

IPI speaks with experts at PharmaLex on Integrated Product Development

Q: Can we start with a brief history of PharmaLex, what are your key offerings into the industry?

A: PharmaLex was established 25 years ago with a vision to make a difference to how the industry interacts with regulatory authorities. Today, we support more than 600 clients worldwide with an expert approach to compliance. PharmaLex offers six solution areas that cover the entire product lifecycle: Post-Launch Outsourcing, Local Affiliate Services, Business and Portfolio Mergers and Acquisitions, Strategic and Scientific Consulting, Innovations to Market, and Integrated Product Development.

I'm a solution lead for our Integrated Product Development (IPD) area. A major part of that is strategic product development, which is about helping clients establish an understanding of what is needed to get their product through development and build a strong foundation for commercial success. It's the centrepiece of what I do. We have experts in all major regions around the globe, including a team of eight here in the US. Our subject matter experts know what it takes to bring products to the patients who need them. They also have a strong working knowledge of the various functional activities that need to be integrated seamlessly in order to ensure the most time- and cost-efficient development program, with a high probability of success. We take a bench-to bedside view across the product lifecycle, from designing a preclinical program that will meet regulatory approval to designing a global clinical/regulatory strategy and helping to guide commercial success. Given the complexity of development and the multi-year programs, a significant challenge for many companies is understanding what questions they should be asking or answering and when. That's how we can help.



Q: We hear a lot about the need for integration in drug development – why is this important to the future of the industry, especially as it relates to small molecules?

A: It's always been important, but now it's even more so, because it helps to move drugs faster and more efficiently through the development process. It's quite simple. Consider an activity such as preparing for a meeting with the Food and Drug Administration (FDA). If this activity is not well planned out, with all of the major contributors in alignment, the meeting may be delayed and critical feedback from the agency will not be available when needed to advance the program further into development. This could lead to a delay in the clinical program, for example, which would ultimately lead to a delay in product launch. For a product expected to return US\$400 million in the first year of sales, each day the program is delayed would mean lost revenue of more than US\$1 million.

All the functional activities needed to bring the product to the market are intricately interconnected. Understanding how the various puzzle pieces fit together is critical to efficient planning of the development phase.

When focusing on single activities or only on the next milestone, it's common for development programs to go through fits and starts, for example having to repeat a study in a different geography because the input of regulators in various regions was not sought or incorporated into the development plans.

So, thinking from an integrated point of view, instead of just getting to the next milestone or the next dataset, taking a holistic view can prevent a lot of that rework and hassle that goes along with it. This is especially true for innovative small molecules, some of which are developed using artificial intelligence (AI) and/or machine learning (ML). The higher the quality of the data being fed into AI/ML, the greater the chance of success in hitting a druggable target with beneficial clinical outcomes.

Q: How can an integrated product development strategy drive speed and innovation across biopharma?

A: Taking an integrated and holistic approach can help reduce cost and white space between key activities. For example, in a typical relationship between service providers and companies, the sponsor company will wait until data is available and then approach the service provider with a protocol for the next study. Of course, this delays study startup, not only due to the wait for the data, but also because the provider will inevitably have questions and input into the protocol, leading to additional startup time. Engaging with a service provider to be a partner in development very early on would allow work to begin on the next study protocol and execution several months ahead of the typical time frame.

Q: What is the key role an integrated product development strategy can play in the drug development process?

A: The key thing you need is a development lead who understands what is needed to bring the drug to the market and also has a strong working knowledge of how the various activities need to come together, and when. This is a unique skill set, as it requires a deep understanding of drug development as opposed to being a subject matter expert in just one functional area.

Q: What prevalent culture issues within pharma companies are holding back strategy?

A: Working and making decisions in siloes and not empowering project teams are two of the prevalent perspectives that prevent the most efficient path through development. Communication across functions and, more importantly, program decision-making in a cross-functional manner can enable efficient development. In contrast, many companies enable each function to make their own

decisions on how to support the development program.

It's important to empower project teams to make certain decisions along the way. These teams have deep knowledge of the program, its history and challenges and are best positioned to decide how to move the program forward most efficiently. One approach to this would be for senior leadership to enter into a "contract" of sorts with the development team revolving around development milestones. The team presents a plan and, if senior management agrees, it commits to providing support for that program. At each milestone, the team reports on progress, describes the key activities to the next milestone and requests resources to support those activities. Teams then are free to work through the program to the next milestone as long as resources and timelines agreed in the "contract" are maintained, within reason.

Q: In general, how has the efficiency and productivity of pharmaceutical companies increased/evolved over the past 20 years and how much of this evolution is due to the knowledge and experience contract development and manufacturing companies bring to the industry?

A: Some things have changed for the better. For example, COVID-19 taught us that we can do more things in parallel and take informed risks as development proceeds. An important part of integrated thinking is to ask "what do you need to know and when do you need to know it?" Answering these questions can help in designing the most efficient and informative development program. It is also important to explore what activities can be done in parallel rather than treating development more sequentially. So, I think those are the things that have changed. Unfortunately, for the most part, this siloing and the risk-averse culture really hasn't changed all that much.

As for having contract development and manufacturing companies, they are part of the larger ecosystem of service providers. Utilising service providers that can provide a broader set of solutions and services can help evolve development to be more efficient. When working with multiple providers there are often challenges in communication, confusion over accountability, decision-making and delays in timelines as deliverables are handed from one provider to the next. With the multi-vendor approach there is a

loss of institutional memory. Every time a new provider is brought on board there is time lost while they get up to speed. When using fewer providers, the need for this ramp-up time is eliminated or reduced.

Q: You prioritise helping organisations hit their product development milestones. We understand how critical this is, not only for the success of the product, but also to meet the next value inflexion point. Can you explain how you do this, and what are the key points our readers should take away?

A: It's focusing on the goal, and the goal is to get to the market, not just in terms of approval, but to ensuring patient access and ultimately commercial success. Planning key milestones and the activities that support them with a sharp focus on that ultimate goal is critical to success.

Then, the second thing is to remember that there are few, if any shortcuts in drug development. Efficiencies can be gained of course, but the efficacy, safety, and market access hurdles to be considered remain the same. Ultimately, the program must generate adequate data to support approval, patient access and commercial success.

Q: It has been widely publicised that innovations in biomedical sciences and technology fuel the opportunity to transform R&D for new drug development holistically, sometimes 500 days faster, better tailored to patient needs, and 25 percent cheaper. Can you explain how this is possible, and how does PharmaLex assist in this development?

A: The numbers you state here stem from an article on the importance of transforming the traditional approach to drug development. While innovative science is paving the way for medicines that could potentially cure many diseases, the type of innovation that can speed development and reduce costs is a process rethink. It's about drug designs that are centred on patients and clinicians, processes that ensure cross-functional collaboration, leveraging digital technologies to automate repetitive tasks, leveraging advanced analytics to improve decision-making, and adopting more agile ways of working. This aligns with our approach to

integrated product development. It is about designing the most efficient and informative development program. It's about empowering project teams and ensuring decisions aren't made in silos.



Mark Lane

Mark Lane, Ph.D., is Vice President of Development Consulting and Scientific Affairs at PharmaLex, where he draws on his experience with leading product development teams and functions accountable for product development across all phases. Mark's expertise combines program, project and portfolio management, a deep understanding of drug development, and a strong working knowledge of cross-functional activities combined with business and scientific acumen.

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