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Regulatory vs. Market Approval: What Innovators are Missing

How to Build a Strong Market Approval Case for Your Next U.S. Market Expansion

In this edition, we highlight that **market approval is important for all innovators across a variety of industries seeking to capture U.S. market share before successful market entry and expansion**

Are you educating the market? Are you moving quickly **based on market changes?** Making your impact for successful commercialization?

These questions underscore a new rule for commercial success: regulatory approval is not enough; you must also earn market approval, and it takes a long time. **Now is the time to act.**

Why Now? A Perfect Storm of Opportunity in the U.S.

You've secured (or are planning to secure) U.S. FDA approval. But have you built market approval?

This was the central question at the recent BDMT Global + MEDevice Boston Innovators Summit, where nine top Korean innovators gathered not just to showcase their technology, but to actively build the U.S. market credibility essential for officially launching in the market and growing commercial success.

They represent those using a **smarter market-expansion approach that is replacing the old model of "Secure FDA, then enter the market."** Instead, they are building market approval and credibility in parallel with the regulatory process by participating at the event.

What's the difference? Product regulatory approval (such as FDA clearance) is a technical and legal milestone that certifies that your device is safe and effective for use. Market approval, however, is a commercial milestone. It is the credibility, awareness, and acceptance that build momentum across different ecosystem players, ensuring that once your product is approved, there is demand to buy.

Market Approval vs. Regulatory Approval

The new, faster paradigm involves building market approval and credibility in parallel with the regulatory process, rather than after it.

Why is this shift from a linear to a parallel strategy so critical now?

According to U.S. leaders who participated in the Summit, there is a "perfect storm" creating a critical window of opportunity for Korean innovators to act. This includes:

Available Capital: "I have never seen so much cash sitting out there looking for a home... in the form of grants that don't dilute you," said Brad Waugh, a seasoned entrepreneur and founder of Life Wear Technologies, during a panel discussion. He emphasized that states like Rhode Island, Texas, and North Carolina are offering "enormous amounts of cash in thw form of grants that don't dilute you," said Brad

Market Approval vs. Regulatory Approval

Waugh, a seasoned entrepreneur and founder of Life Wear Technologies, during a panel discussion. He emphasized that states like Rhode Island, Texas, and North Carolina are offering "enormous amounts of cash in the form of grants" that are ripe for innovators to act. This non-dilutive capital provides the essential fuel to fund early market-building activities (hiring a U.S. team, attending key events, and launching pilot campaigns) without giving away significant equity prematurely.

Market Need: The largest silver tsunami is happening as we speak... we in the healthcare value chain need to understand that and prepare for that" added Sonal Matai, President of KARL STORZ North America.

He pointed to the aging U.S. population where "one in three of all adults who are 65 of age have some ailment or some chronic condition," and the massive shift of care out of hospitals as creating urgent demand for new solutions."The largest shift of care is also happening as we speak," Matai added. "Care is shifting out of the hospital into different sites of care." This decentralization opens up new avenues for products that enable monitoring, diagnostics, and treatment in ambulatory surgery centers, clinics, and even patients' homes, creating fresh opportunities for innovators.

Strategic Necessity: In the world's largest healthcare market, establishing a physical and strategic presence should begin well before FDA approval. "If you want to play in the

biggest market... you've got to have a presence here," asserted Nihar Prasanna, a leading investor in medical devices and pharmaceutical ventures such as Acunova Life Sciences and BTNX Inc. "I tell companies that I speak to that FDA approval is not a prerequisite for us to work." He emphasized that FDA approval, while a major de-risker, shouldn't delay U.S. entry, as companies can start by testing the market with lower-risk or non-regulated devices and then scale up as they build traction.

"There are many, many paths to market. Get your product out there and incrementally add features, rather than waiting years for clinical trials and losing time." The ultimate goal of this early groundwork is to build the credibility and relationships necessary to strategically leverage opportunities across the entire ecosystem—from local community forums and specialized events to the world's largest stages, such as the JPM Annual Healthcare Conference.

Innovators who start building now can use these targeted engagements as stepping stones to ultimately command attention from global investors and partners on the most influential platforms.

