Configuration Quick Reference

How a Pharmaceutical Manufacturer, Virtual CMO, and CMO that all own TraceLink serialization apps establish Links to each other

Revision 01

tracelink | Help

Table of Contents

Configuration Quick Reference 1

How a Pharmaceutical Manufacturer, Virtual CMO, and CMO that all own TraceLink serialization apps establish Links to each other 1

Table of Contents 2

Copyright 5

Revisions 6

Getting Started 7

Overview 8

Pharmaceutical Manufacturer Prerequisites 9

Configure Integration 9

Add a SOAP WSDL (conditionally required) 9

Add Products 10

Create Serial Number Templates 10

Enable Event Workflows (conditionally required) 11

Virtual Contract Manufacturing Organization (CMO) Prerequisites 12

Configure Integration 12

Add Products 12

Create Serial Number Templates 13

Enable Event Workflows 14

CMO Prerequisites 15

Configure Integration 15

Add Internal Location Information 15

Add Internal Locations to Serial Number Exchange 16

Add Products 17

Enable Event Workflows 17

Configuration 19

Configure the Pharma Manufacturer Link 20

Step 1: Add Partner Information 21

Step 2: Add the Virtual CMO to the Appropriate Apps 21

Step 3: Accept the Pharmaceutical Manufacturer's Link Invitations 22

Step 4: Add Serial Number Templates to the Virtual CMO 22

Step 5: Configure Links to the Pharmaceutical Manufacturer's Apps 23

Step 6: Add Partner Information 23

Step 7: Add the Pharmaceutical Manufacturer to the Appropriate Apps 24

Step 8: Accept Virtual CMO's Link Invitations 24

Step 9: Configure Links to the Virtual CMO's Apps 25

Step 10: Add a SOAP WSDL 25

Step 11: Create Serial Number Templates 26

Next Steps 26

Configure the CMO Link 27

Step 1: Add the CMO to the Appropriate Apps 28

Step 2: Accept the Virtual CMO's Link Invitations 28

Step 3: Add Serial Number Templates to the CMO 28

Step 4: Configure Links to the Virtual CMO's Apps 29

Step 5: Add Partner Information 29

Step 6: Add the Virtual CMO to the Appropriate Apps 30

Step 7: Accept CMO's Link Invitations 30

Step 8: Configure Links to the CMO's Apps 31

Step 9: Add a SOAP WSDL 31

Step 10: Create Serial Number Templates 32

Step 11: Add Serial Number Templates to the Internal Locations 32

Next Steps 32

Test the Serial Number Messages 33

Step 1: Test Serial Number Messages – Transfer Product to Virtual CMO 34

Step 2: Test Serial Number Messages – Receive Transferred Product from CMO 35

Step 3: Test Serial Number Messages – Receive Transferred Product from CMO 35

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Revisions

Date	Revision	Description
17 Mar 2019	01	Initial document.

Getting Started

Overview

This Configuration Quick Reference Guide describes the prerequisites and process for linking a Pharmaceutical Manufacturer, Virtual CMO, and CMO that all own TraceLink serialization apps:

1. Each company performs all prerequisite steps.
2. The Pharmaceutical Manufacturer and the Virtual CMO establish a Link.
3. The Virtual CMO and the CMO establish a Link.
4. The Pharmaceutical Manufacturer, Virtual CMO, and CMO can test the Link.

Pharmaceutical Manufacturer Prerequisites

The Pharmaceutical Manufacturer must perform the following tasks before onboarding a Virtual CMO that also owns TraceLink serialization apps. Some of the tasks below must be completed by the Pharmaceutical Manufacturer's TraceLink Technical Consultant.

ⓘ The **Where** sections demonstrate where to go to complete the task. Select the Help icon (?) on that screen for more information on individual fields.

Configure Integration

- A Technical Consultant must set up and test the B2B connection for message exchanges between the companies before any of the following steps can be taken.

  ⓘ Create a Support ticket in the Customer Success Portal or email case@tracelink.com to update a map after going to production.

- A Technical Consultant must set up any WSDLs or Configurable Workflows that are required for the integration if the Pharmaceutical Manufacturer is not using TraceLink as its System of Record (SOR).

Add a SOAP WSDL (conditionally required)

Pharmaceutical Manufacturers that do not use TraceLink as their SOR need a custom WSDL to auto-replenish serial numbers from their Enterprise Serialization Management (ESM) system.

When the WSDL is available, the Pharmaceutical Manufacturer or their Technical Consultant can add the WSDL to *Serial Number Manager*.

