



# **Domestic vs. Overseas Contract Pharmaceutical Manufacturing:** **A Strategic Decision Guide**



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## EXECUTIVE SUMMARY

For pharmaceutical operations leaders like you, choosing between domestic and overseas contract manufacturing partners is more complex than ever. With heightened scrutiny from the FDA, ongoing global supply chain disruptions, and rising costs abroad, pharmaceutical companies must carefully evaluate their options to ensure compliance, quality, and speed-to-market.

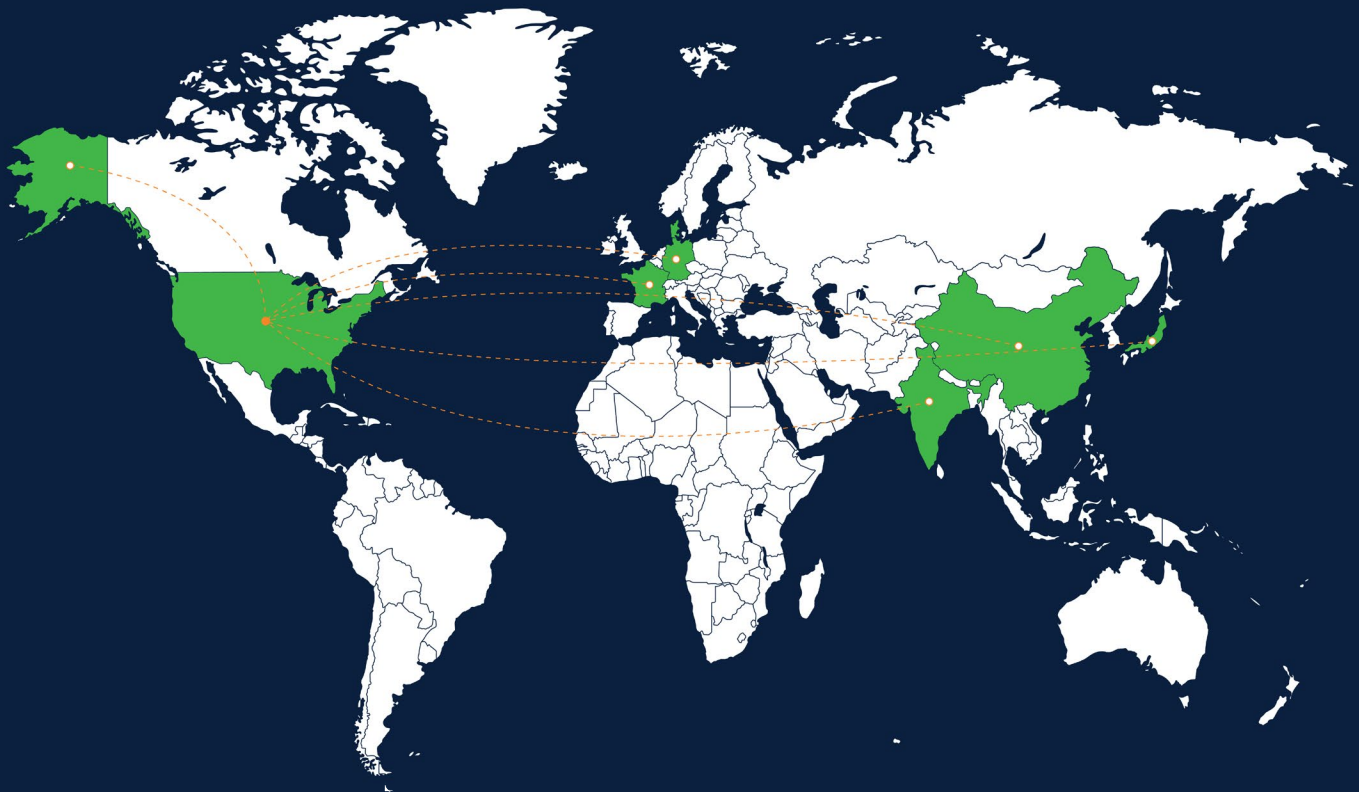
Key considerations include:

- **Regulatory compliance** – ensuring products meet FDA/DEA requirements without delays or import risks.
- **Supply chain reliability** – mitigating risks tied to shipping, customs delays, and geopolitical instability.
- **Quality control** – maintaining patient safety and brand integrity across every production batch.
- **Total cost of ownership (TCO)** – looking beyond per-unit costs to account for hidden expenses like freight, inspections, and remediation of quality failures.

