SWITZERLAND INNOVATION PARK INNOVAARE

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Interview

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Interview with Dr. Fabia Gozzo, Founder and CEO of Excelsus Structural Solutions (Swiss) AG

Excelsus Structural Solutions (Swiss) AG, Villigen, a spin-off company of the Paul Scherrer Institute (PSI), recently moved to PARK INNOVAARE's deliveryLAB. Focusing on industrial R&D, Excelsus offers synchrotron-radiation based analytical services to the industry, with emphasis on pharmaceuticals, food and chemicals for the selection, development and manufacturing of high-quality products.

Excelsus Structural Solutions (Swiss) AG is a spin-off company of the Paul Scherrer Institute (PSI). How was it born?

For more than 25 years, I have been working at synchrotron facilities in close collaboration with industry. Between 2001 and 2011, I have been responsible for the construction and development of the Swiss Light Source Powder Diffraction station at the PSI, where my colleagues at the Materials Science beamline and I have been contributing to its worldwide reputation.

Already as beamline scientist, I was promoting the industrial use of Synchrotron XRPD. Dr. Thomas Laube from Cilag AG (Johnson & Johnson) was a pioneer industrial user of Synchrotron XRPD at the Swiss Light Source (SLS), applying very efficient detection systems specifically optimized for pharmaceuticals. He provided precious feedback to the beamline for its further development for industrial use. The use of Synchrotron X-Ray Powder Diffraction by the pharmaceutical industry was, nevertheless, not a common practice, and industrial applications of X-Ray Powder Diffraction at the SLS was pretty sporadic.

The potential was high, as pilot applications had demonstrated, but the power of fast Synchrotron X-Ray Powder Diffraction for industrial use was still the domain of audacious scientists, such as Dr. Laube. More communication and education efforts were needed from our side to explain the potential of Synchrotron XRPD to the industry.

Furthermore, from the synchrotron experts' side, there was going to have to be a deeper understanding of the industrial problems, compliance with the industry's tight time scales and the development of data analysis methods specifically optimized for the industry (pharmaceutical, in

particular). In other words, providing high quality Synchrotron XRPD data was not enough to serve the industry and that was what, with few exceptions, the large facilities' technology transfer departments had been able to do so far. Without a synchrotron expert in-house, the industry had little chance to deeply profit from the power of Synchrotron XRPD.

At the end of 2011, with the support of the PSI and SLS leadership, I made the decision to found Excelsus Structural Solutions. Fully focused on industrial needs, particularly those of the pharma industry, Excelsus Structural Solutions' mission is not simply to provide Synchrotron XRPD measurements but to help solve problems by means of Synchrotron XRPD based analytical services. Our services range from scientific consulation on specific problems, to experimental design, sample preparation, data collection, analysis and interpretation. Our final product is a detailed scientific report that constitutes a corner piece in a bigger puzzle. It is amazing how the private companies tackle problems in a dynamic and multidisciplinary way, whether problems arise during R&D, manufacturing or intellectual property rights protection activities. It is, therefore, very exciting to be part of this puzzle.

How unique is your technology and why?

The strength of the Swiss Light Source is its proximity to an extraordinarily competent detector group, led by Dr. Bernd Schmitt, and therefore the privileged access to state-of-the-art detection systems. The powder diffractometer at the Swiss Light Source was the first diffractometer in the world to implement the MYTHEN detector system, invented in 2001 by Bernd Schmitt and his co-workers. I had the chance to be part of the team that commissioned this superb detector. Initially developed for time-resolved powder diffraction experiments, we soon realized that its impressive efficiency could make it ideal for applications to organic compounds, such as pharmaceuticals. The high sensitivity of pharmaceuticals to radiation damage, in fact, made them incompatible with Synchrotron X-Ray Powder Diffraction when conventional high-resolution point detectors were used. The MYTHEN detector opened a new gate to the application of Synchrotron XRPD to pharmaceuticals. The MYTHEN detector is commercialized by DECTRIS, an extremely successful spin-off company of the PSI. Therefore, we are not only privileged Synchrotron XRPD scientists, but we also possess many years of experience. The proximity of the PSI detector group still constitutes a very competitive advantage.

Excelsus masters this technology very well, which was developed at the PSI with my contribution, and links it to the specific industrial needs, offering end-to-end services to the industry. Thus there is no need to be an expert synchrotron user to profit from this technology. Excelsus makes it available to the industry.

Traditionally, access to synchrotron facilities has in fact been characterized by long waiting times and a discouraging experience. Since Excelsus' scientific staff works autonomously at the beamline, we guarantee very fast access to our services without disrupting the normal beamline schedule. Of course, the fast and easy access to the beamline would not be possible without the extraordinary co-operation of the SLS Materials Science beamline scientists.

Furthermore, since being established, Excelsus Structural Solutions has been part of the Excelsus Consortium led by Dr. Arturo Araque, CEO and founder of Excelsus Scientific Engineering in the

United States. Excelsus Scientific Engineering is a team of experts in Good Manufacture Practices (GMP) and validation processes consulting services. This co-operation allows us to offer, on demand, GMP and validated services.

What is your market (in terms of industry, geography, client company size) and who are your target clients?

Thanks to the characteristics of the synchrotron source, high photon beam intensity and tunable photon energy, Synchrotron XRPD is virtually applicable to any kind of materials. However, since Excelsus Structural Solutions' services are not limited to the acquisition of good synchrotron data, it is important to keep the focus on a restricted field of expertise and to aim for excellence. At least in this growing-up phase of the company, I have made the decision to focus on pharmaceutical applications, my field of expertise, with a very few R&D projects in the chemical and food industry.

