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Course Introduction

Learning Objectives

By the end of this course, you will be able to:

- Explain the value of a External Manufacturing Orchestration.
- Describe the five orchestration phases: Planning, Procurement, Manufacturing & Execution, Receiving & Inventory, and Finance & Closure.
- Identify key supply chain transactions and their purpose.
- Show how MINT standardizes collaboration between MAH and CMO.
- Apply orchestration workflows to real-world manufacturing scenarios.
- Recognize how digital transactions improve accuracy, efficiency, and collaboration.

Course Introduction

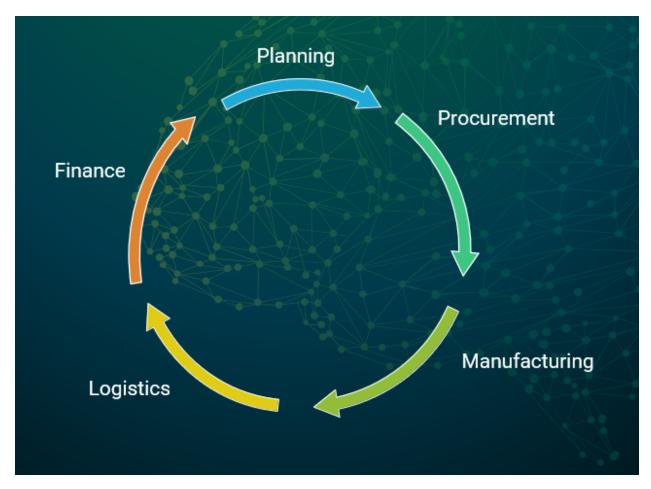
This course provides intermediate-level certification in External Manufacturing orchestration using MINT.

This training module provides a comprehensive introduction to External Manufacturing Orchestration using MINT (Multienterprise Information Network Tower). It is intended for Life Sciences companies and Contract Manufacturing Organizations (CMOs) who must collaborate efficiently across planning, procurement, manufacturing, inventory, and financial transactions.



Overview Supply Chain Management

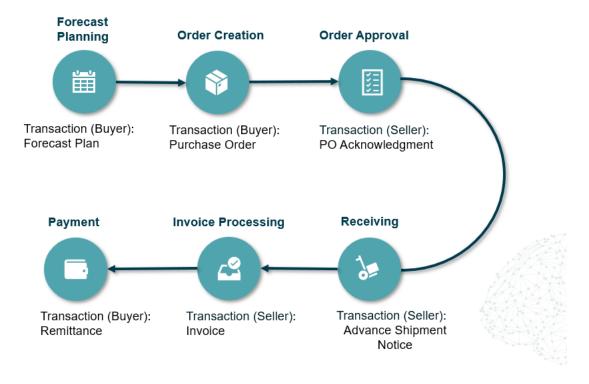
Supply Chain Management (SCM) is the end-to-end coordination of activities required to source raw materials, transform them into finished products, and deliver those products to customers. It spans five core functions: planning, procurement, manufacturing, logistics, and finance. Together, these functions ensure goods move efficiently from origin to end customer, while balancing cost, quality, and speed across the entire supply chain.





Orchestration: Procure to Pay

The Procure-to-Pay (P2P) process covers the full purchasing cycle, beginning with the buyer's forecast planning and purchase order creation, followed by the supplier's purchase order acknowledgment and advance shipment notice. Once goods are received, the supplier issues an invoice, and the cycle concludes with the buyer sending a remittance advice. MINT displays all transactions in the UI to ensure accuracy, timeliness, and transparency between trading partners.





Categorizing Supply Chain Transactions

Functional Phase	Transaction Examples
1. Planning	Forecast Plan, Forecast Response, Planned Order, Process Order, Order Status Report, Batch Closure
2. Procurement	Purchase Order, Purchase Order Acknowledgment
3. Manufacturing & Execution	Batch Creation, Material Issued, Material Consumed, Material Produced
4. Receiving & Inventory	Advance Shipment Notice, Receiving Advice Acceptance, Inventory Balance, Inventory Update
5. Finance & Closure	Invoice, Remittance Advice

This section provides a high-level view of how transactions are grouped by both process phase and flow type, Information, Product, or Finance. Understanding this structure helps clarify the sequence and purpose of each transaction as we explore them in detail later. It is important to note that orchestration subgroups often overlap, with personnel and data shared across multiple areas. Because supply chain processes depend heavily on information and actions from other functions, smooth collaboration requires more than just managing internal workflows. Each organization, internal teams and external partners, must understand its own orchestrations and how they connect with partner orchestrations.



