

### **Anti-Trust Guidelines**

TraceLink University courses are public classes. As such, we ask our students not to engage in discussions regarding pricing, deal-making, selling, promoting or other activities which could be viewed as anticompetitive.

If anyone believes the discussions are approaching these boundaries, please say so and the discussion thread will be halted until TraceLink legal counsel is consulted before proceeding.

# Agenda

- Digital Commerce
- Logistics
- External Manufacturing
- What's Coming: Clinical Supply, Transportation,
   Cell and Gene Therapy
- Blueprint Session



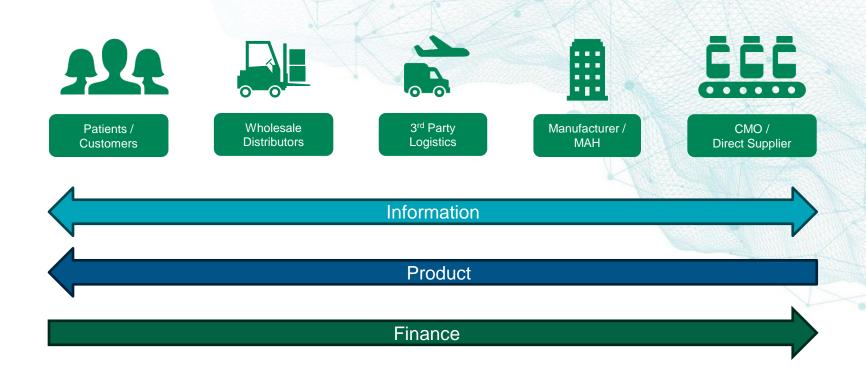








# **Supply Chain Management Flows**



## **Orchestration Subgroups**







### **Product Flow**

Processes and teams that focus on the movement of physical product

- Procurement
- Shipping/Receiving
- Planning
- Production Staff

### **Financial Flow**

Processes and teams that focus on the cost and expenses of an organization

- Finance
- Accounting

### **Information Flow**

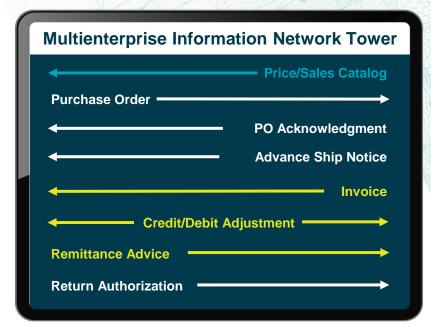
Processes and teams related to additional business details

- Procurement
- Marketing
- Finance

Digital Commerce:
Orchestrating Processes between Life Sciences Companies and Trade Partners

# MINT Transaction Flow for Digital Commerce





Follow the movement of your product utilizing the power of MINT as it passes through the supply chain with transactions such as PO, PO ACK, Advanced Ship Notifications, and Return Authorization.

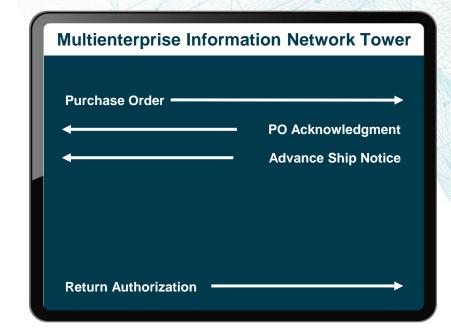




### **Commerce Product Flow**











### **Purchase Order**

**Purpose** 



Place order for goods

Direction



Customer to Supplier/CMO/CPO

Frequency



Order submission

**Notes** 



Followed by PO Acknowledgement

- PO Number
- PO Date
- Customer Information
- Supplier Information
- Ship-To Information
- Billing and Remit-To Information
- Payment Terms
- Delivery Terms
- Line Items
  - Item Code
  - Item Information
  - Quantity, UOM
  - Pricing Information
  - Delivery Schedule Quantities, Dates



# **Purchase Order Acknowledgement**

**Purpose** 



Confirm receipt of the purchase order and communicate potential changes

Direction



Supplier/CMO/CPO to Customer

Frequency



Order submission

**Notes** 



Responds to the received PO (Accept, reject, accept with changes, etc)

