

The Challenge of Pharma Package Design for Manufacturability

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KEY TAKEAWAYS

- Designing for manufacturability must factor in patient centricity, equipment, materials, and budget constraints.
- How design for manufacturability is achieved at company level.
- An effective packaging partnership can serve as a one-stop shop for packaging and manufacturing.
- Embedding sustainability considerations from the start can have large compounding effects.

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OVERVIEW

Designing pharmaceutical packaging is sometimes perceived as a relatively minor consideration reserved for the end of the drug development process. Yet, designing pharmaceutical packaging with an eye on manufacturability is critical for successful commercialization and should be an integral part of product development.

Choosing the right packaging partner is therefore essential for streamlining the process by way of ensuring compatibility with equipment trains, keeping labor and commercialization costs from escalating, and avoiding costly supply chain bottlenecks.

CONTEXT

Roundtable participants discussed the importance of packaging decisions, the optimal time for pharma and biotech companies to start thinking about these strategies, and the potential for partnerships to develop packaging that supports and accelerates product commercialization.

KEY TAKEAWAYS

Designing for manufacturability must factor in patient centricity, equipment, materials, and budget constraints.

There are many considerations that go into pharmaceutical packaging. One of the most prominent is patient-centric design, which facilitates drug administration and supports patients' adherence to a treatment regimen. However, there is growing awareness that patient-centric design should not come at the expense of customizing packaging designs to the point where medicines cannot be packed using available equipment or need new equipment that can only be used for a single design.

That is where the design for manufacturability (DFM) concept comes in. If a product's packaging design is aligned with patient-centric priorities—but is not optimized for the equipment the packaging process is going to run on—it can lead to upfront capital costs, modifications to existing equipment, and higher labor and commercialization costs, ultimately resulting in higher manufacturing costs.

"None of us want to bring to market a package that, while it looks elegant, is not able to be commercially produced," Kahle said.

DFM is developing or optimizing a design to its production process while meeting all patient and product requirements.

Pat Kelly, PCI Pharma Services

One approach to designing with manufacturability in mind is eliminating requirements that specify the exact materials to be used in packaging. Sometimes manufacturers are locked into vendor agreements that include such requirements as part of standard operating procedures, and that diminishes their capacity for flexibility and rapid response in case of supply chain issues that may impact lead times.

Making sure that the specifications that are being drafted for materials for packaging are generic and not brand-led may give [manufacturers] more flexibility.

Gary Orr, Perigord

Another way to optimize manufacturability is by considering package design early in the pharma product lifecycle. This helps companies understand and anticipate what the potential budget or assembly constraints are for a given packaging design and address them before manufacturing begins.

A common occurrence is when a client has a package designed by a third-party design agency, which may fit the end user specification, but which then does not fit on the packaging equipment itself when it comes to commercial manufacture. This results in costly delays and potentially the need to procure expensive equipment. By considering the package design during the late clinical phases and working with an in-house design team such as PCI's, the final commercial pack will ultimately adhere to all end-user specifications, fit seamlessly onto the production lines, and get to market much sooner.

How design for manufacturability is achieved at company level.

To achieve DFM requires a robust cross-functional network of designers, engineers, operations team, the vendor, and client working together. The key focus areas for PCI are developing a design that is (1) suitable for the patient, (2) suitable for the market and (3) cost-effective. In terms of the latter, it is essential to ensure that the design of the package is compatible with the preferred production process, which reinforces the need for harmony across the whole team.

DFM shouldn't be done in a vacuum. It really requires cross-functionality and harmony amongst a diverse set of disciplines to develop a solution.

Pat Kelly, PCI Pharma Services

PCI has a robust, diverse, and dynamic workflow, according to Kelly. The company's design centers are adjacent to its operations. The team understands the impact design can have on the operation and vice-versa, so at the end of the day it comes down to putting those robust workflows together, having streamlined communication, and the appropriate systems developed to create a streamlined solution.

