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Could you briefly outline CMIC's profile and its presence in Japan?

I can proudly admit that CMIC is the first Contract Research Organization in Japan. In 1992, CMIC Group pioneered the CRO business in Japan. More than a decade later, we continue to grow in size, thanks to the support of our customers. When CMIC was established, there were no defined regulations for a CRO, but we worked hard to set-up this establishment as a structured CRO in Japan. We have earned trust and achievement by continuously making small steps by setting study sessions regularly and mediating with the Japanese government. In 1977, the CRO was approved firstly by the revised Pharmaceutical Affairs Act. The approval boosted the CRO industry rapidly and we were also duly recognized and increasingly our business grew and our client list also increased. In 2005, we were the first CRO in Japan to be listed on the First Section of the Tokyo Stock Exchange. And now, our business has stabilized and we have confidently diversified our business into further services like CMO, CSO, Healthcare and IPD.

As a group business how many companies does CMIC hold and what is their focus in the healthcare/pharma vertical?

CMIC group comprises of 21 companies, both in Japan and overseas. The location, size, and business are all different but we work with a uniform mission to serve our clients with complete pharmaceutical services.

Could you elaborate on the company's range of services?

We have five business segments such as CRO, CMO, CSO, Healthcare, and IPD. Our CRO business supports pharmaceutical product development. The CMO supports manufacturing of pharmaceutical products. The CSO supports sales and marketing of pharmaceutical products. The Healthcare segment offers services for medical site evaluation, patient recruitment and consumer demands. The IPD caters to intellectual property related services. We have almost all functions that a pharmaceutical company has and we can create unique synergy by mutual cooperation. CMIC is the only CRO in Japan that has an umbrella of services like CMO, CSO and SMO under one roof.

CMIC is a 'Pharmaceutical Value Creator'! Could you explain this motto?

The CMIC Group utilizes a unique business model as a PVC contributing to the enhancement of pharmaceutical companies' added value. With our five business segments - CRO, CMO, CSO, Healthcare and IPD, CMIC comprehensively supports pharmaceutical companies' value chain, right from development and manufacturing of products to its sales and marketing.
Our unique business model PVC is not only just receiving orders but also being a complete service provider who can contribute to maximize the value of pharmaceutical companies. In this changing circumstance of medical industry, we support all stages of the value chain of pharmaceutical companies such as drug discovery, R&D, application, manufacturing, sales, marketing and distribution.
As a platform for contracted clinical trials, CMIC Group offers an array of services that go beyond pharmaceutical development. Leveraging our wide range of experience and the knowledge we have accumulated over the years as a CRO pioneer, we create added value in such fields as drugs, specific functional foods, and so on. Our commitment to the obligations of medical organizations will strengthen as our efforts as a Pharmaceutical Value Creator (PVC) to create added value in the field of healthcare and contribute to health and well-being of the global population.

How has CMIC expanded its operations in countries outside Japan, especially in Asia?

CMIC has pursued a strategy of building its international business capabilities. In the Asia region, we have established subsidiaries CMIC Korea in South Korea, CMIC (Beijing) in China and CMIC ASIA-PACIFIC in Singapore. In the United States, CMIC-VPS CORPORATION, which CMIC acquired in 2007, has strengthened its structure for the contract manufacturing of ethical drugs, and has begun making shipments.
By drawing on our unique business structure, together with our experience and track record in global clinical trials (simultaneous development in the United States, Europe and Asia), CMIC will further expand the CRO business in Asia. We will also utilize Electronic Data Capture (EDC) services that support Japanese companies expanding into the US and European market, as well as foreign corporation entering the Japanese market. We will further aggressively market directly to foreign pharmaceutical companies expanding internationally.
In January 2015 CMIC established a subsidiary in Vietnam and In March 2015 CMIC began launched its Bioanalysis operations in USA. In the future, we are also considering on developing supply-chain and drugstore management support.

India is now one of the preferred choices for overseas CRO's to collaborate and set-up a subsidiary. What is your opinion on this and does CMIC intend to venture into India?

