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CEO SPOTLIGHT: PETER DEYOUNG

With a track record as a trusted service provider with experience across varied technologies, Piramal Pharma Solutions is a partner of choice for innovator and generic companies worldwide.

Peter DeYoung, CEO, Piramal Global Pharma

Piramal Pharma Solutions (PPS) is a contract development and manufacturing organization (CDMO) offering end-to-end development and manufacturing solutions across the drug life cycle. It serves customers through a globally integrated network of facilities in North America, Europe and Asia.

Piramal's comprehensive range of services including drug discovery solutions, process and pharmaceutical development services, clinical trial supplies, commercial supply of APIs and finished dosage forms. The CDMO also offers specialized services such as the development and manufacture of highly potent active pharmaceutical ingredients (APIs), antibody-drug conjugations (ADCs), sterile fill/finish, peptide products and services, and potent solid oral drug product. *Contract Pharma* recently caught up with Piramal Pharma Solutions' CEO, Peter DeYoung, to talk about company highlights and CDMO market trends in general.

Contract Pharma: What led you to your leadership role as chief executive of Piramal Pharma Solutions?

Peter DeYoung: I have always had an entrepreneurial bent—I formed my first startup while in high school. Sometimes you learn through failure and this venture was a tremendous learning opportunity. My undergraduate degree in engineering at Princeton and my graduate degree in business at Stanford helped me learn how to think, how to work with others and exposed me to really inspiring peers. Early in my career I worked at organizations known for investing in people and which provided platforms to work with and learn from great companies.

I learned a lot about consulting, investing and leading change

in Pharma through my time at McKinsey and Blackstone. I was also fortunate to spend some time at a biotech as they prepared to go public. I gained exposure to better understand the needs of patients through the World Economic Forum's Global Health Initiative. Being raised in a multi-nationality family, I have always looked to learn about other countries and see the strengths one can benefit by harnessing diversity. I have been fortunate to have been able to live and work in the U.S., Switzerland and now India.

Being part of and leading values oriented, mission driven, dynamic and transformative organizations motivates me. While I felt I had learned a lot across these collective experiences, I wanted to more directly drive change. This led me to join the Piramal Group. It's now been more than 10 years since I joined. Immediately prior to my current role, I ran Piramal Critical Care (PCC), which is our complex hospital generics business. In July 2019, PCC and Piramal Pharma Solutions (PPS) were brought together and I was given CEO responsibility for Piramal Global Pharma which is comprised of both PCC and PPS. I am excited with what we can do for patients, customers, employees and investors with this platform.

CP: How has Piramal's business evolved in recent years?

DeYoung: We are in a constant state of evolution, which is dictated by the needs of our customers and their own diverse requirements. We've recently expanded into a few areas that are new for PPS, including peptide products and services, as well as development and manufacturing services for biologics. We've also seen more requests for integrated projects and we've evolved to strengthen the way our organization approaches them on a global basis. That leads to what I believe is most unique about us—our expertise in global integrated services, how we can successfully blend services located in the east and the west, how we have built a project management team that can act as a single point of contact on projects that touch two, three, or even more of our sites.

CP: What are some of highlights from the past 12 months?

DeYoung: We've done quite a few interesting things in acquisitions, expansions, investments and corporate initiatives. We acquired Hemmo, one of the few pure-play synthetic peptide API manufacturers in the global marketplace. Hemmo's capabilities give us access to the growing peptide API market and enhance our integrated services offering. We also made a minority investment in Yapan Bio, an India-based CDMO specializing in large molecules, which adds capabilities in vaccines, gene therapies and monoclonal antibodies.

During the year we committed major capital to expansions and improvements of many of our sites, including added capacity at our API facilities in North America, India and the UK; added capacity at our antibody-drug conjugations site in the UK; and installed new drug product formulation and manufacturing equipment in North America and India.