Where

1. Go to *Management* > *SOAP WSDLs*.
2. Select WSDL.

Add Products

Add product master data for the products manufactured by the CMO. This product master data must match the product master data entered by the Virtual CMO.

Where

1. Go to *Master Data Exchange* > *Products*.
2. Select the ADD PRODUCT button.

Ensure the following in the "Target Markets" tab:

- **Manufactured By** is set to CMO.
- The **MAH ID** is the Pharmaceutical Manufacturer's company identifier.
- The **Manufacturing CMO ID** is the CMO's company identifier.
- The **Virtual CMO ID** is the Virtual CMO's company identifier.

Create Serial Number Templates

Create templates to generate serial numbers for the CMO. If the company replenishes serial numbers from the company's ESM system instead of generating them through TraceLink, create an Auto-Replenished By Other Serial Number Manager template with the **Request From** field set to the Pharmaceutical Manufacturer.

Where

1. Go to *Serial Number Manager*.
2. Select the ADD NEW TEMPLATE button.

ⓘ Assign numbers to the General Pool for maximum efficiency.

Enable Event Workflows (conditionally required)

Pharmaceutical Manufacturers that do not use TraceLink as their SOR need a custom shipment Configurable Workflow so that *Serialized Operations Manager* sends data to the ESM system in the correct format.

After a Technical Consultant adds the Configurable Workflow to *Serialized Operations Manager*, the Pharmaceutical Manufacturer must enable the workflow.

Where

1. Go to *Company Administration* > *Workflow*.
2. Enable the following workflow:
    - **Event** – Transfer Shipment
    - **Event Source** – [Pharmaceutical Manaufacturer] Serialized Operations Manager
    - **Resulting Action** – Generate SOM Transfer Shipment EPCIS Messages
    - **System Type** – MAH Workflow

Virtual Contract Manufacturing Organization (CMO) Prerequisites

The Virtual CMO must perform the following tasks before onboarding a Pharmaceutical Manufacturer and CMO that also own TraceLink serialization apps. Some of the tasks below must be completed by the Virtual CMO's TraceLink Technical Consultant.

ⓘ The **Where** sections demonstrate where to go to complete the task. Select the Help icon (?) on that screen for more information on individual fields.

Configure Integration

- A Technical Consultant must set up and test the B2B connection for message exchanges between the companies before any of the following steps can be taken.

  ⓘ Create a Support ticket in the Customer Success Portal or email case@tracelink.com to update a map after going to production.

- A Technical Consultant must set up any WSDLs or Configurable Workflows that are required for the integration if the Pharmaceutical Manufacturer is not using TraceLink as its System of Record (SOR).

Add Products

Add product master data for the products that the CMO manufactures on behalf of the Pharmaceutical Manufacturer. This product master data must match the product master data entered by the Pharmaceutical Manufacturer.

Where

1. Go to *Master Data Exchange* > *Products*.
2. Select the ADD PRODUCT button.

ⓘ Ensure the following in the "Target Markets" tab:

- **Manufactured By** is set to CMO.
- The **MAH ID** is the Pharmaceutical Manufacturer's company identifier.
- The **Manufacturing CMO ID** is the CMO's company identifier.
- The **Virtual CMO ID** is the Virtual CMO's company identifier.

Create Serial Number Templates

Create a template that auto-replenishes serial numbers from the Pharmaceutical Manufacturer by setting the **Request From** to the Pharmaceutical Manufacturer company. These serial numbers can then be passed on to the CMO.

ⓘ This is a prerequisite for onboarding the *CMO*. The Pharmaceutical Manufacturer **must** be linked to the Virtual CMO's *Serial Number Manager* before this template can be created.

Where

1. Go to *Serial Number Manager*.
2. Select the ADD NEW TEMPLATE button.

ⓘ Assign numbers to the General Pool for maximum efficiency.

Enable Event Workflows

Enable *Serialized Operations Manager* event workflows to prompt TraceLink to send commissioning, aggregation, and shipping information to the Pharmaceutical Manufacturer when a shipment occurs.

Where

1. Go to *Company Administration* > *Workflow*.
2. Enable the following workflow:
    - **Event** – Transfer Shipment
    - **Event Source** – [CMO] Serialized Operations Manager
    - **Resulting Action** – Generate SOM Shipment EPCIS Messages
    - **System Type** – CMO workflow

CMO Prerequisites

The CMO must perform the following tasks before onboarding a Virtual CMO that also owns TraceLink serialization apps. Some of the tasks below must be completed by the CMO's TraceLink Technical Consultant.

