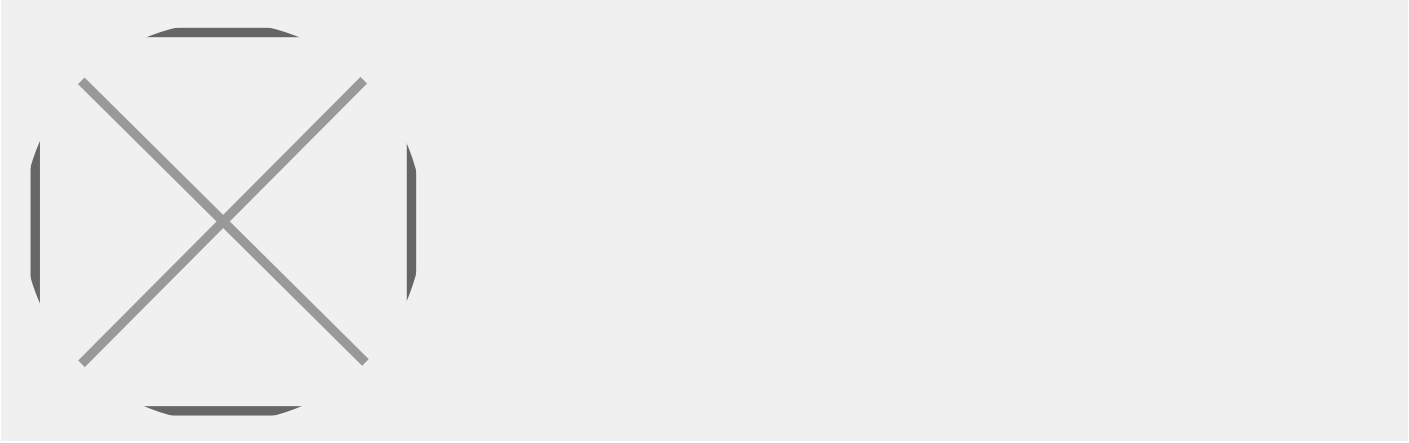
Interview: Katherine Garzón, General Manager, Biotechnova, Colombia



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The founder and general manager of Biotechnova considers the potential of Colombia for biotechnological innovation, and explains the current state of the biogeneric industry in Latin America.

Please start by introducing yourself, and explaining how you came to found Biotechnova.

My background is in microbiology and infections: since 2003, there have been no new drugs, vaccines or antibiotics in this field. In my doctorate thesis, I developed a system of expressions of proteins, with a therapeutic use and different applications: pharmaceutical, cosmetics, and nutrition. The technology works like a photocopier, duplicating proteins.

We founded Biotechnova in 2008, and started looking at pharmaceutical applications for the technology, and afterwards enlarging our portfolio of services. We have multidisciplinary teams, composed of biologists, chemists, industrial microbiologists, and engineers. We built this team because we had a product that we wanted to patent, but we eventually decided to maintain it as an industrial secret.

We are operating in the new area of biogenerics, which will hopefully lower costs for innovative products and increase access for patients. The original biotech drugs were patented according to the gene sequence, but since 1988, this is no longer the case and generics now have a chance to thrive.

What do you see as being the primary growth drivers for the rest of 2013?

As a company, you have to align yourself to the priorities of your government and your current economic situation. Colombia has specific goals for the development of the biotech sector, which are focused in the areas of pharmaceuticals, cosmetics and nutrition. However, the environmental sector is the fastest growing sector in

the country at that moment, even if meeting the environment norms of the Ministry is difficult.

Given the significant increase in generics among pharmaceutical companies across the country, how will the biotech scene in Colombia remain competitive, particularly in a time when companies are looking to cut prices of pharmaceuticals?

We are in a new area: there are 15,050 known diseases of metabolic origin but we have a treatment for only 10 of them. Every day, we are improving the treatments, doing personalized designs for every disease. There is even a group of researchers in Spain that is working on a specific treatment for only one patient. Biogenerics today are at the same stage of development that chemical generics were in 1960! In the last seven years, few patents in the agricultural sector were registered: 450 in the USA, 60 in Europe, 1 in Mexico. This is an open world for innovations.

What is your assessment of the third draft of biotechnology regulation reforms, as proposed by the Ministry of Health?

The biotechnology market, like every other market, is competitive. Companies have to work in a good way from the beginning. Who is in charge of checking that what you are doing is good? The manufacturer. Who is in charge of measuring the impact? The manufacturer.

