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RESEARCH SERIES · U.S. MARKET ENTRY

Why MedTech Companies Outside the U.S. Can Struggle in the American Market — And How to Get It Right

Breakthrough technology is necessary but not sufficient. Companies that win in the U.S. invest in the right leadership from day one.

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Introduction

The U.S. represents the largest single MedTech market in the world. For companies with breakthrough technologies — whether headquartered in Europe, Israel, Asia, or elsewhere — successful U.S. market entry creates a series of transformative value inflection points: a successful clinical trial, FDA clearance, commercial launch, and early market traction can each drive an increase in valuation, improve access to future funding, and unlock meaningful interest from U.S. strategic acquirers.

Yet year after year, companies with world-class innovation have challenges enrolling in U.S.-based clinical trials, and companies with clean regulatory approvals in their home markets have challenges gaining market traction in the U.S. after committing significant resources toward market entry.

The technology and the unmet clinical need are not the issue at hand. What derails these companies is underestimating two critical realities: the complexity of the U.S. market, and the level of investment required in U.S. leadership talent to navigate it.

Why U.S. Market Entry Is Uniquely Challenging

Even for U.S.-based companies, navigating the pathway to FDA approval and commercial success is demanding. Add cross-border operations — managing from Europe, Israel, or Asia — and the challenge multiplies. Time zones create communication lag. Management travel creates inefficiencies. Cultural differences in business practices matter more than anticipated. Distance makes hands-on oversight of complex operations genuinely challenging, not merely inconvenient.

> *"One of our greatest learnings from U.S. market entry was understanding what exact profile of a sales person we actually needed for the American market. The question isn't whether you're a great sales professional — it's whether you're the right person for our product at our specific stage."*
>
> **— Anne Osdoit, CEO, Moon Surgical**

Anne Osdoit's observation points to a broader pattern. Through research with investors and CEOs who've navigated cross-border expansion, we've identified several factors that consistently separate companies that gain U.S. traction from those that stall.

The Foundation: Setting the Stage with the Right Key People

Successfully entering the U.S. market — whether for a clinical trial or commercial launch — is fundamentally about having the right people in place from the outset.

For early-stage companies, this means having at least one senior person, plus one or more key individuals directly employed by the company in the U.S. and fully aligned with company goals. Whether running a trial or launching a product, there must be someone at a senior level in the U.S. who can engage credibly with clinical investigators and hospital administrators and express genuine commitment to the U.S. market — someone in senior leadership who can represent the company physically in a crisis situation involving a patient, a physician, or a hospital administrator. Service providers — CROs, regulatory consultants, reimbursement advisors, legal counsel, and tax and finance specialists — all play important roles. But you need someone on the ground in the U.S., in the right time zone, directly overseeing them and directly incentivized by the company. Companies that attempt to manage U.S. clinical operations from abroad consistently underestimate how much complexity accumulates in the gap between time zones.

The sticker shock that international companies experience when they see U.S. compensation levels can create a dangerous bias toward understaffing. It is understandable — but this is where many companies make their most consequential mistake.

The Compensation Reality

Over the last five years, compensation levels for MedTech executives in the U.S. have increased significantly relative to peers outside the country — and the gap has widened. A senior executive in the U.S. typically commands substantially more than counterparts in Europe, Israel, or Asia.

The math is unforgiving. Under-hiring for the position or hiring a mediocre U.S. leader may save $75,000 to $100,000 annually when compared to hiring at the right level and selecting an exceptional candidate. But that apparent saving can cost far more when a clinical trial misses enrollment targets, a launch strategy languishes, a reimbursement strategy stalls, or the next funding round closes at a suboptimal valuation — or doesn't close at all. Investors who have watched this pattern describe companies that balk at U.S. compensation benchmarks, hire someone cheaper who "seems good enough," and find themselves without meaningful U.S. revenue nine months later.

The cost of great U.S. talent is often less than the cost of delayed trial data, a delayed approval, or a delayed revenue ramp.

The U.S. Market: Stage-Specific Requirements and Hidden Complexity

Leadership needs vary significantly by company stage — and each stage carries its own market complexity that is difficult to anticipate from outside the U.S.

Clinical / Pre-Commercial Stage

Companies need U.S.-based senior leaders who can embed themselves in the U.S. healthcare system and understand clinical site selection, investigator relationships, IRB processes, and patient enrollment dynamics. Clinical trial management in the U.S. is operationally demanding in ways that are difficult to appreciate from a distance: site relationships, protocol deviations, enrollment velocity, and training compliance all require on-the-ground oversight that cannot be effectively delegated to a CRO alone.

Equally important — and frequently overlooked — is the reality that FDA approval/clearance data and payer evidence (whether for CMS or other important payers) require different evidentiary standards. Companies that design clinical programs to answer the FDA's questions and address requirements for U.S. approval, without simultaneously building the evidence base that payers will require, arrive at commercialization with a significant gap. The time to close that gap is during trial design and trial execution, not after approval.

> *"No one in the history of MedTech has ever delivered a product that worked perfectly the first time out of the box. It's extremely important to stage your launch, anticipating that you're going to have to make some changes to the device, the instrumentation, or the training."*
>
> **— Ned Lipes, Former Group President, Stryker**

Commercial Stage

Later-stage companies need strong leaders who can build sales organizations and navigate a market that is far less homogeneous than it appears from the outside. Many international companies assume the U.S. is a single market. It is not.