#### Key Data:

- **PO Number**
- PO Date
- Acknowledgement Type
- **Estimated Ship Date**
- **Customer Information**
- **Supplier Information**
- Carrier Information
- Line Items
  - Item Code
  - Item Information
  - Quantity, UOM
  - **Pricing Information**
  - **Quantity Changes Made**
  - **Date Changes Made**

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# **Advanced Ship Notification**

Purpose



Communicate contents of a shipment to a trading partner

Direction



Supplier/CMO/CPO to Customer

Frequency



Order submission

**Notes** 



Follows the Purchase Order transaction

- PO Number
- BOL/Tracking Number
- Weight/Dimensions of Shipment
- Scheduled Delivery Date
- Customer Information
- Supplier Information
- Carrier Information
- Transportation Method
- Line Items
  - Item Code
  - Item Information
  - Quantity, UOM
  - Lot Number
  - Parent/Child Relationships



# **Return Authorization Transaction Overview**

**Purpose** 



Coordinate a product return

Direction



Customer to Supplier/CMO/CPO

Frequency



As needed

Notes

Initiated to resolve exception scenarios (damaged, expired, recalled, incorrect product received etc.)

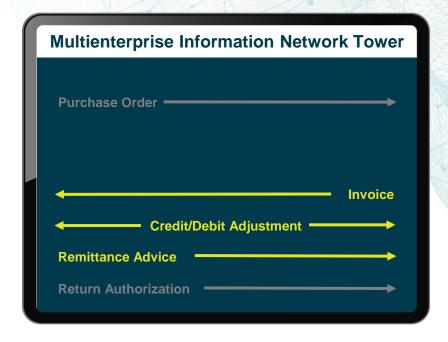
- Date
- Return Reference Identifier
- Purchase Order Reference
- Buyer Company Information
- Seller Company Information
- Return Disposition Code
- Line Items
  - Item Code
  - Item Information
  - Quantity, UOM
  - Return Disposition Code



### **Commerce Financial Flow**











Purpose



Request payment for goods or services provided

Direction



Supplier/CMO/CPO to Customer

Frequency



Order submission

Notes



Follows Purchase Order, typically after product is shipped

#### Key Data:

- Invoice Number
- Invoice Date
- PO Number
- Customer Information
- Payment Terms
- Discount Terms
- Total Amount
- Tax Information
- Line Items
  - Item Code
  - Item Information
  - Quantity Invoiced
  - Unit Pricing Information
  - Allowance or Promotion Information

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# **Credit/Debit Adjustment**

Purpose



Communicate the reduction (credit) or increase (debit) owed by a customer to a supplier.

Direction



Supplier/CMO/CPO to Customer

Frequency



As needed

**Notes** 



Credits or debits may result from fluctuations in material costs, prepayment or contract terms, invoice corrections, returns, fees, or refunds.

#### Key Data:

- Date
- Adjustment Number
- **Amount**
- Credit or Debit Code
- Allowance or Charge Code
- **Customer Information**
- Accounting Structure Code
- Financial Information Code
- Tax Type Code and Amount
- Line Items
  - Item Service Code
  - Item Information
  - **Amount**

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**Purpose** 



Support the payment process

Direction



Customer to Supplier/CMO/CPO

Frequency



Order submission

**Notes** 



Follows an Invoice or Purchase Order to provide documentation of payments made

#### Key Data:

- Remittance Number
- Remittance Date
- PO Number
- Customer Information
- Supplier Information
- Sender Account Number
- Receiver Account number
- Payment Method
- Payment Date
- Amount Paid
- Line Items
  - Invoice Numbers
  - Invoice Amounts
  - Invoice Dates

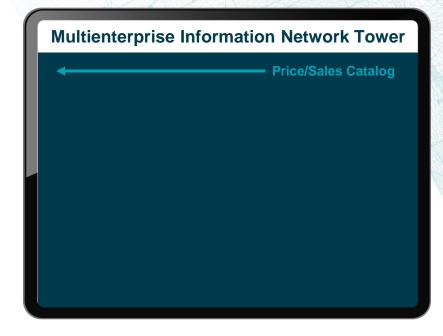
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## **Commerce Information Flow**











# **Price/Sales Catalog**

Purpose



Convey information about products

Direction



Supplier/CMO/CPO to Customer

Frequency



Recurring Schedule (Quarterly, Semi-Annual, Yearly, etc)

**Notes** 



Communicate product catalog or capabilities, contractual pricing, and product information. Showcase product range, share terms and conditions of sale, promotional offers.

