

U.S. Market Entry Playbook

Ten steps, and the pitfalls to avoid, for life-science companies bringing a medicine to the United States.

1 Define the U.S. ambition

Agree what success looks like, the timeline, the budget and the decisions the U.S. team will own. Entry is a multi-year commitment, not a project.

2 Map the regulatory path, with qualified partners

Confirm the FDA pathway (e.g. NDA or BLA for drugs and biologics) with experienced U.S. regulatory partners, and plan launch readiness around the expected approval date.

3 Set up the entity, tax and IP

Choose the U.S. legal structure with counsel, plan tax and transfer pricing, protect trademarks and patents in the U.S., and put contracts and product-liability insurance in place.

4 Treat the U.S. as many markets

Payers, prescribers and competition vary by state, region, segment and channel. Prioritize where your first patients and prescribers really are, and start focused.

5 Build the value story, pricing and access

Coverage and reimbursement across commercial plans, Medicare and Medicaid, the channel (specialty pharmacy and distribution), and the evidence payers will ask for.

6 Choose the route to market

Build your own team, partner with a U.S. company, use specialty distribution, or out-license. Each trades control for speed and capital differently.

7 Hire the U.S. team in sequence

Senior U.S. leader first, then market access and medical roles, then the field. Build U.S. compliance in from day one: promotional review and transparency reporting.

8 Build local evidence and references

U.S. data and respected U.S. clinical advisors. What persuaded physicians and payers at home may not persuade them here.

9 Sequence the launch with a 100-day plan

First accounts and prescribers, access milestones, a few leading indicators, and the decision each one will trigger.

10 Design governance with headquarters

Clear local decision rights on pricing, contracting, hiring and promotion, within guardrails, and a fast way to resolve disagreements across time zones.

COMMON PITFALLS

- Treating FDA approval as the finish line
- Underestimating market access and payer timelines
- Launching everywhere at once
- Hiring the U.S. team too late, or too early
- Copying the home-market playbook
- Slow decisions between headquarters and the U.S. team

THE SCALAR FORMULA

People × Culture × Strategy × Communication × Adoption × Execution = Results

The factors multiply. A zero anywhere, even a strong plan with the wrong U.S. team, sinks the whole entry.

Book a 30-minute call with Emilio

Talk through your U.S. launch plan, no obligation. Or start with the 6-week U.S. Launch Sprint.

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