

# Contract Manufacturers

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# State Licensing Basics

Where to start...

Know your company's business model (from manufacturing to the customer)

Check the state requirements for licensure

Look at the regulations for the state (...check the fine print)

Identify your company's activity and product types

Be sure to select the correct licensing application

Note: Just because you are a manufacturer in your home state, don't assume you'll be a manufacturer in every state



# Manufacturer Types

Actual Manufacturer - a company that manufactures their own prescription drug products and/or medical devices. Distribution can be by manufacturer or 3PL.

- Licensure currently required in all states, except MA (unless manufacturer located in MA)

Contract Manufacturer - a company that is contracted by another company to manufacture prescription drug products or medical devices for them. A contract manufacturer may also be an actual manufacturer and have their own-labeled products.

- Licensure required in 31 states currently - AK, AL, AR, AZ, CT, FL, GA, IA, LA, ME, MI, MN, MS, MT, NC, ND, NH, NJ, OH, OK, OR, PA, SC, SD, TN, TX, UT, VT, WA, WV and WY.

Virtual Manufacturer - a company that sells their own prescription drug products and/or medical devices but outsources the manufacturing and distribution operations. Virtual manufacturers never take possession of the product.

- Licensure required in 39 states currently - AK, AL, AR, AZ, CT, DC, FL, GA, IA, ID, KS, LA, MD, ME, MI, MN, MS, MT, NC, ND, NH, NJ, NM, NV, NY, OH, OK, OR, PA, PR, SC, SD, TN, TX, UT, VT, WA, WV and WY

# State Licensing - Product Types & Activities

## State Licensing Product Types:

- Over the Counter (OTC)
- Prescription (RX or aka Legend Drugs)
- Controlled Drug Substances (CDS)
- Listed Chemicals (LC)
- Medical Devices (MDV)

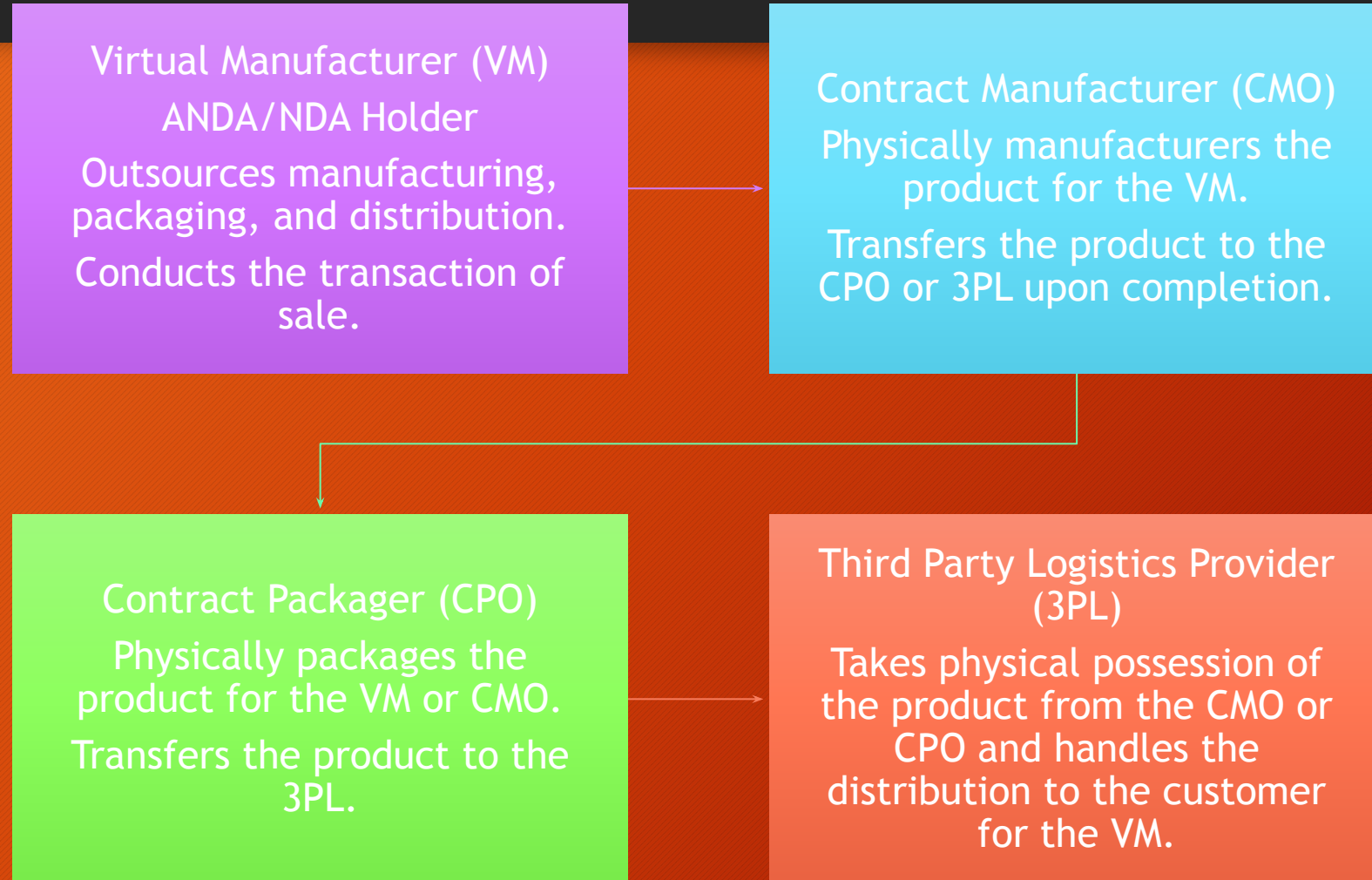
## Types of Activities:

- Manufacturing
- Distribution
- Sales/Marketing (NDA/ANDA and labeler)
- Packager/Repacker





# Different Entities in Supply Chain



# Responsibility

## Virtual Manufacturer (VM)

Labels & Product Inserts  
Invoicing, Sales &  
Marketing Materials

State licenses for selling  
into a state

SOMS

## Contract Manufacturer (CMO)

DEA - 222 forms, Quota,  
ARCOS, SOMs, Theft/Loss  
Reporting, YERS and  
Biennial Inventory

State licenses for  
manufacturing product

## Contract Packager (CPO)

DEA - 222 forms, Quota,  
ARCOS, SOMs, Theft/Loss  
Reporting, YERs and  
Biennial Inventory

State licenses for  
packaging/repacking  
products

## Third Party Logistics Provider (3PL)

DEA 222 forms, SOMs,  
Theft/Loss Reporting,  
YERS

DSCSA - Packing Slips &  
Bills of Lading

State licenses for  
distribution of products



# Challenges

## What license type am I?

- Industry is changing faster than state regulations. Every state is handling VMs, CMOs, CPOs, and 3PLs differently. When in doubt, call and ask. Don't assume.
- More than one type: CMO + Manufacturer of own drugs

## Whose DEA registration should I use?

- Quota is obtained by the CMO or CPO.
- While product is in production it is under the CMO or CPOs DEA registration
- VMs never take physical possession of the product and they do not have a DEA registration.
- Upon processing completion, the product is transferred to the 3PLs DEA registration for distribution



# Additional Challenges

Am I responsible for making sure my business partners are licensed?

- Some states are holding manufacturers responsible for ensuring the CMOs, CPOs and 3PLs are properly licensed.
- If you are caught doing business with an unlicensed entity, you may be fined.
- Some states require proof of an organizational relationship during licensure and may request copies of the 1<sup>st</sup> and last page of the contract.
- Some other states require copies of FDA reports including EIRs, 483s and response letters to FDA as part of licensing process
- Where does transfer of ownership of products happen?



**QUESTIONS**



# Thank you....

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