MINT User Roles

In MINT, the menu items and available actions within the system are determined by the roles assigned to each user. Roles are typically linked to a specific orchestration and perspective, meaning that a user can only create, view, or interact with the transactions relevant to their assigned responsibilities.

There is also a special administrative role that provides a consolidated list view of all B2B transactions. This broader access is particularly valuable for administrators or monitoring personnel who need full visibility across the end-to-end orchestration.

Roles can be configured with different levels of access:

- Full Access Create and edit transactions.
- View-Only Access View transactions, reports, and dashboards (no edits).

For example, Administrators use Full Access to troubleshoot and analysts use View-Only for reporting.

This role-based structure provides the right balance between collaboration and control. It ensures that team members have the access they need to complete their tasks efficiently, while safeguarding sensitive information and maintaining compliance.



Introduction to External Manufacturing Orchestration

Orchestrating Processes between Life Sciences Companies and Contract Manufacturing Organizations (CMOs)

External manufacturing can be a complex orchestration. The complexity stems from limited visibility into the data that must move between entities.

When exchanging data with your CMO, you want as much transparency as possible. From the Forecast being accurate and agreed upon, down to timely Procure-to-Pay. Visibility with the CMO ensures the MAH knows that what is ordered will be available and delivered on time. The CMO can also plan better for their procurement activities, production schedule and Order-to-Cash cycles.





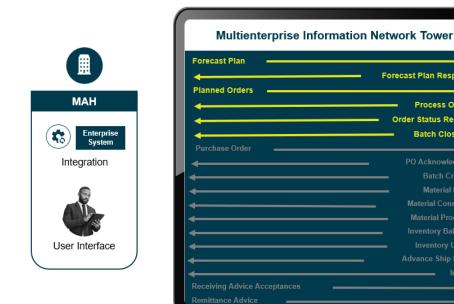
External Manufacturing Planning Phase

The Planning Phase in External Manufacturing establishes the foundation for alignment between the Marketing Authorization Holder (MAH) and the Contract Manufacturing Organization (CMO). In this phase, several key transactions ensure demand and production are synchronized.

In this phase, we can reference Forecast Plan, Forecast Plan Response, Planned Orders, Process Orders, Order Status, and Batch Closures.

> Order Status Reports **Batch Closures**

> > Material Produced





Forecast Plan

A Forecast Plan signals expected demand and release schedules so suppliers can align production and resources. By sharing this anticipated demand and release schedule, the buyer provides the supplier with a roadmap to align production and distribution in advance.

In practice, the buyer submits a Forecast Plan to outline expected product needs over upcoming weeks or months. The supplier uses this insight to build production schedules and prepare resources accordingly. Because demand naturally changes over time, the forecast is not fixed, it can be refined. Purchase Orders (POs) may be adjusted up or



down based on real-world demand and inventory shifts, while suppliers also flex production plans to stay aligned.

The outcome of this process is smarter planning and proactive collaboration. Forecast Plans reduce last-minute changes, prevent supply disruptions, and strengthen the buyer–supplier partnership by replacing reactive firefighting with forward-looking decision making.

Forecast Plan Response

The Forecast Plan Response is the supplier's reply to the buyer's forecast. Through this transaction, the supplier communicates whether they can commit to the forecast, propose changes due to capacity constraints or material shortages, or reject and request adjustments if the forecast is not feasible.

This step ensures that both parties have a realistic and mutually agreed view of demand and supply before moving into order creation. Because supply chain environments are dynamic, forecasting is an iterative process. Both buyer and supplier must continuously refine their plans, as misalignment can cause stockouts, excess inventory, or costly disruptions.

Planned Order

A Planned Order is a system-generated recommendation from Enterprise Resource Planning (ERP) systems like SAP, or from Advanced Planning Systems (APS). It signals the anticipated need to manufacture or procure a specific quantity of a product whether a pharmaceutical finished good or a raw material at a future date. Planned Orders are not yet firm commitments, but act as early planning signals that support supply continuity and production readiness.

Key Benefits

Proactive Supply Planning : Anticipates future needs in advance and helps the organization minimize disruptions by avoiding material shortages.

Improved Inventory Management : Balances supply with actual demand, reducing the risks of excess stock as well as stockouts.



Enhanced Production Scheduling : Strengthens coordination of manufacturing resources and timelines, resulting in greater efficiency and predictability.

Process Orders

A Process Order is a structured set of instructions used in process manufacturing industries such as pharmaceuticals, chemicals, food, and beverages, where production follows formulas or recipes rather than assembling discrete parts. It directs and controls the transformation of raw materials into finished goods through operations like mixing, blending, heating, or fermenting.

