Analysis

6. Training

7. New processes introduced by serialization and updates to SOPs may require updates in the Third Party Manufacturer's (TPM) training program.

2.1.2. Master Data

Master Data and its sources must be defined, prepared and appropriately formatted.

The following are the relevant master data elements for this context:

2.1.2.1 GS1 Company Prefix

Each CMO must obtain their own GS1 Company Prefix in order to generate GLNs and SSCCs. Although a CMO may not have its own product and will not need to assign GTINs, the quantity of SSCCs that will need to be generated will need to be assessed to ensure the length of the GS1 Company Prefix being obtained is suitable to provide the necessary number of SSCCs. Because the SSCC is comprised of the GS1 Company Prefix and a serial reference, a shorter length GS1 Company Prefix allows more serial numbers to be assigned. SSCCs may be re-used or recycled based on a schedule specified by regulatory requirements or agreed upon between MAH and CMO, which must be at least as long as that defined by GS1. SSCCs can be assigned to any logistic unit including, pallets, cases, partial or mixed cases, or entire shipment depending on market or customer requirements. MAH might want to confirm that the CMO has done this, e.g. entering it into the contract/quality agreement.

2.1.2.2. GLN

Each entity (MAH, CMO) should identify Global Location Numbers (GLNs) for their operations that can be used as part of the communication between them; i.e.

- legal entity

- functional entity physical locations such as packaging site, distribution centre (In the event that CMO is also functioning as 3PL and ships directly to MAH's commercial customer)

2.1.2.3. GTIN

The MAH must assign appropriate Global Trade Item Numbers (GTINs) to their products for all levels of packaging (ex. Unit, case…), if not already done.

2.1.3. Serial Number Setup

A determination must be made between MAH and CMO regarding ownership and source of Serial Number allocation.

The MAH may want to generate and maintain their own serial numbers for reasons such as to guarantee uniqueness across several manufacturers. However, the MAH may choose to defer this responsibility to the CMO to generate and maintain the Serial Numbers.

Note: Some government regulations may require that serial numbers are sourced by a MOH/government or some central organisation delegated by the MOH/government. In these cases, it is the responsibility of the MAH to obtain the necessary serial numbers according to the government regulations and disperse them to their CMO's as necessary.

2.1.4. Communication Interface

The MAH and CMO must establish a secure communication interface to allow for serial number requests, allocation and sharing of data. Automated and standardised methods for communication would be preferred. Suggested methods could include: B2B gateway, web services, email, etc.

2.1.5. Data Exchange Protocol

The MAH and CMO must agree on the data exchange method, structure and content. Possible protocols include AS2, HTTPS, and SFTP. It is recommended that Electronic Product Code Information Services (EPCIS) events be used for serialized data exchange. Examples of the EPCIS event data messages will be given in the procedures below.
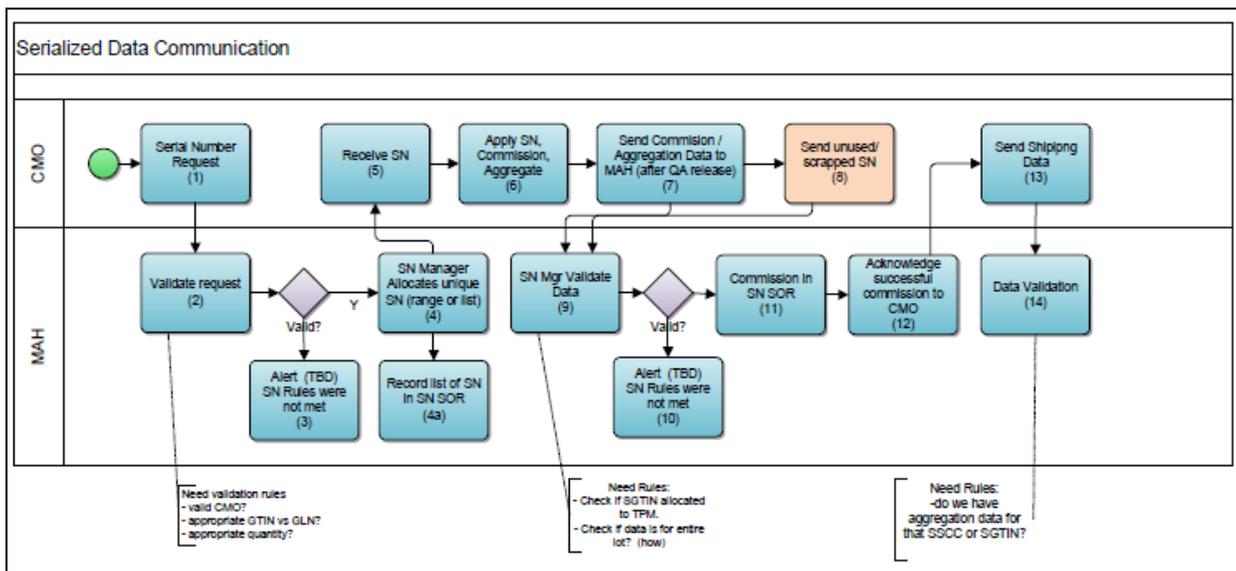
2.1.6. Data Exchange Process

