

**Ricardo Zayas Executive Vice President of
Operations, Romark, Puerto Rico**



Puerto Rico has a very dedicated workforce, with great experience in pharmaceutical manufacturing

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Ricardo Zayas of US manufacturer Romark, highlights the company's ambition to make Puerto Rico its operations and manufacturing headquarters. Currently in the scale-up phase, Zayas aims to expand the capacities of the plant in Manat  and position Romark as the poster child for new pharmaceutical manufacturers coming to Puerto Rico.

Ricardo, after many years working for large pharma companies, you are now the Executive VP of Operations at Romark. What has attracted you to this company?

I have spent most of my career at big pharma companies, amongst others at BMS as the VP of Global Manufacturing. I have been attracted to work for Romark because the working environment and the responsibilities are more diverse in a smaller company. Secondly, Romark has a very attractive product portfolio and ongoing clinical trials for treatment of influenza and other viral infections, which have great potential. Last but not least, the way Romark is structured also played a huge role, as the Puerto Rico operations will be the heart of the company's global manufacturing network. This is a significant difference to other companies, which usually has us on the island as a subsidiary only. Additionally, I see potential in Romark as a pioneer of medium-sized pharmaceutical companies from the US mainland, coming to Puerto Rico and setting up operations here.

I am very excited to create this new facility here in Manat , which not only consists of the construction and hardware, but also of the culture we are aiming to implement. Our operations are still small enough to establish the culture we want to have at Romark. We want to create a new philosophy, where people are not only focused on compliance and to follow procedures, as we see it in traditional pharma companies. Our aim is to employ high powered operators and professionals, who know what to do and why they have to do it and how their tasks fit into the bigger puzzle of Romark.

Can you give our international readers an overview over the company's presence here in Puerto Rico?

Romark is a company based in Tampa, Florida, with the intention to establish its global headquarters of operations and manufacturing here in Manat . Ironically, I have been in charge of this plant when it belonged to Schering-Plough, so I know it quite well, despite the operations being of a much larger scale back then. It was closed in 2007 and Romark purchased a portion of this site here in 2014. A project of this size obviously takes time, as there are permits and licenses required. Additionally, you

need to find the right workforce and service suppliers, which makes it a lengthy process. After some initial construction works being done, Hurricane Maria passed Puerto Rico and left significant destruction, which set everything back here at the site. We have brought in more talent in 2018 and had our ribbon cutting ceremony in spring 2019.

You have taken on your new role as Executive Vice President of Operations three months ago. What are your priorities in this new position?

Apart from our site here in Puerto Rico, we have a chemical manufacturing facility and agreements with third-party manufacturers. My main priority is to seek FDA approval for our plant here in Manat  and to transfer three products here to turn the site into a commercial facility. Two of our products are currently commercially available and the third one will be launched next year. The second priority is to ensure that our site in Belgium, which has undergone some changes recently, comes out with flying colors and restarts API production. Thirdly, I want to create the necessary operations and manufacturing infrastructure, which includes the integration of aforementioned sites and picking long-term strategic partners for third-party manufacturing. This will eventually create a global manufacturing and development network, which adds value for Romark moving forward in the short and long term.

You are already partnering with external manufacturers, so what advantage will your own manufacturing facility bring?

Being a small company, we do not have a lot of products yet, but our pipeline boasts some very exciting products – one amongst them for which we recently finished the clinical trials. Having high expectations for this product, we want to ensure adequate manufacturing capabilities, which are controlled by ourselves. So even though we want to continue partnering with third parties, we also aim to keep a significant amount of control over our supply chain, which our Puerto Rico plant allows us to have. Currently we are doing scale-up work and registration batches to request permission from the FDA to start manufacturing. Our expected date for beginning of commercial production is either in this year or in early 2020.

How do you see Romark’s role as one of the new pharmaceutical manufacturers coming to Puerto Rico?

The primary reasons for the pharmaceutical industry settling in the early 1960s were Puerto Rico’s huge water reserves and cheap labor. Later on, the main attractors for manufacturing on the island were cheap tax rates and today some companies are still here for tax reasons, but mainly because Puerto Rico has a very dedicated workforce, with great experience in pharmaceutical manufacturing. The island is very attractive, as there is incredible talent, particularly in engineering, and many suppliers and services ready at your fingertips. The government over years has pursued big pharma companies to invest to the island, but in the USA, there are more than a thousand small and medium-sized companies – most of them not knowing about Puerto Rico’s capabilities. If we do this the right way and establish Romark as a success story, we can serve as a poster child for the new generation of manufacturing on the island. I can envision that in 30 to 40 years, there will be a few hundred medium-sized companies manufacturing their products here in Puerto Rico, but also being active in areas such as R&D and clinical trials.

What is your vision for Romark's operations in Puerto Rico for the next five years?

I would love to see this plant expanding to meet the future needs of Romark, boasting the right culture and a state-of-the-art hardware and software infrastructure, including automation and the latest manufacturing technology. If the future projections come to fruition, the site will have to be three to four times larger than it is now. Currently, we are only planning to supply the US market, but we have the ambition to meet the global demand, in markets like Europe and Japan. We also want to expand our R&D operations on the island, as we see a lot of talent here on the island.

Leveraging your experience, what do you see as an important trait for operations executives in our industry?

When directly reporting to the CEO of company, it is essential to be a corporate citizen in order to serve as a functional leader for the company. As part of the company's leadership team, it is indispensable to have a view on matters that go beyond one's functional area. Throughout my career, whether working for small or large companies and whether working in the Americas or in Europe, I have seen that having a holistic view on different matters also encourages employees as they see the effect their contribution has on the company's performance.

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