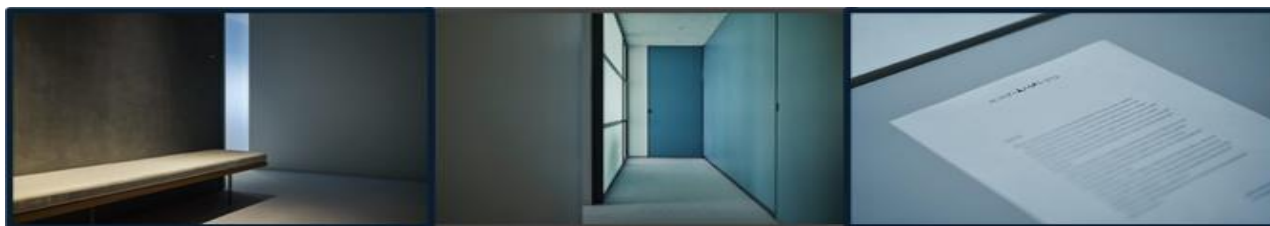


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Navigating the Nuances: Five Key Considerations for Success in Japan’s Healthcare Market

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Navigating the Nuances: Five Key Considerations for Success in Japan's Healthcare Market

By [Hiromi Furushima](#)

[Isshiki & Partners](#)

Introduction

For international pharmaceutical and medical device companies, Japan represents one of the world's most attractive and sophisticated markets. Its aging population, high standards of healthcare, and commitment to innovation create significant opportunities for growth. However, realizing this potential requires more than a great product; it demands a deep understanding of a business and legal landscape that is profoundly different from that of North America or Europe. The cultural emphasis on harmony, long-term relationships, and societal expectations has shaped a unique regulatory and commercial environment.

Simply transposing Western business practices or legal frameworks onto a Japanese operation is a common but costly mistake. It can lead to operational inefficiencies, legal complications, and, ultimately, a failure to connect with partners and customers. Success hinges on navigating the intricate interplay between formal law and informal expectations.

This article outlines five critical areas that foreign business leaders must understand to build a sustainable and successful enterprise in Japan, with a particular focus on the highly regulated pharmaceutical and medical device sectors: employment relations, worker classification, contracts and disputes, administrative guidance, and industry-specific compliance.

1. Employment Relations: A Cautious and Long-Term Approach

In a dynamic global market, the ability to restructure organizations, reallocate resources, and optimize performance is paramount. Multinational companies are accustomed to making swift organizational changes to adapt to new challenges and opportunities. However, the foundational principles of Japanese employment law present a significant counterweight to this agility. The system is built on a bedrock of strong employee protection, historically rooted in the concept of lifetime employment. While this tradition is evolving, its legacy continues to heavily influence legal interpretation and judicial precedent.

For a foreign company, the most striking difference is the difficulty of terminating an employee. In many Western jurisdictions, terminations for poor performance, redundancy, or the elimination of a position are standard business practice, provided proper procedures are followed. In Japan, the bar is set exceptionally high. The doctrine of "abuse of the right to dismiss" means that a termination will be deemed invalid by a court unless there is an objectively reasonable, socially acceptable just cause. What constitutes "just cause" is interpreted very narrowly. A downturn in business, for instance, is often insufficient to justify redundancies unless the company can prove it has exhausted all other options, including soliciting voluntary retirements, cutting executive pay, and ceasing new hires. Terminating a low-performing employee is similarly challenging and requires extensive, documented evidence of coaching, training, and formal warnings over a prolonged period, often with little guarantee of a successful outcome in court.

Given these constraints, a proactive and strategic approach to workforce management is essential. Effective risk management begins at the hiring stage, using job-specific employment contracts to clearly define roles. A documented performance management system is also essential to legally justify actions against underperformers. If separation becomes necessary, negotiating a voluntary retirement with an enhanced severance package is the most pragmatic solution to avoid costly legal disputes.

2. The Complexities of Outsourcing and Worker Classification

The need for operational flexibility naturally leads companies to consider outsourcing and the use of non-permanent staff. Engaging independent contractors, consultants, or temporary agency workers can be an effective way to access specialized skills and manage headcount. However, the risk of misclassifying these workers is a significant legal pitfall in Japan with serious consequences.

The Japanese authorities and courts look beyond the title of a contract to the reality of the working relationship. If an individual classified as an independent contractor is deemed to be a *de facto* employee, the company can be held liable for back-payments of social insurance premiums. The worker may also be granted full employee rights, including the robust protections against dismissal mentioned previously. The key factors in determining employee status include:

- The degree of control and direction the company exercises over the work (e.g., setting working hours, communication between the contractor and the company).
- The integration of the worker into the company's organization and business operations.
- Whether the worker bears business risk or is provided with tools and equipment by the company.

A separate and highly regulated category is the use of temporary agency workers, known as *haken*. This system is governed by specific laws that dictate the types of jobs for which *haken* staff can be used and the maximum duration of their assignment (generally three years for the same position). Foreign companies must be diligent in managing these arrangements to ensure they do not violate these regulations, as liability can fall on both the agency and the client company.

Diligent management of contracts and operational realities is the only way to mitigate the substantial risks associated with worker classification.

3. A Different Philosophy of Contracts and Dispute Resolution

In Western business, particularly in the United States, the contract is often seen as the ultimate source of truth. It is a detailed document designed to anticipate every conceivable contingency and allocate risk with precision. The legal philosophy is that the parties' rights and obligations are contained within the "four corners" of the agreement.

