Cutting Through Complexity:
PCI's Integrated Model for Faster PFS Development

Prefilled syringes (PFS) have rapidly become one of the most influential formats in injectable drug delivery, driven by demand for patient-friendly, ready-to-use drug-device combination products. PCI Pharma Services has positioned itself at the forefront of this transformation with major global investments in sterile fill-finish, assembly, testing and packaging. International Biopharmaceutical Industry (IBI) sat down with Dawn Manley, Director of Global Technical Sales, to discuss why PFS are surging, what biopharma companies need from partners today and how PCI is building an integrated, future-ready global network.

Prefilled syringes have seen remarkable growth in recent years. What's driving this shift across clinical and commercial programmes?

The rise of prefilled syringes has been incredibly fast and it's rooted in a fundamental shift toward patient-centric drug delivery. In clinical trials, PFS eliminate preparation steps and reduce product waste, which simplifies site workflows and improves dosing accuracy. Those advantages translate directly to the commercial world, where ease of administration, safety and reliability are paramount, especially as more therapies move into at-home self-injection.

We're also seeing a strong push from biologics and biosimilars developers, where convenient and user-friendly delivery is a key differentiator. Combined with the growing prevalence of chronic disease, the market trajectory is clear; analysts project the global PFS market to more than double to over USD 16 billion by 2030. It's one of the most dynamic segments in drug delivery today.

What role does PCI play in supporting this growing demand for PFS and combination products?

PCI has made significant strategic investments to support biopharma companies from early development through to clinical trials, launch and ultimately global commercialisation. What differentiates us is that we offer a truly end-to-end integrated solution for PFS programmes from sterile fill-finish, final device assembly, functional testing, labelling and packaging to global supply chain capabilities, all within one network.

That integrated model reduces risk by eliminating handoffs between suppliers, accelerates speed to market and ensures consistency across every stage of production. Whether a client is scaling a Phase I trial or preparing for a major commercial launch, they get access to our deep expertise, advanced technologies and, importantly, global capacity.

Sterile fill-finish capacity and flexibility have become industry bottlenecks. How is PCI addressing these challenges?

Sterile fill-finish is the foundation of any PFS programme and it's an area where we've invested heavily. Across our North American and European network, we operate state-of-the-art isolator-based facilities that can support a wide range of molecules from monoclonal antibodies and mRNA to peptides, oligonucleotides and small molecules.

In the US, for example, we can flexibly scale from 20,000 to 200,000 syringes per batch. In Europe, our new high-speed isolator-based PFS line in León, Spain, can deliver up to 12,000 units per hour, with maximum batch sizes around 300,000 syringes. That gives sponsors both regional redundancy and the scalability they need as programmes progress from early-phase to global launch.

Our goal is always to create a reliable pathway so clients aren't constrained by capacity or geography. With true flexibility and global reach, we're able to support syringe and cartridge filling for everything from needle-safety devices to autoinjectors and on-body delivery systems.

PCI also supports device strategy and packaging design. Why is this early-phase collaboration so important?

Drug-device combination products are increasingly complex, and decisions made early in development can significantly affect timelines, manufacturability and regulatory success. That's why our specialists work with clients early to evaluate device platforms, whether that's selecting established systems with regulatory precedence or exploring novel delivery technologies.

Packaging design is another critical piece. Our in-house team incorporates human factors engineering and technical functionality to ensure the final solution is automatable, scalable, sustainable and compliant. By integrating sterile manufacturing, engineering and operations expertise upfront, we help clients establish robust design-for-manufacture processes.

This proactive approach reduces downstream risk, prevents costly design changes and helps accelerate regulatory submissions. Ultimately, it supports the patient with a device that is intuitive, reliable and safe.

In-house testing often determines how quickly a programme can advance. What capabilities does PCI offer in this area?

Our in-house analytical and functional testing laboratories are designed to streamline the journey from development through to commercial supply. We offer everything from product identification testing, method transfer, release and stability testing, to functional testing of drug-device combination products in alignment with ISO standards.

Having these capabilities under one roof is incredibly valuable. It reduces delays, ensures consistent quality and ultimately ensures that life-changing therapies meet global regulatory requirements and are safe for patients. For many clients, especially those navigating combination-product

testing for the first time, that integrated support is a major advantage.

Many sponsors struggle with long lead times and high upfront costs when developing PFS-based combination products. How does PCI help accelerate projects and reduce the need for clients to invest in dedicated tooling?

