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"Speed to market is a key focus area for us"

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West Pharmaceutical Services, Inc. is a designer and manufacturer of injectable pharmaceutical packaging and delivery systems.

BioSpectrum India interacts with Alagu Subramaniam, Managing Director, West India

What are some of the global trends in the containment and delivery of injectable medicines?

An increasing number of prescription medicines are being developed as injectable drugs. Our customer base is expanding globally, and sales within the emerging markets are currently about 10% of total sales. We are seeing double-digit growth in the Asia Pacific region, with India as a strategic and fast-growing market for West's overall business. Also, stricter regulatory requirements and varying regulations around the world require organizations to be even more flexible with strong internal

capabilities and systems to support evolving needs. Finally, new biologics and biotech therapies require fast, effective, innovative solutions and companies that know how to handle delicate molecules and raw materials. For these reasons, it's critical that companies working in the containment and delivery space, including West, are forward-thinking partners for their pharma customers and bring forward solutions to help them succeed in the marketplace.

Are these trends relevant from an Indian market perspective?

Yes, current trends in the India market are similar to what our customers in other markets are experiencing, many of whom are global companies and are catering to international and domestic markets. Increased global regulatory scrutiny is driving an expectation for high-quality components. For example, regulatory agencies require combination products to include human factors studies and data proving not only that the system is effective in general, but that it is effective for the patient demographic targeted by the drug product. This is also the case for the individual parts and components, or constituents, in the combination products that have previously received regulatory approval. A good example of how West addresses this challenge is our work with a generic drug manufacturer that was looking for a device to be used in combination with their generic prefilled syringe. They needed a device that would enable a high-quality and unique patient experience. West's SelfDose™ injection system provided an ideal solution, as it is a patient-controlled injector designed to make self-administration of subcutaneous injections easier for patients with dexterity challenges. We performed formative human factor testing, which validated the platform's design and informed enhancements to improve the patient experience. West provided a technical package to support the EU regulatory submission and sent a team to India to support final assembly of the injector. This readily available data helped save the drug manufacturer both time and money in delivery system development.

Are there any learnings from India that are applicable in West's other markets? What are some of the unique learnings from the Indian market that have helped West globally?

India is often referred to as the "pharmacy of the world." Indian companies are servicing almost 200 countries and West India plays an important role in partnering with these companies. Additionally, vaccines from India are being shipped all over the world – two out of three pediatric vaccines are currently being made in India.

What are some of the unique challenges being faced in India, if any? Which Pharmaceutical companies is West working with in India?

There is a significant focus on increased speed to market in India, as many customers are global companies catering to international and domestic markets. Because the field in India is so competitive, generic manufacturers are under considerable pressure to get their products to market quickly within a stricter regulatory environment. To meet these standards, generics injectable manufacturers need flexibility and simplicity when dealing with drug containment and delivery. West is working with many local generic companies. A great example of how we meet pharma's needs is our AccelTRA® component platform. A generic drug manufacturer needed to reduce the number of its elastomer SKUs and was open to seeking a higher purchase volume of a single formulation to reduce costs. They ultimately chose West's AccelTRA platform because it could deliver a six-week time savings associated with component testing, which would help their speed to market, provide extractable data analysis on their molecular entities, and lower their number of elastomer SKUs, simplifying the process and providing opportunities for cost savings. Speed to market is a key focus area for us and we will continue to evolve in this function.

What are some of the regulatory challenges impacting the industry?

Here again, the trend toward more stringent regulatory requirements stands. Part of the more stringent requirements is a greater understanding of a containment and delivery system, and drug delivery system manufacturers need to ensure that they're minimizing particulates and ensuring container closure integrity (CCI) over the shelf life of the drug product. Regulatory agencies are looking for more diverse data around aspects of drug containment and delivery that can impact quality and safety, including the container closure systems, the actual material composition that's in contact with the drug and the process, such as filling, device assembly, shipping and storage. Previously, a lot of focus would be on the extractables and leachables of the primary packaging and containment system. Today, they also want to see evidence of the compatibility of the entire delivery system. Therefore, you need to wellcharacterize your delivery system over the shelf life of the product. This includes understanding the effect processing may have on the materials and components and as well as understanding the extractables of the materials in the fluid path. The best approach to reduce risk around extractables and leachables is choose a product that can help minimize interaction between the drug and the containment system. West's FluroTec® stoppers and plungers contain a barrier film that does just this. In addition, the fluoropolymer film reduces absorption and adsorption of the drug product, an important benefit for maintaining the strength and shelf life of most drugs.

What are West's integrated solutions? Any success story examples from the Indian market?

West’s Integrated Solutions program brings together our primary packaging, device, analytical, regulatory and contract manufacturing expertise in a single-source package that is designed for any stage of the drug development lifecycle and across all injectable formats. We offer defined packages for Prescreen and Compatibility, Clinical Phase I, II and III, Lifecycle Management and Generics. Whether a customer is developing a biologic, pharmaceutical or generic product, this new program can help bring new drugs to market quickly while also helping to reduce risks. The response from India is encouraging and we are in conversations with a number of potential customers.

You recently opened a DTC in Bangalore? How is the success of DTC?

In March 2019, West opened our new Digital Technology Center (DTC) in Bengaluru, India. In the opening, West DTC employed 80 technology professionals, and over the past six months, the team has grown to 200 people. The DTC allows our team to create compelling digital experiences for our global customer base across hemispheres, source talent from India’s fast-growing technology industry, and bring forward the latest digital advancements to create insights and value for our customers and team members—ultimately delivering better business results.