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Patient Centricity: The New Nexus For CDMOs

A Patient-centric journey through the pharma supply chain

In the last decade we have a seen a progressive trend across the pharmaceutical industry, with big block-buster drugs gradually becoming less prevalent and a shift towards smaller volume therapies, often for niche patient cohorts. This trend has primarily been driven by the fact that much of the easier, less complex drugs have already been made, with research now looking at more complex compounds and orphan designations. But whilst this change has been necessitated by the discovery pipeline, it has also brought about a new age of more targeted therapies, and in some cases, even personalized approaches and this has profound supply chain implications[i]. The net result of these changes is that the patient is becoming much more central to development as therapies target smaller patient cohorts[ii].

Running parallel to this development, we have seen the patient experience in clinical trials become an important consideration, with adaptive trials and patient engagement and retention tools becoming increasingly common[iii]. Originally this had the vision of ensuring compliance and robust data in trial design, but the industry has shifted quickly up the value chain so that patient, healthcare provider and sponsor can have access to vital information through a mixture of patient selected devices, and eCOA tools[iv].

Accelerating this development was the enactment of 21st Century Cures Act – which has placed an acute emphasis on patient centric development, personalized medicine and increasing utility of real-world evidence. Understandably, patient-centricity has also gained considerable traction in adherence for commercial products and we have seen great strides made by both packaging and delivery device manufacturers. The patient here is rightly now viewed as the direct customer innovator companies are designing products for, and therefore, the user-experience in real-world settings is equally as important as traditional therapeutic efficacy – any therapy is fundamentally only as good as its correct and timely use by patients.

A third key development that has brought the industry to the nexus of a new age is the tremendous desire now coming from patients for greater knowledge about their own care, access to their own data, and transparency in the therapies they receive. The engaged patient is taking back control of their own treatments and using

a combination of apps, remote healthcare access and the internet of connected things (IoT) to better manage their conditions – from simple tools for calorie counting through to complex devices that monitor dose, response and lifestyle factors.

But the future of this concept is transferring it through all parts of the pharmaceutical supply chain and the industry must move beyond working in silos – it's also why Piramal has moved ahead of the curve to become a patient-centric CDMO. But before exploring the implications of this shifting approach, we should take a step back to consider what it means to be patient centric.

A recent study published by Astra Zeneca yielded a collaborative definition of patient centricity as "putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family"[v]. This definition does not solely come from industry, but was driven by direct consent from the end-users themselves – the patients. It is important to note this distinction: in order to be truly patient-centric in thought and deed, one must hear *directly* from the patient.

So with this definition in mind, we explore the potential impact on the CDMOs that support the industry's efforts by efficiently helping discover, develop, manufacture and test new or improved drugs. Every dose decision taken in development, choice of delivery vehicle, administration instructions and packaging all have a direct impact on the patient.

Patients represent the ultimate beneficiaries of these services, and we must place their needs at the heart of the conversation. Understanding their needs – and building an organization that is dedicated to addressing them – is the core of patient centricity. This concept holds true regardless of whether the organization is a pharmaceutical company, biotech, healthcare service provider, digital patient engagement specialist, CRO or even a contract development partner.

For CDMOs like Piramal, this means a new mindset and culture for the organization defined by a fundamental objective of reducing the burden of disease, and how we approach developing and commercial drug substance and product. At every level, the internal staff must transform their identity, shifting from self-identifying as a manufacturing company to thinking and acting like a service company. Of course, the company will still produce products, and it must remain driven to deliver for its customers. But the emphasis shifts from what those products are in and of themselves, to what the products can do for patients. Only by adapting this sentiment as an ethos can an organization become truly patient centric.

At a practical level this means we need to deliver new engagement schemes throughout the workforce so that employees understand the importance of what they do, and how their efforts have a real-world impact on patients. So for example, at the project initiation stage, teams should be briefed on the therapy area, patient population and the impact of the drug. Then to empower employees to meet the people the product will help, patients are brought in through customers to share their journey about how the drug has helped them.

One key initiative that we have pioneered at Piramal to deliver this type of true patient centricity is the creation of Patient Awareness Councils across global sites. These new bodies comprise cross-functional executives and employees, and they act as the patients' advocates and ambassadors for patient centricity through development and commercialization. Their role is exploring in detail the impact of manufacturing choices, development criteria and approaches have on the patient. Moving into the future, they will have an extremely important role to play in every project, and are tasked with creating, managing and monitoring the best practices for applying patient centricity to the entire organization. Ultimately, the goal is to drive patient centricity from the bench to the plant.

This concept is extended to after visits and increasingly we will see 'patient profiles' being brought into the CDMO space – which are essentially daily maps of the patient's experience to better inform the drug development process. It's a key part of the team's discussions with patients, as we want to get a closer picture of the patient. At present, these types of initiatives only run in commercial drugs, but it won't be too far in the future to see this type scheme delineated into early phases of development. Moving forwards, this will also mean creating new guidance – developed with advocacy groups, ethics & compliance, as well as legal – for

employees on how to interact with patient groups. The challenge is to accept that this approach takes time, because it is a change in culture and in the 'way we work' running through the business even into the manufacturing teams.

In other parts of the industry we have seen Patient Advocacy Training groups created – e.g. Sanford Research Institute introduced the Patient Advocacy Certificate Training [PACT] course – and our hope is that the industry will embrace these to ensure it has the right culture and philosophy to achieve true patient centricity[vi].