For over 30 years, Aphenia Pharma Solutions has helped mid-sized pharmaceutical companies navigate these challenges with FDA-registered, DEA-licensed facilities strategically located in Tennessee and Maryland. This paper outlines the decision framework for evaluating domestic vs. overseas partners and shows how Aphenia can serve as a trusted U.S.-based solution.

Keep reading for more insights on how to make the most informed decision for your CMO and CPO needs.





# THE GLOBAL MANUFACTURING LANDSCAPE

Pharmaceutical manufacturing has become increasingly globalized over the past two decades, driven largely by cost advantages and capacity in countries like India and China. However, the industry is experiencing a major recalibration.

## KEY TRENDS RESHAPING DECISIONS

### Reshoring and nearshoring

U.S. **government incentives** and a renewed focus on supply chain resilience are encouraging more domestic production.

### Rising overseas labor costs

The cost gap between U.S. and overseas production has narrowed significantly.

### Regulatory scrutiny

The FDA has increased inspections of imported drugs, with multiple warning letters issued to overseas plants in recent years.

### Supply chain volatility

Port congestion, geopolitical conflicts, and transportation cost spikes have exposed vulnerabilities in global supply chains.

For pharmaceutical companies, these factors are driving renewed interest in U.S.-based partners who can offer regulatory assurance, speed, and proximity to patients.



# KEY DECISION FACTORS WHEN SELECTING A MANUFACTURING PARTNER



## 1. REGULATORY COMPLIANCE & QUALITY ASSURANCE

Compliance is non-negotiable in pharmaceuticals. Domestic partners operate under direct FDA and DEA oversight, with routine inspections ensuring adherence to cGMP standards. In contrast, overseas facilities may face less frequent audits, increasing the risk of deviations.

**Example:** In 2023, the **FDA issued import alerts** on several overseas facilities for repeated GMP violations, delaying product launches for U.S. companies and resulting in costly remediation.

**Bottom line:** Choosing a domestic partner reduces regulatory uncertainty and helps safeguard patient safety.



## 2. SUPPLY CHAIN RELIABILITY

Global logistics remain fragile. Overseas manufacturing often means weeks-long shipping times, customs processing, and risks of geopolitical disruption.

By contrast, domestic partners shorten the supply chain: raw materials can move more quickly, and finished goods can reach 75% of the U.S. population within one to two days of shipping from centrally located facilities.

**Lesson learned from COVID-19:** Pharmaceutical companies dependent on overseas supply chains faced months-long shortages, while those with domestic partners recovered faster. The pandemic also demonstrated the critical importance of having redundant manufacturing and packaging sources. Companies with secondary suppliers maintained market share and minimized disruptions, while those with single-source strategies experienced significant business losses and struggled to meet patient needs.





### 3. TIME-TO-MARKET CONSIDERATIONS

Speed matters. Every delay in production or regulatory approval translates into lost revenue and patient access.

- **Domestic partners** offer time zone alignment, real-time communication, and easier issue resolution.
- **Overseas partners** often struggle with language barriers, slower response times, and overnight email cycles.

The result? Domestic production reduces lag time in approvals, scaling, and problem-solving, accelerating your path to market.

