

## Collaboration The key for vibrant vaccine market in Asia

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As a major high-end supplier to the Asian vaccine market, Millipore has played a major role in contributing to the growth of the market over the past few years. Although the issues vary from country to country, we see a number of common trends affecting vaccine manufacturers throughout the region—and clear implications for suppliers who want to compete successfully in this expanding and exciting industry.

### **Industry Trends: Higher volume, higher quality**

The vaccine market in India is growing at 20 percent per year; and in China, the growth is at 15 percent per year. Figures like these point to sustained double-digit growth throughout the region, and signal Asia's rapid emergence as an important player in the \$21 billion global vaccine market.

The major trend underlying this growth is the increased government support in the form of investments to boost the vaccine industry—particularly in China, India and Indonesia. This increased spending is fueling industry expansion and with it, a new focus on meeting international quality standards.

For example, to increase their market share, a growing number of vaccine manufacturers in Asia are applying for the World Health Organization (WHO) pre-qualification, signaling their willingness to adopt more uniform quality standards in all phases of vaccine production.

We see a similar trend towards higher quality manufacturing in the pharmaceutical market, where a growing number of firms are focused on meeting cGMP (current good manufacturing practice) regulations—strict standards governing exports that are enforced by regulatory agencies such as the Food and Drug Administration (FDA). Although local enforcement varies from country to country, many drug manufacturers in Asia have begun following the same standards for both their domestic and export markets.

In China, in the wake of international concern about the safety of food and drug exports, stricter cGMP standards for APIs (active pharmaceutical ingredients) will come into effect in January 2010. The new standards will expand requirements related to production processes, quality control, validation documentation and personnel qualifications.

An increased focus on global pandemic readiness in the face of the H1N1 threat is also accelerating the move to stricter compliance with quality standards. Manufacturers are competing to produce an effective vaccine in the quantities needed to meet the demands.

All these trends—combined with rising local health standards and the expansion of multinational pharmaceutical firms into Asia—have led to increased competition and a move to more efficient, higher volume commercial vaccine production throughout the region. Many older vaccine companies and academic labs, which for the past 30 or 40 years have focused primarily on low-cost; and low-volume products to meet local needs must now compete with larger firms, which are looking to expand their customer base beyond their borders.

More important, from a high-end supplier's perspective, these trends have led to the demand for greater quality in vaccine manufacturing. To compete in highly regulated markets and improve the safety and purity of their products, many vaccine producers must make a rapid transition to newer, and better production methods.

This transition is complex. The new regulatory environment has led some manufacturers to opt for single-use disposable technologies, in order to avoid the regulatory obstacles associated with the re-use of devices and the high costs of capital equipment investments. It has also led to increased industry consolidation, as firms look at new ways to afford the higher costs of compliance.

### **Key to successful partnership**

Considering the growing competition and costs, heightened quality expectations and stricter safety enforcement, vaccine manufacturers are looking to their suppliers not only for higher quality products, but for greater support and closer collaboration at every stage of production. From Millipore's perspective, successful partnerships with vaccine manufacturers include three critical components. They are industry experience, technical expertise and comprehensive training.

There is no substitute for broad industry experience. Suppliers who can bring to customers a global perspective, an understanding of best practices and a breadth of knowledge based on a long-term investment in the industry, are best equipped to help manufacturers gear up for the future.

Technical expertise is probably the most critical requirement for successful partnership—and also the most difficult for suppliers to achieve and maintain. Vaccine manufacturing is a complicated, demanding and expensive process. The production of polysaccharide-conjugate vaccines for common childhood infectious diseases such as pneumonia and meningitis, which are of high priority for the WHO and is particularly complex and costly.

Suppliers must provide top-quality products for this complex manufacturing environment, because second-rate products no longer meet the strict standards for sterile manufacturing. But beyond that, they must provide experts who understand technologies, products and applications unique to the production of specific vaccines, as well as the complex regulatory requirements involved at every stage of production. These experts must work side by side with scientists and technicians to develop, optimize and trouble-shoot their production processes. There are no shortcuts to producing safe and effective vaccines.

The third component of successful partnership—and probably the most neglected by industry suppliers—is continuous and comprehensive training. Suppliers must provide both formal classroom training and hands-on coaching not only in the operation of their products, but also in the principles of operation, so that users can understand the products and the ways to trouble-shoot problems. To meet the demands of the new regulatory environment, suppliers must also offer documented training, partnering with local educational institutions and government agencies.

### **Eye on the future**

For suppliers who make a sustained and long-term commitment to the Asian vaccine industry, the future is bright. Productive partnerships between manufacturers and their suppliers will fuel further industry growth as their technological expertise increases through close collaboration with experts, manufacturers will be able to produce new products to meet future demands.

When it has achieved the WHO's current goal of addressing common infectious diseases, the industry will be in a position to tap its collective knowledge to produce advanced therapies for even more complex diseases.

For Millipore, it is exciting to be part of this growth and to play a vital role in this important market. Partnering with Asian vaccine manufacturers is one of the ways we fulfill our corporate mission: to collaborate with customers to confront the world's challenging human health issues.