Ultimately, both small- and large-scale events should be used strategically as part of a more detailed market approval approach (vs. attending alone) to truly capitalize on current demand.

Suzy's Insight: *The old model is being replaced because the new market reality demands it. Waiting is the greatest risk of all.*

The U.S. ecosystem is actively seeking and funding solutions right now. The question isn't if you should go, but how quickly you can build the relationships to prove your value.

Another important factor to consider? FDA approval is often delayed. Consider this: if you have established market approval through community partnerships and education, a regulatory delay becomes manageable instead of catastrophic. Your partners stay engaged, your community remains informed, and your brand continues to build credibility. You haven't lost momentum; instead, you've gained insights that will strengthen your eventual submission.

If you wait until after receiving FDA approval to start building relationships, any regulatory delay will leave you completely stalled with no market progress.

To support S. Korean innovators in effectively securing market approval, review the success stories of innovators who are enhancing their credibility and seizing current opportunities.

BDMT Global + MEDevice Boston Innovators Summit Success Case: A Launchpad for Market Credibility

The BDMT Global + MEDevice Boston Innovators Summit served as a direct channel for U.S. market expansion and launch as part of their U.S. commercialization efforts. The event provided a platform for S. Korean companies to engage with the U.S. healthcare ecosystem through multiple opportunities, including panel discussions with industry experts, investor pitch sessions, spotlight presentations, networking receptions, media interviews, and more.

A key event objective was to support market acceptance and serve as a channel to create such a foundation.

Innovators from S. Korea were selected and featured to showcase revolutionary technology to leaders seeking investment and collaboration opportunities, drawing a diverse group of U.S. key opinion leaders (KOLs) and industry decision makers seeking innovative solutions across critical areas such as mental health, wound care, robotic surgery, AI-powered imaging, and point-of-care (POC) diagnostic devices—all of which were represented by featured innovators.

Top Innovators	
BIONEER	MDx Solutions Advancing Global Diagnostics for TB & Beyond
coreline	AI-Assisted Diagnostics from a Single CT Scan
elecell	Biometric Electrical Stimulation Wound Healing
ENCell	Biopharma for Advanced Cell & Gene Therapies
MINDsAI	Biotech & AI All-in-One Mental Health Solution
NEMESIS	Intelligent Biosignal Processing Solutions
ORANGE BIOMED	Breakthrough Microfluidics for Monitoring Diabetes
ROEN SURGICAL	Advancing Surgical Robotics with Flexible Ureteroscopy System
SEVEN POINT ONE	AI-Powered Dementia Screener Using 1-Minute Speech

Selected innovators from S. Korea were selected and featured, representing breakthroughs in diagnostics, therapeutics, and medical devices — including leaders in AI imaging, microfluidics, surgical robotics, and biosignal analysis.

The results were immediate. The event's prestigious Franklin Visionary Award for Innovation Showcase 'Product of the Year' 2025 was awarded to elecell for its nationally-recognized, groundbreaking Chronic Wound Health Patch. **This kind of third-party, U.S.-based validation is a powerful step in building market approval**. By accumulating these market pre-validation processes, innovative companies gain the opportunity to build a market long before FDA approval and establish a foundation for corporate growth and sales well in advance.

The "U.S. Market Entry & Expansion Opportunity - ALL-IN-ONE" panel, featuring Matai, Waugh, and Prasanna, provided strategic insights for expansion to encourage immediate action by innovators. Across the board, U.S. KOLs emphasized the critical need to come to market now and outlined different strategic approaches to get there. **Interacting with these global leaders provides innovative companies with a field validation opportunity to showcase their products and technologies, gain feedback, and even take big steps forward with their "approval."**

Insights for market expansion included entering with pending patents, hiring a product team as a critical step, and other strategic moves to adapt to a market-driven approach Waugh recommends not waiting for patents to expand to the market and to capitalize on

U.S. Market Entry & Expansion Opportunity - ALL-IN-ONE Panel

opportunities as soon as possible. He noted, "I go to market with patent pending. **Do not wait. Get your product on the market. If you've got a good idea, bring it to market right away." This highlights the importance of testing and market approval processes in local markets.**

