Driving Sterile Innovation at Scale:
A Conversation with PCI Pharma Services

PCI recently announced the acquisition of Ajinomoto Althea. How does this acquisition enhance PCI's sterile fill-finish capabilities and strategy?

The acquisition of Ajinomoto Althea in San Diego, CA significantly augments PCI's sterile fill-finish offering in North America. With proven expertise in clinical and commercial supply of sterile vial, prefilled syringe and cartridge filling, this strategic addition expands our capabilities, capacities and technologies, including isolated lines, for the aseptic manufacturing of biologics, including mRNA, mAbs, LNPs, oligonucleotides, peptides, and other complex modalities.

The San Diego site has a rich history of high-quality performance with a broad portfolio of globally approved commercial products. The depth of talent represents a step change in the added breadth of PCI's North American SFF services.

These new facilities complement our existing global network and positions PCI as a premier partner for clinical and commercial-scale sterile manufacturing, including an end-to-end advanced drug delivery offering. The acquisition also brings rare capability in high potent vial filling with lyophilisation in the United States.

Can you share more details on PCI's recent investments in PFS capacity and technology?

We are seeing strong demand for prefilled syringes (PFS) and cartridge-based delivery systems, driven by patient-centric therapies and self-administration trends. To meet this demand, alongside the acquisition of Ajinomoto Althea, PCI is investing in new high-speed isolator-based PFS and cartridge technology at our European sterile fill-finish facility in León, Spain.

These investments enable scalable clinical-to-commercial production while maintaining the highest standards of sterility, drug substance yield, and quality. With true flexibility, our San Diego facility can scale from processing 20,000 syringes per batch up to 200,000 syringes. In Europe as part of a $25M investment, our new fully automated PFS isolator-based filling technology can deliver up to 12,000 units per hour, with a maximum batch size of 300,000 syringes.

Our global expansion is guided by client needs for flexibility, reliability, and regional access. By strategically expanding sterile fill-finish capacity in both the U.S. and Europe, we provide our clients with multiple pathways to efficiently supply clinical and commercial markets. From Bedford, NH, Madison, WI and San Diego, CA in the U.S. to León, Spain in Europe, PCI offers harmonised, quality led services of scalable sterile filling solutions for patient-centric drug-device combination products, including PFS, autoinjectors, and on-body delivery systems.

In the area of advanced injectable drug delivery systems and drug-device combination therapies, PCI is a world-leader in the assembly, packaging and testing of these patient-centric treatments and through our recently announced investments, this latest acquisition, as well as building upon our legacy skills, we are delivering an even more comprehensive full end-to-end CDMO service offering.

Part of the global expansion includes new pharmaceutical development laboratories – how will these accelerate formulation and clinical readiness?

Globally we are investing over $10M to expand our global pharmaceutical development capabilities. Briefly, at our Bedford, NH and León, Spain SFF facilities we are re-purposing existing footprint into standalone Development Centers of Excellence (CoE) where we will deliver phase appropriate formulation, analytical, and process development. The purpose of these investments is to provide agility, technical partnership and modality-agnostic sterile development services with a particular focus on biologics. The new Pharmaceutical Development Centres of Excellence at in Bedford and León are expected to be operational early 2026.

This investment is an important step towards PCI Pharma Services offering integrated development and sterile manufacturing to our clients. These science-led centres of excellence will provide clients with rapid, expert-driven development support. By integrating formulation science with manufacturing readiness, we will help clients de-risk technical challenges, optimise scalability, and accelerate clinical trial supply timelines, ensuring a smooth transition from development through commercialisation.

To meet the growing demand for complex formulation solutions, particularly for poorly soluble molecules, how is PCI evolving its pharmaceutical development offering?

Across the industry more and more molecules present solubility and bioavailability challenges, particularly in the case of novel modalities like targeted protein degraders (TPDs), PROTACs, and molecular glues.

To better support these needs, PCI has expanded our development offering through strategic collaborations with expert formulation partners who specialise in enabling technologies. These include advanced particle size reduction techniques, amorphous solid dispersions, spray drying, and lipid-based delivery systems that enhance the bioavailability of poorly soluble molecules.

The goal is to integrate these early development solutions directly into our broader CDMO services. Acting as the primary point of contact for our clients and managing the development process in close collaboration with our partners ensures the molecule is optimised for manufacturability, scalability, and therapeutic performance. Once the optimal formulation is achieved, the molecule transitions smoothly into PCI's GMP manufacturing and packaging services, without the handoffs or delays that often occur between disconnected providers.