On the corporate side, we are the process of executing a demerger of our pharma business to separate it from non-related businesses. This will simplify the corporate structure and give the pharma business an easier path to organic and inorganic growth. We also launched a global Client Advisory Board which features representation of more than twenty-five of our clients. This board meets regularly to discuss ways in which we can grow or adapt our business to meet our clients' current and long-term needs.

CP: How have you had to change to adapt to COVID?

DeYoung: First and foremost, we had to create new policies and procedures to ensure the health of our staff. While we are an essential business and were able to remain open, we did everything in our power to keep our people safe. With 15 facilities and offices around the world, that was a challenge, especially when you consider how many different national and local restrictions we had to comply with. But we did, successfully.

The supply chain has been a major issue for the entire industry, too. We were forced to change the way we sourced raw materials, not only with secondary suppliers but tertiary partners as well. Shipping was an issue, with both the cost and the timelines on freight posing a major problem. But the services we provide are essential to patients, so we found ways to persevere.

Onshoring across regions is key. We are working on increasing our onshore capabilities in both North America and Europe. The way we conducted everyday business had to change as well, with remote meetings becoming the norm for the business development team and virtual inspections taking over on the regulatory side.

CP: What are some key trends and challenges on the injectable development and manufacturing side of your business?

DeYoung: Increasingly, we see a trend in the area of biologics and biosimilars for targeted drug therapies with a focus on low dose volume. We're seeing quite a bit of activity in nanoparticle-based formulations with biodegradable polymers or lipid-based formulations for better delivery. Our sterile fill/finish site in Lexington, KY, is also seeing new inquiries for conventional oncology drugs and antibiotics, with demand for improved formulations targeting newer indications and strains that have gained resistance. Integrated programs that include injectable drug product are trending as well, with many customers looking for the inherent benefits of working with a single organization through multiple services. Operationally, we are putting more focus on automating processes wherever we can to increase our efficiency.

The key supply chain challenge is the fact that we cannot easily or quickly substitute materials because we are a regulated industry—especially when product contact or secondary product contact surfaces are at play. We have been able to successfully adapt and overcome this by working with key supply chain vendors on ordering strategy, working with our clients to risk assess and perform any required work to demonstrate equivalency of the substitute materials, and by thinking outside the box to be compliant yet utilize creativity when it comes to finding alternatives to allow manufacture of critical need drug products.

Post-COVID lock downs, we have seen an uptick in requests for proposals which reflects the domestic onshoring trend, and we are getting more requests for speed to market and expediting work. However, the definition of "domestic" varies based on the location of our customer and their end market, which plays to our strengths with a global delivery network. We are also seeing an uptick in inquiries as some customers look to de-risk from China to India or from areas affected more acutely by the current conflict. Due to our size, core competencies and plant design we have been able to adapt and overcome these challenges and meet our clients' needs.

CP: How about on the solid dose end of the business? What are the trends here you're noticing?

DeYoung: Challenges on the solid dose end vary depending on the nature of the customer and the development stage of their molecule. One of the recent trends which we observe is that our customers would like to have a well-developed formulation earlier in development. While some customers still prefer easy-to-dose Phase 1 formulations, such as neat drug-in-capsule presentations, more customers now prefer a capsule or tablet dosage form that can cover a wide dosage range in Phase 1, but also has the ability to accelerate Phase 2 dosing. This presents unique challenges with respect to batch sizes; we need to develop and optimize formulations and must have enough API available to support it.

At our Sellersville, PA, site, we are uniquely positioned to support our customers to develop products for early phase clinical dosing in a material-sparing manner. Detailed pre-formulation and drug-excipient compatibility studies are done to converge the composition and manufacturing process in an expeditious manner.

Additionally, many of our customers prefer a dry granulation approach to avoid the stability challenges commonly associated with wet granulated formulations. Having a robust capability to adopt dry granulation strategies, including roller compaction, enables product development across all stages. Having this capability in Sellersville helps us address another trend we notice: onshoring. A number of our customers serving the U.S. market prefer to have a U.S.-based site to meet the requirements for tender business.