The MAH and CMO must agree to a process that establishes the points in the manufacturing, quality and shipping processes at which the serialised data will be communicated. Both in terms of data exchange from the product owner to CMO and receipt of data back from CMO. A recommended process will be outlined in the procedures in this document (See sections *2.3* - *2.10*).

2.2. Structure

Possible architecture models include

1. MAH owned repository
2. 3rd Party repository assigned by MAH to host event data and others

2.3. Process

Third party data exchange of serialization numbers and associated product and event data is best accomplished by following a documented process. Working from an initial process description or flow chart, further use cases can be accommodated to account for any variations across trading partners and their respective capabilities.

A robust process should include steps that account for the business processes in an end to end fashion (request by CMO through to shipping of CMO or MAH). Recognize that the MAH and the CMO may need an additional level of interface between internal systems to manage serialization information.

The process steps may include the following:

■ SN Request, Validation, Allocation, Application, Commissioning, Reporting and Reconciliation

■ CMO SN Management, which may require GMP methods due to regulatory requirements

■ SN Aggregation and Shipping Data Recording and Reporting

■ Quality System Checks for Serial Number integrity

■ Exceptions handling process steps for in-process QA, damage during handling, etc.

2.4. Serial Number Request

Prior to manufacturing (packaging) of the product to be serialized the CMO shall request a batch of serial numbers sufficient for the quantity of product to be packaged. This is typically in accordance with the order quantity from the MAH customer. The CMO will send a request to the MAH for a quantity of Serial Numbers for each level of packaging identified by a GTIN. The request and receipt of numbers should be managed in accordance with cGMP in the same manner the CMO is required to manage GTIN and batch variable information such as Lot Number and Expiration Date. Because this is expected to be an exchange of data electronically, handshakes of receipt of request, sending of numbers and receipt of numbers are recommended.

2.4.1. Pre-requisite

Refer to section 2.1

2.4.2. Request serial numbers: Timing and Quantity

It is the responsibility of the CMO to initiate a request for serial numbers. Before starting the packaging of an order, the CMO must verify that there is a sufficient quantity of Serial Numbers available in their Site Manager or Serialization System. If not, a request for additional serial numbers should be sent to MAH.

The quantity of serial numbers to request should be the result of an agreement between CMO and MAH. It can be based on the size of the lot and be requested before the processing of each lot. It can be based on a monthly/quarterly/annual forecast and be requested on a periodic basis. Or it can be based on a designated quantity. The CMO should maintain a pool or buffer of serial numbers and additional numbers should be requested when the pool of numbers at the CMO reaches a designated threshold level.

Note: When a packaging level carries a GTIN, each packaging level must have a unique GTIN; e.g. The GTIN for the secondary packaging (bottle or carton) will be different to the GTIN for the case of the same product. Serial numbers for all different levels of packaging must be managed separately.