KOLs also emphasized critical hiring decisions that **influence a partner's decision to collaborate.** Matai stressed an often-overlooked role by innovators, defining the essential profile of a U.S. Product Manager. He stated, "Hiring a good Product Manager is the most important role. A Product Manager often acts as a salesperson. This role is integrated in many ways, and is essential to understand the voice of the customer, how to create a compelling value proposition, how to build both the business case and the business model, and to best navigate the regulatory and reimbursement landscape. Even if the technologist or founder is exceptionally skilled, the Product Manager is the most crucial role I look for." This highlights the importance of accurate insight and direction into the capabilities needed locally.

The panelists didn't just offer advice; they singled out and publicly endorsed participating S. Korean companies.

Panelists expressed direct excitement for ROEN Surgical, a company BDMT introduced to our KOL network as part of our KOL program. One panelist mentioned in front of the audience, "We've been speaking to ROEN... what they're trying to drive with their flexible robotic solution and some of the simple AI pieces... I think it's a lot of fun," the panelist praised highly in public. He highlighted the potential to support industrial workflow efficiency demands and offered his open support to this innovative company as it seeks to expand its market.

Another panelist highlighted elecell's market-entry strategy, praising founder Chris Hyung-Seop Han's market-driven approach, noting "He's got a product that brings down the recovery time on healing by over 50%... So he's coming out with that product first as a class one medical device. That means he can start producing bandages to sell at places like Walgreens and CVS. **He's not waiting to release future revolutionary products. He's going to market now."**

This type of public validation cannot be purchased. It can only be earned through strategic positioning and genuine relationship-building. It is a strong process of market approval.

S. Korean innovators also pitched their cutting-edge solutions in front of U.S. healthcare decision-makers at the New England Medical Innovation Center (NEMIC) Investor Pitch & Reception. This provided key decision-makers with the **opportunity to explore investment opportunities and engage directly with the**

selected innovators. the capabilities needed locally.

The Innovation Spotlight session provided an opportunity to showcase cutting-edge solutions in Boston. These breakthrough technologies were also featured in the MEDevice Innovation Center Showcase, **offering attendees an exclusive, up-close look at the solutions ahead of their U.S. launch.** Top innovators were also invited to share their vision as featured media guests on the MEDevice Insider podcast.

Suzy's Insight:

The Summit was a powerful launchpad for strong outcomes, but it was just one destination. True market credibility is built through a sustained campaign of strategic destinations, ongoing efforts that keep your company in the U.S. conversation, and continuously build opportunities to meet and collaborate with local ecosystem leaders.

Innovators must examine their current capabilities and identify strategic paths to get to the U.S. now - regardless of their regulatory status.

S. Korean Innovators Commanded the Innovator Spotlight Theater

Some of the innovators are in discussions with key industry leaders on how their advanced technologies can impact key regions in the U.S. to solve problems across different areas, such as operating rooms, at-home and telehealth opportunities, and more. All of the conversations can help speed up the development of solutions to current market problems.

Some innovative companies are discussing with industry leaders how their cutting-edge technologies can address challenges in various areas, including operating rooms, home healthcare, and telemedicine, across key U.S. regions. They are having active discussions about how to collaborate with distributors and investors and about establishing ways to bring their breakthrough innovations to the U.S. quickly and effectively.

These conversations not only accelerate the development of solutions to address

current market challenges, but also have a significant positive impact on the validation process for future market approval.

This multi-pronged approach, combining expert validation, peer recognition, and direct decision-maker access, provided a strategic launchpad for these companies to build the market credibility essential for commercial success.

Campaign Example: Building Market Approval Through Community Movement

For a Korean health innovator entering the U.S., the single greatest challenge isn't just regulatory, it's cultural. The market is saturated, stakeholders are skeptical of unproven brands, and patients are often unaware of the very problems new technologies aim to solve.

Orange Biomed, with its revolutionary pocket-sized A1c meter, faced this exact challenge: how to create demand for a novel diagnostic solution in a market that didn't yet understand its full value or the critical need it addressed.