Within an ERP system, the Process Order functions as a digital production blueprint, capturing all essential details: production steps, timelines, equipment assignments, material consumption, and quality checks. By standardizing these elements, Process Orders ensure that every batch is manufactured consistently, efficiently, and in compliance with regulatory standards.

Order Status Report

An Order Status Report works much like a package tracking system when you order something online. Just as customers receive order updates such as confirmed, being packed, shipped, in transit, and delivered, an Order Status Report provides buyers, suppliers, and CMOs with comparable visibility into the progress of a purchase order.

This visibility helps all parties understand where the order is, what step comes next, and whether any delays or issues exist, without the need for constant follow-up. By offering timely updates, Order Status Reports improve communication, reduce uncertainty, and support proactive decision-making across the supply chain.

Batch Closure

Batch Closure represents the official completion of all activities tied to manufacturing a specific batch. This step confirms that final production processes have been executed, quality control tests completed, any deviations reviewed, and all required documentation (such as the Batch Manufacturing Record (BMR) or Electronic Batch Record (EBR)) fully approved.

Once a batch is closed, it is considered finalized, meaning:



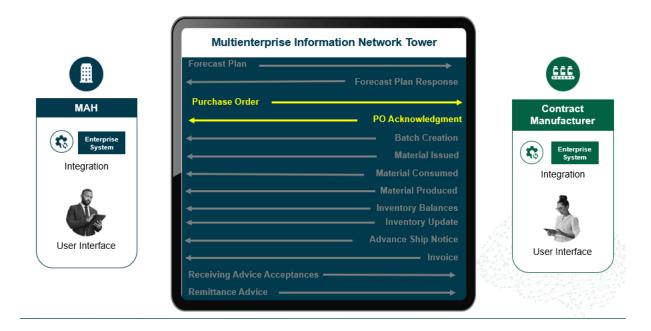
- No further edits or modifications are allowed.
- All data is locked for compliance and audit readiness.
- The batch is cleared and becomes eligible for packaging, release, shipping, or distribution.

Batch closure ensures data integrity, accountability, and readiness for the next stage in the supply chain.



External Manufacturing Procurement Phase

The Procurement Phase focuses on converting planned demand into firm commitments between buyer and supplier. Two key transactions define this stage: the Purchase Order (PO) and the PO Acknowledgment.



Together, these transactions create a clear contractual and operational baseline, reducing ambiguity, preventing errors, and streamlining communication between partners. In some cases, procurement may also involve updates or amendments to POs to reflect real-world changes in demand, capacity, or lead times.

Purchase Order



A Purchase Order (PO) is the buyer's formal request to a supplier to procure goods. It specifies all critical details of the transaction—such as the product type, quantity, agreed price, and delivery requirements—ensuring both parties have a clear and shared understanding of what is being purchased.

In some cases, what the buyer issues as a Purchase Order may be managed by the supplier under a different name, such as a Sales Order. Regardless of terminology, parties must align on the details to avoid errors in fulfillment.

Digitalizing Purchase Orders in MINT eliminates manual-entry errors, duplication, and miscommunication. MINT automatically transforms and routes data consistently between systems, ensuring information is accurate and delivered to the right place. Unlike manual processes, which rely on individuals and may be delayed or lost (e.g., in an inbox while someone is away), MINT ensures that orders are sent systematically to the company, maintaining continuity and reliability.

Purchase Order Acknowledgement

A PO Acknowledgment is the supplier's formal response confirming they have received the buyer's Purchase Order. In this response, the supplier may:

- Accept the order as issued.
- Reject the order if it cannot be fulfilled.
- Propose changes, such as adjusted delivery dates, quantities, or pricing.

This step is a critical point of collaboration and alignment. It ensures both the buyer and the supplier share the same expectations for quantities, timelines, and terms before production or delivery begins. This alignment helps prevent errors, delays, and miscommunication later in the process.

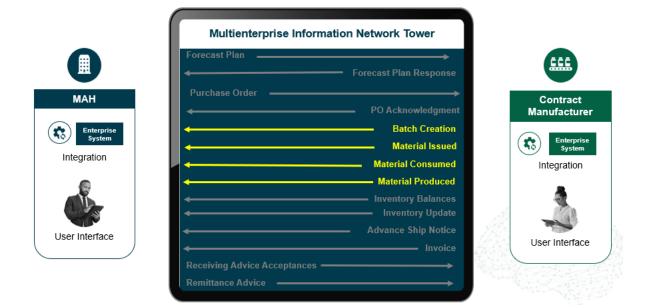


Manufacturing & Execution Phase

The Manufacturing & Execution Phase focuses on the core production activities that transform raw materials into finished goods. Key transactions in this stage include Batch Creation, which establishes the production lot and links all related activities; Material Issued, where raw materials are released from inventory for use in production; Material Consumed, which records the actual quantities used during processing; and Material



Produced, which captures the finished output of the batch. Together, these transactions ensure accurate tracking of inputs, outputs, and process execution, providing visibility, compliance, and efficiency across the manufacturing lifecycle.



