【Newsweek（国際版）】当社記事掲載のお知らせ

2019 年 8 月 30 日発行の「Newsweek（国際版）」に当社記事が掲載されましたのでお知らせいたします。

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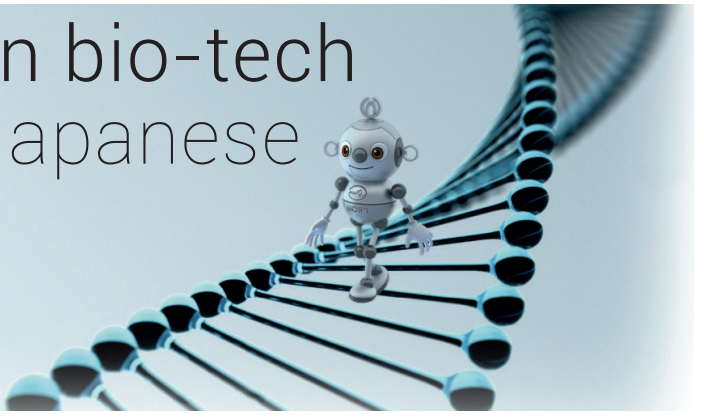
I'ROM helps foreign bio-tech tap into "thriving" Japanese market

A leading medical development and advanced medicinal treatment business, I'ROM Group also offers In Country Clinical Caretaker (ICCC) services to assist foreign bio-techs with their product development in the country.



The older you get, the more medicine you need. It is a simple rule of life known all too well by the pharmaceutical industry – and nowhere more so than in Japan.

Here, the world's most rapidly aging population presents a unique opportunity for drug companies and explains why the country contains the second-biggest pharmaceuticals market internationally, behind the Unites States.

To combat the challenge of its aging society, the government has responded through its Strategy of *Sakigake*, which aims to foster pharmaceutical industry innovation, help local companies grow in the global market, and accelerate drug and device approvals.

Tsukuba GMP certified Vector manufacturing facility.

The simplification of the application processes for innovative medical products, along with the update of Japan's Pharmaceutical Affairs Act and a new law regarding regenerative medicine safety, has drastically reduced the legal and administrative burdens required to launch products in Japan.

Toyotaka Mori, President of I'ROM Group – one of Japan's leading regenerative medicine and clinical trial companies – says that through implementing these changes the Government "has successfully created an ecosystem for bio-techs to thrive."

"Those regulatory changes are important because of the relatively small scale of the Japanese market in comparison to that of the USA," he explains. "While the *Sakigake* framework alone is not enough to convince companies to come to a much smaller market, the combination of these three reforms provides Japan with a powerful argument."

Significantly, the changes provide distinct "financial benefits" for pharmaceutical companies, says Mr. Mori.

"For example, under this framework there exists a policy entitled 'conditional approval for cell therapies, gene therapies and tissue engineering' which gives companies a 10-percent hike on their products' reimbursement prices. This financial incentive entices bio-techs to come to Japan and develop their products here."

What's more, with the number of trials you must conduct to receive application approval in Japan drastically fewer than in competing markets – providing a system which bases itself on 'probable efficaciousness' – bio-techs can additionally save themselves potentially millions of dollars by avoiding a phase three clinical trial.

"This often involves receiving funds from venture capital firms who then take control of the company," explains the I'ROM Group President, "thus, requiring fewer clinical trials ultimately promoting research and independence."

For any pharmaceutical companies attracted by these enticing incentives, I'ROM Group offers In Country Clinical Caretaker (ICCC) services to assist foreign bio-techs with their product development in the country.

"Many enterprises believe that to launch a medical solution in Japan, they must find a local partner to whom they transfer the rights and licence of their product in order to benefit from the attractive framework," explains Mr. Mori.

"However, this is not true. Japan offers the possibility to develop one's product in partnership with an ICCC, which allows one to maintain the licensing rights of one's product. Finding a licensing partner is a difficult process, especially when considering all the risks related to an unproven solution. At I'ROM Group, we want bio-techs to know that they do not have to find a licensing partner because we are here to be their ICCC."

Besides its licensing partnerships with foreign firms, the core business areas of I'ROM Group see the company provide technologies for regenerative medicine and gene therapy drug discovery, clinical trial support for Japanese and foreign pharma firms and medical institutions, as well as the installation and management of "clinic malls".

"The medical industry is making amazing progress globally in the development of therapeutic technologies," says Mr. Mori.

> "We want to enhance our advanced therapy capabilities, which includes strengthening our clinical trial services and positioning ourselves as an ICCC to a large number of companies"
>
> Toyotaka Mori,
> President, I'ROM Group

"We are currently making intensive investments into the further development of our regenerative medicine capabilities. We additionally want to enhance our advanced therapy capabilities, which includes strengthening our clinical trial services and positioning ourselves as an ICCC to a large number of companies.

"As a leading Japanese ICCC, we know that our clients will eventually need to open manufacturing sites domestically. As such, we would like to have the capabilities to assist them in that process."

I'ROM GROUP

www.iromgroup.co.jp/en