

# 5 QUALIFYING QUESTIONS TO EVALUATE SOLUTION PROVIDERS FOR TEMPERATURE CONTROLLED SHIPPING

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*Singota® Solutions is a CDMO located in Bloomington, Indiana, USA that specializes in Parenteral, Early Phase Drug Development and Aseptic Filling projects.*

Life sciences companies with complex warehousing and shipping requirements have a lot of questions – particularly when their requirements include temperature-controlled shipping. For a potential solution provider, it's not enough to simply have a refrigerated warehouse and trucks. The product may not even need refrigeration – it may need to be kept at or near room temperature.

The customer is looking for a specific solution, and will see value in a prospective vendor having a wide variety of experience in pharmaceutical logistics. Once the discussion turns to temperature-controlled shipping, how can the pharmaceutical company identify a logistics vendor with the right competency?

Here are five basic questions a pharmaceutical company can use to evaluate a vendor's qualifications to provide a high-value solution:

1. What assets does the vendor provide on premises? The vendor needs to have the required physical capacity, including GMP space maintained at the required temperature range, and systems in place to maintain an up to the minute inventory. The site must also have a robust selection of temperature-controlled shipping solutions and thermal monitoring devices at its disposal in order to meet the requirements of varying shipment configurations in real time.

2. What are the core components of the vendor's shipping solution?

These are the basic variables:

- The product size – the "payload" – which tells us the size of the container we need to use.
- The duration of the shipment – are we shipping overnight, or are we shipping abroad?
- The temperature requirements – are we required to maintain 2-8°C, 0-10°C, less than 30°C, 15-25°C, etc.?
- Standard operating procedures (SOPs) for selection and handling of the shipping system.

Each "shipper" (container) is qualified with a certain set of components, taking into account the maximum and/or minimum product loads, onboard sensors, and data recording.

At Singota, we use Qualified shippers tested to industry recognized standards, and we review those testing specifications to make sure they meet the requirements of the customer's situation. Companies looking to qualify a product dedicated shipping solution may supply a shipper themselves or allow the vendor to identify one. We can then utilize the actual product load to qualify the solution based on their product requirements and intended method of transport.

The responsibility doesn't end when the product goes out the door, however. The vendor has to find the right carrier to transport it. At Singota, we track metrics on carriers by destination, shipper, shipping lanes, season, temperature requirements, and so on. It is not unusual for a shipment to go to multiple clinical sites; the chosen carrier has to be able to perform well to all destinations. If we have a preferred carrier, but that carrier has had difficulty with the type of container we have specified, we may choose a different container for which that carrier has the right SOPs in place.

An effective vendor will have built up a catalog of solutions – procedures, tools, and relationships – to handle a very wide range of constraints and conditions that a prospective customer might present.

3. What is the vendor's track record?

The vendor should be willing to provide explicit metrics on its current and historical success rate in maintaining the temperature of shipments. (At Singota, we publish these metrics on our website.) The data tells the customer the vendor has the expertise to minimize temperature excursions (deviations from the acceptable range).

Every temperature-controlled shipment should be logged at a minimum by carrier, shipper, required temperature, duration, and destination. Reports must be generated showing any temperature excursions among those shipments. It's part of the quality process, and it allows the vendor to look for trends. For example, one may notice a certain carrier has issues shipping to Brazil in the summer, or with handling a certain kind of shipper.

4. Can the vendor follow our specifications?

Large pharmaceutical companies with fully-developed, proven procedures will outsource storage and shipping, asking vendors to follow their procedures. A vendor must be able to effectively train staff to ensure successful execution of those procedures and that personnel are aware of their situation-specific use. Logistics vendors should always be looking for continuous improvement by evaluating the firm's procedures and providing feedback that could improve the robustness of those procedures. For example, there may be cases where the customer specifies use of a specific carrier that may not be the vendor's preferred choice. Typically, if one has experience with that carrier, any concerns should be voiced up front to help promote collaboration between the two entities.

5. Can the vendor design the entire process for us?

A smaller, research-focused biotech company may market its products through large pharmaceutical partners and contract out the manufacturing.

. Its challenges may never involve truckloads of product – a biotech company's fortunes might be riding on one tiny vial of some unique biologic. The logistics may nevertheless be complex enough to justify outsourcing to an expert partner who can select/qualify the container and design the procedures.

Differentiating questions like these can help identify a pharmaceutical logistics solution vendor with the right profile for each specific shipping problem. Visit the Supply Chain section of our website to learn more about our Materials Management and Cold Chain/Temperature Sensitive solutions.



**Singota Solutions** is a US based CDMO in Bloomington, Indiana. Singota specializes in formulation development and aseptic fill finish for injectable projects. Once a formulation is established, Singota utilizes state of the art robotic filling technology and focuses on smaller batch size requirements. For more information, visit [Singota.com](http://Singota.com) to explore how Singota has established itself as a one-stop solution for all your developmental needs.

Contact [solutions@singota.com](mailto:solutions@singota.com) to schedule a meeting with our business development team to further discuss your current or future projects.