While 60% of Americans live with at least one chronic disease, there is a lack of awareness about how these conditions are interconnected. For instance, many Americans are unaware that a diagnosis of type 2 diabetes significantly increases the risk for 57 other serious health conditions, including cancer, kidney disease, and Alzheimer's.

During local conversations with providers and patients, Orange Biomed found widespread confusion between different diagnostic tests. Many believed a glucose meter replaced an A1C test, when in reality, both serve equal

Campaign Kicked Off with Public Health Webinar

importance in monitoring pre-diabetes and diabetes.

Their response was to **proactively launch a community-oriented campaign**, designed to educate the ecosystem and build market credibility well in advance of their FDA submission. This initiative, entitled "M.A.P. Your Health Campaign," serves as a key example for taking strategic approaches to build market approval from the ground up.

The M.A.P. Your Health Campaign was launched in May 2025 as a nationwide movement to close this knowledge gap and empower communities. Kicking off with a community-focused "Solving Healthcare Challenges" webinar, positioning its CEO alongside nationally-recognized U.S. leaders from the National Association of Chronic Disease Directors (NACDD), in addition to leading media, public health academia, and patient advocacy groups.

To translate national credibility into local impact, Orange Biomed took the campaign on the road, selecting Chicago as the flagship city for its first major in-person event in August 2025**. In just 3 months, Orange Biomed went from a webinar launch to hosting a full-scale community event.**

The M.A.P. Your Health Chicago: Community Forum & Public Health Resource Fair was not a simple booth at a trade show. It was a free, full-day community event hosted at the Humboldt Park Health Wellness Center, designed to bring resources directly to a neighborhood facing health disparities.

Orange Biomed recruited and unified over 20 leading Chicago organizations as partners. This coalition included major players like: Humboldt Park Health, Howard Brown Health, The Illinois Public Health Institute, The Cancer Wellness Center, The Center for Better Aging at St. Bernard Hospital, Rush University, Project Patient Care, and more.

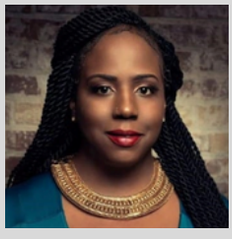
Community Members Engaged with Provider Hosted Sessions

The event featured health screenings, expert panels in English and Spanish, family-friendly activities, and interactive resource tables. The result was a powerful demonstration of local market approval: trusted community institutions were now publicly endorsing and collaborating with Orange Biomed, giving the company an authentic, grassroots presence.

Featured Event Collaborators Included Local Ecosystem Leaders

"The one-day M.A.P. Your Health Chicago event reflects our mission to eliminate healthcare barriers and provide whole-person care that is accessible, inclusive, and culturally grounded," said Diego Lopez, Vice President of Professional Services at Humboldt Park Health. "At Humboldt Park Health, we believe true wellness goes beyond treatment—it starts with access, community, and empowerment. This event demonstrates what's possible when we invest in prevention and create spaces where people feel seen, supported, and inspired to take charge of their health."

"Diabetes is one that everyone should know their numbers and then be able to seek treatment so that they don't end up with severe chronic conditions," said Pat Merryweather-Arges, Executive Director of Project Patient Care. "The lack of access to testing and delayed diagnosis are two of the biggest challenges we must solve, and it starts by engaging with communities directly."



According to Terra Campbell, Associate Director of Community Relations at Howard Brown Health, "It's about awareness and education for the most vulnerable: the everyday person who is raising children, managing a household, and working a nine-to-five job." Campbell added that her goal is "to create interventions that provide awareness and access to improve health outcomes for the most vulnerable."

Suzy's Insight:

Oftentimes, innovators are unsure how to form collaborations without regulatory approval or the funds to sponsor clinical studies. Community campaigns are a key way to get there. It is a win-win scenario driven by shared purpose between an innovator and local ecosystem leaders to close access gaps for patient communities.