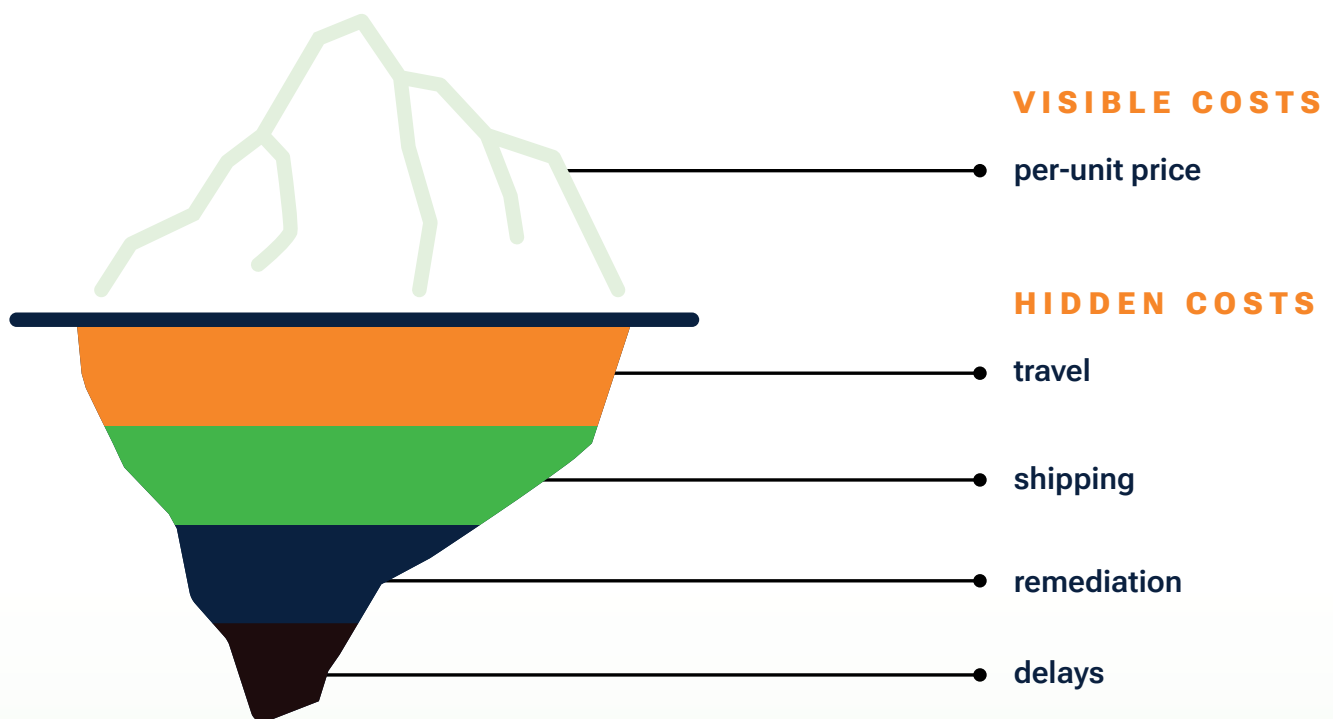


### 4. COST ANALYSIS: BEYOND THE PER-UNIT PRICE

While overseas production may look cheaper on paper, hidden costs often erode the advantage:

- Travel for audits and inspections.
- Shipping, tariffs, and customs fees.
- Quality failures that require costly remediation.
- Delayed launches resulting in lost sales.

In many cases, the true cost of overseas production exceeds domestic alternatives.



