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Pii

Pii

Pharmaceutics International, Inc

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Pharmaceutics International, Inc: Getting Back to its Roots

Pharmaceutics International, Inc (Pii) has continuously evolved throughout its history as market and patient needs emerge and fade. There have been times when Pii developed and manufactured its own products and times when Pii delivered these services to drug sponsors. Pii started in 1994 as a contract drug development solution provider, focused primarily on solid formulations. Throughout the early- to mid-2000s, the company expanded its manufacturing capabilities at its Hunt Valley, MD, campus, which now includes four cGMP- and FDA-inspected facilities, four integrated aseptic filling suites, and 70 manufacturing suites. However, as Sridhar Krishnan, Pii's Senior Vice President, Operations and Strategic Initiatives, recently told *Drug Development & Delivery*, manufacturing is not solely where Pii wanted to be, so the company made a concerted effort to get back to its contract development and manufacturing outsourcing (CDMO) roots. As a CDMO, Mr. Krishnan says Pii can deliver on its passion for helping drug sponsors solve challenging issues associated with complex formulations, drug products that are difficult to manufacture at scale, or formulations that pose high risks to quality and safety, like oncology drugs, highly potent compounds, non-aqueous parenterals or steroids.

Q: Based on this evolution, how do you now describe Pii's business model?

A: Our model is simple: We respond to patients and market changes in real time. Clients working with large CDMOs have a predetermined game plan looking out 2 to 4 years. We don't delineate a schedule to an activity, and we are not selective about onboarding based on a predetermined schedule. We work in real time for the patient and the client. Additionally, we are flexible and agile, providing solutions to complex problems that you cannot get from other large CDMOs. Our flexibility allows us to take a drug from cradle to grave; from small to large batches. And, because our model is responsive to patients, healthcare providers, and market changes, it is absolutely a sustainable model. Sustainability is the construct for everything we do. The outcome of sustainability is increased capacity. Capacity is, of course, our ability to develop and manufacture drug therapies: how many projects we can effectively manage at any given time. Sustainability is applied to every resource and staff area we have available at Pii. We continuously develop leaders throughout Pii, increasing our capacity to apply more leadership to problem-solving and delivering better results faster for our clients and patients.

Q: Exploring this concept of sustainability a bit further, how might this impact getting a drug to market faster?

A: When I think about sustainability, it's all about reducing lead time for a drug to come to market. There are several dimensions to sustainability at Pii. These are having a strong foundation in a safe environment for our staff, business continuity, crisis management, corporate social responsibility beyond our finances, and operational excellence for continuous improvement. These layers work together to make us a flexible CDMO and create capacity creatively to reduce lead times. Growing capacity comes in different forms, such as leadership capacity, scientific capacity or manufacturing capacity.

Q: Can you provide an example of how Pii helped a client reduce its lead time?

A: When a CDMO accelerates the timeline to deliver results, it adds agility to the healthcare supply chain, making it more responsive to drug sponsors and patients. An example of this is Cure HHT, a foundation representing a group of patients and their families, suffering from Hereditary Hemorrhagic Telangiectasia. A pharmaceutical company discovered side effects during clinical trials that might mitigate or even cure the rare hereditary blood disorder, but due to a variety of unexpected circumstances, the program was never completed. However, a clinician who had worked on the original project began working with Cure HHT to re-establish the project. An IND application was filed, but the FDA rejected it for lacking adequate testing and controls. The molecule, a BCS Class II, had originally been developed as 200mg and 400mg tablet formulations for a different indication. The client believed that a 25mg dose was needed for the rare disease, but they required a fully developed, tested, and properly documented formulation and regulatory support to properly file an IND application with the FDA. The most significant challenge was the work needed to be done in an extremely short timeframe. Pii's development, analytical, CMC experience, and ability to work collaboratively for rapid solutions overcame the challenges and filed the IND 14 days after starting the project.

Q: What does it mean to "reimagine" drug development?

A: When I think about reimagining drug development, I think of it in the context of the current pandemic. The whole thing has opened up a huge debate as to how companies can rethink their capabilities and strategies. Drugs needed to be developed and distributed. To reimagine something, especially something as complex as bringing a scientific concept to commercialization, you must start with the question, "what if?" COVID-19 has delivered a devastating blow to humanity. But the pandemic has also served as the catalyst for "what-if" questions. The drug development process has been reimagined as something that can be done in months rather than years. And this success has been achieved by more than just money. Organizational structures, processes, FDA responsiveness, clinical trial recruiting, and protocol execution were transformed in response to the urgency for a vaccine and treatments. The COVID vaccines development effort caused us to reorganize to co-develop a drug and coordinate with clients to make sure to reduce dependencies on sources, such as ingredients. The silver lining to the challenges of the pandemic is adoption of new accelerating technology to reduce commercial development time, bringing important products to patients faster. Also, we are managing knowledge and analyzing data more effectively and efficiently with integrated data acquisition systems. I am excited to apply the lessons learned from this rapid vaccine development and mRNA technology and apply them to other diseases and healthcare challenges. So, because of COVID-19,

we are reimagining everything – from technology to ways of working together to be more agile and flexible.

Q: Will the speed of developing a COVID-19 vaccine make it difficult to return to traditional development timelines?

A: When you learn to run, it is difficult to go back to walking. Before 2020, we only talked about what it would take to significantly reduce the time to bring a drug to market. Now that it has been achieved, many of the reasons given for the time it has traditionally taken to develop a drug therapy are no longer valid. It will be difficult for us all to accept going in reverse. Also, the credit for these recent COVID vaccine achievements goes to the people in this industry. I work with incredibly gifted people, their tremendous knowledge and experience directs their efforts. Even when the answers are not clear, they are able to navigate challenges with scientifically sound solutions.

Q: Based on what you just described, how will the role of a CDMO change? And more specifically, how will Pii adapt to that change?

A: Traditionally, CDMOs have been considered service providers. However, I see the role of CDMOs as collaborators in the development process and the entire pharmaceutical ecosystem, or supply chain. Rather than a contractual relationship, the CDMO is a partner that takes the time to understand what outcomes the drug sponsors are seeking and how patients will be better served when a drug therapy is successfully delivered to them. This requires business continuity between the CDMO and the drug sponsors, and when this is achieved, amazing results can be achieved faster. At Pii, we believe challenges frame opportunities, and so our culture is one that embraces, even seeks, complex development and manufacturing programs. We enjoy working with complex formulations, and this has given us the knowledge and skills to solve problems associated with them. It all comes down to bringing a drug to market safely and efficiently, but still ensuring compliance. To quote a former colleague: "Compliance is not an option." ◆