#### Key Data:

- **Catalog Number**
- **Catalog Version Number**
- Date
- Seller Name and Contact Information
- Catalog Purpose Code
- Composite Unit of Measure
- Line Items
  - Item Code
  - Item Information
  - Minimum Order Quantities
  - Price, Currency, Discounts or Promotions

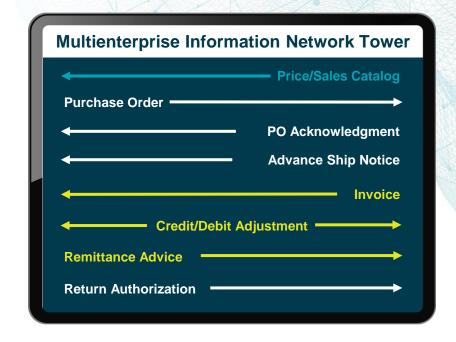
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## **Commerce End-to-End with MINT**









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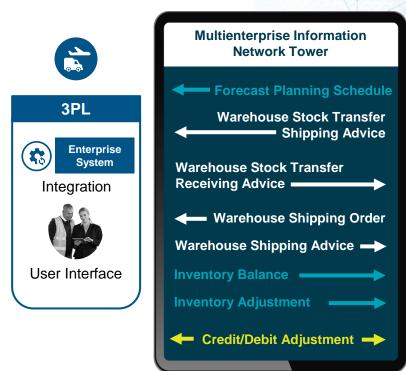








## **MINT Transaction Flow for Logistics**



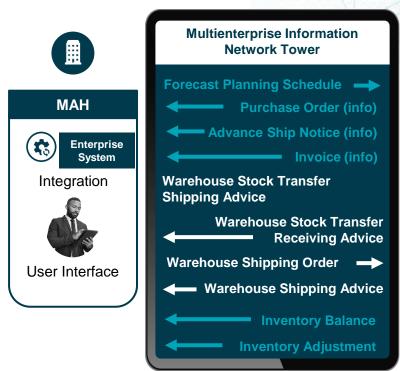


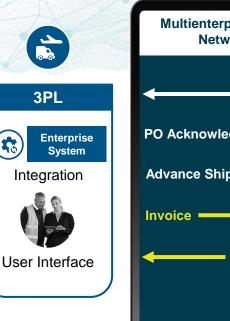


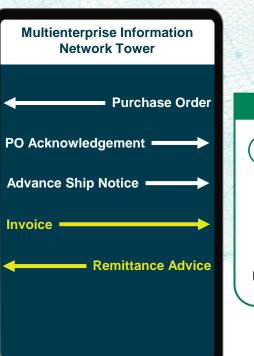


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## **MINT Transaction Flow for Logistics**



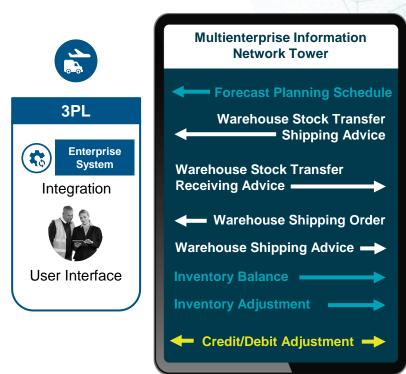




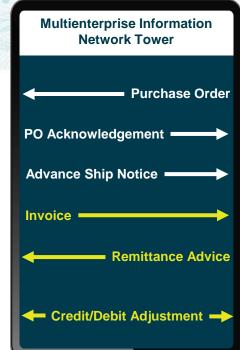


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## **MINT Transaction Flow for Logistics**











## **Logistics Product Flow**



3PL



Enterprise System

Integration



User Interface

Warehouse Stock Transfer
Shipment Advice
Warehouse Stock Transfer
Receipt Advice
Warehouse Shipping Order
Warehouse Shipping Advice



MAH



Enterprise System

Integration



User Interface









Enterprise System

Integration



User Interface



### Warehouse Stock Transfer Shipment Advice

**Purpose** 



Communicate the movement of materials from one warehouse location to another

Direction



MAH to Warehouse/Logistics Provider

Frequency



As needed for inventory relocation

Notes



Used to balance stock, anticipate seasonal needs, launch new product, or facilitating returns. Followed by warehouse stock transfer receipt advice.

