

## Virtual Manufacturers — Operating Without Touching Product

### Executive Summary

#### Introduction

The virtual manufacturer model has rapidly gained traction across the pharmaceutical industry, especially among emerging companies aiming to bring products to market without investing in physical infrastructure. These entities retain legal ownership of the product and are responsible for FDA filings and commercialization, but contract out every operational step, from manufacturing to distribution. The model is agile, cost-effective, and attractive to early-stage companies.

But there's a catch: outsourcing operations does not eliminate regulatory responsibility. From a legal and compliance perspective, the moment your company takes title to a pharmaceutical product, you are subject to a complex web of federal and state requirements, even if you never physically touch the product.

This white paper explores the obligations that virtual manufacturers must meet to remain compliant, outlining both the risks and best practices for navigating a licensing landscape that wasn't designed with them in mind.

#### What You'll Learn

- Why owning the product title (even for a single day) triggers licensing obligations
- How outsourcing manufacturing and logistics still leaves you legally accountable
- Federal requirements under FDA and DSCSA
- State-by-state licensing expectations for entities with no physical facilities
- How to build a scalable compliance strategy without overengineering your business



## What Is a Virtual Manufacturer?

In today's regulatory environment, the term *manufacturer* no longer refers solely to the company operating a facility. Increasingly, manufacturers are lean, agile businesses that own and sell pharmaceutical products while outsourcing every aspect of physical production and distribution. These are known as virtual manufacturers.

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### Definition and Structure

A virtual manufacturer is typically defined as a company that:

- Holds title to the product (owns the inventory)
- Holds or sponsors the product's NDA/ANDA or 510(k)
- Contracts out manufacturing, packaging, warehousing, and distribution
- Never physically handles the product at any point in the supply chain

While this model reduces fixed costs and accelerates speed to market, it introduces new complexities in compliance—because regulators don't base responsibility on who touches the product. They base it on who owns it.

This means that even if you don't have a warehouse, production line, or fulfillment team, you are still considered a “manufacturer” for licensing and compliance purposes in most jurisdictions.

### Why Companies Choose the Virtual Model

- Cost efficiency: No capital investment in infrastructure
- Speed to market: Bypass facility buildout and equipment procurement
- Focus: Teams can concentrate on commercialization, not logistics
- Flexibility: Scale operations through partnerships as needed

It's a proven model for startups and mid-sized companies—but one that requires equal sophistication on the compliance front.

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### Key Takeaway

A virtual manufacturer owns the product and regulatory approvals, but outsources everything else. This model is lean and efficient, but ownership of title comes with full regulatory responsibility.

## Why Licensing Still Applies

One of the most common and costly misconceptions held by virtual manufacturers is that outsourcing operations means outsourcing liability. This is not the case.

Licensure is triggered not by whether you ship, store, or manufacture the product—but by whether you own it and direct its commercial distribution.

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### The Regulatory Lens

In nearly every state, the moment your company takes legal title to prescription product and arranges for it to be shipped or sold (even via third parties) you're considered to be “engaged in distribution.” And under federal law, the Drug Supply Chain Security Act (DSCSA) places specific serialization and documentation responsibilities on the entity introducing the product into commerce.

#### Key Legal and Regulatory Triggers:

- Ownership of product title (even briefly)
- Possession of the FDA labeler code or listing responsibility
- Directing or arranging shipments into regulated jurisdictions
- Releasing product for sale under your company name
- Receiving proceeds from product sales

#### Misconceptions That Lead to Risk:

- *“We never touch the product, so we don’t need licenses.”*
- *“Our CMO or 3PL is licensed, and they’re doing the physical work.”*
- *“We’re only a brand company; we don’t operate facilities.”*

These views overlook the key fact: regulators follow the ownership trail. If you are the legal manufacturer or labeler of record, you bear compliance obligations even if you never break a seal.

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### Key Takeaway

Licensing obligations follow the product title, not the pallet. If your company owns the product, arranges its sale, or appears on the label, you must secure appropriate licensure and comply with all related regulatory responsibilities.

