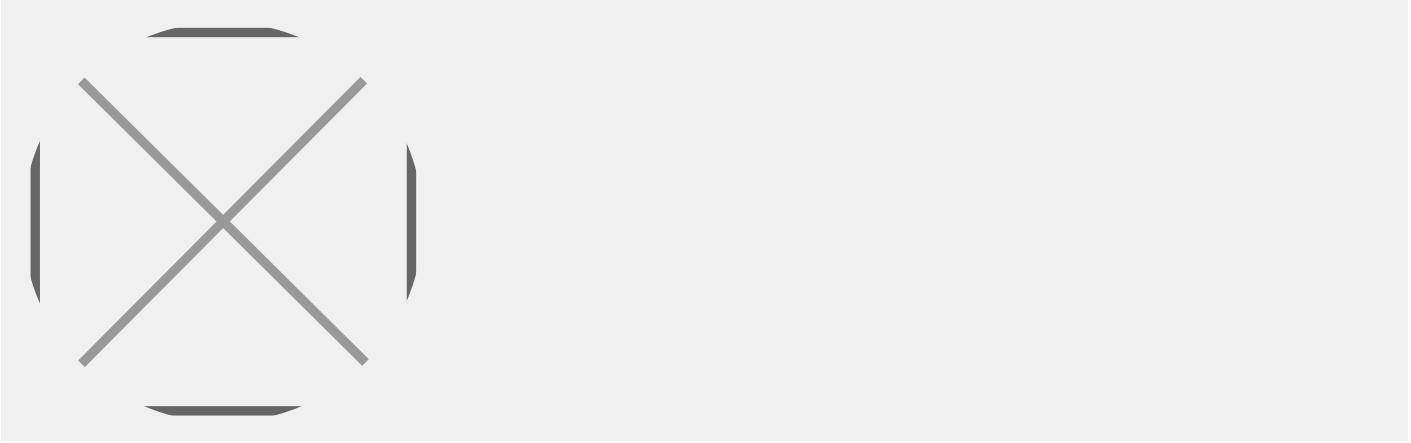
Interview with Dino Mangion, Plant Manager, Medichem (Malta)



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Medichem began production at its plant in Malta in 2006. Can you give us a brief overview of the facilities, and of the importance of the subsidiary to Corporación Medichem as a group?

Medichem was set up as a state-of-the-art facility for the manufacture of active pharmaceutical ingredients (APIs) in 2006. It represents Corporación Medichem's first venture abroad and it was spurred by a desire to develop generic drugs in advance of patent expiry, which is possible within Malta's legal framework.

The Malta plant is located in an industrial park which is only a few km from Malta's international airport and its containers sea-port. The plant is built on an area of 8,800 m2, and currently has a reactor capacity of 6,000 L, although this is easily expandable to 30,000 L with the current plant infrastructure.

Over these first few years of operation, the plant has been essentially in an incubation phase, focusing mostly on R&D work, developing products and processes and preparing exhibition and validation batches for clients. The emphasis has been on building a product portfolio and a client base. It is only now that some of our products are beginning to mature, so within the next few years we will be experiencing a shift to larger scale commercial manufacturing. Having said that, R&D will always remain an important aspect of our operations because Medichem is a broad portfolio company which relies on a continuous stream of new additions to its products line.

The Malta plant is designed to be a multipurpose plant and relies on the flexibility this brings with it to be able to target a large variety of different products and processes. Chemical synthesis of small molecules is our key competence.

The Malta plant, just like its counterpart in Spain, is GMP, ISO 9001 and ISO 14001 certified and also approved by the US FDA.
In 2009, the Malta site contributed about 8% of the company's sales. Our estimate is that in 2011 this will increase to about 35%.

Malta of course is a very interesting market for generics manufacturing given the favourable patents environment, but it is not the only country which boasts such advantages so why did Medichem choose Malta for the development and manufacturing of your APIs? What added value can Malta bring?

The main reason for Corporación Medichem setting up operations in Malta is, needless to say, the country's favourable patents environment. However, there are several other factors that have also contributed to this choice.
Malta supported the initiative to set up operations here by aiding in the construction of the facilities and also by providing fiscal support through a competitive tax regime.

Furthermore, the availability of qualified personnel, a very rapidly developing modern infrastructure and EU membership have also played a role. Malta's geographical location was also important, being close enough to Spain where the mother company is located so as to facilitate rapid communication, transport and travel between the two sites. Travel has been further improved over the last years by the availability of low-cost, direct flights between Malta and Girona, which is where the Spanish manufacturing facilities are located. Now it is possible to have breakfast at home in Malta and be in the Spanish facility before lunch time!

The sharing of a common Mediterranean culture between the mother company and the local site is yet another factor. The fact that Malta is on the same time zone is something that cannot be ignored either.

And, last but not least, the fact that Malta is bilingual, with English being one of the languages, is definitely an asset.

How supportive was the government in this Maltese adventure and looking back, are you happy with the decision of your group to set up here?

The Malta government acting mainly through Malta Enterprise, which is the government agency responsible for the promotion of foreign investment and industrial development in Malta, has been very supportive from the concept stage. Malta Enterprise has aided in a variety of ways, ranging from providing professional advice and contacts in the early conceptual stages to financial

assistance during the construction of the cGMP facilities we currently operate from. During these years we have also received R&D investment aid through Malta government schemes as well as EU development schemes.

Within a very short period of time, the pharmaceutical industry in Malta has become a keystone of the Maltese manufacturing industry, with about 15 foreign companies operating in Malta, employing over 1000 people and exporting EUR 150 million of product per year. This is very significant for a small nation like Malta. This leads us to expect that the infrastructure needed for a thriving pharmaceutical industry will continue to expand and improve.

In order for Medichem to lower manufacturing costs and optimise the profitability of the Maltese operations to what extent is custom manufacturing part of your business today? And how are you positioning Medichem as partner of choice for companies looking to take advantage of custom manufacturing and project management in Malta?

Custom manufacturing has always been a part of our business strategy. We offer a wide range of services and tailor-made integrated packages to our customers that include early concept development, collaborative R&D, scale-up from grams to commercial quantities, mature market supply, as well as focused regulatory and intellectual property support. All this is done by dedicated and experienced project management teams who commit to successfully complete customers' projects on time, on budget and to the quality expected, within a framework of complete confidentiality.

Our facilities in Malta are fully cGMP compliant and certified, and are available to potential customers who are interested in custom synthesis of fine chemical intermediates and APIs under full cGMP requirements within a legal framework in advance of patent expiry.

Medichem is one of two companies under the Corporación Medichem umbrella with facilities in Malta, given your focus on process development and manufacturing of APIs in particular, and Combino Pharm's on generics, what are the complementarities between the two plants?

Corporación Medichem encompasses two subsidiaries, Medichem as a manufacturer of APIs and Combino Pharm which manufactures generic finished dosage forms. Both subsidiaries have manufacturing sites within the same industrial park in Malta. The two companies develop products independently as well as in conjunction, depending on the economic and legal requirements of the product in question.

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