### Key Data:

- Shipment Date
- Shipment Number
- Estimated Delivery Date
- Manufacturer Identification Information
- Ship-From Location Details
- Ship-To Location Details
- Carrier Details and Contact Information
- Weight/Dimensions of Shipment
- Line Items
  - Item Code
  - Item Information
  - Quantity
  - Unit of Measure

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### Warehouse Stock Transfer Receipt Advice

**Purpose** 



Communicate receipt of materials at a warehouse location

Direction



Warehouse/Logistics Provider to MAH

Frequency



As needed for inventory relocation

Notes



Follows a warehouse stock transfer shipment advice to report product receipt, stock reconciliation, or updating inventory records

- Shipment Date
- Date of Receipt
- Shipment Number
- Manufacturer Identification Information
- Ship-From Location Details
- Ship-To Location Details
- Carrier Details and Contact Information
- Line Items
  - Item Code
  - Item Information
  - Quantity
  - Unit of Measure
  - Indication of Missing or Damaged Goods



### **Warehouse Shipping Order**

Purpose



Request shipment of goods from a remote warehouse or 3PL to end customer

Direction



MAH to Warehouse/Logistics Provider

Frequency



Order Submission

Notes



Typically followed by Warehouse Shipping Advice

- PO Number
- PO Date
- Ship-To Information
- Customer Information
- Expected Ship Date
- Carrier Details
- Line Items
  - Item Code
  - Item Information
  - Quantity
  - Unit of Measure



### **Warehouse Shipping Advice**

**Purpose** 



Communicate shipment of goods from a remote warehouse or 3PL to end customer

Direction



Warehouse/Logistics Provider to MAH

Frequency



Order Submission

**Notes** 

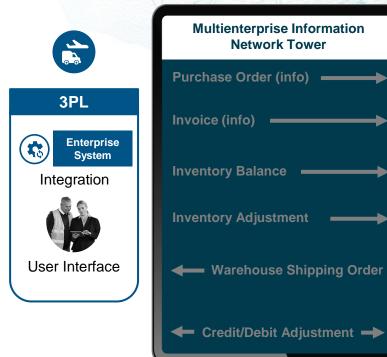


Follows Warehouse Shipping Order

- Shipment Date
- Tracking Information
- PO Number
- Ship-To Address
- Receiver Contact Info
- Expected Delivery Date
- Carrier/Broker Details
- Pallet Configurations
- Line Items
  - Item Code
  - Item Information
  - Quantity
  - Unit of Measure
  - Batch or Lot Information



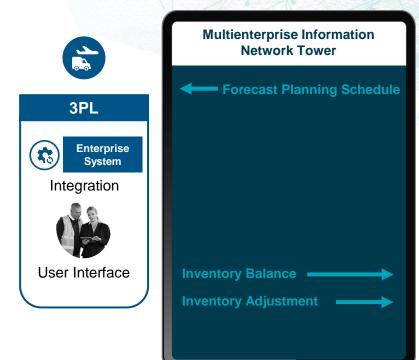
# **Logistics Financial Flow**







# **Logistics Information Flow**







### **Forecast Plan**

**Purpose** 



Inform suppliers of anticipated needs for a certain amount of time

Direction



MAH to Supplier/Logistics Provider

Frequency



Recurring Schedule (Weekly, Monthly, Quarterly, etc)

Notes



Forecasted targets enhance planning capabilities to help optimize stock levels and reduce bottlenecks

- Forecast ID
- Forecast Date
- Forecast purpose code
- · Releases against a PO
- Customer party information
- Supplier party information
- Line Items
  - Item Code
  - Item Identifier
  - Quantity, UOM
  - Item Description
  - Forecast version number
  - Forecast date
  - Forecast timing qualifier



### **Inventory Balance**

**Purpose** 



Reconcile inventory levels for stock of product in different locations

Direction



Supplier/Logistics Provider to MAH

Frequency



Recurring Schedule (Daily, Weekly, Monthly, etc)

**Notes** 



Provides real time inventory visibility for products across storage facilities and locations

#### Key Data:

- Company Information
- Reporting Location Information
- **Transaction Date**
- Line Items
  - Item Code
  - Item Information
  - Lot Number
  - **Expiration Date**
  - Quantity
  - Quantity Type (ex: On Hand, On Order)
  - Unit of Measure
  - Location