The **Where** sections demonstrate where to go to complete the task. Select the Help icon ( ) on that screen for more information on individual fields.

Configure Integration

- A Technical Consultant must set up and test the B2B connection for message exchanges between the companies before any of the following steps can be taken.

  Create a Support ticket in the Customer Success Portal or email case@tracelink.com to update a map after going to production.

- A Technical Consultant must set up any WSDLs or Configurable Workflows that are required for the integration if the Pharmaceutical Manufacturer is not using TraceLink as its System of Record (SOR).

Add Internal Location Information

Add master data and identifiers for the company's internal locations to *Master Data Exchange* and *Company Administration*.

Where

1. Go to *Master Data Exchange* > *Company*.
2. Select the Add Location link in the **Actions** column.

> ⓘ Add a GLN identifier for the company and an SGLN identifier for each location to ship product in *Serialized Operations Manager*.

and

1. Go to *Company Administration* > *Partners*.
2. Select the Set Identifiers link in the **Actions** column for the company.
3. Add the identifiers for the locations.
4. Go to *Company Administration* > *Locations*.
5. Select Can participate in TraceLink applications for each location.

Add Internal Locations to *Serial Number Exchange*

Add internal locations as Partners to the company's *Serial Number Exchange* app so that the locations can send commissioning and aggregation data.

Where

1. Go to *Management* > *Applications*.
2. Select the Partners icon (👥) in the **Actions** column for the correct app.
3. Select ⊕ Partner.

Add Products

Add product master data for the products that the CMO manufactures on behalf of the Pharmaceutical Manufacturer. This product master data must match the product master data entered by the Virtual CMO.

Where

1. Go to *Master Data Exchange* > *Products*.
2. Select the ADD PRODUCT button.

ⓘ Ensure the following in the "Target Markets" tab:

- **Manufactured By** is set to CMO.
- The **MAH ID** is the Pharmaceutical Manufacturer's company identifier.
- The **Manufacturing CMO ID** is the CMO's company identifier.
- The **Virtual CMO ID** is the Virtual CMO's company identifier.

Enable Event Workflows

Enable *Serialized Operations Manager* event workflows to prompt TraceLink to send commissioning, aggregation, and shipping information to the Pharmaceutical Manufacturer when a shipment occurs.