The GTIN plus the serial number is a compound key. The serial number must be unique to a GTIN and must be processed together with it.

Note: Some packaging level are identified by SSCC rather than GTIN when they are not a fixed composition. (e.g. Not all packaging levels are assigned a GTIN, higher level packaging may be identified with an SSCC created by the CMO and may be determined by regulation.

2.4.3. How to implement

A request message is composed and sent from CMO to MAH.

1. CMO determines need for numbers based on existing pool and upcoming production orders for a given product
2. CMO prepares and sends the request for serial numbers to MAH electronically via its B2B system (synchronously or asynchronously)

2.4.4. Option 1

The MAH may supply a secure portal with a user interface to allow an individual at the CMO to login and manually request the serial numbers.

Through the portal, the CMO will provide the quantity of serial numbers being requested for the GTINs of each level of packaging required.

Other information that needs to be provided should be supplied by the MAH to the CMO in User Documentation. This will typically include the name of the system or company making the request.

2.4.5. Option 2

The CMO system directly interfaces to the MAH system via a secure B2B gateway. The CMO will generate the request message in an XML message in a format agreed to between the MAH and the CMO.

■ The essential elements of a request message should be:

- □ Sending System – sender of the request must be identified in order to validate the sender of the request and ensure the response is sent to the correct party. It is recommended to use GLN to identify the sending system.

- □ Receiving System - the recipient of the request must be identified in order to ensure the message was sent to the correct party, and help manage asynchronous messages. It is recommended to use GLN to identify the receiving system.

- □ ID Type (GTIN, etc…)

- □ Product_ID (value of GTIN, etc…)

- □ EncodingType (description of how serial numbers are to be encoded)

- □ Quantity (quantity of serial numbers requested).

2.5. Serial Number Allocation & Response

Upon request, the MAH must allocate the appropriate number of serial numbers to the CMO for each level of packaging requested. The serial numbers must be transmitted through secure communication to the CMO.

Note: For the time being, there is no GS1 standard for a dynamic allocation of serial numbers. GS1 may develop a set of standardised business messages for serial number management at a later point of time, if requested by Industry.

2.5.1. Pre-requisite

- ■ Product master data, CMO location access and any allocation thresholds must be setup prior serial number request.

- ■ Serial Number request has been received by the MAH from the CMO.

- ■ The method used to communicate serial numbers in the serial number response message should be agreed to in advance and configured as part of the GTIN setup before any serial number requests are made by the CMO. This includes the security protocol for transmission.

2.5.2. When to Allocate Serial Numbers

Serial Numbers should be allocated to the CMO if the request is determined by the MAH as valid.

2.5.3. How to implement

1. The MAH, upon receiving the Serial Number request from a CMO, must validate the request according to the following rules:

   a. The CMO is authorized to package the GTIN identified in the request.

   b. The quantity of serial numbers requested does not exceed an acceptable quantity as agreed upon by the CMO and MAH.

   c. There are no errors in the serial number request

   d. If any portion of the SN request validation fails, an error handling process must be implemented which includes notifying the CMO

2. The MAH must ensure that duplicates serial numbers are not generated or allocated.

3. Additional considerations for allocating serial numbers.

    a. The field length of the Serial Number shall comply with the GS1 standard of up to 20 alphanumeric characters regardless of any defined subset used by the MAH.

    b. In this context, the recommended approach is to use only numbers and letters and avoid the use of special characters (e.g.!,",%,&,',(,),*,+,-,.,/,:,;,<,=,>,?) [see *GS1 General Specifications*, *GS1 Subset of International Standard ISO/IEC 646*] Regardless, applications that process serial numbers must be prepared to accept any character that is permitted by the GS1 General Specifications

    c. Because of XML message size restrictions or processing times, it may be necessary to send multiple lists of serial numbers (multiple XML messages) to fulfil a single serial number request.

    d. Be aware that a SN request must be issued by CMO for each level of packaging for the same product. Each level of packaging will have its own GTIN and thus require a separate set of serial numbers.

