ARE YOU STILL PIECING TOGETHER YOUR PREFILLABLE SYRINGE SYSTEM OR ARE YOU ALREADY FILLING IT?

Dr Bettine Boltres of **West Pharmaceutical Services** introduces the West Synchrony™ prefillable syringe system, explaining how the device, as a single comprehensive package, minimises regulatory complications and delays.

Despite having been employed since the turn of the 20th century, it was not until after the Second World War that the term "supply chain" really started gaining traction in the world of manufacturing. By the 1980s, the phrase had moved from poetic metaphor to part of the lexicon. It neatly and somewhat simplistically presented the concept of co-dependent stakeholders linked in a continuous series, facilitating the efficient flow of materials and components towards their ultimate destination as a finished product.

Over time, this image has become increasingly intricate in line with the highly complex multi-supplier ecosystems that underpin product development and manufacture today. Evidence of this can be seen clearly in the pharmaceutical industry, and in drug delivery more specifically. Here, ever more sophisticated approaches are continually being explored and accommodated within supply chains to optimise the efficacy and quality of drug products, and to enhance convenience, safety and health outcomes for patients. More complex manufacturing solutions are accepted as the price of innovation and the cost of progress.

In a previous article, West Pharmaceutical Services highlighted prefillable syringe (PFS) system technology as the embodiment of this dilemma. Over time, PFS technology has grown into a global platform drug delivery system, both in terms of market volumes and its value to healthcare professionals and patients. Advances in engineering, design and

materials science mean that PFS systems have evolved to ensure that the quality of drug products, even sensitive biologics, remains protected, allowing patients to self-administer accurate doses within non-clinical settings, including the home. A recent publication even estimated significant cost savings for hospitals in using PFSs versus the traditional vial and syringe approach.[1] But bringing these products to market is the culmination of a lengthy, highly involved and tightly regulated process, which begins with product design and component specification while also encompassing compatibility testing, clinical and human factors studies, technology transfer and scale-up manufacture.

Currently, these various goals can only be achieved through the co-ordination of a sophisticated network of interlinked supply chain partners. This comes down to the fact that, in reality, PFSs are an aggregation of multiple components, each of which must be carefully combined to form a coherent whole. And for the growing number of emerging biotechnology companies targeting the launch of exciting new therapies, this represents a multifaceted manufacturing challenge where there are few opportunities to shortcut, bypass or accelerate the many stages involved.

Thankfully, this paradigm is now shifting. At CPHI Worldwide 2025 in Frankfurt, Germany, West unveiled the West Synchrony™ PFS system, marking the introduction of an entirely new model for the development of PFS drug delivery solutions.

Commercially available from January 2026, the West Synchrony PFS system will enable pharmaceutical partners to simplify and accelerate the development, manufacturing and regulatory approval of primary packaging for their drug. This is achieved through the provision of an integrated and fully design-verified PFS system, encompassing the syringe barrel, plunger and needle shield/tip cap, all from a single, robust, experienced and expert supplier. This integrated, system-based approach removes much of the difficulty and complexity associated with the sourcing, design verification and integration of individual components from separate providers.

"THE PRINCIPLE OF SIMPLIFYING COMPLEXITY MAKES THE WEST SYNCHRONY PFS SYSTEM IDEALLY SUITED TO BIOLOGIC APPLICATIONS, WHICH ARE OFTEN THE DOMAIN OF EMERGING BIOTECH COMPANIES."

The principle of simplifying complexity makes the West Synchrony PFS system ideally suited to biologic applications, which are often the domain of emerging biotech companies. While the emphasis for these newcomers is centred on progressing their molecules through to clinical trials to obtain funding for their projects and obtain marketing authorisation, difficult questions and important decisions must be addressed in relation to drug delivery as part of this process. For smaller companies, however, limitations are likely to exist in terms of their resource capacity and the depths of specialist component-level expertise available to them in-house, all of which intensifies the task of selecting the appropriate PFS.

Faced with this uphill struggle, companies must either rely on recommendations from their selected CDMOs or take it upon themselves to pursue a component-by-component approach to system design, often turning to external consultants and laboratory service organisations to fill in the relevant knowledge gaps. However, these organisations can only ever consult and recommend, with the final decisions solely in the domain of the biotech company. Within this process, the performance of each element and the combined packaging system as a whole must be understood in regulator-approved detail. This necessitates the pulling together of disparate data threads into a unified and robust Design & Development File to support the submission as an Electronic Common Technical Document and/or a Technical File for Notified Bodies in the EU.