We think India is a worthy country to expand our business. Although we don't have a practical plan as yet, there is enough scope and possibility of venturing into India.

What kind of assistance do you offer to overseas clients who intend to enter the Japanese pharmaceutical market?

Although Japan is an attractive market for overseas pharmaceutical companies, sometimes it is difficult for them to develop their business because of Japan's own business practices and strict regulations. Owing to the amount of time necessary for therapeutic trials and approval inspections within Japan's new drug approval process, Japan suffers from a 'drug lag' compared to other countries in getting new drugs to market as well as the high development costs owing to the long approval process in Japan makes it difficult for overseas companies. This is when we utilize our unique PVC model to provide individual strategy and consulting depending on our overseas clients' requirements.

How has the globalization of the pharmaceutical company impacted on CMIC?

As the industry is progressively changing, we have strengthened our overseas branches with knowledge on global clinical trial methodology and we are also strengthening our English communication ability in CMIC's head office located in Tokyo.

In comparison with other countries, new drug approval in Japan is said to be slow with stringent procedures. What is your opinion on this and how does CMIC help in getting faster approvals?

All of Japanese application and approval programs are not slow. Even in some fields like regenerative medicine, the procedure of application is very quick. CMIC educates our overseas clients on this aspect. We utilize CMIC's competent analysts who have advanced expertise and experiences to support quick application and speedy approval of drugs.

To what extent has in-house innovation and drug discovery helped in CMIC's CRO business and how much does the company monetarily invest in R&D?

The Group aims to accumulate intellectual property and build a new profit model through in-house and joint development of orphan drugs, diagnostics and other products. At present, we are conducting in-house development of a diagnostic application of L-FABP to predict kidney disease progression. This product will become our first successful IPD project, opening the way to development of a royalty-based business model.
We have developed many orphan drugs and our key product is the bio-marker for kidney 'L-FABP'. In the FY 2014, we have invested 291million yen (after subsidy deduction), for R&D.

What kind of products and medicines need speedy approval in Japan and how is the Government working to help these drugs reach the market?

Demand for Unmet Medical Needs, such as Alzheimer disease, cancer, and ALS is high. A cell therapy is also one of necessary medical devices. Regenerative medicine and antibody drugs are also high in interests. In CMIC, we have founded a professional team for consulting on regenerative medicine field. On the other hand, the government has also revised the Pharmaceutical Affairs Act to suit current needs of the industry and to facilitate quicker approval.

Implementation of IT solutions into clinical trials, drug development, and data management has been adopted by most leading CROs. How has CMIC adopted latest IT solutions and apps?

We are constantly upgrading our IT-enabled systems to enhance EDC services. Our stable cooperation with Medidata Solutions has yielded positive results. With the cooperation of Medidata, CMIC has implemented a collaborative trial in Asia that involves Korea and Taiwan, and is actively moving ahead on providing contract services to setup data management in domestic trials and clinical research.
This year CMIC has also adopted Vault QualityDocs of Veeva Japan as its standard operation procedure (SOP) management platform. It is the latest cloud technology in the life science industry. With the use of cloud-based solution Vault QualityDocs as its platform for the CMIC group-wide SOP creation processes, document creation has been changed from paper-based to electronic processes. This change will not only improve efficiency in the industry, but also provide management with assured compliance to customers.
This product requires a short time for installation, improving operation quality and document creation efficiency. CMIC has been advancing its global business proactively, and the number of contract clinical trials has been increasing drastically. These factors led CMIC to use Vault QualityDocs in order to install the system at several of their locations, including Japan.

Could you please outline the company's strategic financial plans for the period between 2015 and 2020? Would there be any M&As and collaborations in Japan and overseas?

CMIC has plans to invest in CMO, manufacture antibody-based drugs, and launch analytic techniques and also develop new techniques to enable our current tasks. We are also trying to expand business related to regenerative medicine and bio-medicine proactively. We are open to consider M&As and joint ventures.