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## **Inventory Adjustment**

**Purpose** 



Modify recorded inventory levels or status to reflect actual inventory on hand

Direction



Supplier/Logistics Provider to MAH

Frequency



Triggered by an inventory adjustment event

**Notes** 



Sent after cycle count or as inventory levels change from returned product or other reasons (expired, damaged, consumed, etc)

- **Transaction Type**
- **Transaction Date**
- **Transaction Number**
- Company Information
- Line Items
  - Item Code
  - Item Information
  - Adjustment Type
  - Adjustment Qty
  - Adjustment Reason Code
  - **Location Information**

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- ✓ Digital Commerce
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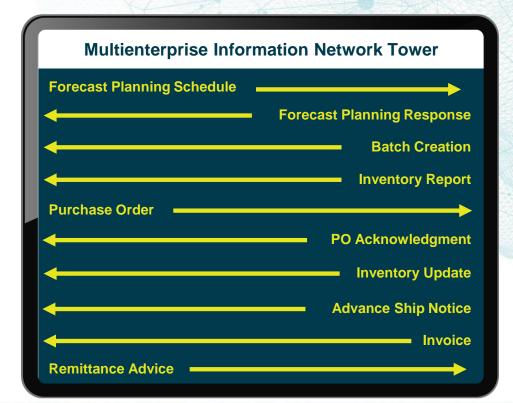






## **MINT Transaction Flow for External Manufacturing**

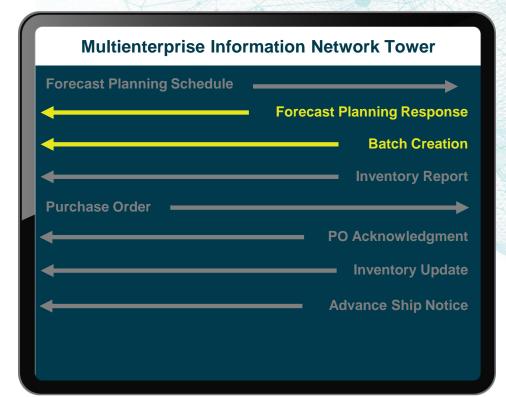






# **External Manufacturing Product Flow**







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### **Forecast Plan Response**

**Purpose** 



Confirm planning schedule

Direction



Supplier/Logistics Provider to MAH

Frequency



Recurring Schedule (Weekly, Monthly, Quarterly, etc)

**Notes** 



Typically follows the Forecast Plan transaction to communicate a response (Accept, reject, accept with changes, etc)

### Key Data:

- Forecast ID
- **Forecast Date**
- Forecast Response Type
- Customer party information
- Supplier party information
- Line Items
  - Item Code
  - Item Identifier
  - Quantity, UOM
  - **Item Description**
  - **Forecast Version Number**
  - **Forecast Date**
  - **Forecast Period**

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**Purpose** 



Creates a group of items which have the same characteristics

Direction



CMO to MAH

Frequency



At batch creation

**Notes** 



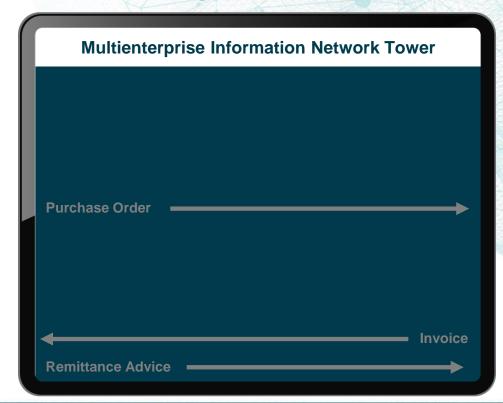
A batch can represent manufacturing a new batch, identifying products in a recall, or a group of items used in quality testing

### Key Data:

- **Shipment Date**
- **Material Number**
- **Batch Number**
- Location identifiers
- Date of Manufacture
- Shelf Life/Expiration Date
- Batch Status
- **Vendor Name**
- Last Goods Receipt
- City/Region of Origin

