Interview: John Manusu â?? Managing Director & Dr. Hari Nair â?? Executive Chairman, PrIME Biologics, Singapore

> â??The technology itself was introduced to me in 1990 and I was highly impressed by the potentially disruptive nature of this technology, as well as the widespread social impact that it could have in the future.â?•

07.11.2016

Tags:

Singapore, PrIME Biologics, Biotech, Plasma, Innovation Disruption, Asia

Having recently obtained cGMP from Singaporeâ??s Health Sciences Authority, the founders of PrIME Biologics showcase the role of PrIME Technology in driving plasma self-sufficiency in Asia, while highlighting how this innovative technology is disrupting industry standards of plasma fractionation.

Could you please introduce to our international readers the background underlying PrIME Biologicâ??s foundation?

Dr. Hari Nair (HN): The history behind PrIME Biologics starts in 1986 when the scientist Dr. Joel Margolis invented what we now call the PrIME Technology. The technology was inspired by the challenge of protein separations in space, then being undertaken by NASA. The technology itself was introduced to me in 1990 and I was highly impressed by the potentially disruptive nature of this technology, as well as the widespread social impact that it could have in the future.

Using currently available plasma protein separation technologies, only around 50 percent of plasma proteins can be isolated. As a result, the yields in the fractionation industry are generally low. The first challenge then was to improve the process yields of plasma protein fractionation and this was clearly achievable using PrIME Technology.

John Manusu (JM): Initially, we thought we could sell this technology to the existing players in the plasma market. Unfortunately, the development and regulatory costs were too great for the existing players to adopt such a disruptive technology.

Now, after around 40 years of cumulative development, we received cGMP approval by the Health Sciences Authority (HSA) of Singapore in July 2016 for the production of human albumin. In the area of therapeutic plasma, it is important to consider that there has not been any new process approved by a regulator since the introduction of chromatography some 35 years ago. PrIME technology is a very disruptive approach that can significantly improve the industry yields from around 50 percent to

roughly 85 percent while increasing the level of product safety.

How significant is cGMP approval to the companyâ??s expansion strategies?

JM: Very important. It isthe biggest milestone in PrIME Biologicâ??s history, validating a business plan that weâ??ve been working on for the last 30 years! In addition, the HSA works under EMA standards, meaning this validation is just as relevant to Europe, as it is to Asia. We are currently focused on scaling up our processes, with the longer term goal of obtaining FDA approval.

HN: It is worth mentioning that we have had to face several technical challenges in this region because there were no existing fractionation plants in Southeast Asia, and therefore had to implement things that did not exist here. We bought a plant in Singapore and transform it into a fractionation facility, which required substantial investments and engineering. Itâ??s been a huge learning exercise and overall experience, and has ultimately proved the commercial validity of establishing a plant of this caliber in Asia.

[Featured_in]

In which stage of the plasma processing value chain does PrIME technology add the most value to the industry?

HN: In our industry there are three important processes: plasma collection, plasma protein manufacturing, and regulatory compliance. All these stages have to be aligned in order to launch a product. Briefly, regulators have the obligation to set the quality standards needed to ensure pathogen-free products, ultimately complying with the pharmaceutical industryâ??s high safety requirements. This poses a challenge to the industry, especially in emerging countries where the collection of the plasma cannot be as controlled as in developed countries.

Our technology, besides significantly improving processing yields, also balances the safety challenges that currently exist in the collection process of countries such as the Philippines or India.

JM: It is also important to consider that the current industry processes needs alcohol (ethanol). Our system fractionates directly from plasma without the need for ethanol treatment, therefore reducing the operational costs while improving the ecological cost of plasma fractionation.

With over 30 years since the initial conception of PrIME Technology, how have you evolved your scope to maintain relevance within the industry?

HN: We have had several pivotal technology events before finally bringing this technology to commercial reality. Strategic changes to our approach have been driven by stakeholder responses and industry trends such as the UN resolution for plasma self-sufficiency in emerging nations, as well as the growing burden of chronic disease over the years.

We ultimately decided to implement our technology in Singapore as a 30,000L to 50,000L per year plant meets the needs of the Singapore market. The Singapore facility is a showcase of -plasma mini mills for emerging nations where plasma collection is not always as developed as in the West.