Our customers come from all over the world. Our services are offered with the highest flexibility and affordability, so we serve small, medium and large companies. It is only with large companies, however, that we have been able to develop long-term R&D projects.

Since we are based in Switzerland, there is a majority of Swiss and European companies among our customers, but samples can be efficiently and rapidly shipped from anywhere in the world. We have customers in North America and Asia as well. The PSI has given us access to controlled laboratory storage space, helping us put in place efficient Standard Operating Procedures (so-called SOP's) to comply with virtually all companies' requirements for sample storage before the execution of synchrotron measurements.

Who are your competitors? What differentiates your offer and your technology from theirs?

Efficient technology transfer departments exist in several synchrotron facilities that direct industrial customers to the appropriate technique and beamline. This, however, does not necessarily guarantee the delivery of full analytical services to the industrial customers. At Excelsus we have developed analytical services specifically optimized for industrial applications. We can, for example, perform quantitative phase analysis of phases at trace level (<0.1%wt) in formulated drugs. We also offer the highest level of confidentiality of the information exchanged and results; the publication of results is certainly not a priority for us the way it is in academic environments.

There are not too many dedicated companies like Excelsus offering complete synchrotron radiation based analytical services to the industry. Although Excelsus' activities have exponentially increased since it was founded in 2012, we are still covering only a small fraction of the existing market. I would not view the foundation of companies such as Excelsus as a danger, but more as an opportunity to cover more and more fields of expertise. Healthy competition never hurts.

Companies offering laboratory-based XRPD services are, on the other hand, not competitors at all, but partners. The majority of XRPD analytical services required by the industry can be very successfully tackled with good laboratory-based techniques. However, when very high resolution

and sensitivity to traces are needed, nothing but Synchrotron XRPD can successfully perform such analyses. Laboratory-based XRPD analytical services are therefore complemented by synchrotron-based analytical services, without being in competition with them. In 2015 we officialized a partnership with Crystallics in Amsterdam.

Have you already worked with some big pharma companies? What were the results of this cooperation?

Yes, we collaborate very closely with big pharma companies. Cilag AG (J&J) and Novartis Pharma are excellent examples of successful collaboration on several projects. Key factors for such success are certainly the competence and open-minded scientific attitude of the contact scientists: Dr. Thomas Laube, as cited before, at Cilag AG and Dr. Arnaud Grandeury at Novartis Pharma in Basel.

To start a new company is always a challenge. What was your motivation to start a business?

It was clear to me already as beamline scientist that industrial applications of Synchrotron XRPD had huge potential. However, as a beamline scientist I never would have had the opportunity to make this idea a success. The responsibilities of a beamline scientist are too broad and are surely not compatible with such businesses. You can occasionally establish a good synergy between a research program and an industry need, but what we are doing is quite different.

The motivation to start a business was therefore to create the conditions for demonstrating the power of Synchrotron XRPD for industrial applications. For a scientist, of course, it is a big challenge to create a business out of his/her scientific expertise since we are not trained to be business people. I like such challenges.

You have over 20 years of academic background. Which of your qualifications do you find the most valuable for Excelsus?

If you grow professionally at synchrotron facilities, you develop a very peculiar attitude towards instrumentation – your equipment and tools – and experimentation. You learn very quickly that even if you purchase an off-the-shelf piece of equipment, you will need to integrate it into your complex instrumentation, and in order to do so, you will need to know all the details and to ask yourself the *why* and *how* of everything. You learn that everything can be improved, changed, optimized, invented to serve your scientific purposes. You learn that nothing is, in principle, impossible. You learn not to be scared by complex instrumentation and that understanding correlations among many experimental parameters is what will help you optimize the performance of your instruments. Once you acquire this attitude, you end up tackling all problems, difficulties, challenges the same way. If one day you found a spin-off company, you apply the same principles.

Furthermore, professional growth at synchrotron facilities, whether or not you are involved in academic or industrial research, requires learning very quickly the art of planning, organizing and finding quick solutions to problems. Synchrotron facilities are user facilities and if you want to build up a good reputation, your instrument always needs to perform well for every experiment you host.

What is Excelsus' biggest achievement so far?

When I founded Excelsus, I gave myself two years to demonstrate that the idea behind the business was a valid one and could work. Excelsus' activities have grown by 150% since it was established in 2012, and a fourth collaborator has signed a contract with us for a permanent full-time position. After less than five years of activities, we already have more than 15 Master Service Agreements in place and are successfully serving our customers. Five years is not a long time frame for a new business to develop. This growth reflects the appreciation of our services by our customers. It also reflects the good synergy between us and the Swiss Light Source scientists with whom we closely collaborate.

Where do you see a future challenge for Excelsus? How will you manage it?

The big challenge of high tech companies is to find good collaborators. The requirements are many: excellence in science, great determination and motivation, customer orientation, respect for deadlines, and the capability to work efficiently – both autonomously and in a team context – and often under pressure. I constantly look for good people, but for a small, self-financed company like Excelsus, it is always difficult to match the rare event of finding the good person and the conditions to generate a new position. For this reason, we also have scientific collaboration with outstanding scientists in my scientific network who can support part of our work, in particular R&D research.

How will Excelsus continue to develop? What are its prospects?

It is hard to predict how Excelsus will develop. I believe it is important that we reach a critical mass of collaborators to offer better guarantees for reliable deliveries to our customers, but I also believe that part of our success so far relies on the one-to-one relationship that we have been able to establish with our customers. This will always be preserved.

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