The definition of patient centricity, as defined by the aforementioned Astra Zeneca study, requires pharma to 'put the patient into your working standards'. So for Piramal, this means ensuring that the patient first approach also extends into how we as an industry react to helping patients get access to the therapies they need.

As an example, a customer recently approached us to manufacture a drug for an orphan indication that affects just 3 patients per 100,000 births. Therefore, the volume requirement was very low, and it did not make commercial sense for the (Lexington) site to manufacture the injectable drug. The treatment was targeted towards a pediatric population, with a genetic disease that greatly shortened life expectancy. There was no other treatment available on the market for this disease, but in our endeavor to make this treatment available for pediatric patients, we agreed to partner with the customer to manufacture and supply clinical batches of this injectable drug and went on to support commercialization of the drug. In the future, we will see more examples of this, as CDMOs back up their patient centric credentials with a commitment to doing the right thing by patients, even in cases of little or low profit. Similarly, putting in place patient centric cultures within the workforce at CDMOs. So for example, when the FDA recently approached our customers to increase production of a generic injectable drug used in the treatment of a variety of cancers – due to issues with another manufacturer – we immediately stepped up production. Adapting the site for higher volumes, the team worked additional shifts to accommodate the extra batches that were required to fill the gap. So, patient centricity is not just about tangible factors, but also recognizing that the responsibilities we have extend beyond the delivery of pharmaceuticals, and we have a duty to adapt to the wider conditions facing our patients.

Drug Discovery

Another area that, even just a few years ago would have seemed unlikely, is the growth of patient and charity organizations directly funding discovery programs of biotechs and early stage researchers. Understandably, these groups have an acute focus on patient centricity, and in the future, they may take a more active role in the supervision of outsourcing with the goal of delivering the greatest cost benefits and, more importantly, partners that offer the Investigational New Drug the best possible chance of success.

Transparency

Running parallel to the patient centric approach we are taking, there is the trend globally of the 'informed patient' – people want far greater depth of information than before, and not just on clinical trials data and side effects, but also running into the manufacturer's reputation for quality. What started as a trend out of the internet that was breaking-down the traditional silos of medical information has now shifted to a focus of life cycle impact of medicines. This trend has been accentuated by many of the FDA infringements seen in the last few years, and a growing awareness of the role that outsourcing plays in the patient supply chain. Whilst scandals like adulterated heparin undoubtedly cast a long shadow on the industry, the move towards full patient transparency in the supply chain is shining a new light on good manufacturing practice (excuse the pun). In the future, it may become

greatly more common for license holders to share and celebrate the manufacturing records of CDMO partners. An early example of this type of trend can be seen with the recent serialisation initiatives in both Europe and the United States. These are already delivering much greater trust, and it is translating through to the patient as there is greater visibility on every drug's journey - it can be tracked moving between manufacturer, distribution channel and all the way to pharmacy[vii].

What the patient will want to see is the best possible regulatory standards are adhered to, but also, that their therapies are made with partners that look to go beyond these standards using approaches that included PAT, QbD and continuous processing. Undoubtedly, the future will see patients taking an increasingly active interest in exactly how, when and where their vital therapies are discovered, developed and manufactured.

Environmental footprint

We are not there just yet, but the next natural evolution of this trend will be for the patient to be assured that not only are their therapies safe and effective, but they have also been made with minimal environmental impact in mind, from reducing the number of process steps and hazardous chemicals to the safe disposal of waste products. It does not take one to look too far into the future for us to envisage the use of some kind of environmental certification to be placed upon CDMOs that could translate through to patient packaging. Certainly, in devices and packaging, the industry is already heavily advanced on its journey towards extrapolating not only its immediate environmental challenges, but the full life-cycle impact[viii].

Conclusion

The implications for pharma of patient centricity have been well documented but what is under appreciated is the new significance it will bring to bear on the CDMO sector – especially with the new types of drugs coming through the pipeline. So rather than being fundamentally a b2b facing proposition, increasingly, contract service providers will view the patient as the end consumer – and never 'just someone we simply sell to'. This will be a relationship built upon mutual understanding and partnership. The pharmaceutical supply chain is increasingly opening-up and the patient must be placed at the center of industry efforts. Increased transparency and a new age of dialogue between manufacturers will increase trust, help us achieve better efficacy rates and, most importantly, develop better medicines for the patients we serve globally. Questions no one thinks to ask today (e.g. 'how are my drugs manufactured', 'what is the supply chain process' and even 'its environmental footprint') will be key parts of the supply chain and patient engagement package in just a few years' time. At Piramal, we are striving to be a key driver of this transformation and we are working with forward looking pharma partners and patients about how we can together begin delivering a better kind of healthcare. This is the future we envisage, one in which, above all else, we recognize the responsibility we bear should be solely to patients. We are at the nexus of a new age, whereby patient centricity will become the integral philosophy around which we design all services even technical approaches – from implementing dosage form and delivery, packaging and logistics right through to meeting regulatory standards and good manufacturing practice.

Patient Centricity to the Core at Piramal

As a global organization with sites in Europe, North America, India and China, it's vital for PPS to instill a patient centric ethos that transcends cultural boundaries with the fundamental objective of reducing the burden of disease. At every level of our organization, we put patients first.

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