Batch Creation

After the Forecast Plan Response is reviewed, the next step is to translate demand into actual production. This begins with Batch Creation, where the details of how products will be manufactured are defined based on forecasted needs.

Batch Creation records essential information such as batch number, production date, expiration date, ingredients, quality control results, and storage conditions. This data allows suppliers to verify product authenticity, check expiry dates, ensure compliance, and manage inventory accurately at the batch level.

In addition, Batch Creation provides the foundation for progress tracking and resource monitoring throughout the production lifecycle. It keeps manufacturing teams aligned with planning, supports efficient execution, and reduces the risk of errors caused by missing or inaccurate data.

Material Issued

The Material Issued transaction records the movement of raw materials or components from inventory to the production floor or another operational process. This step ensures



that materials needed for manufacturing are available when required and that the usage is properly documented.

Recording this transaction is critical because it provides accurate inventory tracking, supports traceability, and directly impacts cost valuation. By capturing what has been issued, organizations can monitor material flows, assess resource efficiency, and maintain compliance with manufacturing and financial controls.

Material Consumed

Material Consumed represents the actual quantity of raw materials used during the manufacturing process. This often differs from Material Issued, since factors such as scrap, rework, spoilage, or operational inefficiencies can reduce the amount that is ultimately used.

For example, in a simple analogy: if a chef takes out ten tomatoes but only uses eight in the dish, the eight tomatoes represent the consumed material, while the remaining two are considered waste.

Accurately tracking material consumption is critical for several reasons:

- Measures efficiency by comparing issued vs. consumed quantities.
- Supports cost accuracy by calculating the true material cost of production.
- Reduces waste by highlighting process losses and rework.
- Identifies improvement areas to refine operations and strengthen resource planning.

By capturing this data, organizations can make better decisions, lower costs, and drive continuous process improvement.

Material Produced

Material Produced marks the output of the manufacturing process, whether as finished goods or intermediate (semi-finished) products. Once production is complete, this transaction is recorded in systems such as ERP to update inventory levels.

Capturing this step is critical because it often triggers quality inspections, ensures products are ready for packaging, release, or shipment, and provides real-time visibility into production outcomes. By accurately recording Material Produced, organizations



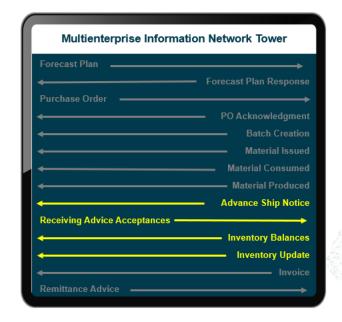
maintain supply chain transparency, support customer order fulfillment, and establish accountability for every unit manufactured.



External Manufacturing Receiving & Inventory

The Receiving & Inventory Phase focuses on confirming deliveries and maintaining accurate stock records across the supply chain. Key transactions in this stage include the Advance Shipment Notice (ASN), Receiving Advice Acceptance, Inventory Balance, and Inventory Update. Together, these transactions ensure visibility, traceability, and accuracy of inventory while enabling downstream processes such as quality checks, packaging, or customer order fulfillment.







Advance Shipment Notice

An Advance Shipment Notice (ASN) is like receiving a text that your food delivery is 10 minutes away. It is an electronic document sent by the supplier to notify the buyer of goods in transit before they arrive.

An ASN typically includes details such as shipment contents, quantities, expected delivery date, and tracking information. This early visibility allows buyers to prepare by allocating space, scheduling labor, and planning for smooth receiving operations.



By acting as the bridge between shipping and receiving, the ASN keeps both buyer and supplier in sync, reducing surprises, improving efficiency, and ensuring accurate, timely handoffs in the supply chain.

Receiving Advice

Receiving Advice is the formal confirmation that goods have been delivered to the buyer's location. This transaction verifies that the shipment has been received, matches the details provided in the Advance Shipment Notice (ASN), and is in acceptable condition.

The Receiving Advice confirms that the shipment:

- Has been delivered.
- Matches the details provided in the Advance Shipment Notice (ASN).
- Meets the agreed quality and condition requirements.

This transaction plays a critical role in keeping the supply chain synchronized, providing an auditable record of deliveries, and ensuring data integrity across systems.