One of the biggest barriers to speed and cost efficiency in drug-device combination programmes can be the need for bespoke tooling for filling, assembly and testing. At PCI, we've removed that barrier by investing in an extensive library of established, validated tooling sets that support a wide assortment of syringe formats, needle-safety devices, autoinjectors, pens and packaging configurations.

Because we already have these tooling solutions in place, clients don't need to purchase or wait for custom tooling to be manufactured. That eliminates long lead times, reduces capital expenditure and allows projects to begin much earlier. It also minimises risk; the tooling has already been proven in production environments, which gives sponsors confidence that their product can move smoothly into fill-finish, assembly, or functional testing without unplanned engineering and validation work.

This readiness is one of the key ways we accelerate timelines. Instead of spending months designing, ordering and validating tooling, clients can leverage our established platforms and our experienced teams to move rapidly from development to GMP production. In today's competitive landscape, especially with biologics and chronic-disease therapies, that speed can make all the difference.

Device assembly and packaging needs vary significantly from clinical to commercial scale. How does PCI maintain flexibility?

Flexibility is absolutely essential. We support early development, niche orphan drugs and clinical supply with multi-platform assembly solutions that handle prefilled syringes, needle safety devices and autoinjectors at low volumes. These lines are ideal for rapid iterations and device refinement.

As programmes move into later phases or commercial launch, we offer mid- and high-volume assembly technologies operating from 3 to 300 ppm. One of our strengths is that these lines can be quickly and cost-effectively retooled for new drug-device combination product formats. That means clients can keep pace with evolving delivery technologies without compromising supply reliability. The ability to scale seamlessly without switching suppliers is something our clients truly value.

PCI has significantly expanded its global footprint. What recent investments should biopharma companies be aware of?

Our global expansion and investment plans have been substantial and very intentional. We've made strategic investments across the US and Europe to increase capacity, strengthen regional supply and address rising demand for sterile filling and advanced drug delivery.

A few highlights:

- **San Diego, US:** We acquired Ajinomoto Bio-Pharma Services' facility, adding proven expertise in sterile vial, syringe and cartridge filling. This site supports complex modalities, including mRNA, LNPs, peptides and biologics, and enhances our US isolator-based filling capabilities, particularly for syringes and cartridges.
- **León, Spain:** As part of a USD 25 million investment plan, we're installing a fully automated isolator-based PFS and cartridge filling line. This high-speed system significantly bolsters our European clinical-to-commercial capabilities.
- **Ireland:** We expanded with a 90,000 sq ft packaging facility in Dundalk and will soon open an additional 80,000 sq ft site at our CityNorth campus. These facilities add major capacity for final assembly, labelling, packaging and cold-chain storage for injectables and drug-device combination products.
- **Rockford, US:** One of our largest expansions includes two new facilities at our Rockford campus. Together, they'll house more than 25 suites equipped with both low-volume and high-speed lines for PFS, autoinjectors, vials and pen-cartridge systems. They also include advanced testing labs and extensive top-load cartoning capability. Both will be GMP-ready early 2026.

Across all regions, our guiding principle is the same: build flexible, future-ready capacity that keeps our clients' programmes moving to deliver life-changing therapies to patients.

With all these investments, how does PCI see its role in shaping the future of injectable drug delivery?

The future is clearly headed toward ready-to-use, patient-centric delivery systems and prefilled syringes are central to that shift. Our role is to provide an integrated pathway that makes it easier and faster for clients to bring these therapies to patients worldwide.

By combining sterile manufacturing, device strategy, assembly, packaging, testing and global supply chain services, we help simplify complex processes and reduce development risk. Clients can move confidently from early phase right through to global launch with a partner fully invested in their success.

Standing at the forefront of this evolution, we see our mission as empowering the next generation of therapies with the infrastructure, expertise and customer service excellence to support them.

Dawn Manley

Dawn Manley is the Director of Global Technical Sales for PCI's Commercial Packaging and Advanced Drug Delivery Business Segments. Dawn has over 25 years of experience in the pharmaceutical industry, with 17 years focused on injectables, including self-administration and combination products. Prior to joining PCI, Dawn held the role of Business Development Leader at Becton Dickinson in their Pharmaceutical division, advancing the relationships with contract manufacturers. Dawn attended nursing school and holds a B.S. in Business Management from North Park University, Chicago, Il.