



Medical Device State Licensing Overview

Brought to you by Two Labs,
an Envision Pharma Company



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OBJECTIVES



Introduction



Medical Device State Licensing



Looking for More Help?

TwoLabs CORE BUSINESS
AN ENVISION PHARMA COMPANY VERTICALS

*Over the past 20+ years, Two Labs and it's parent company, Envision Pharma Group, have worked with **150+** medical device companies and manage more than **8,500** state licenses*

STRATEGIC CONSULTING



150+

Medical Devices companies supported

COMMERCIALIZATION



255

employees



150+

Two Labs thought leaders with expertise across the entire lifecycle

GOVERNMENT & COMMERCIAL CONTRACT OPERATIONS (RIPARIAN)



20+

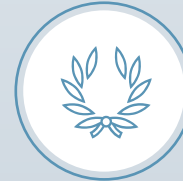
Years as an industry leader



14

Wholesalers and 3PLs work with Two Labs

MARKET ACCESS



90%

Loyalty rating from the Loyalty Research Center



2

Offices: Powell, OH Johnson City, TN

MEDICAL AFFAIRS & COMMUNICATIONS



8,500+

State Licenses under Two Labs' team management

Two Labs Project Leads & Support Team

Cross-Functional Subject Matter Expert Team to Support Engagement



Ryan Fields

SVP, Compliance Services
Ryan.Fields@TwoLabs.com

21+ years leadership experience in Pharmaceutical & Medical Device distribution (Cardinal Health, Abbott Nutrition) across various business functions: Business Development, Commercial Operations, Consulting, Sourcing, Trade & Distribution Management



Carley Kelly

Sr. Director, State Licensing Services
Carley.Kelly@TwoLabs.com

Service line lead with 8+ years experience in pharmaceutical and medical device state licensing: 69 product launches, Leads 25 state licensing consultants, Subject Matter Expertise and Implementation Experience in: Virtual & Self-Distributing Manufacturers, 3PLs and Wholesalers, Cell & Gene, CAR-T, Med Device, Compounding



Kim Cline

SVP, Global Business Development
Kim.Cline@TwoLabs.com

Kim has been crafting solutions for partners in the healthcare industry for 12+ years. Her consulting experience has brought her close to understanding the needs of both Pharmaceutical & Medical Device companies. Expertise is in listening where opportunities lay, problem solving and being efficient in driving successful outcomes.

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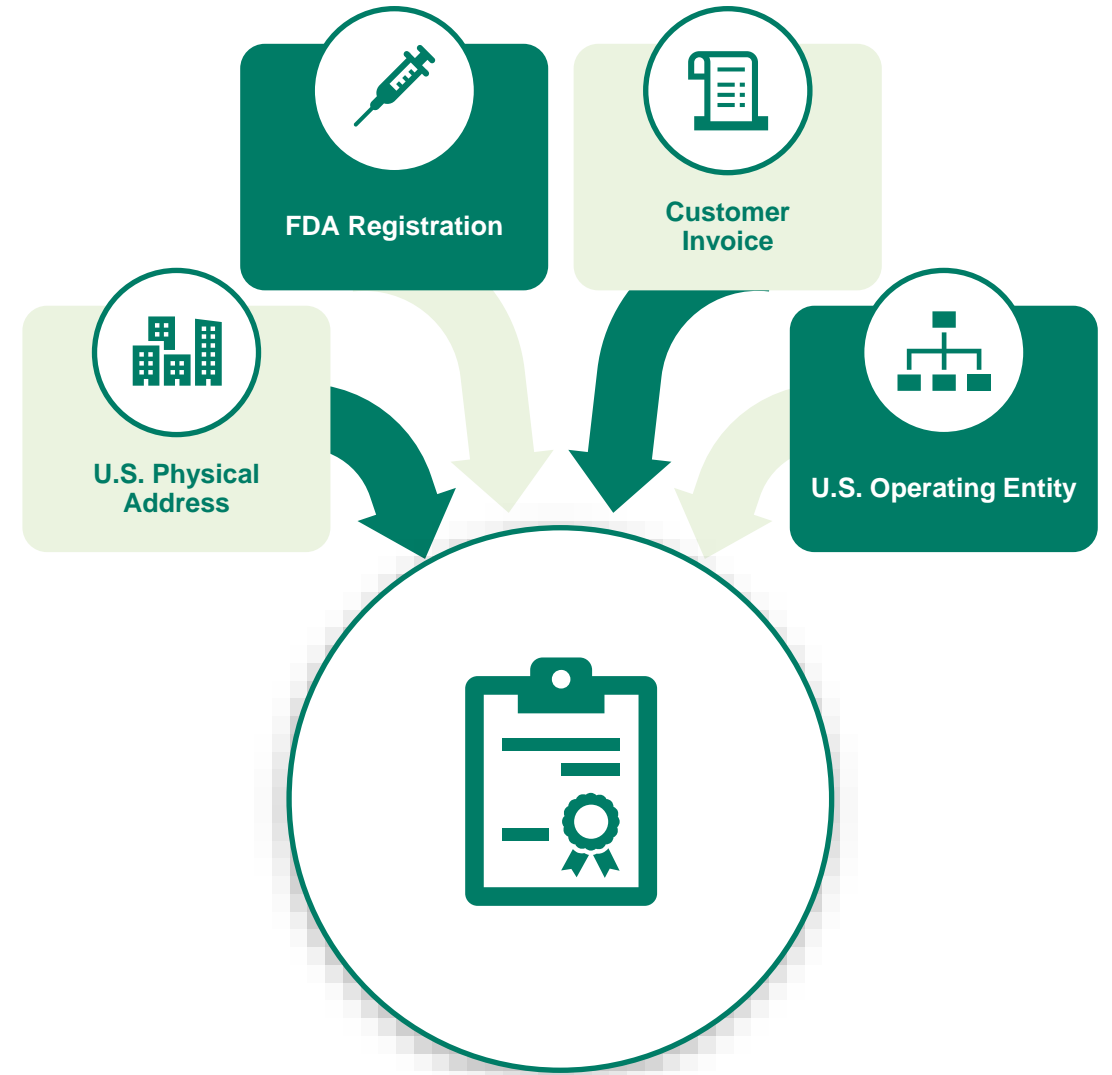
Medical Device State Licensing



Looking for More Help?

