Interview: Markus Arigoni – CEO, Micro-Macinazione, Switzerland



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Markus Arigoni, CEO of Ticino-based micronization specialists Micro-Macinazione, describes the scope of the company's operations, the enlargement of the firm's R&D capacities, and emerging trends in the micronization niche.

Micro-Macinazione SA was founded back in 1970 and has subsequently developed into one of Europe's most renowned providers of micronization of active ingredients for the pharmaceutical and fine chemical industry. The firm was acquired by Cross Equity Partners in 2012 and has since undergone considerable investment. Could you please start by introducing the scope of your operations today?

That is absolutely correct. The firm initially started out as a designer and manufacturer of micronization equipment, but over time progressed to outsourced services. Nowadays contract micronization forms the mainstay of our business, but we still retain strong capabilities for manufacturing jet mills, glove boxes and pneumatic conveyors. The beauty of jet milling micronization is that it creates the particle collision of crystals without any need for physical contact of metals so, in contrast to mechanical milling, there is minimal resulting debris.

In terms of sales of equipment we have the capacity to design and put together up to three fully customized and bespoke Glove Boxes a year costing anything in between 250,000 and 1.5 million Swiss Francs. In addition to that we aim to manufacture somewhere in the region of 10-20

standardized pieces of equipment. We maintain two manufacturing sites in the canton of Ticino – at Molinazzo di Monteggio and Madonna del Piano respectively – and possess a workforce of some 120 personnel attaining total sales of around CHF 25 million a year.

An important function of our engineering division nowadays is thus to support our contact micronization operations by ensuing that we are abreast of the latest trends in terms of upgrades and technology. It goes without saying that we also produce all of our own machinery. By continuing to invest deeply in in-house engineering and R&D functions we have managed to build a very synergistic apparatus, which keeps us ahead of the game and in front of many of our competitors.

You've alluded to how Micromacinazione has been investing heavily in building up its R&D functions. What is the underlying rationale behind this?

Essentially it's about ensuring that we have a strong pipeline and order book stretching out long into the future. We are not just concerned about the customers sending over several tons of product each year for micronization, but also attentive to new chemical entities in the pre-clinical stage and phase I / II, because they will be the products that will fill our pipeline of tomorrow. Today we have clients sending us as little as 5 grams of synthesized material and our R&D team with put together a design of experiment (DOE) that will enable the eventual scaling up. Then, 10 years later, when the product comes in for commercialization and we start receiving campaigns of 5 to 10 tons, we already have the knowledge of how to handle that material. It's also about gaining familiarity and early exposure to the most up to date grades of material.

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Who do you identify as your main competitors?

Micronization is the sort of activity that is generally best undertaken regional so that you can liaise closely and frequently with your client base. Distance can be a limitation. Unless you commit considerable funding to building up a large-scale sales force and are willing to establish regional hubs, most of your customers in this business are likely to come from the same continent.

In engineering we are active worldwide with the jet-mills selling especially well in markets such as Japan, China and India. The bulk of our micronization contracts, however, come from Italy, Germany, the Nordics and Central Europe, and likewise our most direct competitors tend to be other European entities. What makes us unique is that we possess the entire panoply of engineering, contract micronisation services and R&D whereas none of our rivals can boast such a

broad suite of functions. Some will only produce the jet mills, while others will only conduct the micronization.

Ironically though, the biggest threat potentially comes from our clients themselves, who always have the option of undertaking micronization in-house as opposed to contracting out this activity. This is why we consider it to be especially important to be their development partner for new chemical entities and to be selling the micronization equipment. These activities act as the “door opener.” Then when they arrive at the stage where they need to conduct large-scale micronization and can no longer handle that in-house, we can present ourselves as the obvious partner of choice as we operate exactly the same machinery, just on a larger scale, and already have familiarity with the relevant chemical entity.

Demand for micronization services has been steadily increasing year on year. What do you detect as the main emerging trends in this market?

More micronization is being conducted globally than ever before. The reason is simple. The finer you are able to mill, the higher the surface area of the product and the better the bioavailability to the patient. The lower you can make the dose, the fewer side effects the patient will encounter.

Another driver of demand is that many of the latest generation chemical entities are highly complex constructs that are partially or completely water insoluble, unlike small molecules like aspirin, which easily dissolve in water. The lower the solubility, the more important it is to micronize the product.

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90 per cent of micronization today is done in-house, but companies like ours still need to be there to cover the peaks and to handle difficult-to-handle, high potents. Nowadays every large pharma firm requires a backup in case their production line experiences difficulties. When you’re talking about important blockbusters, the norm is for every big pharma firm to have a couple of micronization partners as part of having a sound risk mitigation strategy.

Right now, the market is definitely trending towards the use of highly potent and hazardous substances. This has, in turn, translated into a mushrooming in demand for containment capabilities. In the past, we used to micronize a lot of products with a low occupational exposure level (OEL), but the market has been swinging the other way in recent times. Having containment capabilities covering down to 20 ng/m3 is thus becoming ever more important.

How, then, have you been adapting to these developments?

Firstly, we've been upgrading our production facilities to include a new banding system and a product segregation regime. This is especially important for a multi-purpose facility like ours whereby we micronize over 150 different APIs per annum. Instead of the standard category 1 containment level where you can use an open mill we have been upgrading our mills for categories 2 / 3 to have flexible containment or fully closed glove boxes in conformity with category 4a and 4b where containment is reduced down to nanogram levels..

Conscious that big pharma is increasingly attentive to process monitoring and eager to have data covering the entire micronization process so that they can conduct statistical analysis and spot out of trend anomalies, we have simultaneously been implementing electronic data recording systems.

How relevant to your business model is it to be a Ticino-based company?

Being Swiss is definitely a boon because of worldwide perceptions that equate Swiss machinery and services with superior quality and reliability. International pharma companies demand high standards, punctuality and reliability and are willing to pay a premium to be assured of these factors. In this day and age when supply chains are so interconnected the importance of having a product delivered on time and to the expected standard has never been greater.

I consider being situated in Ticino also to be an advantage. We are part of Switzerland so we gain easy access to the Germanic and Northern parts of Europe and yet, at the same time, are able to tap into the historic chemical pedigree of Italy and engage with Southern Europe. We have the very strong economic area of Milan and Northern Italy on our doorstep, which affords us ready access to a multitude of pharma and chemical companies. Effectively we straddle the gateway to two very different catchment areas and find ourselves easily doing business with both.

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