4. The MAH system will allocate SN to the CMO using the parameters specified in the request (See section *2.4.2*)

    a. The MAH system will send a response to the CMO based market or mutual agreement between the MAH and CMO. The following are the most common options in the market: Communicate serial numbers in a range, identifying the first and last number in a sequential set. This message is short and concise.

        i. If random serial numbers are required, the MAH may communicate a larger range of serial numbers and arrange for the CMO to select random serial numbers based on an agreed upon algorithm.

        ii. The CMO also has the obligation not to duplicate serial numbers within the allocated range.

    b. Communicate serial numbers in a list, where each number in the set is listed separately. Sequential lists or random lists can be communicated this way. This method allows the MAH to monitor each number allocated and provide reconciliation the serial numbers used and not used.

5. The response method should be the same as the request.

OPTION 1

If the serial number request was made through a portal provided by the MAH, then the serial numbers will be allocated through the portal and downloaded by the CMO.

OPTION 2

If the request was made through a B2B gateway, the MAH will generate the response message in an XML file in a format agreed to between the MAH and the CMO.

The essential elements of a response message should be an echo of the elements in the request, in addition to the ActionCode and the serial numbers:

    a. Sending System – recommend using GLN to identify sending party

    b. Receiving System – recommend using GLN to identify receiving party.

    c. ActionCode - to indicate whether the request is confirmed or rejected.

    d. IDType (e.g. GTIN, etc…)

    e. Product_ID (value of GTIN, etc…)

    f. EncodingType (description of how serial numbers are encoded)

    g. Quantity (quantity of serial numbers requested).

    h. Serial numbers identified in a range or list as previously configured for that GTIN.

2.6. Coding Applied to Packaging

During final packaging of product, serial numbers will be applied to the product in a data carrier (e.g. GS1 DataMatrix barcode) and possibly in human readable format, by printing or adding a label on the package. During this time, the CMO must collect data on the serialized identifier used on the packaging, and the packaging hierarchy (aggregation).

2.6.1. Pre-requisite

■ The necessary coding (e.g.: GS1 DataMatrix, Human Readable information) has been defined for each packaging level.

■ Packaging artwork or labels have been updated to arrange for appropriate space and location for the defined coding/labelling, based on market requirements.

■ Enough Serial Numbers for the batch are available for all required levels of packaging.

■ Aggregation requirements must be defined.

2.6.2. When to apply coding to packaging

Packaging will occur when a Purchase Order (P.O.) is issued from the MAH to the CMO. The serialized coding or labelling will occur during the packaging process.

2.6.3. How to implement

Each manufacturer will have its own equipment and its own processes. A detailed method to implement the coding of the product cannot be prescribed here. However, certain aspects of serialization should be consistent.

1. Barcode symbology should be read and verified as matching the human readable information that accompanies it on the packaging, if suitable scanning equipment is available to undertake this step.

2. Reconciliation of Serial numbers:

    a. Serial numbers applied to the product as normal processing must be reported back to the MAH

    b. Serial numbers on product that is scrapped <u>must not be used again</u> and reported back to the MAH.

3. Serial numbers not transferred to the product line/printer <u>can be used again</u>

4. Commission Data:

    a. Product Aggregation of commission data (serial numbers) to the Lot/Batch number must be recorded

5. Aggregation Data:

    a. Product aggregation of units to serialized bundles (if applicable) must be recorded by CMO

    b. Product aggregation of units/bundles to a serialized case (if applicable) must be recorded by CMO.

    c. Product aggregation of cases to a serialized pallet (if applicable) must be recorded by CMO.

2.7. Commission Data Transfer

Refer to the *GS1 US Pharma Implementation Guideline.*

This process is to define which serial numbers have been used by the CMO when producing a specific product SKU. It is independent if the serial numbers are pre-defined e.g. China, provided by the MAH or generated by the CMO.

2.7.1. Pre-requisite

The MAH and CMO should agree on the granularity of data to be transferred between them, e.g.

