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Achieving coordinated goals in pharma manufacturing to address the growing diabetes burden in Asia-Pacific

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Kok Li Kwang, Director of APAC Scientific Affairs and Technical Services, West Pharmaceutical Services The critical role of early collaboration to prevent stability and compatibility challenges in drug development



Diabetes prevalence in the Asia-Pacific region is rising rapidly, bringing increased focus on scaling treatments such as GLP-1 therapies. This growth has highlighted the need for effective containment and delivery systems to ensure drug integrity and meet patient demand. Addressing this challenge involves considering how manufacturers can develop robust solutions for these treatments, designing patient-centered devices that support safe and reliable self-administration, and fostering industry collaboration to tackle the region's growing diabetes burden. These aspects underscore the importance of innovation and coordinated efforts in managing diabetes care, emphasizing the role of scalable, safe, and patient-focused approaches in shaping the future of treatment in the region.

In a recent discussion with Biospectrum Asia, **Kok Li Kwang, Director of APAC Scientific Affairs and Technical Services at West Pharmaceutical Services**, describes a notable shift in the perception of pharmaceutical packaging—from a compliance requirement to a vital factor in ensuring therapy success.

- **The rise of GLP-1 receptor agonists has reshaped how diabetes is managed globally. What unique challenges do these molecules present, and how is the containment and delivery industry adapting?**

As GLP-1 receptor agonists (RAs) are large, often peptide-based molecules, they are particularly sensitive to agitation, temperature and interactions with container materials. Compared with small-molecule injectables, they pose technical and commercial challenges, as many such products also have high viscosity or novel delivery formats (i.e. depot/extended-release), which require specialized containment systems that go well beyond those use for small-molecule injectables. These attributes poses challenges for primary packaging, elastomeric closures and delivery devices.

With the widespread application of such products in chronic care, we are seeing the containment and delivery industry responding mainly on three fronts: material sciences, device engineering and supply chain process adaptation.

Elastomeric closures and primary containers are being reformulated to minimize extractables and adsorption and to preserve peptide stability over the product lifecycle. Products are also being designed to handle higher viscosities and to control dose delivery profiles while remaining comfortable for self-administration.

At the same time manufacturers are improving aseptic processes, cold-chain management and device/primary-container qualification so compatibility is proven early and robust at scale. The net result is a tighter integration between the drug formulation and the container-closure and delivery system than we've typically seen.

- **Self-administration is central to diabetes care. What design principles or technologies are emerging to improve usability and reduce dosing errors in home settings?**

For self-administered therapies, the fundamentals of design must prioritize simplicity, clarity and reliability. Devices must incorporate clear affordances such that patients instinctively understand what to do, while minimizing the number of critical steps and ensuring tactile/visual confirmations of dose delivery. Designing ergonomics that support diverse patient populations (for example, patients with reduced grip strength, vision differences, dexterity issues) are equally essential to promote safe, confident use at home.

At West, these principles are built into our development philosophy. For instance, our NovaPure® components for vials, prefilled syringes, and cartridge systems are designed and manufactured with tight dimensional control and low extractables, helping to ensure consistent, reliable drug delivery. These high-quality components form the foundation for safe and effective self-injection devices.

Across the industry, we are also seeing a strong focus on single-action autoinjectors, dose-locks/physical interlocks to prevent overdosing, integrated needle shielding, and injection-rate/dose-assist mechanics for viscous formulations.

As more patients take charge of their care at home, this combination of intuitive device design and proven containment performance, exemplified by our NovaPure® plungers and stoppers, will help enable truly seamless patient-centric self-administration.

- **Many of these new injectable therapies have complex formulations. How critical is early collaboration between drug developers and containment manufacturers to ensure compatibility and stability?**

Early and ongoing collaboration has become a necessity and should no longer be a 'nice-to-have'. Stability or compatibility issues often emerge when the drug interacts with the container or device under real-world storage, handling and delivery conditions. The late discovery of such issues can force reformulation, new device selection, or complex regulatory workarounds, any of which slows development and increases cost.

In our experience, engaging containment expertise early – often from the preclinical or formulation-design stage – helps reduce these risks. Many of our customers choose to collaborate with us at these stages to leverage our experience in packaging design, material selection, and container closure system qualification. By aligning formulation scientists and West containment expertise from the outset, it becomes possible to anticipate potential interactions, define sterilization and qualification strategies, and ensure consistent drug stability – all before costly late-stage changes become necessary.

For complex biologics and GLP-1 based injectables, this early collaborative model has enabled successful use of laminated closures and advanced elastomeric formulations that combine barrier films, clean elastomers and specialty coatings to minimize interaction while maintaining a robust seal. Such thoughtful material science is ultimately what helps improve drug stability and machinability.

