Mayra L Guzman-Kaslow – President & CEO, GK CMO, Puerto Rico



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Mayra L Guzman-Kaslow, president and CEO

of GK Pharmaceuticals Contract Manufacturing Operations (GK CMO), the first biopharmaceutical company owned by minority woman in the US, highlights the obstacles she and her business partners faced on the way of setting up the company. She also explains why Puerto Rico has been the right place for establishing GK CMO, which is first and only pharmaceutical and biotechnology company on the island to have the technology and capacity to manufacture biologics, biosimilars, drug substances and solid drug products within the same facility.

GK CMO is a very unique player in the industry as it is the first biopharmaceutical company owned by a minority woman, not only in Puerto Rico but in the whole USA. Could you please introduce your company?

Our journey started two years ago when a client of my consulting business was looking for a contract manufacturer for biosimilars. This sparked the idea of setting up our own CMO here in Puerto Rico together with my two daughters Carla and Cristina and my friend Maritza. In 2017, we presented our business plan to the Puerto Rican government officials, which was very well received, and we found a place in Ciales, to set up our operations.

However, after Hurricane Maria our facilities were completely destroyed, so we had to look for new options for our operations. At this time, TEVA announced its plans of closing the plant in Manatí, so the government offered its support for us to take over this plant, as they have been convinced by our vision. We have very high standards due to the strict requirements of our clients, but when inspecting the plant, we realized that is was very suited for our needs and more importantly in great condition and ready start production, as soon as the necessary compliance requirements have been fulfilled. We then presented the purchase plan to TEVA's real estate head, which was accepted in April 2019. We are currently in the compliance process to reach FDA standards. After this, we will start the technology transfer stage with our clients and start production.

As four women, born, raised and educated in Puerto Rico, we had to overcome many obstacles, so we want to be pioneers for a home-grown Puerto Rican pharma industry. We want to open doors and help the Puerto Rican community, showing that it does not matter where you from to open a manufacturing facility on this island. Professionals from the island are very competitive and committed and we are proud of our roots and want to show this.

While Puerto Rico is a manufacturing hub for pharmaceuticals, we do not see too many CMOs on the island. What was the rationale of setting up GK CMO in Puerto Rico rather than in Florida, where your consultancy is based?

There is currently only three CMOs on the island – GK CMO included – however we are the only company that can offer multiple production services. GK CMO will have a focus on biosimilar production and Puerto Rico is the right place to do this as the island has great infrastructure and a tradition of excellence in pharmaceutical production with many big pharma players here. With the federal policy of having more products produced on US soil, GK Pharmaceuticals CMO has a strong value proposition for companies looking to produce pharmaceuticals and biopharmaceuticals in the US.

In the global CMO market, we see some players with high volume capacities, while we have highly specialized service providers in niches in Europe. Can you tell our international readers where do you position yourself in the competitive landscape?

Our core service is the production of biosimilars, from cell culture purification all the way to commercial manufacturing. Moreover, we have a diversified service offering, which includes small-

molecules, as well as solid-dose manufacturing and even medical devices. We are the first and only pharmaceutical and biotechnology company in Puerto Rico to have the technology and capacity to manufacture biologics, biosimilars, drug substances and solid drug products within the same facility. Moreover, we are the only CMO in Puerto Rico that has the commercial capabilities, scale and capacity for sterile injectable and ophthalmologic dosage forms, which will have approvals from the DEA and FDA.

Our manufacturing facilities include 2,000L fermenters, quality control and microbiological laboratories, stability rooms and clean room manufacturing suites as well as a research and development laboratory for new products.

The global CDMO market amounted to USD 65.8 billion in 2016 and is set to experience a sustained growth moving forward to eventually reach USD 85 billion by 2020. With this growth in mind, which types of companies do you see as your main client base moving forward?

We are looking to create strategic partnerships with global companies like Merck, Intas and Celltrion. Merck, in particular, has recently received approval for two biosimilars for the US market and has a long-standing history of partnering with CMOs to support their production. Other companies such as Intas that keep expanding their international reach can benefit greatly by partnering up with a CMO that will fulfil their compliance and manufacturing needs abroad. Companies such as GK CMO have FDA approved facilities in Puerto Rico working under cGMP standards while also having lower labour costs than US mainland states. We aim to help clients enter the US market by providing the development, manufacturing and regulatory approval services with the FDA and other regulatory agencies for pharmaceutical companies.

There is a lot of talk about turning Puerto Rico into a full life sciences hub with large R&D capabilities. To what extent do you also intend to scale up your R&D capacities, to further complement you offering to clients?

Besides our CMO services, we have our own R&D team currently working on the development of orphan drugs for our own portfolio. Our research director has previously been involved in the development of bio diagnostics devices, so we aim to develop testers for identifying these diseases and eventually find treatments.

How do you want to be GK Pharma to be perceived and positioned as a local CMO in the country?

We want to give exposure to Puerto Rico and its economic capabilities, as in the past a negative image has been attached to the island since Hurricane Maria. In terms of business, we want to remain a flexible CMO with additional research capabilities to address relevant health issues on the island, in cooperation with the government and research institutions. GK CMO wants to be known as a reliable, quality-driven contract manufacturer, which is the first choice of contact if a business has the need for new introductions and capability requirements. Our priorities are cost-effectiveness, quality and customer service.

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