David Fuster – Plant Manager, PuraCap Caribe



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21.10.2019

Tags: Puerto Rico, Manufacturing, PuraCap, Capsules

David Fuster, plant manager of the Dorado factory of Chinese pharma outfit PuraCap, shares the company's strategy behind the investment in Puerto Rico and how the PuraCap Caribe is leveraging technologies at the facility for new product development. He underlines the importance of Puerto Rico as a manufacturing location for PuraCap's US business and gives insights in modernization plans for the plant.

PuraCap Pharmaceutical took over this facility with their acquisition of Blu Pharmaceuticals and Blu Caribe in 2016. What made them choose this facility in particular?

PuraCap is originally specialized in the development and manufacture of prescription and OTC soft gelatin capsules at its cGMP facility in Wuhan, China. In fact, the company is one of the top manufacturers of gel capsules on the Chinese market. PuraCap acquired Blu Pharmaceuticals and Blu Caribe in order to expand its manufacturing expertise beyond soft gelatin capsules to include oral tablet and capsule dosage forms for both the US and global markets. In addition to Blu Caribe's 145,000-square-foot manufacturing plant, PuraCap also acquired Blu Pharmaceuticals' warehouse and distribution centre in Franklin, Kentucky.

PuraCap develops products at its R&D site in New Jersey but did not have any manufacturing capabilities in the US. As a result, the management came on the island and met with the Puerto

Rico Industrial Development Company (PRIDCO). They evaluated the facility, the equipment and the staff and determine it was a good opportunity. Less than two months later, PuraCap acquired another facility in New York.

PuraCap wanted to transfer manufacturing of products already developed at its R&D site in New Jersey as soon as possible, and later on start production of new products. This is a huge chance for us, as, even though this facility is mid-sized, we have a lot of room to grow as we are only operating at about 30 percent capacity, and own 24 acres of land, which could be used to expand operations. In contrast, the New York facility is already operating at full capacity. Here in Puerto Rico, we have the capability to produce over 3 million tablets per year, based on many different manufacturing processes due to the diverse previous ownership of the plant. For instance, Biovail was specialized in developing and manufacturing improved medicines through extended-release coating technologies. Finally, we have a medium-sized GMP certified pilot plant for small laboratory-scale batches, which can be used to develop new products.

PureCap has a diversified product portfolio with branded prescription drugs, generics and OTC products. Which products are you manufacturing here?

We manufacture solid dosage tablets of generic drugs in different presentations. For instance, we produce antibiotics, statins and blood pressure-lowering drugs. Since the New York plant is operating at full capacity, PureCap has transferred production of some products here. In addition, we plan to start production of seven or eight newly developed products in the next nine to fifteen months. A few products are ready to be launched in the next few weeks. For now, we only supply the US market, but there are plans to manufacture for the Chinese market as well.

The Puerto Rican government is trying to attract more research and development activities on the island. Is there any plan to conduct more R&D activities here?

PuraCap is leveraging the technology we have acquired from previous owners for product research and development. For instance, Biovail used to have the technology for the production of extended-release products in the form of coated beads. This technology was one of their specialty and we retained some of the equipment here. When PuraCap’s R&D team visited the facility, they realized they could use this technology to develop and manufacture extended-release formulas of their compounds.

Other plant managers have told us how they are adapting to the rising trends in pharma manufacturing such as AI, robotics and paperless environment. How are you implementing these technologies in your operations?

As most of our systems are manual, we are currently modernizing our operations. At the moment, we are in the process of implementing QAD's MFG/Pro, a recognized manufacturing ERP software system, which will enable us to go paperless and approve everything easier requiring less effort from operators and reviewers and reducing the risk of making mistakes. We will be able to facilitate every single step from A to Z and expedite production. The new system should be operational at the beginning of next year. I would also like to implement robotics. As other manufacturers are decommissioning some of their equipment in order to implement newer technologies, we may acquire a packaging robot.

How do you ensure the plant's production is not interrupted?

The building is well-prepared since we have redundancies for all of our utilities. We have two generators, two boilers as well as two chillers and air compressors to spare.

We are trying to add redundancies in production equipment as well. For example, one of our products runs in one production train, blender, coater and table press. My goal is to have different blenders, coaters and tablet presses in the same process. In that way, if we run into a problem with one tablet press, I use another one. At the same time, if product sales increase, I can also adapt production. By having two tablet presses, we can run two batches at the same time, doubling production. In this way, we will have more flexibility in the production of every single product.

What are your objectives for the next few years?

Today, we are producing six products, but the facility only runs five days a week. I would like this facility to be running 24/7 again. We need to increase the sales of current products or bring additional products. I have worked here for 13 years with different companies so I am attached to this facility and our people, and I want to see us grow in the next few years.

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