- Finished product
- In Process Control (IPC) Samples
- Analytical Samples
- Destroyed packs

The MAH needs to define if Commission Data need to be transferred or if Packing Data Transfer is sufficient.

2.7.2. When to Commission Data Transfer

After finalization of the packaging process and after application of serial numbers to the product, communication of serialized data to the MAH should occur. (Commission Data Transfer)

All serial numbers that were used during the packaging process for a specific SKU have to be recorded and transferred, no matter if they were applied to a product or not.

The only exceptions are those packs or labels where the 2D Matrix Code is not readable.

2.7.3. How to implement

The CMO will send via EPCIS the Commissioning Event information to the MAH.

2.8. Packing Data Transfer

This process is to define the serialized contents of parent containers for each level of packaging.

Refer to the *GS1 US Pharma Implementation Guideline.* There might be variation in jurisdictions other than the US, while the basics are the same. Below is an example of specific requirements from other jurisdictions:

China: Requires every parent and child serial number to be associated with specific China Subtype and Resource Code. Additionally, parent container must be classified as full, partial, mixed full, or mixed partial.

2.8.1. Pre-requisite

- MAH and CMO should pre-define the level of aggregation that should be captured and recorded by the CMO.
- Before packing into containers, serialized items must first be commissioned.

2.8.2. When to send packing data

After completion of a serialized batch run, the CMO sends packing data to MAH to report the relationship of serialized containers to their serialized contents.

2.8.3. How to implement

The CMO will send via EPCIS Aggregation Event information to the MAH

Upon receipt, MAH will perform validation checks to ensure data integrity of packing hierarchy. This includes verifying that parent containers have unique commissioned serial numbers and that all child items are accounted for in the aggregation message.

2.9. MAH validate and acknowledge Serialized Product Data

Although CMOs are expected to perform data quality checks before sending serialized data to MAH, upon receipt of commissioning and packing event data from the CMO, the MAH should validate the data based on a set of rules to ensure the serial numbers are unique and previously allocated, and the packing data is complete. If the data is found to be contradictory to the rules, a defined exception process must be followed. If all data is found to be accurate, the MAH will store the serialization data in its system of record and send an acknowledgement to the CMO that processing of the product can continue.

2.9.1. Pre-requisite

All previous steps involving the allocation of serial numbers, application of serial numbers to the product packaging, and communication of serialized data must have occurred.

2.9.2. When to Validate Commissioning and Packing Event data

After each communication of commissioning event data and packing event data from the CMO, the MAH must validate the data against its own data management system and acknowledge the success or failure of that validation to the CMO. Note: This process may be system dependent.

2.9.3. How to implement

1. The MAH will receive the EPCIS Commissioning Event messages from the CMO.

2. The CMO should validate the EPC data against their own serial number system of record according to documented rules such as (Box 9):

   a. Verify the proper GTIN in the EPC of each item.

   b. Verify that all item serial numbers received in commissioning event have been allocated.

   c. Verify that all item serial numbers received in the commissioning event were previously allocated to the CMO (GLN).

   d. Verify that all serial numbers received in the commissioning event were not previously commissioned (duplicate), destroyed, or decommissioned.

   e. For containers identified by SSCCs allocated by the CMO, the MAH should verify that the SSCC is unique in its own system according to GS1 re-use rules or rules agreed upon between the MAH and CMO.

   f. If requested, CMO should provide a report to the MAH that shows the results of CMOs data quality verification checks.

3. If any of the defined verification rules are not satisfied (Box 10), the MAH must alert the CMO of the error according to an exception process agreed upon by the two parties. This exception process should include:

   a. Identification of parties at the CMO and MAH that must be alerted to the process exception.

    b. A method to communicate the exception and a possible backup method.

    c. A response timeframe, so that further action can be taken if the CMO does not receive/acknowledge the exception notice in a set amount of time.

    d. Expected actions to be taken by the CMO to remedy the error causing the exception, including process to re-submit corrected data.

