A Reborn CDMO Helping Partners Navigate the Product Development Continuum

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Abstract: *Pharmaceutics International Inc (Pii) is returning to its contract development and manufacturing organization (CDMO) foundation in order to help partners navigate product development from beginning to end.*

Initially founded in 1994 as a services organization helping partners solve formulation development and processing challenges, Pii gradually adopted a dual strategy, offering services and proprietary products, relentlessly utilizing and leveraging our deep understanding of pharmaceutical sciences and regulatory approval pathways. The goal has always been to deliver high-quality medicines to partners, physicians, and patients.

When pressures on the generics market increased, we moved quickly to diversify our portfolio to include both partner and self-funded R&D programs. More recently, driven by our belief in the fundamental purpose of the pharmaceutical industry—to enhance the lives of patients worldwide—we determined that Pii could have the most significant impact by returning to our CDMO roots, supporting partners' product development strategies across the continuum.

The bricks of Pii's foundation are made from our expertise in pharmaceutics. For over 25 years, we have been supporting our pharmaceutical partners (from virtual to multinational) with extensive technical capabilities, know-how, and the highest level of customer service. With more than 400 development programs completed, Pii's scientific team has extensive experience working with drug substances representing a range of physicochemical characteristics (and challenges). Our specialized capabilities, multi-product facilities, and deep knowledge allow us to work with potent compounds and hormones, develop complex dosage forms, and support varied manufacturing processes.

Today, Pii provides drug development solutions to global pharmaceutical clients, with services including preformulation testing, formulation development, and clinical and commercial manufacturing of parenteral, solid, semi-solid, and liquid dosage forms. Core services are supplemented with quality management systems, analytical support, and expert regulatory guidance.

Our focus is on small- to medium-scale manufacturing processes, which we support with a unique combination of agility, flexibility, innovation, and responsiveness, whether those products are conventional small molecule drug products, biologics, or other unique entities.

For R&D and technology transfer projects, our agility and responsiveness make us an ideal fit for smaller companies with small, highly motivated, and agile scientific teams that really engage in the collaboration process and are empowered to evaluate the data and drive the decision-making process. Pii is that same type of agile entrepreneurial company, and as such similarly structured companies can potentially realize the greatest benefits of a relationship with Pii.

On the commercial side, we align best with customers that have one—or just a few—products and are looking to enter the market in the most efficient manner possible. We can help them figure out how to expedite approvals and provide guidance on developmental and regulatory strategies to ensure that approval applications are sufficiently flexible for a range of commercialization scenarios. This approach is particularly beneficial for companies with little available working capital that need to start slow and be able to respond quickly—from a regulatory and supply chain standpoint—if demand takes off faster than expected.

While Pii prides itself on our science-based approach to product, formulation, and analytical development, we also realize that we need to go beyond the science to understand the challenges that our customers face. Our ultimate goal is for all of our partners to view Pii as a natural extension of their development operations and commercial supply chain—to function as a trusted and reliable strategic partner. This is facilitated by our world-class regulatory affairs department, which advises our clients on enabling strategies, approval cycle time reductions, and where common and uncommon issues and risks might occur, not just with respect to manufacturing and supply, but also with FDA approval of their applications.

In addition, we are consistently building in proactive elements that will increase the likelihood of first cycle approval and reduced timelines for post-approval regulatory moves. This approach leads to better overall strategies and the delivery of products on time and with the flexibility to quickly adapt the scale of manufacturing to meet changes in market demand.

We do not treat technology transfer merely as a theoretical exercise, but have personnel with years of first-hand experience using a well-established method for breaking down problems into their constituent parts so that actions can be identified that will keep programs moving forward. Pii seeks to learn as much as possible about our customers' timing constraints, including why these constraints exist. We also investigate our customers' working capital strengths and challenges and determine how we might be able to provide solutions.

