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# How to specify your commercial supply chain logistics requirements

# Contents

Top tips for procurement

# Introduction

**Outsourcing is now a fundamental part of drug development and distribution.**

Setting up a robust supply chain to ensure business continuity is among the most pressing issue facing pharmaceutical and biotech manufacturers when launching their product commercially.

Outsourcing is now a fundamental part of drug development and distribution.

Finding the right logistics provider and creating a collaborative relationship that delivers value beyond shipping, storage and packing is key to the high-performing commercial logistics and distributions required for increasingly complex therapies.

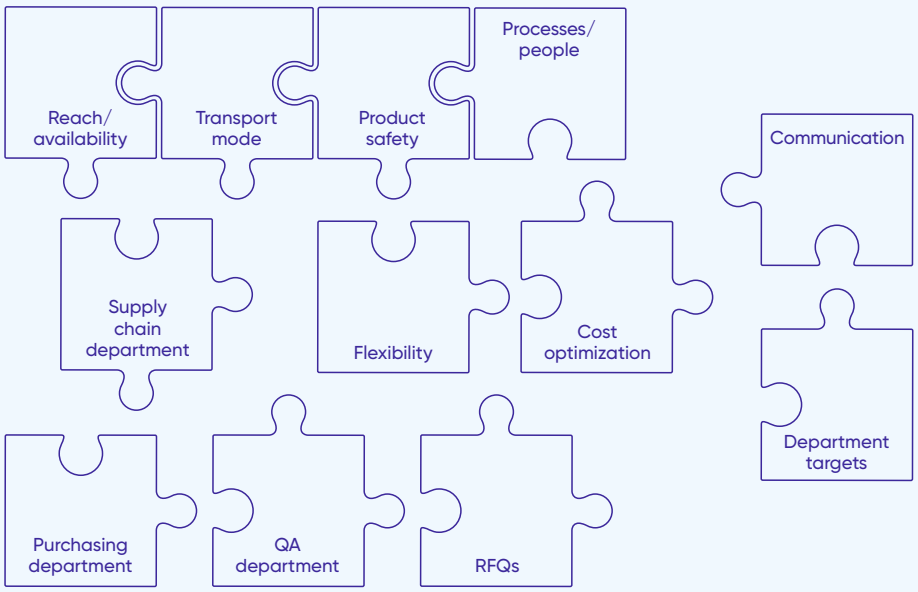
## The first step to a successful partnership: understanding your product's requirements

To expedite the procurement, proposal and quotation stages, and improve the onboarding of a new logistics and distribution partner, you need to share a detailed understanding of your product, its requirements and your needs as an organization. This can be complicated when there are multiple departments on both sides of the relationship, each with responsibility for logistics, procurement, and quality.

# Introduction

## Market pressure.

Source: Presentation from C.Engel




Especially when you called for tender already in the past, it may be tempting to utilize previous tender documents and established frameworks. However, not only may the product requirements change or vary, but the target audience for your tender may be different freight forwarders versus third party logistics (3PL) companies versus integrators versus specialty providers etc. Given the growing product complexity due to the paradigm shift of moving from small to large molecule drugs, we should appreciate every tender process is unique and there is no one size fits all. By following the checklist below, it should allow you to provide essential information that a partner will need to create a customized logistics approach for your product.

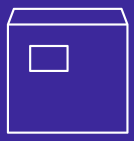
## Format

The type and format of your substance or product will dictate much of its commercial logistics requirement. Some cell and gene therapies (CGTs) will require highly choreographed, responsive, and rapid delivery to patients with a likely need for cryogenic storage at some point in the supply chain.

A new drug therapy approval based on a high-value, low-volume large molecule biologics — especially a specialty or orphan drug — will need low-volume temperature-controlled logistics.

While biosimilars competing against a recently off-patent biologic might require high-volume, temperature-controlled logistics so they can be made available to a larger patient population.

Your commercial logistics partner should be able to flex and respond to your varying requirements, however, communicating them from the off will simplify the relationship.



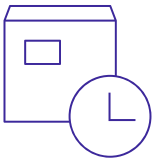
## Volumes and packaging

Understanding the number of doses (volume, tertiary or inner product container dims) and weight of your shipments are key as it will influence whether ground logistics, air freight, belly cargo, or even air charter solutions are viable.

