Interview: Arleen Paulino – VP Site Operations, Amgen Singapore



Our Next-Generation Biomanufacturing facility is our newest manufacturing site and the first in Asia, which uses a revolutionary approach incorporating multiple technologies to enable greater speed, productivity and flexibility

05.10.2016

Tags: Amgen, Singapore, Manufacturing, Biotech, Biopharma, Pharma, Pharmaceuticals,

Established in November 2014, Amgen's Next-Generation Biomanufacturing facility in Singapore heralds a new juncture of efficient and innovative commercial-scale production of medicines. VP of Singapore Site Operations, Arleen Paulino, pinpoints the elements that distinguish this facility from current standards in manufacturing, while highlighting the key role that this facility will play in Amgen's global supply chain when becoming fully operational in 2017.

Could you introduce yourself to our international readers as well as the scope of your role and responsibilities as the vice president of site operations here in Singapore?

I have been developing my career within the biotech industry for more than 25 years, most of which has been in the space between pure R&D and commercial.

Prior to coming to Singapore, I was responsible for the development of Amgen's end-to-end supply chain for all clinical development programs, including upfront planning, procurement, device assembly, labeling, packaging and distribution. Pilot facility capabilities were also under my scope, so many of the newer technologies that eventually made their way into commercial sites also ran through my organization.

Our Next-Generation Biomanufacturing facility is our newest manufacturing site and the first in Asia, which uses a revolutionary approach incorporating multiple technologies to enable greater speed, productivity and flexibility. I maintain all site-related operations and ensure our products

going to patients around the world meet Amgen’s high quality standards. This also includes overseeing the health and safety of our own workers, implementing programs to scale up our operations and connecting back to our global headquarters. Additionally, I represent Amgen and interface with various local government organizations and external stakeholders in Singapore.

What factors prompted Amgen to venture out of the US and establish this facility in Singapore?

While we have previously had a presence in the region—through various partnerships—it was never large and we’ve certainly never had a manufacturing presence here. Consequently, the decision to set up our first manufacturing facility in Asia was immediately in line with our global strategy to build our presence in Asia Pacific and enable the tremendous patient population more access to our medicines. The next question then was where?

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As you can imagine, we considered numerous locations, but ultimately Singapore was the most suitable location for various reasons. Singapore exhibits a very high level of economic and political stability, coupled with an extremely transparent, business-friendly environment and strong intellectual property protection—a crucial factor for innovators like Amgen.

The caliber of talent and standards in education have also never ceased to impress me. Organizations like the EDB and A*STAR have done a phenomenal job of cultivating the proper talent pool to develop and sustain a sector as knowledge-intensive as biomedical science, especially in manufacturing. We’ve now hired approximately 250 local talents, many of who are straight out of university.

What would you highlight as the distinguishing factors that truly depict Amgen’s Next-Generation Biomanufacturing technology as the “future of manufacturing”?

This site actually utilizes many different existing technologies and integrates them in a way that has allowed us to enhance speed, productivity and flexibility. As a result, Next-Generation Biomanufacturing is able to produce the same output as a conventional facility while taking up 75 percent less space, which I like to say is how we wow visitors with our smallness and simplicity. In fact, the facility took half the time and one fifth to a quarter of the costs that it would normally take to construct. Once fully up and running, we anticipate roughly a 30 percent reduction in operating expenses compared to a traditional facility.

The design of the facility is also highly reconfigurable because of our widespread use of single-use components, which translates to added levels of flexibility and adaptability. In terms of manufacturing, this is crucial in keeping pace with our innovative pipeline and getting treatments faster to patients around the world.

By design, a smaller footprint and single-use components will also entail a significantly diminished energy profile— with 80 percent less energy and water — seamlessly aligning with Singapore's ambitions of promoting sustainable and innovative economic development.

What is the feasibility of scaling this model across the rest of Amgen's manufacturing network?

This site has been used as a pilot in order to assess the results and the scalability to the rest of our sites and future facilities. Amgen boasts a long history of manufacturing, having established a very extensive global network of facilities that incorporate conventional technologies and infrastructure. We now have the luxury to choose: Do we put a molecule into the type of facility that we have here in Singapore? Or is this molecule more amenable for one of our more conventional facilities?

We always continually assess how we can advance and improve our existing facilities, and determine which sites might benefit from completely replicating the Singapore model from the ground up versus using certain portions to enhance present capabilities.

Once it's fully up and running, what key role will the Next-Generation Biomanufacturing serve in Amgen's global supply chain?

This site will eventually produce Amgen's global supply of denosumab, which then gets fed to our Puerto Rico facility to ultimately produce Prolia® and XGEVA®—two medicines for patients with skeletal-related disorders (e.g. osteoporosis and bone metastasis).

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Given the speed at which this facility was built and the positive working relationships we've had with the Singaporean government, we are planning to build a second facility here, which will be the first chemical synthesis facility that Amgen is internally running. This site will manufacture carfilzomib, an active ingredient used in the production of Kyprolis, which is used for the treatment of multiple myeloma. Similar to Next-Generation Biomanufacturing , this will serve as the first stage in manufacturing, and our facility in Ireland will proceed with the final formulation and global distribution.

How would you assess Singapore's ability to maintain relevance as a manufacturing hub given some of the challenges inherent in the country such as cost and space?

Since 2013, Singapore's Ministry of Trade and Industry has highlighted pharmaceuticals as a high-value industry that will continue to provide growth for the economy. As a result, the government has committed S$16.1 billion in continued support of research, innovation and enterprise activities between 2011 and 2015. [1]

I also sit on a steering committee for the future of manufacturing in Singapore, and its agenda very much focuses on how to maintain the country's relevance for the future — not just today, but 10, maybe 20 years down the line.

It is astonishing when you see a national body like the EDB investing large portions of its time listening to industry stakeholders in order to truly understand the challenges as well as the opportunities in the industry. After collecting industry insights, the EDB defines an action plan to overcome those challenges and take advantage of the opportunities. In this regard, there are some innovative programs that the EDB is working hand-in-hand with companies such as improving the quality and quantity of the talent pool.

You've had quite a vast and successful career with Amgen so far. What factors have led you to choose Amgen as the path for your professional development?

I find myself really identifying with the values that Amgen embodies and the mission it has pursued. In operations, our motto is "every patient, every time." This goes beyond words on paper and is reflected daily in the way people work and how they collaborate to deliver to patients.

As an example, we had a situation during my previous role in clinical where a father of a young girl wrote a letter to our global CEO Bob Bradway saying, "We've tried everything. My little baby is on her last hope. We would really love to get this treatment you have, but it's not available."

In a matter of days, people across multiple sites were trying to figure out how to get this treatment to this little girl. This relentless focus on the patient makes all the difference, and for me, that's why Amgen.

And how will you measure success moving forward?

Our success revolves around stabilization and ensuring we continue to deliver on excellence in quality. This also applies to creating a sustainable and long-lasting culture linked to our Amgen values.

In terms of the facility itself, we’re going to be focused on meeting our milestones: Putting the proper systems in place, establishing standard operating procedures (SOPs) and obtaining FDA approvals by 2017. It is Amgen’s first manufacturing venture in Asia, and we’re striving to have people in the region immediately recognizing Amgen as an innovative company with high value products.

I feel it is also my duty to ensure that my colleagues in the United States understand what it means to operate in this environment and how some of our systems work or do not work out here; as well as putting Asia Pacific in the spotlight of our global strategy.

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