4. If all the verification rules are met, the MAH will commit the commissioning event to their system of record. (Box 11)

5. Upon successful recording of the commissioning event data, the MAH will acknowledge to the CMO that commissioning was successful and that the CMO may proceed with sending the packing data. (Box 12).

6. A response timeframe should be set for an expected response from the MAH to the CMO.

7. The MAH will receive the EPCIS Packing Event message from the CMO, which defines the aggregation or packaging hierarchy of objects into larger containers.

8. The CMO should validate the EPC data against their own serial number system of record according to documented rules such as (Box 9):

    a. Verify all EPC's received were previously commissioned as part of this lot.

    b. Verify all EPCs received were NOT previously destroyed or decommissioned.

9. If any of the defined verification rules are not satisfied (Box 10), the MAH must alert the CMO of the error according to an exception process agreed upon by the two parties. This exception process should include the same topics outlined in the exception process above.

10. If all the verification rules are met, the MAH will commit the packing events to their system of record. (Box 11)

11. Upon successful recording of the packing event data, the MAH will acknowledge to the CMO that commissioning/aggregation was successful and that the CMO may proceed to the shipping process. (Box 12)

12. The MAH may receive additional events such as decommission and destruction events when the CMO is able to identify EPCs that have been pulled for sampling or were identified as scrap/rejects during packaging (Box 8).

13. The MAH will verify the decommissioned/destroyed EPCs similar to previous verification steps (Box9). The events will be recorded in the MAH system of record (Box 10). This will allow the MAH to better reconcile the state of each allocated serial number for more accurate authentication of EPCs later in the supply chain.

2.10. Shipping Data Transfer

Refer to the *GS1 US Pharma Implementation Guideline*.

Once the products are encoded and packaged, and optionally commissioning and/or packaging information provided, they will be shipped by the CMO to either the MAH or a partner of the MAH. Additional information may be required as part of this process as trade or regulatory requirements. It may also be used to load information into the recipient's EPCIS repository, assist in receiving reconciliation and other operations and/or government reporting.

2.10.1. Pre-requisite

■ EPCs applied to products, products packed and ready to ship.

■ Trade Agreements with receiving organisations to understand any additional information requirements.

■ Knowledge of the information requirements regarding required regulatory data depending on the source and/or target markets.

2.10.2. When to use Shipping Data Transfer

Shipping data transfer is used any time product being is being shipped from CMO to MAH or to a trade partner of the MAH.

2.10.3. How to implement

The implementation is achieved using EPCIS 1.1. If the commissioning and packing information were shared with the recipient beforehand (e.g. as in section 2.7, 2.8), the message would only contain the shipping events with the topmost EPCs. If the commissioning or aggregation information has not yet been shared with the recipient, those events could be contained in the same message as the shipping event as is common practice in the *GS1 US Pharma Implementation Guideline.*

Depending on the trade agreements in place, additional information may need to be provided as part of the EPCIS message. This information, if not part of the standard vocabulary, would be represented as extension elements in the message.

Depending on the regulatory requirements in force for the shipment (largely dependent on the source and/or destination markets), there may be additional information required in the events. This information would also be implemented as extensions.

The message can be sent using standard EPCIS transfer mechanisms between the CMO and the MAH or MAH partner.

3.   Acronyms / Definitions

Term	Definition
Aggregation	the action of identifying all items in a package in order to register the parent-children relationship information
AS2	Applicability Statement 2: is a specification about how to transport data securely and reliably over the Internet. Security is achieved by using digital certificates and encryption.
CMO	Contract Manufacturing Organisation
EPCIS	Electronic Product Code Information Services http://www.gs1us.org/resources/standards/epcis
HTTPS	Hypertext Transfer Protocol Secure: is a communications protocol for secure communication over a computer network
MAH	Marketing Authorization Holder , Brand Owner
Master Data	Data that is associated with a product and mostly remains unchanged, e.g. the product description.
MOH	Ministry of Health, Government entity
SFTP	Secure File Transfer Protocol
SN	Serial Number
TPM	Third Party Manufacturer