To understand volumes, we first need to understand the exact types of product packaging (for example, cartons, cases, or pallets), the number of vials and doses and their configuration (such as 10 vials per carton, or 30 cartons per case). You also need to know the inner and outer dimensions of the package, and its weight.

Packaging affects logistics and supply chain efficiency as it interacts with handling (whether manual or equipment), transportation, and information systems (such as aggregation). At its most basic level, the size and dimensions of packs can impact cubic utilization in transport, and material choices could increase waste.

If there is a cold chain requirement and dry ice and a thermal container is needed, this could increase the weight and size of your shipment significantly, so this needs to be considered as early as possible.



## Timeframes

There are two things to consider when it comes to timeframes:

01 When materials need to be shipped (with flexibility to respond to regulatory approvals when given) and required at the point of delivery.

02 The shelf-life of the product (for instance, human or animal cells have a shelf-life of a few hours or days, typically 24 to 48 hours). Such materials should be handled accordingly.

## Storage

- **Controlled substances** - Some substances and products will require facilities and handlers to have specific licenses. The DEA has tiered its controlled substance schedule with companies needing to implement procedures and have specific capabilities in place to handle materials defined under each schedule. If you are shipping a product that meets the criteria, you need a partner with the appropriate licenses.
- **Cryostorage** - The stability data of your product may indicate a requirement for ultra-cold storage as this removes the issue of shelf life and builds flexibility into the supply chain. It requires rigorous quality standards and specific shippers that your prospective partner may not have at the scale you require.

## Chain of custody (COC)/identity (COI) needs

COI is the association of a donor's unique identifier to their tissue or cells and the resulting drug product, for the entire process from order through manufacturing to administration.

COC is the capture of data related to who handled the collection of a product, what actions were performed, and the location, date, and time of the actions from the start of tissue collection through to administration.

Sharing information about all players in the value chain and how the information above is to be collected and communicated is a crucial element of commercial C&GT logistics.

## In-transit tracking

Commercial shipping is often a multi-party process which can create gaps in the visibility of where your product is and whether there have been any excursions that pose a potential risk to efficacy and safety for some products. Eliminating these gaps wherever possible to create transparency and standardize data for a true end-to-end view requires that your logistics partner has, or has access to, the required technologies and understands the need to apply them. GPS monitoring and tracking is one option to ensure your product's location is clearly understood throughout its journey. If GPS monitoring is required you also need to clarify as early as possible what devices shall be used and who is responsible to source, supply and recover them after a successful delivery is done.

## Cold chain

Temperature-controlled transport is a high-risk operation especially when only little stability data is available, for example during the launch of a new drug. While the cost of transport is comparatively low compared with the rest of the pharmaceutical development and manufacture, there are a lot of potential issues in the cold chain that needs to be addressed to ensure business success.

### Choosing between active and passive containers/packaging

Active containers can be compared to movable refrigerators. When refilled with dry ice or recharged, they can keep a specific temperature interval indefinitely. Envirotainer's certified air cargo unit load devices (ULDs), for instance, maintain product temperatures in the +2°C to +8°C range, controlled ambient temperature (+15°C to +25°C) range or at any chosen set temperature between ±0°C and +25°C.

There are also different varieties of passive packaging. Thermal blankets can protect the products temporarily, whereas insulated boxes containing dry ice or phase change materials, can keep a specific temperature range for a certain amount of time.

As passive packaging has no active temperature control, it cannot adjust the temperature inside the packaging according to changes in the ambient temperature.

The choice between the two will be informed by several factors led by the product's requirements — your logistics provider can help you optimize shipment loading and calculate which is best for you.

**Cocoon**

Our proprietary passive shipping solution is revolutionizing the transport of pallet-sized shipments. Qualified for long periods of temperature stability, Cocoon increases your access to global markets. And since Cocoon was developed by our very own CORE Labs, we are independent of external thermal container contractors — leading to considerable cost savings and flexibility that we pass on to you.

More Info

### Managing excursions

A quality management system (QMS) helps avoid temperature deviations during the storage, transport, and distribution of products by documenting and analyzing each deviation and investigating the root cause. However, managing temperature excursions if they occur is imperative to minimize the negative effect on product quality.

Logistics partners should be able to provide solutions with measurement devices that record and communicate temperature — sometimes in real time for more responsive environmental management. Some probes will also be able to measure and record humidity levels. As such, it is important that their expected role in the process of managing an excursion is well-defined.