## Federal Compliance Requirements

Virtual manufacturers may not operate a facility, but they are still considered manufacturers by the FDA. The absence of physical infrastructure does not exempt these entities from core federal obligations tied to product registration, serialization, and quality oversight.

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### Core Responsibilities for Virtual Manufacturers:

1. **Establishment Registration & Drug Listing:** Even if all manufacturing is outsourced to a CMO, the virtual manufacturer must ensure that:
    - a. The facility is properly registered with the FDA
    - b. The drug is listed correctly in the FDA's database under the labeler code
  2. **Labeler Code Ownership:** Virtual manufacturers typically hold the product's labeler code, which forms the basis of the National Drug Code (NDC). This code links the product to the company and, critically, designates the manufacturer for regulatory purposes.
  4. **DSCSA Compliance:** As the entity introducing the product into U.S. commerce, you are responsible for:
    - a. Ensuring serialization at the unit level
    - b. Maintaining electronic transaction documentation (TI, TH, TS)
    - c. Investigating and reporting suspect or illegitimate products
  5. **GMP Oversight (Even When Outsourced):** Although your CMO is responsible for following cGMP regulations, the FDA expects virtual manufacturers to exercise active oversight. This includes:
    - a. Quality agreements with your CMO
    - b. Review of batch records and deviation reports
    - c. Audit and inspection readiness
  6. **Pharmacovigilance and Recall Capability**  
As the owner and labeler, you are the responsible party in the event of a recall or safety concern. You must:
    - a. Have an adverse event reporting system
    - b. Coordinate recall strategy with your partners
    - c. Maintain up-to-date SOPs for post-market surveillance
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### Key Takeaway

Federal compliance doesn't require a facility, but it does require full accountability. As a virtual manufacturer, you are responsible for product quality, serialization, and safety, even when third parties do the work.

## State Licensing Overview

If the federal framework defines your role, the state-by-state patchwork dictates your reach. Every state has its own interpretation of what constitutes a manufacturer, and many expect licensure even if your company never physically distributes product within their borders.

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### License Types That May Apply:

- **Manufacturer License:** Common in states that recognize product ownership or NDA sponsorship as a trigger
- **Wholesaler/Distributor License:** Often required if you're arranging for product movement into the state (even through a 3PL)
- **Virtual Manufacturer License:** A growing number of states recognize this as a distinct category
- **State-Level Triggers to Watch For:**
  - Product title is held by your company
  - Your labeler code appears on the product
  - Product is shipped into or through the state (regardless of physical location)
  - You invoice customers in the state
  - Product is manufactured on your behalf by a contract facility located in the state

### State License Volume by Product Type:

- **Non-Controlled Prescription Drugs:** Many states require a license for companies shipping these products across state lines
  - **Controlled Substances:** Most states require a separate license or Controlled Substance Registration (CSR)
  - **OTC Drugs and Medical Devices:** Fewer states require licensure, but a handful still do depending on the category
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### Key Takeaway

State licensing is not a one-size-fits-all process. You must evaluate each jurisdiction's laws based on your distribution model, product category, and commercial footprint. Ownership, not physical possession, is what many states regulate.

## 3PLs, Distributors & Your Licensing Footprint

Third-party logistics providers (3PLs) are essential partners in the virtual manufacturing model, managing warehousing, shipping, and even customer invoicing. However, relying on a 3PL's infrastructure does not eliminate your own licensure obligations.

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### Why Your Partners' Licenses Don't Cover You:

- Licenses are issued to specific entities; they are not transferable
- Most states define licensure requirements based on ownership, not logistics
- Regulators expect every party with commercial responsibility to be licensed independently

**The Flash Title Misconception:** Some 3PLs offer “flash title” services, where they temporarily take ownership of product to act as the seller of record. While this can shift the licensing burden temporarily, it doesn't necessarily exempt the original product owner from all state requirements, particularly in states that license based on labeler code or NDA ownership.

