

## Strategies for Success in Japan's Biotech Ecosystem

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### Complying with Japan's regulatory requirements is a critical aspect

Japan's biotech sector is a landscape rife with opportunity, yet also a complex market that requires a deep understanding of local ecosystems and cultural nuances. For nearly two decades, successful commercialisation projects in Japan have often depended on our ability to navigate these challenges. Having facilitated projects with 32 of Japan's 40 largest pharmaceutical companies and as a writer of an award-winning blog on biotech business strategies and opportunities in Japan, I have seen firsthand what it takes to succeed in this complex environment.

#### Successful Market Entry

Entering Japan's biotech market demands more of you than showing up at a tradeshow. You must consider aspects like regulatory, pricing, reimbursement, MAH, KOLs and who to partner with. Companies successful in Japan often form alliances with local entities. That means immediate access to market insight and gaining market access. A beneficial partner also provides paramount credibility.

Moreover, complying with Japan's regulatory requirements is another critical aspect. The process is manageable when approached with sound strategies and guidance. Two pieces of advice: Study the regulatory environment and then work with a regulatory consultancy.

#### Trust is Key

I cannot overstate the importance of understanding Japan's business culture. Trust is the cornerstone of all business relationships, and in Japan, it is built through consistent and respectful engagement over time. For instance, signing a distribution agreement in Japan can take up to one year after the first handshake or bow. This lag is due diligence being conducted the Japanese Way.

A key aspect of this trust-building process is understanding the Japanese approach to decision-making. Unlike in many Western cultures, where decisions may be swift, Japan sees consensus-building. While this process may appear slow, it ensures decisions are well-considered and supported by all stakeholders, leading to stronger and more enduring business relationships. Over time, this means Japanese companies are risk-averse and make very few, costly mistakes.

### **The Future is Here**

The sector is seeing significant transformation, driven by national initiatives like BioStrategy 2030, which aims to position Japan as a global leader in biotechnology. Underpinned by government support and strategic investments, it fosters innovation in all segments.

Central to this transformation is the Greater Tokyo Biocommunity (GTB), a key innovation hub in Japan that connects companies, research institutions, and investors. Biocommunity Kansai (BioCK) is similar but in the Kansai region. For those aiming to enter the Japanese market, aligning with such initiatives offers a strategic advantage, providing access to cutting-edge research and collaborative opportunities.

### **Key Points to Success**

Take a strategic approach to commercialisation in Japan's biotech sector. Working with local experts means invaluable insights and guidance at your fingertips. Japan External Trade Organization (JETRO) is a government-affiliated organisation that offers free support services, including market research and business matching. Since networking in Japan is inherently slow and relationship-based, tapping into the existing networks of professionals already established in the biotech community will speed things up.

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