## Geographies and markets

Planning for time-in-transit, customs requirements, local regulations, and capabilities is a must. There will be nuanced differences that require local expertize to navigate, which is all dictated by the markets you plan to ship from and to — your partner will need to understand this and be able to guide your approach accordingly.

### Regulatory considerations

- **Customs** - Customs requirements can vary significantly between regions, having a partner that can navigate them is vital. Some customs requirements may lead to products spending a significant amount of time in processing which needs to be factored into the logistics solution and the packaging selection.
- **Industry** - Your products may be classified differently and require import licenses beyond those you expect.

### Serialization/aggregation requirements

Serialization regulations are mandated in over 50 countries (with many covered under the EU FMD Directive) and they vary greatly in their requirements and complexity. Aggregation is not presently a legal requirement across the board but is demanded by many wholesalers. Your logistics provider will need to engage with you, your supply chain partners and regulators in some instances to ensure compliance.

## Working with multiple supply chain partners

As mentioned above, commercial logistics is a multi-party process with little consistency between projects. Multiple parties need to effectively collaborate to get your product where it needs to go, safely. Transparency on who these partners are and their role is a key enabler.

### Technology and software integrations

Where there are multiple partners in a supply chain it is likely that they will have independent and/or proprietary technologies and software — these will need to interface to enable a successful logistics solution. Gathering and sharing the requirements of each party is a must. You as a sponsor will also likely have requirements in this area — such as cell orchestration software for CGTs — that your partners will need to integrate with or any other transport management system you want your supplier to be connected with to directly input and transmit data. Specifying this early is essential as in-house systems may require a longer lead time to develop connections.

## Complementing patient solutions and other services

Patient-centricity is driving companies to develop and deliver more support services around a therapy, which need to be complemented by an appropriate commercial shipping solution. DtP or home distribution applications must be coordinated with all involved parties to ensure product integrity is maintained. Deliveries must often be precisely timed to coincide with the patient's availability or home visits with proof that temperature control has been maintained before administration.

This requires precise planning and execution.

## Environmental, social, and corporate governance (ESG) and Sustainability

ESG and sustainability are fast becoming a priority for the biotech and pharma industries, and logistics play a significant role in improving performance. Understanding a product's requirements to shape an optimal solution around it and report measurable ESG metrics is an area where specialist partners can make a significant difference.

## Contingencies and redundancies

With global demands continuously pressuring biopharma companies to increase production volumes, accelerate development and drive costs down at a time when major disruptions caused by pandemics and conflict, supply chain resilience has become a priority.

Contingency planning and creating redundancies are more relevant strategically than ever and need to require upfront planning and transparency to ensure success.

## Recall processes and reverse logistics

Product recalls and reverse logistics are an integral consideration in commercial supply chain planning. Ensuring that every player understands their role, responsibilities, and the processes they will need to implement or adhere to is essential to the efficient, reliable and safe return of goods.

## Waste material and drug disposal

Most supply chains create unavoidable waste, whether it be in the form of packaging and shipping materials or less sophisticated single-use cold chain containers. This waste has to be managed in a compliant way; where the economies involved in the supply chain are less developed, then a solution that matches the ESG policies of the companies involved has to be implemented. There is also the potential need to dispose of active drug products — this is heavily regulated and appropriate plans must be put in place accordingly.

## Just-in-time (JIT) logistics

Despite pressure to move away from JIT models due to their perceived fragility, some distribution models will continue to operate in this way. Prescriptive timing of raw material delivery, manufacture, packaging, and distribution are required to make it a success, so logistics partners need a full view of the chain to function efficiently within a JIT network.

## Reporting requirements

It is important for pharmaceutical companies to agree on the data and the format that they would like their logistics partner to report on. Discussions at the request for quote (RFQ) stage between the company and the logistics partner are crucial to arrive at an appropriate reporting solution, providing the necessary information about the effectiveness of the transport network for the product.

### Flexibility in pricing

These tenders can often result in contracts that span multiple years. Given the stress and tensions in the air freight market and other inflation-related cost increases that markets are inevitably prone to, flexible approaches to pricing need to be built in contractually to mitigate any risk.

