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WHEN INNOVATION MEETS GROWTH



THE BUSINESS OF MEDTECH

USA and EU Are Not Always First: Think Outside the Continent

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When medical technology founders talk about going international, the conversation almost always begins with two places: the United States and the European Union. I understand why. They are large and wealthy markets, they set the regulatory standards that much of the world follows, and investors like to see them in a plan. But over many years of international business development, I have come to believe that the USA and EU are not always the right place to start, and that some of the most rewarding markets for a young company sit in Asia, Latin America and other regions that rarely appear on the first slide.

This is not an argument against the big markets. It is an argument for thinking more widely about the order in which you approach them.

Why the USA and EU are hard places to begin

The United States has one of the most complex payment systems in the world, and a cleared device can wait a long time before clinicians have a reliable way to be paid for using it. Competition is intense, buyers have seen many products, and building a credible presence usually requires a local team or partners, which is expensive for a company that is still small. Europe has its own challenges. The Medical Device Regulation has made the road to a CE mark longer and more demanding than it used to be, and once you have it, you still face many different health systems, languages and purchasing practices under one regulatory roof. In fact, many manufacturers and entrepreneurs I have spoken to in the last few years have decided not to enter the EU or seek CE marking under the MDR because of the costs and complexity, and, you know what, I totally agree with them.

The world can also change around you. In April 2025 I wrote a preliminary review of the new American tariffs on imported medical devices, and one of my conclusions was that non-US competitors, particularly in Europe and Asia, were positioned to benefit, while price sensitive markets such as Latin America and Southeast Asia would become more competitive. I noted at the time that in government tenders in countries such as India, Brazil and South Africa, even a small price difference can disqualify a bid. Whatever has changed in the details since then, the lesson has stayed with me: a company that depends on one or two markets is exposed to decisions it cannot control.

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Asia: large needs, fast decisions and real relationships

I have spent a large part of my career in Asia, and it has taught me that many Asian markets combine enormous clinical need with a genuine openness to new technology. India has well over a billion people and a rich pool of talented and skilled healthcare professionals. After one visit to IIT and AIIMS I wrote that India is no less a start up nation of its own, and any foreign company that arrives assuming it is bringing something the country has never seen will quickly find that it is talking to people building advanced technology themselves. Most marketing executives do not understand that when you sell to India, you are not selling to 1.2 billion Indians but rather to 300 to 400 million people, similar in size to the population of the USA. Selling to India, though, is a completely different kettle of fish, and I will explain it in detail in another article.

Southeast Asia has been just as instructive. In Indonesia, the world's largest Muslim majority country, a company I represented received import clearance for its device through the patient work of a local partner who knew the system and stayed with the process until it was done. When it finally came through, I wrote on LinkedIn that I rarely feel so proud, and I feel it was one of my best moments (that partner is a true partner, through good times and bad)! In Thailand this August I had the honor of representing Israel at Corporate Spark 2026 in Bangkok, hosted by the National Innovation Agency, which brought together 24 global startups, and it showed me how actively some Asian governments look for foreign innovation. Japan is a very different market again, with a careful and structured way of evaluating new partners, and I will come back to what it taught me later in this series.

Smaller Asian markets deserve attention as well. On one visit to Sri Lanka I fitted seven meetings into a single trip, including one with the healthcare arm of a conglomerate with more than eighty years of history that most people in the country know as an importer of cars. In recent years that group has brought its medical activities together under a single identity and expanded into medical devices and hospital equipment. When long established local groups start investing seriously in healthcare, it tells you that the market is changing, and it often means there are capable partners looking for new products.

Latin America and beyond

Latin America is another region that founders often overlook, partly because of language and partly because each country has its own regulator. In my experience the right local support makes a great difference there. When a company I represented began working in Argentina, the Israel Economic Mission played an important part in our first steps there, and I wrote formally to its head to thank him, because his understanding of the local market had been instrumental. We went on to talk with Israel's missions in other Latin American countries as well, and the experience convinced me that a region many people consider difficult can be approached step by step with the right help. I have worked in Mexico as well, and across the region I have found that a well prepared registration file and a committed local partner open doors that a foreign company could never open alone.

Australia is a different case again. When I visited Melbourne and Sydney in 2025, looking for partners to distribute a medical technology, I told a local newspaper that I was thinking of rural communities where a patient might have a therapist a couple of hundred kilometers away and see them once a month. Geography like that creates needs that technology can genuinely help with, and it shapes the market in ways that a plan built for Europe would miss.

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How to think outside the continent

None of this means skipping the United States or Europe. For many devices they will be essential, and an FDA clearance or CE mark is often what makes registration elsewhere possible in the first place. Many regulators in Asia and Latin America take an existing major clearance into account, so the sequence can be designed to use one clearance as the base for several markets at once.

What it does mean is looking at the whole map before deciding the order. A market where a committed partner is ready, where the regulator is reachable, where the need is visible and where you can afford to be present may teach you more, and earn you more

credibility, than a slow and expensive first year in a market where you are one of hundreds of newcomers. Revenue and reference sites from those markets can then support the larger effort in the United States and Europe, rather than the other way round.

LET'S TALK

At Synergen, I help medical technology companies look at that whole map with fresh eyes. If you have only ever considered the USA and EU, I would be glad to talk about what else might fit your device. Write to me at **gary@synergenmedtech.com** and tell me about your commercialization or international business development challenges. In the next article, I look at whether you should sell directly or through distributors once you have chosen your markets.

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