# **External Manufacturing Financial Flow**

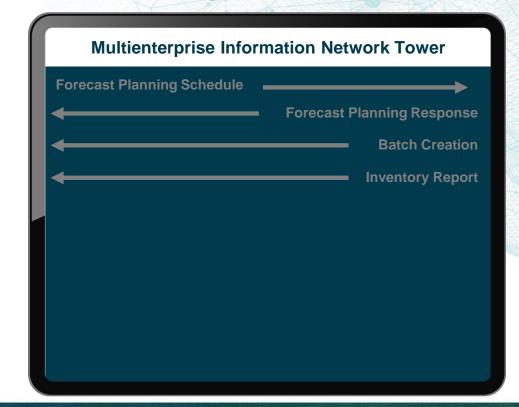






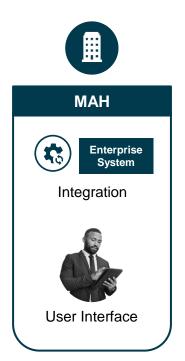
# **External Manufacturing Information Flow**

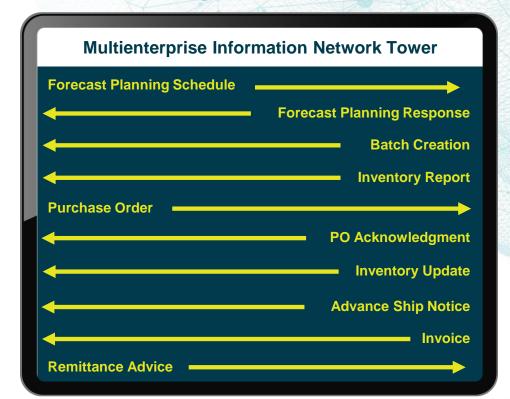






## **External Manufacturing End-to-End with MINT**







## Agenda

- ✓ Digital Commerce
- √ Logistics
- ✓ External Manufacturing
- What's Coming: Clinical Supply, Transportation,
   Cell and Gene Therapy
- Blueprint Session







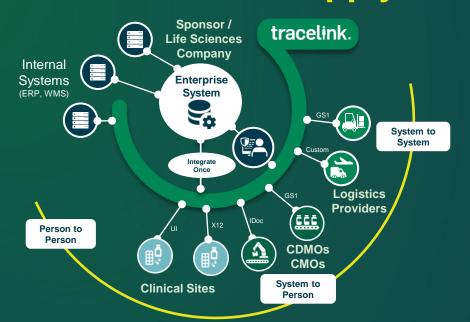




What's Coming: Clinical Trial Supply, Transportation, and Cell and Gene Therapy



## MINT for Clinical Supply Chain



### Integrate-Once<sup>™</sup> for:

- Inventory Balance Request & Response
- Inventory Status (Release Status)
- Inventory Status (Kit Status Change)
- Ship Order Request & Acknowledgement
- Shipping Advice
- Advance Ship Notice (Despatch Advice)
- Receiving Advice
- Dispensing Advice
- Drug Return Order
- Destruction Confirmation

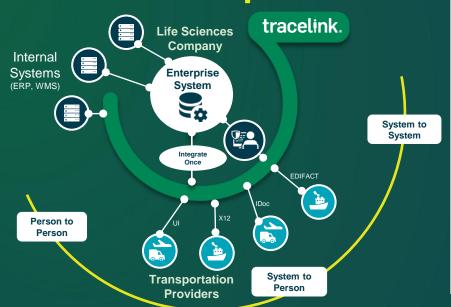
### Real-time business transaction exchange to:

- Align on production volumes for clinical kits
- Improve inventory visibility at CDMO of materials and kits
- Coordinate distribution of kits to patients

- Keep clinics updated on delivery status
- Automate the drug return process
- Confirm proper disposal of expired/excess drugs

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### **MINT for Transportation**



# Integrate-Once<sup>™</sup> for Multimodal Transportation for Air, Ocean, Rail and Motor Carriers:

- Transportation Booking Request
- Transportation Booking Confirmation
- Bill of Lading
- Manifest
- Waybill
- Routing Instructions
- Customs Documentation
- Shipment Status
- Invoice

### Real-time business transaction exchange to:

- Ensure prompt shipment booking and on-time delivery at the lowest cost
- Improve visibility through real-time data exchange to avoid late or lost shipments
- Ensure shipping documents are available and loss-proof to avoid delays and quarantine of product

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### MINT for Cell & Gene Therapy