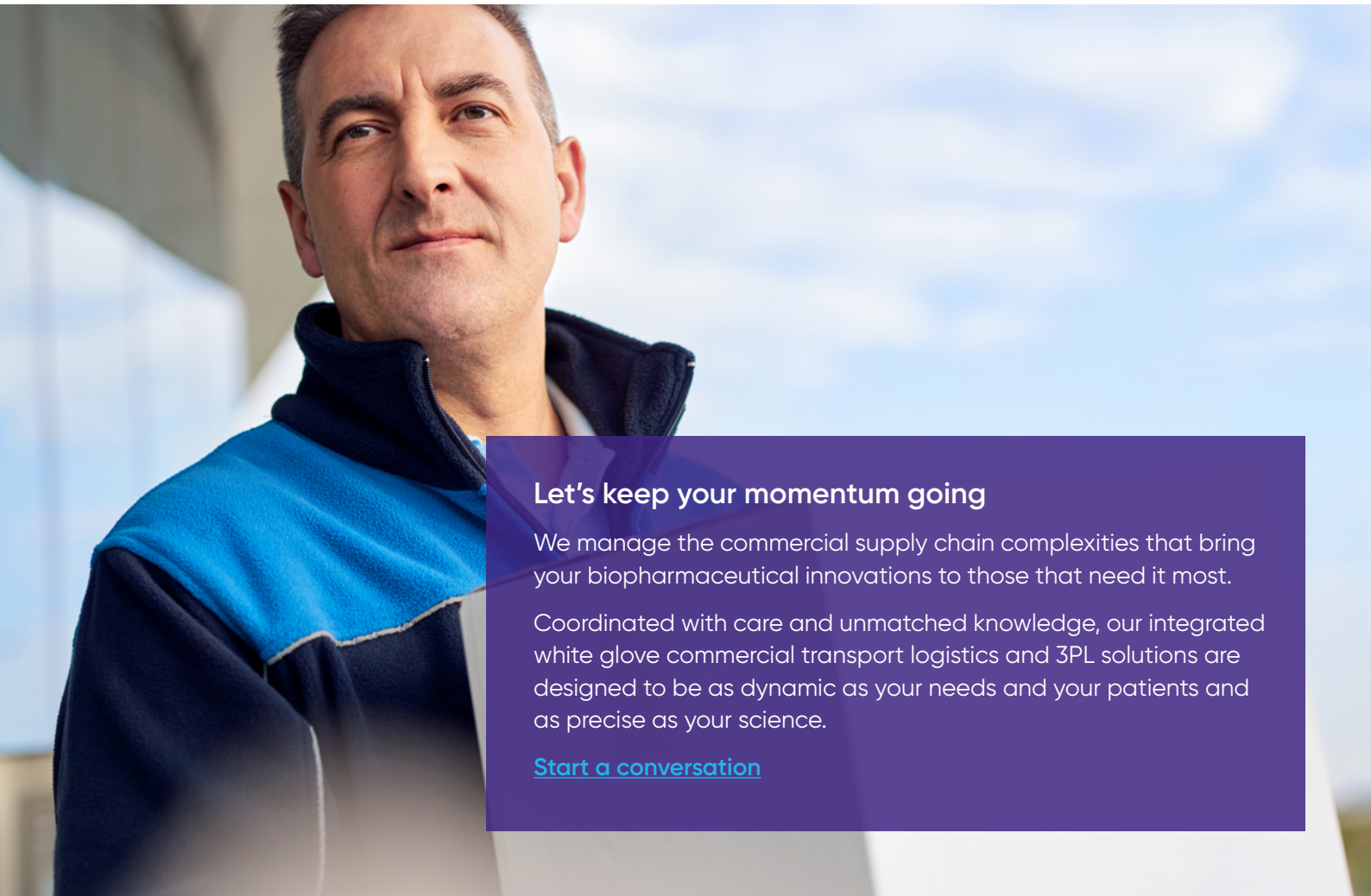
## Specialist support.

### DtP and home distribution

DtP delivery is on the rise as patient and digitalized healthcare engagement become more prominent. This approach requires supply chains, especially last-mile logistics, to be carefully designed with more transparent and regular communication a must.

### Specialty distribution

As the biopharma market pivots towards more personalized therapies, serving niche patient populations and specialized healthcare centers, specialty distribution has steadily increased. As with home distribution models, a full picture of the supply chain is required for logistics partners to accurately scope and plan a solution.



### Let's keep your momentum going

We manage the commercial supply chain complexities that bring your biopharmaceutical innovations to those that need it most.

Coordinated with care and unmatched knowledge, our integrated white glove commercial transport logistics and 3PL solutions are designed to be as dynamic as your needs and your patients and as precise as your science.

Start a conversation

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