

Interview: Maria Seriakov - CEO and Founder, M bioserviceS, Austria



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Maria Seriakov, CEO and founder of M bioserviceS, a young Austrian company dealing globally that specialises in logistics, regulatory affairs and quality control of biologics, discusses the challenges of navigating differing regulations across the globe as well as the how a hands-on approach ensures a product's high quality. Furthermore, she highlights the exciting R&D collaboration to investigate bovine haemoglobin extract to be utilized for human blood transfusions.

What was the reasoning in 2013 to establish your own company?

In the world of biologics, nature does not like to replicate itself and there will always be a need on the market to make available specific biological products that are consistent in terms of quality each and every time they are utilized. There is such a large variety of requirements in the biotechnology sector that companies struggle to find their own specific solution. M bioserviceS is able to connect the dots and with our enormous network of contacts, supply the right products to the right company. This requires a lot of regulatory and logistical knowledge as well as experience in differentiating high quality materials.

I had started drawing up the business model to found M bioserviceS back in 2008, and in 2013 I was ready to leave the rigid model of Big Pharma and start my own company. My past work had me travelling to abattoirs and having a very hands-on approach with the collection of animal serum, and I saw the market need for sourcing these products, ensuring their quality, and getting

them from point A to B. Furthermore, I was a member of the International Serum Industry Association and the European Diagnostic Manufacturers Association, so I already had experience with international authorities.

Thus far the experience and feedback has been extremely positive. Many of my former business associates across the pharmaceutical industry are using us for logistical work, as they understand we can move their products without any concerns.

What are the geographical areas that are of most interest and what challenges exist in the biologics sector?

The two largest global markets are the US and Europe; therefore, our role is to facilitate the movements of goods between the two locations. Saying that, we source products also in other regions, such as South America and Australia, and really go wherever our role is required.

There are two large concerns that the biologics industry faces. Firstly, in today's biologics market frequently products only come from one or two sources. There may be a lot of brands, but all this means is that the original product is being sold under a different brand name. Therefore, the end users of the product often don't know if their supplier is also the manufacturer. This lack of transparency is a big concern as if a problem occurs due to the product, it may be extremely difficult to track the true source. M bioserviceS ensures that every product obtained through our supply chain has the name or registration number of the plant it was manufactured in and sourced from, allowing accountability and transparency in the industry.

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Secondly, currently many companies are consolidating; therefore, many producers of biologics are being acquired by larger entities. To streamline processes, the new owner may cut their portfolio of biologics. The end users that require this biologic may not know this until it is all too late and are unable to source the material themselves. This is where we come in to help connect the dots and ensure companies can find a timely alternative.

Quality is extremely important for biologic products. How do you guarantee to your partners that the resource will be up to their standards?

I physically go to slaughterhouses and see it for my myself! This experience of understanding how raw materials are collected and what entails high-standards is something I have done over decades; therefore, I know what steps are needed so the end result is what my partners require for their needs.

For example, when raw material is collected from a certain slaughterhouse, I would go to the plant and teach the staff responsible for the collection how they should operate and what steps must be regulated and maintained to ensure high-quality. This is not only with the key people of the business, but with the individual workers. They appreciate this direct approach as they then completely understand their importance in the overall system. I even learned a few foreign languages in order to communicate efficiently with the staff in operations anywhere in the world.

How are you able to manage the differing standards of biologics across the globe?

Within the abattoir the entire process is Hazard analysis and critical control points (HACCP) regulated; therefore, general international standards are met. Additional requirements depend on the purpose of the raw materials. For example, some materials are later processed in accordance with good manufacturing practice (GMP) standards during the next production step.

The challenge is that different countries may have their own standards for importation of animal biologics. For example, not the same principles apply for importation of biologics into the US and the EU. Additionally, within the EU each country may have its own approach to implementing the regulations, and in larger nations, like Germany, each individual region may be handling certain things differently. In the US, the practical implementation of the same legislation may vary from state to state. Our role is to manage this issue for our partners, so authorities and experts are consulted in advance. This way when a product is shipped, it will arrive safely at the point of final destination and exactly on time.

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Which particular project is the best indication of the services you provide?

There is no single project – although – we are proud to connect products and people and bring clarity and optimization to the entire process. When we start with any company, large or small, it is about understanding the specific needs, defining the project's guidelines and delivering a high-quality, tailored service on time. This in-turn allows us to obtain repeat business and build a reputation throughout the industry. Therefore, each time we deal with a new client, we must be clear in what and how we will do complete the task, as we are at times dealing with multiple nations, companies and modes of transport.

The company is involved in undertaking research to develop an extract from bovine haemoglobin to be a substitute for human blood donations. What attracted you to this opportunity?

The challenge and curiosity! This particular German company required a bovine haemoglobin extract and their team consists predominately of researchers; therefore, logistics is not their forte and they sent out an inquiry to some hundred companies to assist them. We informed them that M bioserviceS can develop a manufacturing method to make this product. It is an incredibly difficult task as we are taking a resource out of animal mass production and ensuring the raw material is safe enough and can be utilized within the human body.

We found the abattoir site in Tyrol, Austria, a destination that manufactures organic meat and deals exclusively with local farmers; important, as Tyrol is one of the cleanest parts for farming in the world. Furthermore, we had to conduct our own R&D to discover the perfect way to collect and package the product, and found the best manufacturer for the packaging system in the mountains of Utah. We are able to collect, store and deliver the biologic resource to the processing lab within 24 hours. This collaboration started in 2015 and this year we have as a collective group received EUROSTAR funding.

What lies ahead in the future for M bioserviceS?

My big hope is to develop similar products in the US. Although many biological products sourced and manufactured in the EU are very successful, it may not be possible to ship them to every market in the world due to import restrictions regarding their country of origin. Therefore, we must replicate the same operations there, and tailor our approach to their standards.

As a company, we want to continue conducting interesting projects and growing our network in a transparent and open manner. We must continue to produce a high-quality, tailored approach to any project so we are attractive to all current and future partners.

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