Hospitals range from integrated delivery networks — which combine provider and payer functions and evaluate technology through a total-cost-of-care lens — to academic medical centers, community facilities focused on procedure volume and reimbursement adequacy, and large publicly traded health systems. Physician practices span independent solo practitioners, large group practices, employed physician models, and private equity-backed specialty platforms. Each requires a different value narrative and a different commercial approach.

As outlined in the MedTech Value Framework developed by Deloitte and AdvaMed,[1] successful market entry requires articulating value across multiple dimensions: clinical outcomes, economic impact, patient experience, and organizational fit. Which dimensions resonate most varies substantially by customer segment — and getting that segmentation right before launch, not during it, meaningfully improves adoption rates and commercial velocity.

The most effective companies extend this segmentation thinking into clinical trial design itself, not just commercial launch planning. Clinical programs built around the questions that specific customer segments actually care about generate evidence that is far more persuasive at the point of commercial adoption — and far less likely to leave reimbursement gaps that require expensive post-approval studies to close.

Beyond segmentation, two additional challenges consistently surface at the commercial stage:

Reimbursement is strategic, not administrative. Competitors may actively work on codes designed to exclude your technology. Navigating that dynamic — including proactive engagement with medical societies — is part of the competitive game in the U.S., and the rules of this game can surprise companies based outside the U.S.

> *"It's not just reaching out to payers. Your U.S. competitors are actively working on codes designed to exclude your technology. How do you work with medical societies to counter that?"*
>
> — Chip Hance, CEO, Regatta Medical

Distribution is relationship-driven. Getting in front of enough U.S. physicians — who are already cultivated by established reps carrying multiple product lines — requires a deliberate distribution strategy, not just a headcount plan. Companies that underinvest here often have a product that works and satisfies an unmet clinical need but are unable to reach the hands that would use it.

> *"We had a fabulous product — breakthrough technology, tremendous IP, great clinical value. And we could never solve the sales equation. We could never get this thing in front of enough people to make the company commercially viable."*
>
> — Ned Lipes, Board Director, Accelus

Manufacturing Considerations

In a climate of evolving tariffs and supply chain scrutiny, U.S.-based production is worth evaluating early rather than reactively. The decision has implications for both commercial positioning and cost structure — and building the necessary local expertise takes time.

The Path That Works

Companies that succeed in the U.S. tend to share several common disciplines:

- **Invest at U.S. scale.** Labor costs represent roughly 20% of medical device company expenses in the U.S. Operating meaningfully below that threshold can leave companies without the talent needed to compete.
- **Place senior leadership in country, early.** Hiring strong U.S. leaders before entering the market — not after struggling — shapes better clinical strategies, stronger regulatory approaches, and more effective commercial plans. Geography matters more than expected.
- **Stage the approach.** Hub-and-spoke strategies — starting with centers of excellence in specific U.S. regions and expanding from proven nuclei — tend to outperform national launches attempted with limited resources.
- **Segment before you sell.** Understanding how your product creates value for different customer types — IDNs vs. academic centers vs. community hospitals vs. private-equity-backed physician groups — and sequencing entry accordingly improves adoption rates and commercial velocity.
- **Treat talent as a strategic investment.** The right U.S. leaders are force multipliers. Under-hiring — whether in seniority level or talent caliber — can cost far more than the salary saved.

The investors and operators we spoke with were consistent on this point: when evaluating companies for funding, the team receives as much scrutiny as the technology. Great leadership with solid technology tends to outperform exceptional technology in the hands of a mediocre team. The U.S. market's complexity rewards execution discipline — and execution discipline starts with the quality of the people you place in country.

There is a proven formula for achieving market traction in the U.S., and this paper has outlined its core elements. The U.S. market can be a genuine valuation multiplier — but only for companies willing to invest directly in U.S.-based leadership from day one, not after the first miss.

REFERENCES

1. AdvaMed® in collaboration with Deloitte Consulting LLP. "A Framework for Comprehensive Assessment of Medical Technologies." AdvaMed Strategic Value Initiative, January 2023. https://www.advamed.org/our-work/policy-areas/payment-health-policy/medtech-value-framework/

About the author

Glenn Snyder advises and coaches CEOs and leadership teams of growth-stage medtech companies through Shannon Lane Group. Over three decades at Deloitte, he founded the firm's Medical Technology practice and grew it to more than $500M in the U.S., advising C-suites and boards on growth, transformation, and governance. He serves on the boards of Larmor Bio and World Telehealth Initiative and mentors medtech innovators at StartX.

Contributors

Rick Geoffrion is a serial medtech entrepreneur and senior executive who has founded or reorganized seven medtech and pharmaceutical companies. He serves on multiple industry boards, including the Executive Committee of the Medical Device Innovation Consortium (MDIC).

Bernie Haffey, of Haffey&Co, is a former CEO and CCO of multiple successful medtech companies and the innovator of the High-Performance Management System (HPMS), which has created over $15B in medtech exits. He serves on multiple industry boards and has extensive experience leading companies through commercial expansion.

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