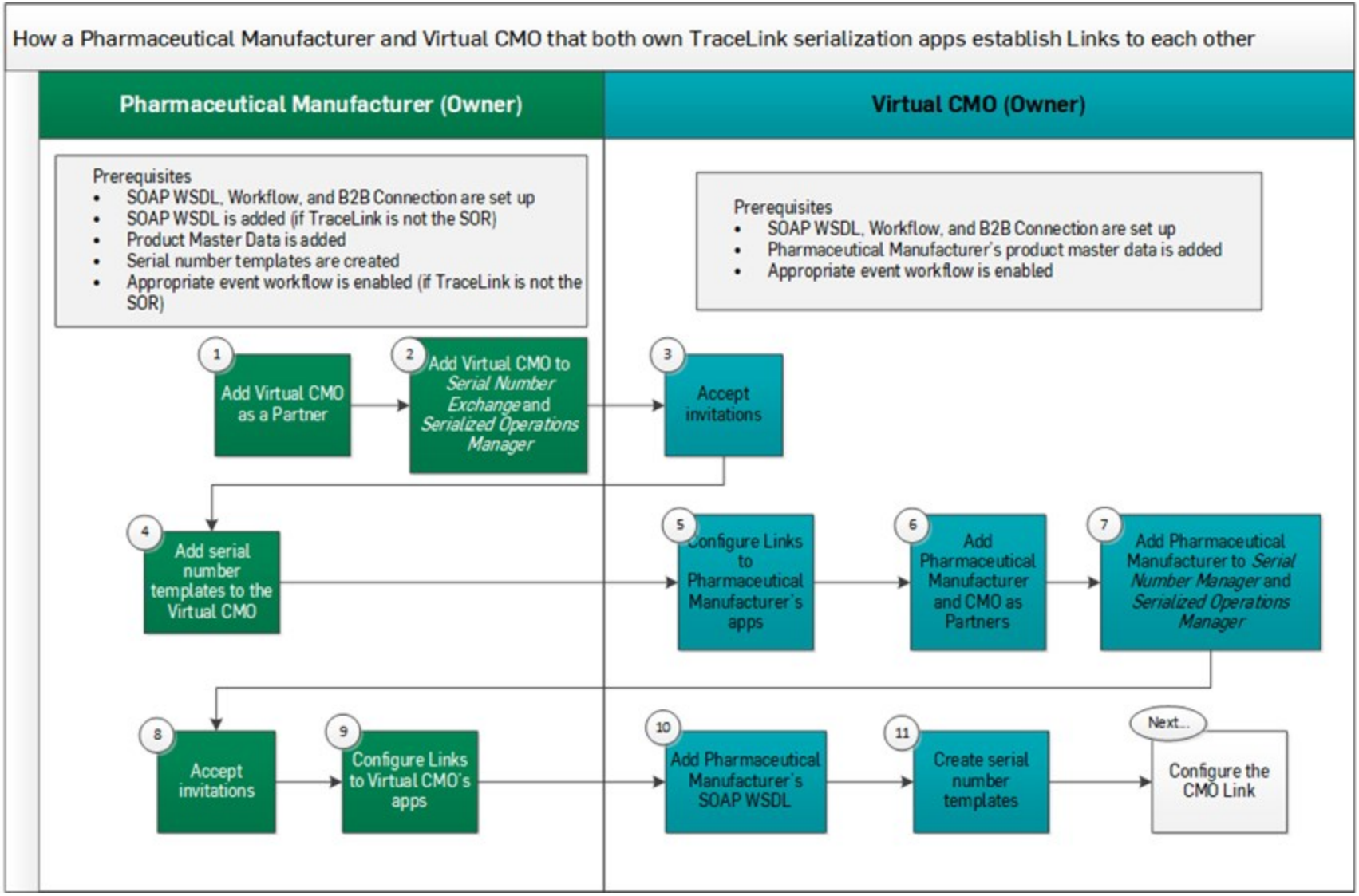
Where

1. Go to *Company Administration* > *Workflow*.
2. Enable the following workflow:
    - **Event** – Transfer Shipment
    - **Event Source** – [CMO] Serialized Operations Manager
    - **Resulting Action** – Generate SOM Shipment EPCIS Messages
    - **System Type** – CMO workflow

Configuration

Configure the Pharma Manufacturer Link

This flowchart displays the steps to successfully establish and configure a Link between a Pharmaceutical Manufacturer and a Virtual CMO that both own TraceLink serialization apps.



ⓘ The **Where** sections demonstrate where to go to complete the task. Select the Help icon (?) on that screen for more information on individual fields.

Pharmaceutical Manufacturer

Step 1: Add Partner Information

Add the company and location information for the Virtual CMO to *Master Data Exchange* and *Company Administration*.

Where

1. Go to *Master Data Exchange* > *Partner*.
2. Select the ADD PARTNER COMPANY button.

and

1. Go to *Company Administration* > *Partners*.
2. Select the ADD PARTNER button.

ⓘ Identifiers added here must match Partner Master Data, and must be added at the same level as the Link (i.e. if the Virtual CMO is linked at the company level, all identifiers are added at the company level). A GLN identifier should be added for the company and an SGLN identifier should be added for each location, if necessary.

Pharmaceutical Manufacturer

Step 2: Add the Virtual CMO to the Appropriate Apps

Invite the Virtual CMO to link to *Serial Number Exchange* and *Serialized Operations Manager* at the company level.

Where

1. Go to *Management* > *Applications*.
2. Select the Partners icon (👥) in the **Actions** column for the correct app.
3. Select ⊕ Partner.

Virtual CMO

Step 3: Accept the Pharmaceutical Manufacturer's Link Invitations

Accept the Pharmaceutical Manufacturer's *Serial Number Exchange* and *Serialized Operations Manager* Link invitations.

Where

- Go to *Application Settings* > *Link Invitations*.

Pharmaceutical Manufacturer

Step 4: Add Serial Number Templates to the Virtual CMO

Add the serial number template for each packaging code that the Virtual CMO needs.

Where

1. Go to *Serial Number Exchange* > *Manage Profiles*.
2. Select the [Company Name] - [Location Name] link in the **ServiceLink** column for the CMO location.
3. Select the ADD PACKAGING CODES button.

Virtual CMO

Step 5: Configure Links to the Pharmaceutical Manufacturer's Apps

The identifiers in the Virtual CMO's Links to *Serial Number Exchange* and *Serialized Operations Manager* must match the identifiers that the Pharmaceutical Manufacturer uses in those apps.

Where

1. Go to *Company Administration* > *Services*.
2. Select the Configure Subscription link in the **Actions** column for the correct Link.