Early consultation with the client is important in pharmaceutical packaging projects. It is the vendor's responsibility to guide and partner with their clients throughout their commercialization journey. Developing a design without having the production process in place can have severe cost implications. PCI uses its expertise in design, engineering, operations, quality, and other disciplines not just to meet clients' design needs, but their full product and commercialization needs as well.

"For package design, we are a turnkey solution provider. We can develop a design and partner with the customer from design ideation through to commercialization," Kelly said. "One of our key standard offerings is design conceptualization, where we can develop their design concepts from the onset and consult the client through the commercialization process."

"We look at DFM as a key differentiator for PCI because the team has the skilled resources, software, and equipment capabilities to develop highly innovative, complex, and sophisticated designs to meet the client and market needs, while also developing a design that's suitable for the operation." This differentiation has led to DFM being named as one of PCI's core speedsolutions™, helping clients to increase their drug product's speed to commercialization.

Another standard offering for PCI is design optimization, i.e., taking customers' existing designs and optimizing these to achieve cost savings or a more sustainable solution, among other things. The team is able to create commercial-grade samples in the prototyping lab that is representative of the complete primary and secondary packaging during the commercial operation.

Prototype creation can be scaled from small- to large-scale samples and can be developed for various functions including, but not limited to, proof-of-concept samples to support design conceptualization offering, market research, human factor studies, shipping and distribution studies, and child-resistant studies. Due to readily available material inventory, in-house tooling creation, and staff to support the operation, lead times are minimal. PCI also has the subject matter expertise and third-party testing partnerships to manage any testing services that may be required by the client.

An effective packaging partnership can serve as a one-stop shop for packaging and manufacturing.

To bring to life sustainable packaging solutions designed with manufacturability in mind, PCI employs a team of package engineers that develop a packaging concept and create 3D renderings, models, and packaging samples. This team works collaboratively with PCI's New Product Introduction and Operations teams to build design timelines, with the aim of getting packaging samples into clients' hands early in the product development process. Clients can therefore get a feel for what the product packaging would look like ahead of time.

"The more variables you bring into the equation, the more complexity, handoffs, and potentially more waste that's introduced. We make sure we're keeping all of these things in mind from the very beginning," Kahle said, explaining PCI's holistic approach in working with life sciences organizations.

Being that one-stop shop, single-solution provider to the client, PCI can help minimize costs, streamline the client journey from ideation to commercialization, and develop a valuable and collaborative partnership with clients.

Pat Kelly, PCI Pharma Services

Embedding sustainability considerations from the start can have large compounding effects.

Just as planning for manufacturability early in the product development cycle ensures that packaging design is compatible with available equipment and cost considerations, so does planning for sustainability in relation to reducing the overall carbon footprint. But because sustainability is a big, messy, complex topic, companies may get derailed due to the scale of planning it requires.

Orr noted that sustainability considerations should encompass not only secondary packaging, but primary packaging as well. To make addressing sustainability across the board more digestible, organizations can benefit from breaking it into smaller steps, such as understanding what their largest material usage is and which products in their portfolio generate the largest carbon footprint.

From there, they can implement marginal efficiencies which have a compounding effect. Optimizing secondary packaging is low-hanging fruit that everybody should be exploring, but the real opportunity is around new product development processes.

Three trends in packaging design that follow the reduce, reuse, recycle principles of sustainability and that address the pharma industry's unique characteristics are:

- **Reduce:** Smart packaging that replaces informational paper leaflets with e-leaflets
- **Reuse:** Development of reusable drug delivery systems (e.g., devices for administering biologics)
- **Recycle:** Takeback programs that recycle packaging at the end of a product's lifecycle

In designing for sustainability, we further enhance patient-centricity. Smart design is a great solution for patient-centric issues that we are trying to resolve.

Shruti Parikh, Takeda

Whatever approach to embedding sustainability companies choose, it does not have to involve a complete package redesign or another drastic change. “A lot of time when folks hear ‘sustainability’, they think everything needs to go out in a mycelium-based package or a package that’s compostable within 90 days,” Cade Curtis-Crockett said. “But there are lots of incremental improvements that can be made that have large compounding value—it doesn’t need to always be one broad stroke.”