### Practical Considerations:

- Confirm your 3PL's license status in each target state
  - Review your contractual agreements carefully. Are you transferring title, or just delegating logistics?
  - Be aware that some states may still require you to hold a license, even if your 3PL is fully licensed and titled
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### Key Takeaway

Your 3PL may ship the product, but you own it. Ensure your licensing strategy reflects this reality, and don't assume a partner's compliance protects your business.

## Common Pitfalls for Virtual Manufacturers

Many virtual manufacturers begin with a smart operating model, but overlook or misunderstand the regulatory frameworks that apply to them. The result? Compliance issues that can derail product launches, delay sales, or invite regulatory scrutiny.

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### Top Pitfalls to Avoid:

1. **Failing to License in All Applicable States:** Some states regulate based on ownership or labeler code alone; ignoring this can create unlicensed distribution risk.
  2. **Assuming Your Partners Cover You:** Your CMO and 3PL may be licensed, but those licenses do not apply to your company unless you're listed directly or hold your own authorization.
  3. **Misinterpreting "Ownership":** Holding inventory title, even for a brief window, can be enough to trigger licensure.
  4. **Delaying Licensing Until Launch:** Some licenses take weeks or months to obtain. Waiting too long can postpone your ability to ship product.
  5. **Not Tracking Renewal Deadlines:** Once licensed, you must stay licensed. Missing a renewal window could result in unintentional noncompliance.
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### Key Takeaway

A proactive compliance strategy prevents reactive problems. Understand the rules early, and build licensing into your operational planning, not as an afterthought.

## Best Practices for Compliance

Compliance doesn't have to be overwhelming. With the right tools, team, and process, you can build a licensing infrastructure that supports growth without creating internal drag.

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### Strategies for Success:

- **Create a State Licensing Map:** Know exactly which licenses you need, when you need them, and what triggers apply
  - **Designate an Internal Owner:** Appoint a team member or third-party compliance partner responsible for licensing and renewal oversight
  - **Conduct Periodic Audits:** Review licenses quarterly to ensure nothing has lapsed or changed
  - **Lean on Experts:** Work with partners who understand the regulatory landscape and can expedite the process
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### Key Takeaway

Strong compliance starts with structure. Delegate ownership to trusted resources, hire experts when needed, and audit often to avoid gaps.



## How Licensure Rx Can Help

Licensure Rx was built to serve companies just like yours: pharmaceutical organizations that need to navigate a complex and fragmented licensing environment.

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### **Our Services Include:**

- End-to-end state licensing support, including filings and renewals
- Strategic licensure mapping aligned with your distribution footprint
- DSCSA compliance planning
- Real-time tracking and reminders for license maintenance
- Advisory services for virtual manufacturer-specific challenges

With extensive experience working with virtual models, our team of licensing experts know the difference between paperwork and practical execution. Our team moves quickly and thoroughly, so you stay compliant without sacrificing speed or quality.

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### **Key Takeaway**

Licensure Rx helps you get licensed, stay licensed, and launch with confidence. We bring speed, precision, and reliability to every engagement.

## Conclusion

The virtual manufacturer model is smart, efficient, and increasingly common, but it's not exempt from regulation. If your company owns the product, your company is responsible for the licenses and compliance work that goes with it.

From FDA listing and DSCSA serialization to multi-state licensing and controlled substance registrations, the compliance landscape for virtual manufacturers is real, and avoidable only at your peril.

You don't need to touch the product to trigger licensing. But with the right plan, you can remain lean, stay compliant, and operate with confidence.


Build your licensing roadmap early. Choose the right partners. With the right approach, you can commercialize effectively and compliantly, giving you the peace of mind you need to focus on growing your business.

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### Need Licensing Support?

Let Licensure Rx help you build a compliant foundation for commercialization. Whether you're preparing for your first product launch or expanding into new markets, our team can simplify the licensing process and ensure you're covered.

**Reach out to schedule a consultation today.**

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