> ⓘ Make sure that the **Shipment Event** on the "Transaction Delivery Rules" tab is enabled to automatically deliver messages.

Virtual CMO

Step 6: Add Partner Information

Add the company and location information for the Pharmaceutical Manufacturer and the CMO to *Master Data Exchange* and *Company Administration*.

Where

1. Go to *Master Data Exchange* > *Partner*.
2. Select the ADD PARTNER COMPANY button.

and

1. Go to *Company Administration* > *Partners*.
2. Select the ADD PARTNER button.

> Identifiers added here must match Partner Master Data, and must be added at the same level as the Link (i.e. if the Pharmaceutical Manufacturer is linked at the company level, all identifiers are added at the company level). A GLN identifier should be added for the company and an SGLN identifier should be added for each location, if necessary.

Virtual CMO

Step 7: Add the Pharmaceutical Manufacturer to the Appropriate Apps

Invite the Pharmaceutical Manufacturer to link to *Serial Number Manager* and *Serialized Operations Manager*.

Where

1. Go to *Management* > *Applications*.
2. Select the Partners icon (👥) in the **Actions** column for the correct app.
3. Select ⊕ Partner.

Pharmaceutical Manufacturer

Step 8: Accept Virtual CMO's Link Invitations

Accept the Virtual CMO's *Serial Number Manager* and *Serialized Operations Manager* Link invitations.

Where

- Go to *Application Settings* > *Link Invitations*.

Pharmaceutical Manufacturer

Step 9: Configure Links to the Virtual CMO's Apps

The identifiers in the Pharmaceutical Manufacturer's Links to *Serial Number Exchange* and *Serialized Operations Manager* must match the identifiers that the Virtual CMO uses in those apps.

Where

1. Go to *Company Administration* > *Services*.
2. Select the Configure Subscription link in the **Actions** column for the correct Link.

> ⓘ Make sure that the **Shipment Event** on the "Transaction Delivery Rules" tab is enabled to automatically deliver messages.

Virtual CMO

Step 10: Add a SOAP WSDL

If the Pharmaceutical Manufacturer does not use TraceLink as their SOR, Virtual CMOs need the Pharmaceutical Manufacturer's custom SOAP WSDL to auto-replenish serial numbers from their ESM system. When the WSDL is available, the Virtual CMO or their Technical Consultant can add the WSDL to *Serial Number Manager*.

Where

1. Go to *Management* > *SOAP WSDLs*.
2. Select the Manage SOAP WSDLs link in the **Actions** column for the *Serial Number Manager* app.
3. Select ⊕ WSDL.

   The **Soap Class** must be "ServiceToService."

Virtual CMO

Step 11: Create Serial Number Templates

Create a template that auto-replenishes serial numbers from the Pharmaceutical Manufacturer by setting the **Request From** to the Pharmaceutical Manufacturer company.

Where

1. Go to *Serial Number Manager*.
2. Select the ADD NEW TEMPLATE button.

ⓘ Assign numbers to the General Pool for maximum efficiency.