Many different stakeholders such as the associations AFIDRO and ASINFAR have approved this third draft of reforms. It was an effort to prove that we are capable of improving what already exists. The biotechnology products that are currently in the market have existed since the 1980s, but since then, the forms of expression, purification, and detection have improved. Moreover, when there is competition, there is no better thing than competing against the best. This regulation should help the industry reach those new levels.

Which model do you think Colombia should follow in the Latin American continent? How do those countries sharing the best practices?

Sometimes, we can be too restrictive, like in Europe with EMA (European Medicines Agency).

To make the regulation reforms, ASINFAR did an analysis taking into account what happened in other countries, the ranking of the biotechnology molecules according to their sizes, expression, and time in the market.

A laboratory has two options: if you are new in the market, you have to show all the requirements .If you are already in the market, you can choose to be compared to others or not. The decision belongs to each manufacturer.

Many tools do exist to show that the molecules are good, to evaluate them and check if they meet all the requirements. Biotechnova is responsible for production of a wide variety of products, including pharmaceuticals, food, agriculture, environmental, etc.

One of Colombia’s richest characteristics is its biodiversity potential. As a biotech company, are you able to enjoy the most of it?

It depends I would say. There are five very distinct geographic regions in Colombia. They are all characterized by a monoculture: palm, banana, or coffee, for example. There is no massive agricultural diversity. For the cosmetics applications, in order to produce one liter of natural essence, we need to produce between 10 to 15kg

of raw materials. Cosmetics would require too many cultures! Moreover, it means companies have to convince the local population, coordinate them, have employees, pay taxes. Besides this, the climate conditions are very difficult. So the companies choose to import the raw materials.

During the last decades, Colombia focused on subsistence crops, that is to say culture without any transformation. New companies, bio entrepreneurs are just starting the industrial processing. For example, at Biotechnova, we do have aloe vera crops, but we import them from abroad. The reasons why are that the requirements to be approved are very strict, and it is very complicated. Moreover, people are not trained to collect, to process the plants.

How important is clinical research to the company's activities overall? Which partnerships do you have?

We are open to collaboration with universities and associations. We are doing training as well.

We have partners both in Colombia and abroad. We have foreign partners to share the best practices aiming to reach a better efficiency in the processes of research. Strategic alliances allow you to dedicate to you core projects and to enjoy the facilities of others partners. We have a partnership with CONICET in Argentina (National Scientific and Technical Research Council) and one of their plants in Salta. Similarly, we have different alliances in Spain, in Canaries, Madrid and Seville.

At the national level, since there are financial barriers in the public universities, people are knocking at our door to do different research with us. We are helping them, but we give them strict limits of time, because projects can be very long and the administrative procedures are long and complex. The private industry is looking for efficiency, rapidity.

Colombia has a big potential in terms of biotech services. Unfortunately, it will not be developed in the university laboratories. The reason why is that we need specific institutions to accredit the laboratories, the devices, the practices, in order to guarantee traceability. Most of the laboratories in Colombian universities are teaching laboratories and do not have the accreditation.

What advice might you give to a young entrepreneur looking to start up his own biotech company in Colombia?

In our company and foundation, we have more than 2400 young motivated people, not only eager to learn but to *do* as well. The important is not only to have ideas, but to make them happen. Bioentrepreneurship is a dynamic, multidisciplinary process and requires teamwork. One person alone cannot do it. Indeed, you need farmers, biologists, engineers, and doctors. The key success factor is to be able to interact. Teamwork is crucial: a team can get to answers much faster than only one person.

If we were to return to Colombia in the next three to four years, where would you like BiotechNova to be at that point?

The mission of this company has been changing all over the years. Our first goal was exclusively teaching. In four years' time, Biotechnova's teams will have developed new products; we will have our own plant. We believe in the generation of start-ups, we support them and we want them to be independent. We have the ambition to become one of the leaders in offering services, so Colombia can become one of the top countries in the world for biotech services.

We have been working and growing for four years. Our main challenge is that not everybody knows what we are doing. In Colombia, the actors are very few, and we have not specialized like Argentina did into agricultural applications and biotech development for blood supplements, or like Brazil in the agriculture and veterinary sector, or like Chile in the mining sector. As for Colombia, we would like to be specialized in the pharmaceutical area of biogenerics. In Biotechnova, we have this expertise and experience for doing therapeutic products. It is our main strength.

As the president of Generacion Bio, we would like to cover all Latin America, we already have different headquarters in many countries: Peru, Chile, Mexico, and Argentina. This association helps people who want to study or work in the biotechnology field.

Biotechnology is the future of life. Colombia is such a diverse country: it is the second country in the biodiversity ranking after Brazil. There are 16,000 plant species that can only be found in Colombia. The potential is huge.

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