INZIGN

A SINGAPORE-BASED COMPANY WITH BIOMEDICAL DEVICE CONTRACT MANUFACTURING AMBITIONS

Outsourcing Trends

he outsourcing trends that have become a deeply entrenched business model in the EMS (electronics manufacturing services) industry is fast becoming more evident in the traditionally conservative medical/healthcare industry. In the past, almost every activity within the product development cycle was closely held within the guarded domain of the medical OEMs (original equipment manufacturers). Now, more and more companies are turning to third party vendors to outsource an increasing level of activity.

The driving factors of this change that have been instrumental in transforming the way OEMs in the electronics industry carry out their business, are also experienced by the medical industry. The costs of in-house manufacturing, the demands on time to volume and the time to market, emerging manufacturing technologies, supply chain management issues are push factors that have caused a dramatic increase in the level of outsourcing. From outsourcing of production tools to components and sub-assemblies, more OEMs are turning to vendors to undertake turnkey contract manufacturing of complete products. An even more dramatic trend that has emerged in this industry is the outsourcing of product design and development, with OEMs focusing on the regulatory and marketing and distribution aspects of the business. In extreme scenarios, there have also been cases of OEMs adopting an asset acquisition strategy by transferring its entire manufacturing operations to the contract manufacturer, much like what has transpired in the automotive and telecommunications industries. With increasing pressure on price and armed with a more expansionist view of the markets in Asia, OEMs are slowly but surely looking beyond their traditional outsourcing options in their home markets in North America and Europe.

A senior executive with a major medical device OEM based in Singapore said, "The driving factors behind moving production to Asia were improved market access and service to our customers, and, on reaching economies of scale for certain products, reduced cost at consistent worldwide quality levels. What many multinational companies find is that the quality of people, skills and resources available in several parts of Asia are the same as can be found in the US or Europe but often at a lower cost." Asia has been the beneficiary of huge manufacturing investments over the last few decades by OEMs from the US, Europe and Japan. Starting with Singapore in the mid-to-late 60s, Asian countries had been a magnet for mainly electronics OEMs looking at investing in or outsourcing of their manufacturing. Biomedical OEMs in medical devices, pharmaceuticals and biotech started making their presence felt later from the mid 80s. Their presence has contributed to the development of a pool of highly competent suppliers/vendors supplying a wide variety of products and services to these OEMs. Inzign Pte Ltd in Singapore is one such company.

Evolution into a Biomedical Device Contract Manufacturer

Inzign started out as a precision engineering company (then called Techplas Mold in 1981), specializing in mold making to support customers in the electrical, electronics and other consumer related industries. In the mid-80s, with the entry of medical device OEMs into Singapore, Inzign was fortunate to have worked with them to develop new capabilities to meet their specific requirements, such as in the design and fabrication of multi-cavity molds. In 1987, the company was re-incorporated as Mold Technic Pte Ltd, and subsequently it diversified its core business into downstream plastics injection molding. With its continued success in developing business relationships with new partners in the medical and healthcare related industries, it shifted its focus into this niche so as to develop depth of knowledge and track record. This was vital for success in this highly regulated industry.

The company entered a new phase of development in 2001, with its renaming as Inzign – a hybrid name born of innovation and design, signifying the company's long term vision of evolving into an enterprise powered by innovation. From being a supplier of precision mold tools to injection molding of parts/components and sub-assemblies for medical device and other healthcare customers, Inzign has evolved into a biomedical device contract manufacturer. It has achieved this by recently being given the project to contract manufacture a complete drug delivery device for an international pharmaceutical company. To achieve and maintain its pioneering position in this niche, Inzign's vision is to be:

To be the biomedical device industry's preferred design, development and manufacturing partner.

Inzign's Current Partnerships and Future Strategic Focus

Presently, Inzign serves biomedical customers across a broad range of therapy areas such as hemodialysis, obstetrics and gynecology, biotech diagnostics, medicine management, surgical devices, drug delivery and animal health. Moving forward, Inzign's strategy for growth is focused on enhancing its present partnerships, as well as developing new partnerships across other biomedical industry clusters and therapy areas, such as wound management, cardiology related, diabetes treatment, etc.

In today's competitive global markets, customers seek to partner vendors who have a balanced matrix of capabilities as well as cost competitive manufacturing locations. As a relatively small player in this unique and niche industry, Inzign seeks to form strategic alliances with potential partners so as to offer an appealing contract manufacturing proposition to its customers.

Its Value Proposition

The biomedical device industry is, to a large extent, a conservative one, although there are clear signs that OEMs in the US and Europe have become more willing to venture beyond its traditional comfort zones, to explore potential outsourcing opportunities with new Asian suppliers. While price is an important factor, OEMs will not compromise on the need for robust quality management systems. A proven track record of experience for the manufacturing of biomedical products would be a huge plus factor.

Inzign has proven itself capable of meeting the stringent demands of its biomedical OEM customers. Through its long term partnerships with customers over the last more than 20 years, it has garnered a wealth of experience in product design and development, prototyping, tool design and fabrication, injection molding and assembly in Class 10,000 and 100,000 cleanrooms located in Singapore as well as in Batam, Indonesia. When required, post-manufacturing operations such as packaging, kitting and sterilization can also be managed by Inzign. It also ensures that its suppliers of non-plastic parts or services are pre-qualified and have processes in place that will be subjected to regular audits and qualification.

With its highly qualified team based in Singapore managing its design and engineering, tooling, quality assurance, validation, injection molding and automated assembly functions across three facilities in Singapore and another at its fully owned subsidiary in Batam, Indonesia, Inzign is well positioned to offer its customers tailored and competitive manufacturing solutions appropriate for the type of medical product and the processes to be employed in its manufacturing.

Quality Counts at Inzign

Quality is of utmost importance at Inzign and its customers demand no less. Its manufacturing facilities are certified to ISO9001:2000 and ISO13485, which is the internationally recognized and accepted standard for medical device manufacturing quality management system. In addition, its contract manufacturing facility has been designed, built and will be operated in compliance with the US FDA cGMP guidelines 21 CFR Part 820.

Supporting its Future Growth

The future of outsourcing in the biomedical industry is indeed a bright one. It is estimated that in North America alone, 86% of OEMs already outsource parts and components to vendors, while 14% outsource complete finished products in 2004. By 2010, the proportion will be 73% for components and 27% for complete products. With further evidence to indicate that some of that business could flow to Asia, Inzign with its track record in biomedical device contract manufacturing is set to capitalize on that potential growth.

To support its ambition to evolve into a leading biomedical device contract manufacturer, Inzign was able to convince two financial investors, JAFCO Asia and Rothschild Ventures Asia Pte Ltd, to back its plans by investing in it.

With all its building blocks in place, Inzign is poised to take up a leading position in the contract manufacturing space for the biomedical industry.

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