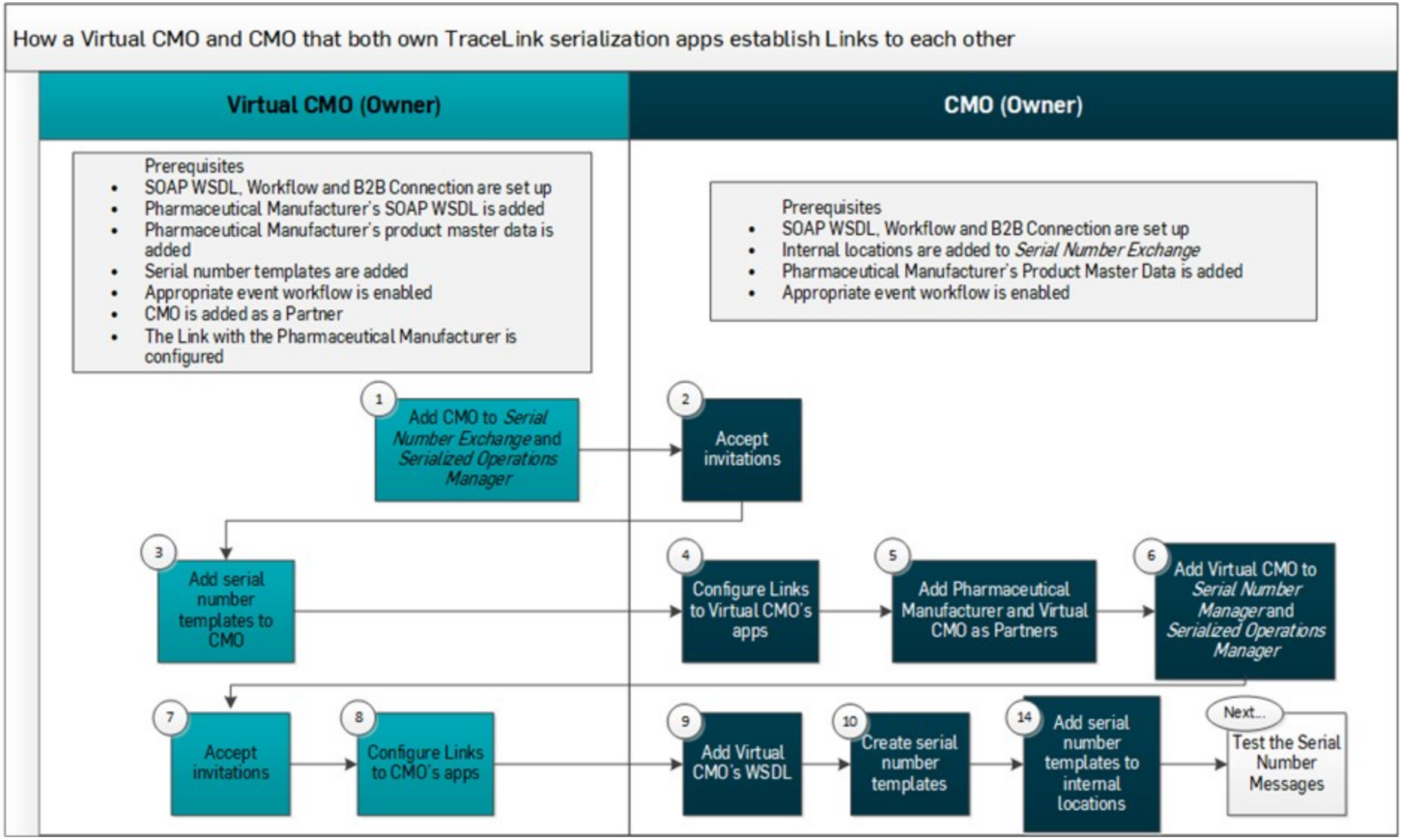
CMO Virtual CMO Pharmaceutical Manufacturer

Next Steps

After the Virtual CMO establishes and configures the Link with the CMO, all three companies can test that the Links are configured correctly. See Test the Serial Number Messages.

Configure the CMO Link

This flowchart displays the steps to successfully establish and configure a Link between a Virtual CMO and a CMO that both own TraceLink serialization apps.



ⓘ The **Where** sections demonstrate where to go to complete the task. Select the Help icon (?) on that screen for more information on individual fields.

Virtual CMO

Step 1: Add the CMO to the Appropriate Apps

Invite the CMO to link to *Serial Number Exchange* and *Serialized Operations Manager* at the company level.

Where

1. Go to *Management* > *Applications*.
2. Select the Partners icon (👥) in the **Actions** column for the correct app.
3. Select ⊕ Partner.

CMO

Step 2: Accept the Virtual CMO's Link Invitations

Accept the Virtual CMO's *Serial Number Exchange* and *Serialized Operations Manager* Link invitations.

Where

- Go to *Application Settings* > *Link Invitations*.

Virtual CMO

Step 3: Add Serial Number Templates to the CMO

Add the serial number template for each packaging code that the CMO needs.

Where

1. Go to *Serial Number Exchange* > *Manage Profiles*.
2. Select the [Company Name] - [Location Name] link in the **ServiceLink** column for the CMO location.
3. Select the ADD PACKAGING CODES button.

CMO

Step 4: Configure Links to the Virtual CMO's Apps

The identifiers in the Virtual CMO's Links to *Serial Number Exchange* and *Serialized Operations Manager* must match the identifiers that the Pharmaceutical Manufacturer uses in those apps.

Where

1. Go to *Company Administration* > *Services*.
2. Select the Configure Subscription link in the **Actions** column for the correct Link.

> ⓘ Make sure that the **Shipment Event** on the "Transaction Delivery Rules" tab is enabled to automatically deliver messages.

CMO

Step 5: Add Partner Information

Add the company and location information for the Pharmaceutical Manufacturer and the Virtual CMO to *Master Data Exchange* and *Company Administration*.