### Integrate-Once<sup>™</sup> for the Cell Journey:

- Purchase Order & PO Acknowledgement
- Transportation Booking Request & Response
- Transportation Carrier Shipment Status
- Production Status
- Order Status
- Inventory Balance
- Warehouse Ship Order & Shipping Advice
- Advance Ship Notice
- Receiving Advice/Acceptance
- Invoice & Remittance Advice
- Dispensing Advice
- Drug Return Order
- Destruction Confirmation

### **Real-time business transaction exchange for:**

- Continuous visibility with linkage to COI to track chain of custody from cell collection to production to treatment center
- On-time supply for patients for treatment plan
- Treatment hospital preparedness by providing status updates, confirmed tracking numbers and delivery dates

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## Agenda

- ✓ Digital Commerce
- √ Logistics
- ✓ External Manufacturing
- ✓ What's Coming: Clinical Supply, Transportation, Cell and Gene Therapy
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Blueprinting:
Developing an Orchestration Blueprint



# **Agenda for Blueprint**

- Introductions
- What is Blueprinting
- Template Review
- Brainstorm & Create
- Blueprint Discussion
- Wrap-up, Q&A

## What is a Blueprint? Why do we need one?

### What

- Detailed plan to outline functionalities of a software system
- Guide for stakeholders and project managers to ensure requirements are understood and agreed.
- Ensure solution aligns with business objectives
- Description of business process flows
- Capture functional and non-functional aspects of operation

### Why

- Confirm the customers' requirements and landscape (IT and Business)
- Assess the scope and costs
- Guides the implementation process
- Creation of Statement of Work (SoW)
- Value impact analysis and value realization plan (post implementation)

### **Guided Discussion**

- How do we obtain content?
- What questions do we ask?
- Who should be involved?
- What is going on today?
- Current challenges?
- IT landscape!

Executive Strategy – Supply Chain Workshop VP Supply Chain; Planning & Procurement; IT

#### Questions (remove any that you already qualified)

#### Objectives and Strategy:

- What is your company's overall goal for the next 3-5 years? What KPIs and success factors will be most relevant for this goal?
- How does the Supply Chain Strategy play into this plan? What are the specific goals from a SC perspective for the next years?
- What improvements have priority? Value? Examples:
  - Spreadsheet and manual entry reduction
  - o Better and faster Information exchange
  - Data Reliability and Quality
- What are the most critical management KPIs?
- Where do you see growth potential (markets/products)? What revenue growth do you expect?
- What are the top priorities for digitalization in the supply chain? Why?
- · What has so far given the best value in terms of digitalization projects for supply chain?

#### Operational Supply

- What kind of information needs to be exchanged with your partners? How much of that is manual?
   What are the consequences?
- · How do you categorize your suppliers? How many are there in total?
- How does the communication process with your CMOs work? What are the challenges?
- Are you able to measure there on-time and OTIF delivery performance?
- How often (%) do you receive a PO ACK and ASN?
- What is the cycle time for your complete Procure-to-Pay process (estimate)? Benchmark: 45 days

#### Demand Planning

- What is your approximate number of customers? Do you group your customers? Are any of them based in other countries?
- Do you have any SLAs that you need to fulfill? What if they are breached? Are you able to grow in the way you currently operate within these SLAs?
- · What would customers say about the current way of working with you?

#### **Business Planning**

- Describe your planning process. What data from external partners (up- and downstream) flow into that. What is your planning accuracy FC vs. budget?
- · How often do you discover problems with matching demand and supply? What can be an issue there?
- . What happens if you are not able to get the correct information from your suppliers on time?

### Magnetic Opus: An Architect's Prototype to Orchestrate





### **Activity: Order to Cash**

Scenario: You are working with a pharmaceutical manufacturer responsible for manufacturing and distributing a critical drug, CureX. The manufacturer uses a 3PL and has little visibility into the movement of their products.

Drag and drop the magnetic pieces to best create a orchestration blueprint that solves this challenge.

