Manufacturer

In State:
- Anyone manufacturing prescription-only drugs in West Virginia must be licensed by the state as a manufacturer.

Out of State:

Traditional Manufacturer—you own the product and manufacture the product.
Virtual Manufacturer—you own the product, but someone else manufactures it for you on contract or otherwise at their facility.
Actual Manufacturer—you manufacture a product on contract or otherwise that you do not own.
3PL—you act as a third party shipping product that you do not own or manufacturer.

• (Traditional) If you are a drug manufacturer located outside of West Virginia, but distribute any of your product into West Virginia, either yourself or through the use of a Third–Party Logistics Provider (3PL), you must be licensed by this state as a manufacturer (in other words, if you distribute or have your product distributed into West Virginia on your behalf, you must be licensed). And your 3PL must have a 3PL distributor's license.
  o Controlled Substances: (Traditional) If controlled substances are involved you must have a controlled substances handling permit as well.

• (Virtual) If you are a drug manufacturer located outside of West Virginia, but distribute any of your product into West Virginia, either yourself or through the use of a Third–Party Logistics Provider (3PL), you must be licensed by this state as a manufacturer (in other words, if you distribute or have your product distributed into West Virginia on your behalf, you must be licensed). And your 3PL must have a 3PL distributor's license.
  o Controlled Substances: (Virtual) If you do not handle the product, then you do not have to also get the CS handling permit since you won't actually touch the product.

• (Actual) If it is manufacturing the drugs on behalf of a virtual manufacturer and it sends that product into West Virginia on behalf of the virtual manufacturer or otherwise, it must be licensed as a manufacturer.
  o Controlled Substances: (Actual) If controlled substances are involved you must have a controlled substances handling permit as well.

• (Actual) If the actual manufacturer is outside West Virginia, it does not need licensed if it never sends the product into West Virginia on your behalf (i.e., it transfers it to a 3PL or wholesaler outside of West Virginia, and it is that other entity that actually sends it into West Virginia).

• (3PL) 3PL must have a 3PL distributor's license. For any product you are shipping in on behalf of a traditional, virtual, actual manufacturer or other party who actually owns title to and control over the drug, that traditional, virtual manufacturer, actual manufacturer, or other party must be properly licensed as a manufacturer.
  o Controlled Substances: (3PL) If controlled substances are involved, the 3PL must have a controlled substances handling permit as well.