In contrast, with the West Synchrony PFS system, all relevant drug-independent design verification testing of the PFS system comes in a complete data package, providing reassuring evidence of all required performance characteristics. A particular advantage is that it can remove an entire phase of scouting, decision making and testing, saving valuable costs and effort while enabling teams to progress directly to the clinical fill phase. Moreover, it also avoids the uncomfortable uncertainty that can arise when forced to interpret and mesh the findings from independent component-level tests.

Building confidence in the combination product development process is crucial when products are developed under the highly critical gaze of global regulatory bodies, which demand accuracy, depth and consistency within data submissions. However these qualities are difficult to guarantee as part of a multi-component approach, where documentation from separate parties must be standardised and compiled into a unified package. Further complications can also arise when regulators question the data provided, as this could trigger simultaneous information requests from different suppliers, as well as the need for collaboration to arrive at a consensus. If this is the case, commercial sensitivities can potentially introduce a demand for multiple three-way confidentiality disclosure agreements to be implemented to ensure that stakeholders are protected.

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Problem solving and challenge resolution are, of course, an accepted and expected part of the process when developing a regulated combination product. However, the scale of those problems and the speed and effort required to achieve resolution are critical risk factors in terms of the overall development schedule for a PFS product. If regulatory complications are not easily fixed or if data requests require further testing, development schedules can be delayed, milestones might be missed and launch timeframes become extended. All the while, costs inevitably escalate. Indeed, research from the Tufts Center for the Study of Drug Development (Boston, MA, US) suggests the cost of missing a single day in drug development equates to approximately US$500,000 (£375,000) in lost prescription drug or biologic sales, while approximately $40,000 is lost per day on Phase II and III trials.[2]

The West Synchrony PFS system reduces the risk of regulatory delays and complications by incorporating all relevant information into a single comprehensive regulatory package that has been compiled with the needs and expectations of regulators in mind. This system mindset is further emphasised with one Drug Master File that encompasses the entire PFS system. Furthermore, it comes with a system specification that it is tested against at each batch release. All of this provides pharmaceutical partners with a detailed evaluation of critical quality attributes and design inputs as guided by current GMP regulations across global territories, which include Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals) and Part 820 (Quality Management System Regulation) of Title 21 of the Code of Federal Regulations in the United States (21 CFR Part 211 & 820) and the GMP guidelines in the EU.

Acting as a "single source of fact", content from the package can be directly transferred into the marketing authorisation submission, ensuring accuracy and consistency while generating significant savings in terms of time and effort. Rather than ownership of information being diluted across stakeholders, it is concentrated into the hands of the drug product owner, who need only liaise with one supplier in the form of West. The benefits of this simplified structure are further underlined when considering any future iterations to PFS components, with West having a robust change management process in place to proactively alert partners to any changes that might impact their filing and necessitate updates to be made with regulators.

As already highlighted, achieving consistency is a particular challenge when managing the flow of information from multiple suppliers. But the challenge of consistency extends beyond the regulatory submission process. Indeed, when it comes to the practicalities of managing product volumes, pharma and biotech companies face a difficult challenge in balancing the various forces of supply and demand in this highly volatile market.

Supply, in particular, can present many points of friction. The ideal scenario of on-demand ordering, as-needed volumes and just-in-time delivery is frequently replaced by significant mismatched minimum order quantities, long lead times and variation in delivery timeframes. Across multiple components, this can exacerbate pressure on cashflow and result in stock-holding issues or unnecessary product wastage.

The West Synchrony PFS system alleviates these pressures through a make-to-stock strategy of complete PFS systems in quantities that are more closely aligned with levels of demand. Inventory can, therefore, be managed more economically, more efficiently and more reactively, with shorter lead times allowing for supply to be matched to volatile market movements.

This security of supply is complemented by assurances of quality and accountability. In terms of quality, the West Synchrony PFS system has been tested at system level prior to distribution, which, by definition, cannot be said of any individual components, where the onus is placed on manufacturing facilities to conduct incoming inspections and system-level testing. Accountability is also improved in a single-supplier arrangement, whereas uncovering the root cause of a post-market issue becomes far more complicated when multiple suppliers are involved.