Orange Biomed's campaign is a key case study in the parallel path to market approval. The M.A.P. Your Health campaign directly engaged both B2B partners (hospitals, clinics, nonprofits) and B2C end-users, ***creating a wave of third-party validation and public goodwill.***

The strategy proves a critical point: market approval is an active process, not a passive milestone. By educating the market on the "why" behind their technology, they ensure that upon securing FDA clearance, they will not be an unknown company with a novel gadget, but the recognized leader of a movement that the U.S. healthcare ecosystem is already eager to support. ***The window of opportunity in the U.S. is open. For Korean innovators, the decision is not if, but how.***

KEY TAKEAWAYS: WHY YOUR MARKET APPROVAL JOURNEY MUST START NOW

S. Korean innovators who wait for regulatory approval before building market credibility will find themselves entering a crowded marketplace as unknown entities, struggling to gain traction despite having regulatory clearance in hand.

The evidence is clear: companies like Orange Biomed and elecell are proving that parallel strategies work.

By building market approval alongside regulatory processes, they're putting their names in industry conversations, creating demand, and establishing partnerships all before their products hit the market — **effectively building communities that will support their long-term market success.**

The process of building market approval isn't just about being early. It's about being strategic. The "perfect storm" of available capital, urgent market need, and ecosystem readiness that U.S. KOLs described won't last forever.

The organizations and funding opportunities actively seeking solutions today may not be as accessible a year from now.

The strategy is proven. The window is open. The U.S. healthcare ecosystem is ready and actively seeking the innovations you've developed.

For Korean innovators, the decision is not whether to begin, but how quickly you can start. Your U.S. market approval journey begins today, not after regulatory approval.

If you are interested in potential partnerships and long-term relationships with the companies mentioned in this article or others in the U.S./ S. Korea, contact Suzy at sim@bdmtglobal.com.

Suzy Im

BDMT Global
TRANSFORM AND DRIVE DEMAND

A widely known name in global business development—an award-winning business growth and commercialization transformation leader, an accredited investor, and architect of market-entry ecosystems—Suzy Im is at the forefront of the rapidly advancing high-tech and medical industries, fast-tracking start-ups and scale-ups with Tomorrow's Innovation Today. She has dedicated two decades to mentoring the next generation on Emerson's Senior Marketing Faculty and Board of Advisors.

Suzy established Business Development & Marketing Transformation (BDMT) Global with an innovative business model that combines the two most critical functions for technology innovators entering the new market, with a built-in network, know-how, and resources. Headquartered in Boston, BDMT Global is led by award-winning experts, providing complete end-to-end solutions for driving market demand and leadership, from strategic go-to-market planning to full execution, effectively de-risking new market entry and expansion for cutting-edge companies across AI, robotics, medical devices, digital health, and more. The team specializes in market entry, expansion, and innovative product launches into new markets.

In her 20+ years of experience, Suzy has worked with technology and healthcare enterprises and startups, including Siemens, GE, HP, Teradyne, and Samsung, as well as leading IT and medical industry analysts, influencers, and KOLs. She boasts a proven track record of building innovation gateways, leading BDMT's solid foundation of successful initiatives, beginning with the Boston Live Webinar Series in 2020 and the Digitization, Automation, Cross-Industry Collaboration (DAC) movement in 2021, accelerated by a flagship 2023 event sponsored by Mayo Clinic Laboratories. This was bolstered by the establishment of the Sponsors of the Future (SoF) community and patient group in 2023, a KOL management program and webinar series expansion in 2024,and the expanded Market Approval Starter-Scaler Solutions (MASS) program in 2025, providing a strategic shortcut for innovators of all sizes from early-stage to enterprise.

Suzy enables rapid market validation and commercialization success through a built-in network of Key Opinion Leaders (KOLs) and industry leaders from renowned institutions such as Mayo Clinic, MassRobotics, Disher, Cleveland Clinic, Johns Hopkins, Yale, CVS Pharmacy, and the CDC. This powerful ecosystem provides clients with direct access to decision-makers, analysts, and influencers, effectively building the community and credibility needed to secure funding and partnerships.

A recognized industry thought leader, Suzy has served as a columnist for a variety of global media, a published author on leadership communications, a Head Mentor for MassBio, and a sought-after keynote speaker featured in numerous global publications. Her work has been instrumental in helping thousands of innovators navigate complex regulatory landscapes and establish successful global to local market presence.