Where

1. Go to *Master Data Exchange* > *Partner*.
2. Select the ADD PARTNER COMPANY button.

and

1. Go to *Company Administration* > *Partners*.
2. Select the ADD PARTNER button.

> Identifiers added here must match Partner Master Data, and must be added at the same level as the Link (i.e. if the Pharmaceutical Manufacturer is linked at the company level, all identifiers are added at the company level). A GLN identifier should be added for the company and an SGLN identifier should be added for each location, if necessary.

CMO

Step 6: Add the Virtual CMO to the Appropriate Apps

Invite the Virtual CMO to link to *Serial Number Manager* and *Serialized Operations Manager*.

Linking the Virtual CMO to *Serial Number Manager* at the **company level** allows the CMO to auto-replenish serial numbers from the Pharmaceutical Manufacturer's Enterprise Serialization Management (ESM) system. The CMO needs to link the Virtual CMO to *Serialized Operations Manager* to transfer product, typically at the company level as well.

Where

1. Go to *Management* > *Applications*.
2. Select the Partners icon (👥) in the **Actions** column for the correct app.
3. Select ⊕ Partner.

Virtual CMO

Step 7: Accept CMO's Link Invitations

Accept the CMO's *Serial Number Manager* and *Serialized Operations Manager* Link invitations.

Where

- Go to *Application Settings* > *Link Invitations*.

Virtual CMO

Step 8: Configure Links to the CMO's Apps

The identifiers in the Virtual CMO's Links to *Serial Number Exchange* and *Serialized Operations Manager* must match the identifiers that the CMO uses in those apps.

Where

1. Go to *Company Administration* > *Services*.
2. Select the Configure Subscription link in the **Actions** column for the correct Link.

> ⓘ Make sure that the **Shipment Event** on the "Transaction Delivery Rules" tab is enabled to automatically deliver messages.

CMO

Step 9: Add a SOAP WSDL

CMOs need the Virtual CMO's custom SOAP WSDL to auto-replenish serial numbers from the Pharmaceutical Manufacturer's ESM system. When the WSDL is available, the CMO or their Technical Consultant can add the WSDL to *Serial Number Manager*. The **Soap Class** must be "ServiceToService."

Where

1. Go to *Management* > *SOAP WSDLs*.
2. Select the Manage SOAP WSDLs link in the **Actions** column for the *Serial Number Manager* app.
3. Select ⊕ WSDL.

CMO

Step 10: Create Serial Number Templates

Create a template that auto-replenishes serial numbers from the Virtual CMO by setting the **Request From** to the Virtual CMO company.

Where

1. Go to *Serial Number Manager*.
2. Select the ADD NEW TEMPLATE button.

ⓘ Assign numbers to the General Pool for maximum efficiency.

CMO

Step 11: Add Serial Number Templates to the Internal Locations

Add the auto-replenishment template for each packaging code that the CMO's internal locations need.

Where

1. Go to *Serial Number Exchange* > *Manage Profiles*.
2. Select the [Company Name] - [Location Name] link in the **ServiceLink** column for the CMO location.
3. Select the ADD PACKAGING CODES button.

