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ASIA EDITION

Single use processing technologies on rise in vaccine manufacturing

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Asia Vaccine initiative is a market segment focused action plan by Process Solutions/ Merck Millipore, a division of Merck headquartered at Germany. Merck Millipore has been investing on technology, tools and services for vaccine development and manufacturing for more than a decade.

Dr Priyabrata Pattnaik is driving the initiatives and strategies for Asia market for vaccine programs, supporting R&D and integrating solutions for vaccine manufacturing through innovative technologies and processes. In an interview with *BioSpectrum*, Dr Pattnaik talks about how Asia is evolving as a center of new vaccines development, integrating new technologies to improve the process and the challenges involved in the region.

What are the activities involved in Asia Vaccine Initiative?

Merck Millipore provides tools, technologies and services to the pharmaceutical and biotech industries. As an integral part of this community, we understand the complexity and risk faced by our customers, and work in close partnership with them to ensure their success. In last several years, we have had a strong focus on the vaccine industry, including that in Asia which is the one of the fastest growing regions for vaccine development and manufacturing. Our objective is to deliver innovative and integrated products and services that address the evolving needs of vaccine developers and manufacturers.

What are the current projects?

We are currently working with several customers in Korea, China, India and Japan, supporting their vaccine process development and scale-up. We are also working with the Developing Country Vaccine Manufacturers Network (DCVMN) to share knowledge and provide education related to process development, scale-up and manufacturing to vaccine manufacturers in emerging countries.

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We have been assisting China's vaccine manufacturers in their effort to secure WHO Vaccine Pre qualification by holding workshops with ex-WHO experts and assisting individual manufacturers on their specific needs. Besides, Merck Millipore has several projects in research and development focused on addressing unmet needs of vaccine customers and improving overall process economics.

Elaborate on the vaccine initiatives by Merck for diseases prevalent in Asia.
Hepatitis, pneumonia, dengue, malaria, cholera, cervical cancer, influenza and many other infectious diseases are prevalent in Asia. During the most recent influenza pandemics, Asia received vaccines after the peak season of the disease was over. This situation led to a drive towards building in-country capacity for influenza vaccines. Pandemic response is one area where we are working with our vaccine customers to enable them to be well-prepared for such situations and enable them to quickly ramp-up capacity in timely manner.

How do you see Asia evolving as an innovative vaccine developer globally?
Asia's vaccine industry is in a phase when most of the innovation takes place in the Western countries and the Asia Pacific region follows them. Most of the Asian countries are currently in capacity building mode. Vaccine industry in Asia is rapidly evolving and growing at more than 20 percent per year, much faster than the industry average estimate of eight percent.

Currently, Asia contributes to a large portion of the global vaccine supply, but mostly for low cost, high volume traditional vaccines. It may be surprising that several of the leading low cost producers are also leaders in innovation. Successful development for HFMD (EV71) and the Hepatitis E vaccine in China or conjugated typhoid and rota vaccine in India are examples. These innovators argue that Asia needs to transit from low cost producer to a being a more balanced supplier of both low and high value vaccines.

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Which are the emerging technologies in vaccine manufacturing?

Globally, the vaccine industry is diverging in terms of technology platforms. Focus has shifted towards innovative approaches to solve complex diseases like cancer, HIV, TB, malaria, dengue, and others. Independent of these newer initiatives, the vaccine industry as a whole continues to look for ways to increase productivity (through robustness, capacity increase, etc) and reduce cost. Here, we see increased adaptation of single use technologies particularly in upstream processing and formulation and finish/fill of vaccines.

What are the challenges faced by a vaccine manufacturer in Asia?
Firstly, Asia has always been known for low labor cost, however, the situation is changing fast. Secondly, getting skilled manpower in Asia is challenging. Also, there is lack of awareness among students to pursue career in biotechnology. There is general perception that life science means only research and development, which in reality is a small part of the whole process. Besides, Asia is competitive for high volume, low cost manufacturing. But having a readily available site that gives low cost manufacturing is not enough. There are several other issues involved in vaccine development that need to be addressed by a country, for instance security of supply chain, availability of skilled manpower, regulatory compliance, and smooth availability of resources.