What was the strategic rationale behind moving the companyâ??s original headquarters in Australia to Singapore?

JM: While the technology was originally developed in Australia 30 years ago, it was difficult to raise the USD 20 million needed to bring our product to the cGMP level in Australia. The investors in Singapore and Malaysia were interested in the PrIME process as it addressed the Singapore market.

In addition, Singaporeâ??s HSA, which operates under the EMA guidelines is arguably the fourth most recognized regulator globally.

HN: I was born and raised in Singapore and therefore had a network of people I could count on to assist in getting this project off the ground. Also, one of the main attractions of Singapore is the high caliber of talent, coupled with an extremely business-savvy government that has built an incredible network of infrastructure to support the growth and development of an entire sector as knowledge-intensive and resource-demanding as biomedical sciences.

How will you position yourself against other plasma fractionators in the region?

HN: Weâ??ve built the very first plasma fractionation plant in Southeast Asia. Perhaps aside from some players such as Korean Green Cross or SK, we do not have any direct competitors in this region. China has approximately 38 plasma fractionators plants, but to put things in perspective, we donâ??t consider them direct competitors, as the majority of their facilities utilize Cohn fractionation technology.

JM: Worldwide, plasma products market is worth USD 15 billion, of which USD 1.5m is in Asia. Currently Asia accounts for 60% of the worldâ??s population, but only 15% of the world consumption of plasma products. As the wealth increases in this part of the world so is the demand for plasma products. For the next five years our primary focus is Asiaâ??with markets such as Europe and North America certainly on the horizon thereafter.

What is your future outlook on Asian demand for blood plasma and plasma-derived therapies?

[related_story]

HN: The demand for blood plasma therapies in Asia is huge and it will become bigger as proteins become more widely available. Proteins are used to develop drugs, and despite the existence of roughly 3,000 plasma proteins, only around 20 are used regularly in hospitalsâ??demonstrating the sheer challenge in fractionating plasma proteins.

Most plasma fractionation plants are located in the US, Europe and Australia. Plasma is collected at very high standards and processed at both FDA and EMA guidelines. Plasma in Asia, however, is not necessarily collected at this level and therefore poses major issues for contract manufacturing in large fractionation plants in the US and Europe. This also precludes Asia from being self-sufficient for plasma products. The need for a technology capable of ensuring the safety of the final product is evident in the Asian market.

JM: There is a large volume of plasma collected in Asia, but not at the standards required for processing in the West. Therefore, most of this plasma is discarded. PrIME Biologics can process some of this plasma as the PrIME Technology is a disposable batch process eliminating some of the current technology issues.

So, the increase of the demand goes hand-in-hand with the increase in supply. The need for additional products in Asia is significant and only a process like the PrIME Technology can address this unmet need.

What steps then will you take to effectively capitalize on this demand in the coming years?

HN: As mentioned before, we are currently working towards scaling up our facility. In this regard, we expect to be fully commercial by the end of next year and, in the meantime, we are occupied with

identifying the proteins that we want to sell and develop.

JM: We are developing our business on two separate fronts: manufacturing of the existing finished product and replication of our fractionation facility in other countries. Indeed, our initial planning is to start supplying to countries like India and Sri Lanka, while evaluating different countries where we can replicate our fractionation facility.

What factors ultimately gave you the courage to become entrepreneurs and start your own business?

HN: The prospect of saving lives is what initially prompted me to move into this field. From the get-go, this technology was designed to address unmet medical needs and improve patient outcomes. But, of course, my business partner and very good friend was instrumental in bringing that dream to fruition and getting us through the sleepless nights. Weâ??ve both had that single-minded focus to make this happen. Spanning this as a business owner and entrepreneur, I certainly agree that it takes a little bit of madness to be successful.

JM: During our journey, there were many instances where we were on the edge. Itâ??s the ability to breakthrough in these moments that separates success from failure. Until youâ??ve faced such a moment you canâ??t say if you will have the courage to be an entrepreneur. Itâ??s not for everybody, and as Hari said, you do have to be slightly insane to get through some of these moments. This insanity has to be balanced with a very strong moral compass as itâ??s more than money you are playing with, itâ??s other peoplesâ?? lives. But thatâ??s also what makes it so rewardingâ??helping make a difference in other peoplesâ?? lives!

See more interviews