This integrated approach not only addresses the technical complexity of modern drug candidates but also simplifies the supply chain, shortens development timelines, and reduces overall project risk, ultimately accelerating the path to clinic and to market for our clients' most challenging compounds.

Previously you reported a $100M investment at your Bedford, NH facility, can you provide an update on the current state of readiness and the capabilities it provides?

With site construction and infrastructure installation now complete, we have commenced qualification activities for our latest, Annex 1-compliant sterile fill-finish facility named 7 Commerce. Among other highlights, the facility houses a late-phase clinical and large-scale commercial isolated aseptic vial fill-finish line with twin 430-sq-ft lyophilisers featuring automated loading and unloading systems.

Providing additional capacity to accommodate our recent and anticipated growth, the robust, high-speed integrated filler can produce batches of up to 300,000 vials at nominal speeds up to 400 vials per minute. Other best-in-class production infrastructure at the new site includes Smart Fill modules that maximises product yield and prevent underfills, SKANFOG® decontamination technology, and comprehensive quality control systems such as 100% check-weighing and inline camera inspection.

This high-throughput operation enables robust support for lyophilised and liquid fill formulations and is the fifth high-throughput, commercial sterile fill-finish facility that we have built in the last five years. As it comes online, the new facility further bolsters our capacity and capabilities for the sterile fill-finish of late-phase clinical and large-scale commercial small molecule and biologic drugs – including life-changing, high-value drug products such as mAbs, fusion proteins and peptides.

As the line approaches GMP production this summer, we are actively onboarding client programmes, delivering end-to-end support for sterile injectables, from formulation and lyophilisation cycle development to commercial launch.

What are PCI's capabilities in final assembly, packaging, and device integration for combination products?

PCI offers comprehensive, scalable solutions for drug-device combination products, from aseptic filling to final device assembly, testing and packaging. Our device-agnostic approach allows us to support a wide variety of delivery systems, including autoinjectors, wearable injectors, and pen devices. We ensure regulatory compliance through robust device assembly validation and human factors considerations. Our investment in advanced packaging auto-mation, labelling, and serialisation capabilities ensures supply chain security and market readiness for combination products across global markets.

PCI has made significant investments to expand its injectable manufacturing and packaging capabilities across its global network. How do these investments position PCI as a leader in delivering end-to-end solutions for patient-centric therapies, and what are the key innovations that differentiate your approach in this space?

At PCI, our purpose is to support the development and delivery of life-changing therapies. Over the past several years, we've made strategic, global investments to significantly expand our sterile fill-finish capabilities and advanced drug delivery / drug-device combination product packaging infrastructure, enabling us to meet the increasing complexity and scale required by today's injectable drug products.

These investments include the addition of advanced isolator-based aseptic filling lines, a high-capacity lyophilisation suite, and the expansion of prefilled syringe and cartridge capabilities across both the U.S. and Europe. Additionally, we've built dedicated infrastructure to support final assembly, labelling, and packaging for a wide range of drug-device combination (DDC) products, such as needles safety devices, pens, autoinjectors and wearable systems. This ensures we can manage everything from early clinical studies to global commercial launch, all within a fully integrated end-to-end model.

What truly differentiates PCI is our ability to align pharmaceutical development, aseptic manufacturing, and device integration. By embedding human factors engineering, regulatory foresight, and scalable technology into our model, we help clients de-risk development while accelerating time-to-market.

PCI's strategic expansions both through acquisitions like Ajinomoto Althea and organic investments in PFS, lyophilisation, and drug-device assembly ensures we can offer scalable solutions from early-phase development through to commercial launch. Our integrated service approach, combined with global reach and technical depth, enables PCI to support our clients and accelerate their path to market with speed, quality, and confidence. Ultimately, these investments reflect our commitment to patient-centric innovation delivering therapies in formats that promote ease of use and improve health outcomes for patients globally.

John Ross

John Ross, SVP, Drug Product Development & Manufacturing at PCI Pharma Services is a member of the strategic leadership team at PCI focused on drug product pharmaceutical development, clinical trial materials manufacturing, and ongoing commercial supply for sterile fill-finish (vials, syringes, opthalmics) and novel oral dose formulations. Spanning over 25 years in pharma, including both commercial and operational roles, John has spent most of his career in the CDMO sector including as Chief Operating Officer of Contract Pharmaceuticals Limited and President of Mayne Pharma US (parent of Metrics Contract Services). Early in his career, John worked at Eli Lilly in Finance and in Sales and at PwC as a supply chain consultant.