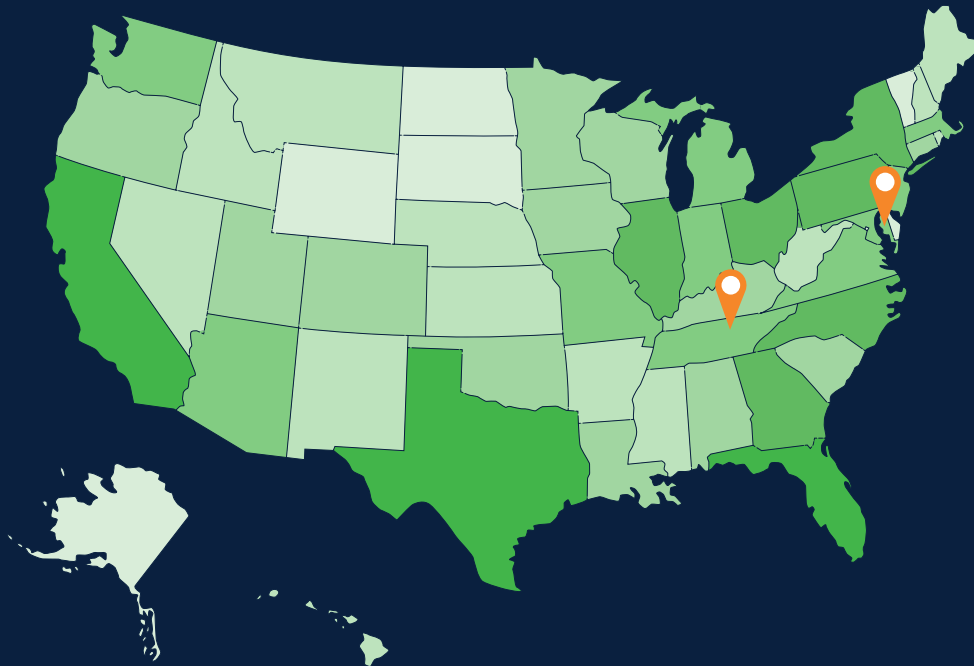
# RISK ASSESSMENT FRAMEWORK

To **evaluate partners objectively**, companies should assess risks across four categories:

1. **Regulatory** – risk of failed inspections or import bans.
2. **Supply chain** – vulnerability to port closures, geopolitical tensions, or raw material shortages.
3. **Communication/quality** – potential for errors caused by misaligned teams.
4. **Intellectual property** – higher risk of IP leakage in some overseas markets.

## DOMESTIC MANUFACTURING ADVANTAGES

Aphena has two USA-based facilities.



### WHY DOMESTIC MANUFACTURING DELIVERS STRATEGIC VALUE

- **Location Advantage:** Aphena's facilities in Tennessee and Maryland reach 75% of U.S. consumers within one day.
- **Compliance Confidence:** Streamlined FDA/DEA oversight reduces delays.
- **Communication Clarity:** No time zone or language barriers.
- **Simplified Logistics:** Lower freight costs, fewer customs risks.

# WHEN OVERSEAS MANUFACTURING MAKES SENSE

While domestic manufacturing provides strategic advantages, overseas partners may still be suitable in cases such as:

- High-volume, low-margin products where per-unit pricing dominates.
- Global market entry strategies, where local production aligns with foreign regulatory needs.

## DECISION-MAKING FRAMEWORK & CHECKLIST

### Questions To Ask a Potential Manufacturing Partner:

- ☒ Are you FDA- and DEA-compliant?
- ☒ What backup supply chain strategies do you have in place?
- ☒ What is your average time-to-market for new products?
- ☒ How do you protect client intellectual property?

### Red Flags:

- ☒ Lack of regulatory transparency.
- ☒ Overdependence on international freight with no contingency plans.
- ☒ Pricing that omits customs, tariffs, or audit costs.



# ABOUT US

Aphena Pharma Solutions was formed through the strategic merger of several established pharmaceutical companies, including PrePak Systems, TestPak, Celeste, and Integrated Pharmaceutical Packaging. This combination brings together over 30 years of industry experience.

As one of the top contract pharmaceutical manufacturing and packaging companies in the United States, Aphena serves multiple markets, including prescription pharmaceuticals, over-the-counter products, dietary supplements, consumer health products, medical devices, and biologics.

## LOCATIONS & CONTACT

### Solid Dose Division | Cookeville, Tennessee Facility

1976 Chocolate Drive, Cookeville, TN 38501

- Solid & Semisolid Dose Packaging
- Bottling, Cartoning, Blister Packaging, Pouching, Secondary Packaging, Rework Projects & Kit Assembly
- Facilities Totaling 578,000 Square Feet

### Liquids & Topicals Division | Easton, Maryland Facility

7978 Industrial Park Road, Easton, MD 21601

- Liquid & Topical Manufacturing and Packaging
- Full Manufacturing and Lab Services, Bottling, Tubes, Vials, Pouching, Form-Fill-Seal, Kit Assembly & Secondary Packaging
- Facilities Totaling 184,000 Square Feet

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Liquids & Topicals Division | Easton, Maryland Facility