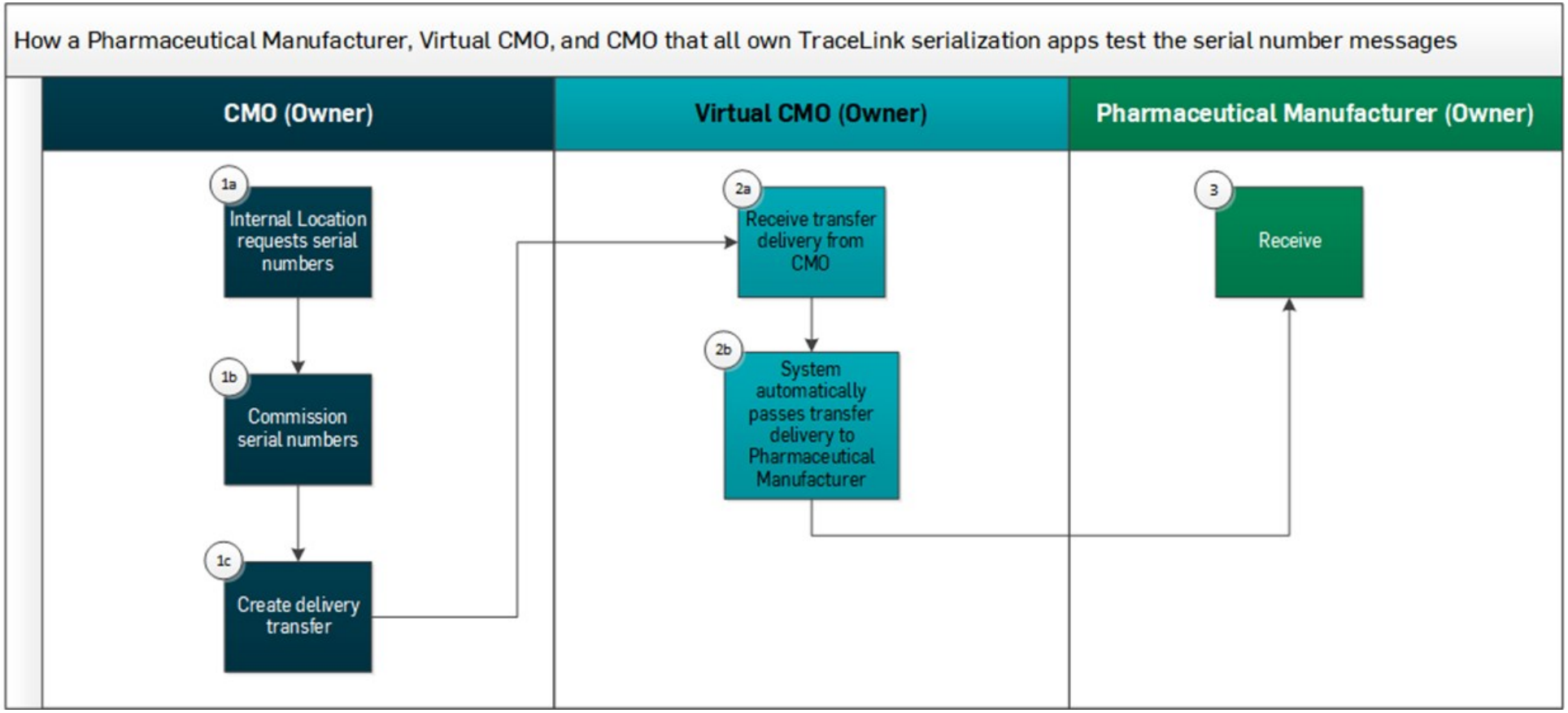
CMO Virtual CMO Pharmaceutical Manufacturer

Next Steps

After the Virtual CMO establishes and configures the Link with the CMO, all three companies can test that the Links are configured correctly. See Test the Serial Number Messages.

Test the Serial Number Messages

After the Links are established between the Pharmaceutical Manufacturer and the Virtual CMO and between the Virtual CMO and the CMO, all three companies can test that the Links are configured correctly by following the steps below.



ⓘ The **Where** sections demonstrate where to go to complete the task. Select the Help icon (?) on that screen for more information on individual fields.

CMO

Step 1: Test Serial Number Messages – Transfer Product to Virtual CMO

Request, commission, and transfer serial numbers to the Virtual CMO to make sure that the Link is configured correctly.

Where

1. Go to *Serial Number Exchange* > *Request Numbers* to request serial numbers from the Pharmaceutical Manufacturer.
2. Go to *Serial Number Exchange* > *Commission Numbers* to commission serial numbers for finished product.
3. Go to *Serialized Operations Manager* > *Outbound Movement* and select the Create Delivery link to transfer the serial numbers to the Pharmaceutical Manufacturer.

   Ensure the following:

   - The delivery has a **Sale Type** of Transfer - In Country or Transfer - Export.
   - The following fields have the correct identifiers:
     - The **From Business** should be the Pharmaceutical Manufacturer's GLN.
     - The **Ship From Location** should be the CMO location's SGLN.
     - The **To Business** should be the Pharmaceutical Manufacturer's GLN.
     - The **Ship To Location** should be the Pharmaceutical Manufacturer location's SGLN.

Virtual CMO

Step 2: Test Serial Number Messages – Receive Transferred Product from CMO

Receive the transfer delivery from the CMO to make sure that the Link is configured correctly. The event workflow automatically sends the transfer shipment on to the Pharmaceutical Manufacturer after the Virtual CMO receives it.

Where

1. Go to *Serialized Operations Manager* > *Inbound Movement*.
2. Select the Create Receipt link.

Pharmaceutical Manufacturer

Step 3: Test Serial Number Messages – Receive Transferred Product from CMO

Receive the transfer delivery from the Virtual CMO to make sure that the Link is configured correctly.

Where

1. Go to *Serialized Operations Manager* > *Inbound Movement*.
2. Select the Create Receipt link.