CONCLUSION

Pharma and biotech companies looking to optimize design packaging for manufacturability are grappling with multiple trends, requirements, and end user expectations. In an era of persistent supply chain disruptions, life sciences companies can benefit by breaking free from vendor agreements that limit their choice of materials and increase lead times, while keeping costs manageable and baking in sustainability throughout the packaging process.

To reach those objectives, it is crucial to move packaging considerations as far upstream in the product development process as possible. “A lot of people leave packaging to a later stage in the process—embed it in your stage-gate process to mitigate risks and allow yourself to scale quicker,” Orr noted.

Partnering with a packaging solutions provider that has subject matter expertise, internal and external networks, and a deep understanding of all of the steps involved in the process can ensure that those considerations take place at the right moments.

DFM is a very dynamic process and involves decisions that can’t be made in a vacuum.

Matt Kahle, PCI Pharma Services

BIOGRAPHIES

**Cade Curtis-Crockett**

Associate Director, Pharmaceutical Packaging, Eidos Therapeutics

A veteran of OSD pharmaceutical packaging and serialization, Cade is currently at BridgeBio and focusing on the needs of the rare disease patient populations after stops at Gilead and Exelixis. Helping to improve patient's lives through better packaging and treating the planet as an end user are the pillars of his packaging ethos.

**Matt Kahle**

Senior Director, New Product Introduction, PCI Pharma Services

Matt has been with PCI for over 18 years and currently serves as Senior Director, New Product Introduction. In this capacity Matt is responsible for the successful onboarding of new clients and new products into PCI's global Commercial sites, which introduce 100+ new products into the global market each year. Matt oversees the dedicated team of professionals that Commercialize these products shepherding them from Award to Launch. Based at PCI's Rockford facility, his previous roles include Operations Management, Lean Manufacturing, Process Engineering, Project Management, and Business Unit Leadership. Matt holds an MBA from the University of Iowa, is certified in Lean Manufacturing and holds a Lean Six Sigma Black Belt.

**Pat Kelly**

Director of Services, PCI Pharma Services

After graduating from Rutgers University in 2011 with a degree in Chemical Engineering, Pat occupied roles elsewhere as a Project Engineer and Senior Project Engineer before joining PCI in 2017. Based at PCI's site in Philadelphia, Pat has served as Serialization Project Manager, Engineering Manager and Senior Manager of Engineering, before moving into his current role as Director of Services. As Director of Services, Pat leads several of PCI's global service offerings and is responsible for the development, growth, and sustainability of the programs.

**Gary Orr**

Chief Commercial Officer & Global Head of ESG, Perigord

Gary is a seasoned executive with over two decades of experience in the industry. As the Chief Commercial Officer and Global Head of ESG, he brings a wealth of knowledge and experience to the table. Throughout his career, Gary has worked with a diverse range of global, European, and national brands, both on the agency and client side. His expertise includes brand strategy, design management, product launch processes, brand implementation, and print origination, all of which are grounded in a strong commercial focus.



Shruti Parikh

Packaging Design Lead, Takeda

Shruti Parikh is the Packaging Design Lead, Takeda Pharmaceuticals based out of Massachusetts, USA, where she is leading and building Industrial Design, Sustainable Design and Patient-Centric Design capabilities across the company.

As the design lead in packaging development Shruti and her team works towards the remit to integrate design across the company's consumer, medical device, and pharmaceuticals sectors. In addition to helping improve the lives of the patients using Takeda products every day, the Design team is also focused on improving the environmental impact by reducing the carbon footprint of Takeda packaging.



Dean Rudge (Moderator)

Senior Writer, Citeline

Dean has built up a wealth of knowledge on the global generics and biosimilar medicines industries since joining Generics Bulletin in 2013. He specializes in commercial and legal issues, writing in-depth analyses of corporate strategy and getting under the skin of patent infringement proceedings and other litigation. He attends investor and regulatory meetings with business leaders, favoring the investor days with their focus on corporate strategy.