Inventory Balance

The Inventory Balance provides a real-time snapshot of available stock across all stages of the supply chain, including raw materials, work in process, and finished goods. It serves as a two-way communication channel where either the buyer or supplier can initiate the transaction to share or request information about on-hand inventory levels.

Inventory Update

An Inventory Update is an electronic transaction used to notify trading partners about adjustments to inventory levels within a warehouse or distribution center. This ensures that stock records remain accurate, which is especially critical for regulatory compliance, product availability, and patient safety.

Suppliers typically initiate an Inventory Update when inventory levels change due to events such as receiving new stock, shipping orders, product damage, expiration, or recalls. Buyers then use this information to update their own records, maintaining a synchronized and accurate view of available products.

Accurate and timely inventory updates are essential for preventing discrepancies, improving planning, and ensuring reliable order fulfillment across the supply chain.

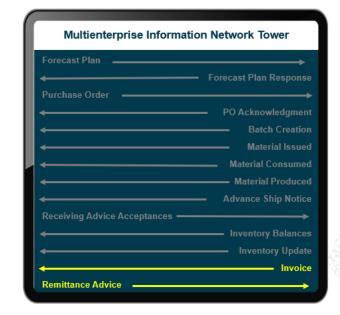




External Manufacturing Finance & Closer

In the Financial Flow of external manufacturing, two key transactions complete the procure-to-pay cycle: the Invoice and the Remittance Advice.







Invoice

Once goods have been ordered, shipped, and received, the next step is for the supplier to request payment. This is done through an Invoice, the formal document issued by the seller to the buyer.

An Invoice typically includes key details such as:

- Item descriptions
- Quantities delivered
- Unit prices and applicable taxes
- Total amount due
- Payment terms and conditions

Material Issued



After a payment is made, the buyer sends a Remittance Advice to the supplier. This transaction serves as more than a simple payment notification. It also provides a detailed breakdown of what was paid and why, ensuring full financial transparency between both parties.

A Remittance Advice typically includes:

- Related invoice numbers or purchase orders
- Amounts paid against each invoice
- Payment method and date

By exchanging Remittance Advice digitally through MINT, buyers streamline their accounts payable process, while suppliers gain immediate clarity on which invoices have been settled and for how much. This enables faster reconciliation, helps identify discrepancies instantly, and keeps accounts receivable accurate and up to date.

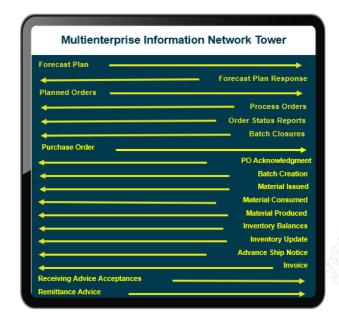




External Manufacturing End-to-End with MINT

In conclusion, the end-to-end orchestration of transactions across Planning, Procurement, Manufacturing & Execution, Receiving & Inventory, and Finance & Closure ensures timely and reliable information sharing between all supply chain partners. By digitalizing these processes in MINT, organizations can produce goods in alignment with actual demand, avoid costly disruptions, and minimize excess inventory. The result is a more agile, efficient, and collaborative supply chain that supports both operational excellence and customer satisfaction.

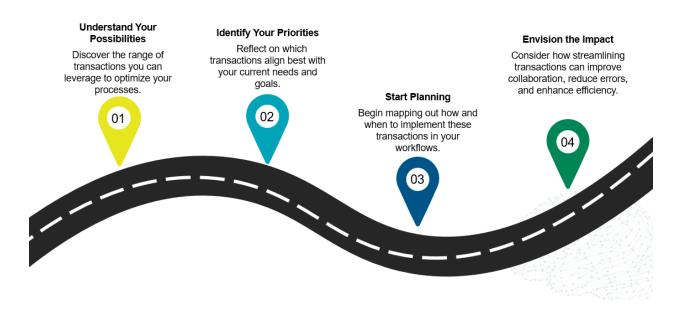








Key takeaways:



As you review the transactions covered in this course, keep the following in mind:

- Understand Your Possibilities Explore the full range of transactions available to help optimize and streamline your supply chain processes.
- Identify Your Priorities Focus on the transactions that best align with your organization's current needs, challenges, and goals.
- Start Planning Map out when and how these transactions can be implemented in your workflows for maximum impact.
- Envision the Benefits Recognize how digital orchestration improves collaboration, reduces errors, strengthens visibility, and enhances overall efficiency.

Next Steps: Reflect on which phase of your external manufacturing process could benefit most from digitalization and orchestration, and begin planning your path forward.