In Japan, the role and nature of a contract can be quite different. Japanese contracts are frequently shorter and less detailed, often focusing on the core commercial terms while leaving other aspects open. This is not a sign of carelessness but reflects a different business philosophy. The contract is seen not as a final, rigid set of rules, but as the starting point of a long-term relationship. There is an underlying cultural expectation that if unforeseen circumstances arise, both parties will act in good faith to negotiate a reasonable solution, rather than strictly enforcing the literal text of the original agreement.

This can create a significant disconnect. A foreign company might present its comprehensive global template, believing it is ensuring legal protection. Their Japanese counterpart, however, may view it as a sign of distrust and an unnecessarily rigid and adversarial approach. This can slow down negotiations and even damage the business relationship before it begins.

When disputes do occur, the Japanese approach again diverges. Litigation is far less common and is generally seen as a last resort. The preference is for negotiated settlement. If a case does go to court, judges often place significant weight on the "reasonable interpretation of the parties' intent" when faced with ambiguous contractual language, looking at the context of the relationship and standard industry practices.

Furthermore, the entire legal process, from contracts to court proceedings, is conducted almost exclusively in Japanese. This language barrier is not just a logistical hurdle; it can prevent a foreign party from fully understanding the nuances of its own legal standing.

The key for foreign companies is to find a balance. Instead of rigidly applying a home-office template, it is crucial to conduct a nuanced risk assessment. What are the true material risks in this specific transaction? Can they be best mitigated by a detailed clause in a contract, or would they be better managed through strong communication, clear operational monitoring, and building a relationship of trust with the Japanese partner? A hybrid approach, using a clear but not overly adversarial contract and investing heavily in relationship management, is often the most effective path.

4. The Power of "Unwritten Rules": Administrative Guidance

In any country, regulated industries must maintain a close relationship with government authorities. In Japan, this

relationship is shaped by a unique practice known as *gyōsei shidō*, or administrative guidance. This refers to the non-binding advice, recommendations, and requests issued by government ministries and agencies to the industries they oversee. While this guidance does not have the force of law, it is almost universally followed.

For a foreign company, this can be a bewildering concept. In many legal systems, the line between a legal requirement and a mere suggestion is bright and clear. In Japan, it is blurred. Ignoring *gyōsei shidō* from a powerful ministry like the Ministry of Health, Labour and Welfare (MHLW) is done at one's peril. While it may not trigger a direct legal sanction, it can result in more intense scrutiny and damage to the company's reputation and relationship with the regulator—a critical asset in Japan. In the pharmaceutical sector, *gyōsei shidō* is pervasive. It can influence everything from clinical trial to the content of promotional materials.

To operate effectively, companies must not only understand the letter of the Pharmaceutical and Medical Device Act but also stay actively informed about the latest guidances and notifications from the MHLW and its associated agencies. This also requires building relationships with regulators, participating in industry dialogues, and relying on experienced local experts who can interpret the subtle signals from government bodies.

5. Navigating the Complex Web of Healthcare Compliance.

Beyond direct government regulation, the pharmaceutical and medical device industries in Japan are governed by extremely detailed and rigorous codes of conduct set by industry associations. These include the Japan Pharmaceutical Manufacturers Association (JPMA), the Japan Federation of Medical Devices Associations (JFMDA) and Fair Trade Councils of the Ethical Pharmaceutical Drugs and Medical Devices Marketing Industry. These organizations exert a quasi-legislative influence, and their codes of practice are, in effect, the mandatory standard for the industry.

These codes are primarily designed to ensure ethical interactions with healthcare professionals and institutions, and to prevent any form of bribery or improper inducement. The rules governing promotional activities are far more detailed than in many other countries. For example, they place very detailed rules on wordings and figures to be used in promotional materials.

For a foreign company, it is critical to understand that these industry codes are not optional best-practice guidelines. They are the price of admission to the market. A violation can lead to sanctions from the association, including public reprimands, temporary suspension of membership, and even scrutiny from regulators. The resulting reputational damage can be severe and long-lasting in a market that places a high value on trust and ethical conduct.

A robust internal compliance program, tailored specifically to the Japanese industry codes and not just the home country's laws and regulations is absolutely essential. This program must be supported by continuous training for all staff, particularly sales and marketing teams, and a culture of compliance that is championed from the highest levels of leadership within the Japanese subsidiary.

Conclusion

Doing business in Japan requires more than translating a strategy or transplanting a business model. It demands a deep and nuanced understanding of how legal frameworks, employment customs, regulatory systems, and business culture interconnect—especially in highly regulated sectors like pharmaceuticals and medical devices. Foreign companies that succeed in Japan are those that respect and adapt to these local characteristics. By approaching employment with care, managing outsourcing strategically, handling contracts with contextual awareness, engaging proactively with regulators, and maintaining high standards of compliance, companies can build sustainable and reputable operations in one of the world's most compelling markets.

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About the Author and Firm

Hiromi Furushima

Partner

Attorney at Law

Japan and California

hiromi.furushima@issshiki-law.com

Hiromi Furushima is an attorney admitted in Japan and California. She began her career in private practice with a focus on corporate and IP law before transitioning to in-house leadership roles at global pharmaceutical companies. There, she headed the legal, IP, and compliance departments, gaining extensive experience in IP strategy and litigation, regulatory violations, corporate governance, and business development negotiations. She currently serves as an outside director of a biotech company and a medical device company.

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