"THE WEST SYNCHRONY PFS SYSTEM TURNS THE IDEA THAT PROGRESS IN DRUG DELIVERY MUST CORRELATE WITH COMPLEXITY ON ITS HEAD."

In this context, taking a component-based approach to PFS design, if not unviable, is not advisable. It is simply difficult to justify applying additional layers of complexity to an already onerous task. Drug delivery is a sector driven by innovation, with new technologies, processes and approaches continually being implemented either to enhance manufacturing practices or improve patient outcomes. However, with every innovation, there is a risk to accepting another link added to an already complex supply chain.

The West Synchrony PFS system turns the idea that progress in drug delivery must correlate with complexity on its head. By merging several links in the PFS supply chain, it simplifies the primary packaging challenge facing developers of biologics and vaccines, bringing speed to the selection process, accelerating the pathway to clinical fill-finish and easing global regulatory submissions while also providing assurances of consistency in quality and supply. The notion of the supply chain has already witnessed evolution over the past century, and, with the West Synchrony PFS system, the drug delivery sector has an opportunity to rethink, reframe and redefine it once more.

Synchrony is a trademark of West Pharmaceutical Services, Inc.

Dr Bettine Boltres

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REFERENCES

1. *Borms M et al, "Improving Efficiency and Safety with Prefilled Syringes: A Model-Based Economic Evaluation for US Healthcare Settings". Clinicoecon Outcomes Res, 2025, Vol 17, pp 673–685.*
2. *Smith Z, DiMasi J, Getz K, "New Estimates on the Cost of a Delay Day in Drug Development". Ther Innov Regul Sci, 2024, Vol 58(5), pp 855–862.*

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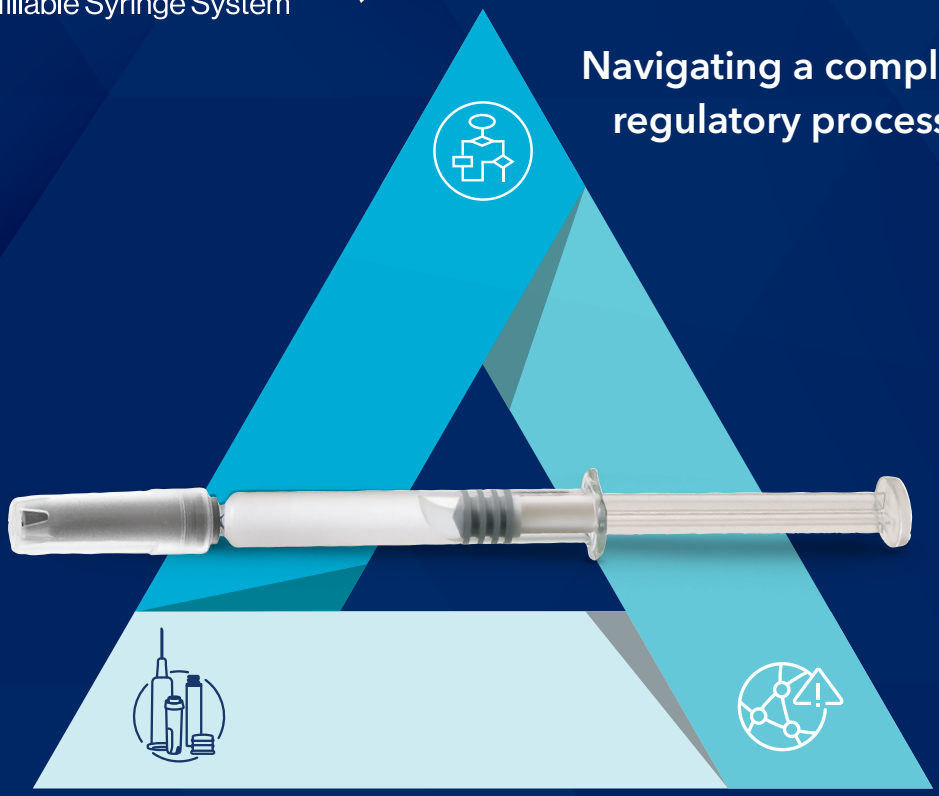

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