State Licensing Overview

- ▶ Each state has its own independent licensing framework, no national governing body or process
- ▶ Licenses are held by a specific facility address & operating entity...not at a device, drug or parent/holdings company level
- ▶ Whether manufacturing, warehousing and/or shipping medical devices from your own facility or using a third party, you are required to hold licenses from up to 28 states
- ▶ There are additional prerequisites and requirements based upon the type of Medical Device (DME, Non-Rx, Rx-No Drug Component, Rx w/ Drug Component)

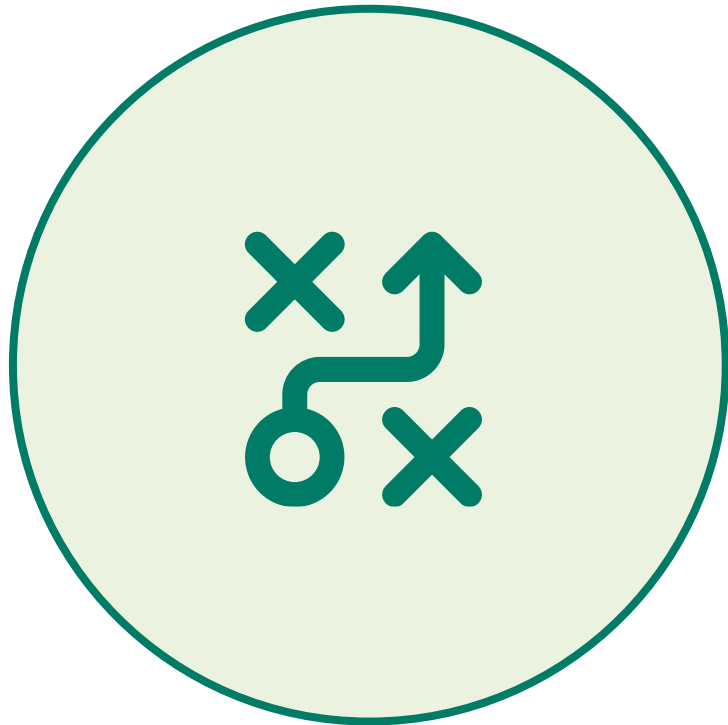


State Licensing Requires a Strategy

Strategy Build

Implementation

Renewals & Business Changes



- ✓ **All states require you to have a licensed physical facility in your resident state as a prerequisite:**
 - Even if operating as a Virtual Wholesaler and/or Manufacturer (using a contract-manufacturer and/or 3PL to manufacture and distribute finished good commercial product), your physical corporate offices are still subject to licensure and physical inspection in your resident state
 - If distributing direct to customers from your own manufacturing or distribution site, that physical facility will be subject to wholesale/distributor licensure
- ✓ **8 states require FBI Criminal Background check and/or fingerprints for one or more:** Section 16 Officer, Designated Representative and/or Authorized Rep
- ✓ **8 states require your domestic Contract Manufacturer & Packagers to carry their own state licenses and/or to submit an unredacted FDA Inspection report**
- ✓ **22 states require the 3PL to have a license**
- ✓ **7 states will not issue a license until your product has FDA approval**

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**LICENSING IS
DYNAMIC**

- ▶ **All licenses require renewal...dates, periods and methods vary**
- ▶ **States add new or change interpretation of current regulation without proactive notice**
- ▶ **All of the below changes require a new application or formal notification to be provided to all states:**
 - Change of Ownership
 - Address Change
 - Change in Designated Representative
 - Controlled Substances
 - Name Change
 - Change in Officers/Directors
 - Termination of Business

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Contact Two Labs for more information!



PharmaLicense: State Licensing Managed Service



Dedicated Implementation Manager and Licensing Analyst on your workstream



Dedicated Regulatory Analysts proactively monitor ever-changing licensing landscape



PharmaLicense Customer Portal: secure online tool to collect sensitive, proprietary company info



Full management:

- Escrow account to manage state application fees on your behalf
- Coordinate mobile fingerprinting service to come to your office,
- Strategic relationship with general business filing service provider

STARTED IN 2008

25 FTE CONSULTANTS
dedicated to State Licensing

208+ ACTIVE CLIENTS

- Virtual Manufacturers
- Self-Distributing Manufacturers
- CMOs
- Wholesalers
- 3PLs
- Rx Drug
- Cell & Gene
- Medical Device
- OTC

138+ PRODUCT LAUNCHES

37 MEDICAL DEVICE CLIENTS

14 WHOLESALERS & 3PLs



LEARNING
CENTER

Thank you for watching!

For more information or any questions you may have regarding State Licensing or Two Labs and Envision Pharma Group, please contact Kim Cline at Two Labs: Kim.Cline@twolabs.com

For additional professional development on healthcare distribution, market insights, supply chain and reimbursement & advocacy, visit <https://www.hida.org/learningcenter>

**All information in this presentation is accurate as of May 1st, 2024.*