This empathy, supported by over 25 years of extensive experience tackling issues related to tech transfer and scale-up, enables Pii to rapidly provide solutions so that our customers can bring their life-changing and life-saving medicines to the market more rapidly than they otherwise could. Our relentless approach to development and tech transfer is unique and is welcomed by our customers.

We have recently intensified our focus on quality and service excellence. Quality is embedded at every level of Pii, but we are pushing our established quality organization and proactive quality culture further, determining how we can best anticipate and exceed customer expectations at each stage of an R&D project or commercial product launch and supply.

Our quality systems are driven by process performance and product quality monitoring, corrective action and preventative action (CAPA), change management, and internal, customer, and regulatory inspections. Every project begins with the establishment of mutually agreed key performance indicators (KPIs) in consultation with the customer, and performance data are analyzed and reviewed monthly by our Quality Council to ensure that we exceed cGMP requirements and our customers' expectations at every step in the program's life cycle. We recognize that challenges will arise and ensure, using KPIs, scorecards and open and transparent lines of communication, that we proactively address potential program and delivery issues before they become problematic.

With our unique synthesis of pharmaceutics experience, service excellence, and entrepreneurial adaptability, we are able to say "yes" to customers who have heard "no" too many times (for too many reasons) from other, often larger, CDMOs. We bring our wide spectrum of core competencies together in a unique offering that enables us to provide solutions tailored to each of our valued customers.

Meeting the needs of our customers today and into the future also requires continual investment in new technologies and capabilities. Pii continuously adds offerings at the small to medium scales for clinical trial and commercial manufacturing for both oral and parenteral drug delivery technologies. In some cases, investments are made to directly support a customer with a specific problem, because they enhance our ability to support other Pii customers. We also monitor developments in the industry to identify opportunities for proactive investment in new technologies. Ideally, we look for trends involving the unique confluence of different Pii capabilities and determine how best to integrate our core capabilities to provide optimal solutions as quickly as possible.

Recent investments have included expansion of our aseptic capabilities to provide lyophilization cycle development services and CTM fill/finish supply. Using our integrated preformulation and lyophilization cycle development capabilities, we can support customers in the early-phase development of this technical challenging pharmaceutical manufacturing process, providing them with a solution that can be readily transferred and scaled up for CTM or commercial manufacturing.

The addition of a state-of-the-art, fully robotic, automated AST filling line that can support small- to medium-scale production of syringes, vials, and cartridges to our already substantial aseptic fill/finish capacities and capabilities ensures that we can support projects involving both small molecule parenterals and biologics. The highly efficient, flexible, and adaptable line can be used to produce anywhere from a few hundred to 50,000 vials per day.

Going forward, Pii will continue to leverage our pharmaceutics background, extensive experience, and customer service excellence as we attract a growing number of partners. We are currently taking the necessary steps, backed by the right combination of people, processes, and geographic distribution across cities and regions that serve as centers of pharmaceutical development.

As a CDMO that has had experience developing and manufacturing our own products, we have stood in our partners' shoes. This experience is particularly important when it comes to development scale-up and technology transfer. We also investigate our partners' timing constraints, working capital strengths, and challenges and determine how we can provide the optimal solutions. This empathy, supported by over 25 years of extensive experience tackling issues related to tech transfer and scale-up, enables us to rapidly provide solutions so that our partners can bring their life-changing and life-saving medicines to the market more rapidly than they otherwise could.

We intend to build on this value over the next 10 years by becoming an early adopter of technology and an investor in leading-edge solutions, including novel drug delivery technologies and more reliable drug manufacturing platforms, such as continuous processing and next-generation medicines like cell and gene therapies.

Most importantly, Pii will continue to be engaged in and inspired by the work that we do. We know there is so much more at stake than any one particular activity we are pursuing at the moment. Our work isn't about just one method or one formulation. The products we help to produce—provided that they meet regulatory requirements and fill an unmet medical need—will make a real difference for people. Products, Partners, and Patients are the ultimate focus of everything that we do.