- Company information
- Strategy details
- Therapeutic area
- **Financials**

### **Overviews**

- Participants and Roles
- General information
- Problem
- Opportunity



Enabling patient-driven, end-to-end orchestration and analytics

#### 1. COMPANY PROFILE

#### 2. SOLUTION BLUEPRINT OVERVIEW

From the spark of innovation in the corridors of the (MIT) to the expanse of the digital cloud. Tracel ink

This document defines the solution blueprint for [CUSTOMER] for Network Tower (MINT).

ness processes th

#### the life science 3. SOLUTION OVERVIEW

Dahod, collec with decades patient safety products wer global supply

TraceLink, or in 2003, was early days we compliance a groundwork

The company transformativ healthcare su world standa by the globali compliance r of innovation world, netwo

etings. This docu The MINT solution powers end-to-end supply chain visibility, collaboration, and intelligence with a digital network platform. Leveraging the proven, industry-wide integration capabilities of the Opus platform and TraceLink network, MINT provides the foundational capabilities required for supply chain participants to finally gain full visibility with a supply network through the exchange of interoperable commerce, inventory, logistics, and other supply chain



MINT is a transformational capability for the supply chain, enabling rapid trade partner onboarding and a Business-to-Network Integrate-Once™ approach for sharing timely, critical business information necessary to prevent supply disruptions and optimize key performance metrics. MINT achieves these goals through transformative capabilities, including:

 MINT leverages a proven model for trade partner identification, authentication, onboarding. and integration which provides the foundation for developing a true digital twin for each company, its products, and its partners across the end-to-end pharmaceutical supply chain. TraceLink has onboarded and integrated more than 7,400 CMOs.

## **Customer Requirements**

- Business requirements
- High level KPI metrics
- Use case summary
- Transaction Types / Direction



Enabling patient-driven, end-to-end orchestration and analytics

#### 4. [CUSTOMER] REQUIREMENTS

#### 4.1. CUSTOMER BUSINESS REQUIREMENTS OVERVIEW

During our discussions with your <u>team</u> we have identified the following processes as being the ones to focus on for the implementation to ensure we meet the requirements of your top KPI, OTIF and reduce the effort by 20% for manual tasks such as emails, stand up meetings and phone calls with your suppliers.

#### Supply Management - Integration with CMO

MINT Transactions	Ref ID	Direction	Customer Business Process Overview	Format Requirements (sFTP, AS2, LinkAction or UX)
PO	BP1.1	CMO to MAH	Digitalize to reduce manual efforts	
PO Ack	BP1.2	CMO to MAH	Digitalize to reduce manual efforts	
Advanced Ship Notice (ASN)	BP1.3	MAH to CMO	To inform of completed production	
Inventory Balance	BP1.4	CMO to MAH	Regular visibility into stock levels	
Inventory Adjustments	BP1.5	CMO to MAH	Portray changes to stock levels when they occur	

#### Logistics Management – Integration with 3PLs

MINT Transactions	Ref ID	Direction	Customer Business Process Overview	Format Requirements (sFTP, AS2, LinkAction or UX)
Inventory	BP2.1	3PL to	Daily insight into sales and	
Balances		MAH	stocks	
Invoice	BP2.2	MAH to 3PL	Digitalize to reduce manual efforts	

#### 4.2. Any Custom requirements

Please outline any custom requirements that have been learned.

# Integration Requirements

- Customer enterprise system information
- Formats



BP2.2

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#### 5. Integration and Transformation Requirements

TraceLink will deploy a single MINT Network solution for use by your teams. Adaptions to teams can be performed by yourselves and if required multiple Networks can be created to segregate the Teams for appropriate business context.

#### 5.1. CUSTOMER CONNECTIVITY INFORMATION

IDoc

+					
	Process	Customer System	Format (e.g <u>, IDoc</u> , UX only)	Transaction	Average Quantity per Month
Γ	BP1.1	SAP	IDoc	PO	150
Γ	BP1.2	SAP	IDoc	PO ACK	50
	BP1.3	SAP	IDoc	ASN	250
	BP1.4	SAP	IDoc	Inventory Balances	30
	BP1.5	SAP	IDoc	Inventory Adjustments	20
	BP2.1	SAP	IDoc	Inventory Balances	35

Invoice

### As Is - To Be

- Review the challenges being faced today
- Confirm the MINT solution opportunity

### Value Metrics

KPI discussion



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#### 5.3. As Is - To BE FLOW

#### Use Case 1: MINT for External Manufacturing

Current state of the use case including any manual/digital interactions including personas.

Desired state to leverage digital transaction deployed via MINT.

#### Use Case 2: MINT for Logistics

Current state of the use case including any manual/digital interactions including personas.

Desired state to leverage digital transaction deployed via MINT.



### Magnetic Opus: An Architect's Prototype to Orchestrate



Discuss/Q&A

Review blueprint boards

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