- **As GLP-1 therapies surge in demand, what are the key technical or operational considerations to ensure containment systems can scale safely and efficiently across diverse markets?**

Scaling production quickly for high-demand, complex injectables call for careful management, while manufacturers must also balance speed with validated quality. Key technical and operational considerations include maintaining a qualified supply of primary container components that meet stringent quality specifications, ensuring device designs are manufacturable at scale without compromising performance, and managing cold-chain integrity for temperature-sensitive products. Dual sourcing, validated material substitutions, and strong traceability systems are also essential to managing scale safely across markets.

Equally important is ensuring that these operational strategies align with evolving regulatory expectations. New standards such as USP <382> and the revised EU GMP Annex 1 will require pharmaceutical companies to demonstrate that their packaging and delivery systems are safe, sterile, and robust under real-world manufacturing and handling conditions. Meeting these expectations calls for system-level testing, rigorous quality and process controls, and proactive risk management from the outset.

Across Asia Pacific, where supply chains remain highly fragmented, pharma companies must adopt holistic validation approaches to ensure compliance across multiple jurisdictions. This becomes even more critical as markets across the region strengthen their ambitions to become biologics and injectable manufacturing hubs.

West combines deep technical expertise with proven containment and delivery experience to support our partners in scaling safely and efficiently. By engaging early and aligning technical, regulatory, and operational priorities, we help customers bring complex therapies like GLP-1s to patients reliably and at the pace the market demands.

- **Regulatory frameworks around combination products and prefilled systems are evolving unevenly across Asia. How does West navigate this complexity while maintaining global quality standards?**

In a region as heterogeneous as Asia, regulatory expectations for combination products, prefilled systems and containment systems can vary materially between jurisdictions, from differing data requirements to distinct interpretations of local guidelines or global standards, such as ISO and ICH. For pharmaceutical partners, this can make it challenging to navigate multiple agencies, manage staggered review timelines, and ensure alignment across regional launches while maintaining speed to market.

The approach that works for us is threefold: (1) maintain a single, high bar for quality and documentation that meets the most rigorous global standards, (2) map local regulatory variations early and tailor submission packages to each market, and (3) engage proactively with regulators and local partners to clarify expectations.

This means adopting robust regulatory strategies and producing data packages aligned to global standards, while creating jurisdiction-specific modules where needed. By keeping one consistent global quality system while producing targeted regulatory dossiers, we can be both compliant and nimble in a complex regulatory environment.

Given how APAC is fast emerging as a global biopharma hub, with countries such as Singapore, South Korea and China leading advances in biologics, biosimilars and CDMO capabilities, we have also been investing in regional operations to support such efforts. We have expanded our facilities in both Singapore and South Korea to help our customers meet their market demands in timely manner, while maintaining the highest global standards of safety, efficacy and quality,

- **With the growing integration of connected health solutions, what opportunities or challenges do you foresee in merging drug delivery systems with digital monitoring tools?**

Connected delivery systems can dramatically improve adherence tracking, enable remote monitoring, and create data that informs dosing optimization and pharmacovigilance. For chronic conditions like diabetes, that connection can improve outcomes, personalize support and reduce clinic workload.

They are, however, not without their challenges. These can range from adhering to data privacy and cross-border data transfer rules to ensuring cybersecurity across the device lifecycle. Ensuring clinical validation that digital markers truly correlate with clinical outcomes and avoiding complexity that undermines usability are also key concerns from a manufacturing and regulatory standpoint.

Adding electronics fundamentally changes the classification and compliance pathway as well. Overall, businesses looking to explore this space should start with low-friction features (dose confirmation, simple reminders), ensure data security and interoperability, and validate the clinical value before layering on advanced analytics. Partnering with digital health specialists and adopting privacy-by-design are beneficial in this regard.

- **Drawing from your experience across scientific and technical roles, what do you see as the most significant shift in how pharmaceutical packaging is viewed—from a compliance function to a critical enabler of therapy success?**

Across the industry, packaging can no longer be perceived as a passive compliance function – it is an active enabler of therapy success. At West, we see this shift every day across our partnerships with biologics and combination product developers, where the choice of containment and delivery systems can directly impact product stability, patient safety and adherence.

The growing complexity of biologics and combination products means decisions made early in the packaging design process – from elastomer selection to device usability – can materially affect time-to-market, total cost of therapy and real-world effectiveness. That is why we work closely with our partners in materials science, engineering and experts in human factors to complement formulation and regulatory teams from the outset.

When packaging is treated as a strategic asset rather than a compliance checkbox, it becomes a bridge between innovation and the patient. We have seen firsthand the results of such advanced collaboration, such as through our Daikyo Crystal Zenith® and FluroTec™ barrier films, which help maintain drug integrity and support more reliable delivery. This ultimately ensures that better therapies reach patients safely and perform as intended.

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