CP: How can development and manufacturing projects benefit from CDMOs like Piramal?

DeYoung: It's a combination of things, but it all starts with our people. We have built a really strong team of talented people across all our service areas. They're smart, enthusiastic and both customer- and patient-centric. We've made a point over the years of focusing on specialized areas of the CDMO universe.

Take high potency as an example. We acquired a site that was experienced in high potency APIs and we built on to it from there. We have crossover capabilities at our other API sites as well. We have similar expertise in antibody-drug conjugations and HPAPI, and we are solid in project management. If you put all that together it validates our expertise in integrated services programs. It takes smart people and defined processes to weave together programs that cross sites with multiple layers of tech transfer, and to get it done in a timely fashion with the necessary quality, too.

CP: What are your customers' key project concerns?

DeYoung: Most customers are concerned about lead times and their CDMOs delivering as promised. On time and in full is a mantra of our industry for a reason. As discussed earlier, supply chain is a major issue. Customers are feeling the supply chain pinch across their organization and want assurances from their suppliers; that's why local production and strategies to increase resilience have become such hot topics. Quality and IP protection are always a concern, but they are givens; if you don't excel in those areas you cannot be considered a serious player in the CDMO game.

CP: Broadly speaking, what are some of the current pharma/biopharma trends impacting CDMOs and services?

DeYoung: Capacity, capacity and capacity! So many companies are sold out and facility expansions take time. It's especially telling when you consider how many programs are on fast timelines; the bottleneck is real and difficult to overcome. Think about the accelerated trials currently going on. There are more orphan drug projects and more development programs designed to address unmet medical needs. All these things clog the development pipeline. Then you have to factor in how we are seeing faster development to commercialization in many programs. It means both innovators and CDMOs need to be prepared for launches earlier than they were in the past.

CP: What are some other challenges service providers like Piramal face in today's outsourcing market?

DeYoung: In addition to everything mentioned above—supply chain, onshoring, lack of capacity, demand for integrated projects and shortened timelines—talent acquisition and retention is a huge challenge. There are not enough great candidates out there for the number of important positions that need to be filled. Retention is tough too. When you have good people, you have to keep them. We spend a great deal of time addressing this challenge. It's vital to our short- and long-term success.

CP: What are your goals for Piramal moving forward?

DeYoung: We want to expand, add capacity and fill out any gaps in our service offering. We want to continue to add talent at all our sites around the world. We want to grow, both organically and through acquisition. We want to improve our infrastructure and systems to support our growth. Sustainability is important to us and we are emphasizing it throughout the corporation, from Environment, Social and Corporate Governance to social consciousness. Adding new customers is, of course, vital to our organization, but we are also emphasizing global Key Account Management so that we can be a better partner for our best customers.

CP: Lastly, any other company news to report or anything else you'd like to comment on and let Contract Pharma readers know about the business?

DeYoung: You've probably heard us talk about Patient Centricity over the last few years; that's a core ethos of the company and vitally important to us. We've appointed a Chief Patient Centricity Officer, Stu Needleman, to take responsibility for the initiative on a global basis. Our goal is to instill a patient-first perspective to what we do. We have Patient Awareness Councils (PACs) at all our sites who are charged with making the concept a reality on a local level. In fact, we just awarded our second annual Award for Excellence in Patient Centricity to the PAC at our Grangemouth site for their work educating the site staff on how antibody-drug conjugates compare to traditional oncology treatments.

In terms of capabilities, we recently increased our stake in Yapan Bio, enhancing our position in the large molecule market, and we've made a big play into the peptides market. In addition to the expansions/additions at our sites in in the U.S. and UK that I mentioned earlier, there are more coming in India and the West. We should soon begin to see the fruits of the labor associated with our demerger. It's safe to say there's been a lot of activity and there's a lot more coming, too. **CP**