indegene
Scientific Insights. Transformational Solutions.

Packaging Artwork Labeling Services —The Next Wave of Consolidation

Meeting the Demand of the Globalized Marketplace

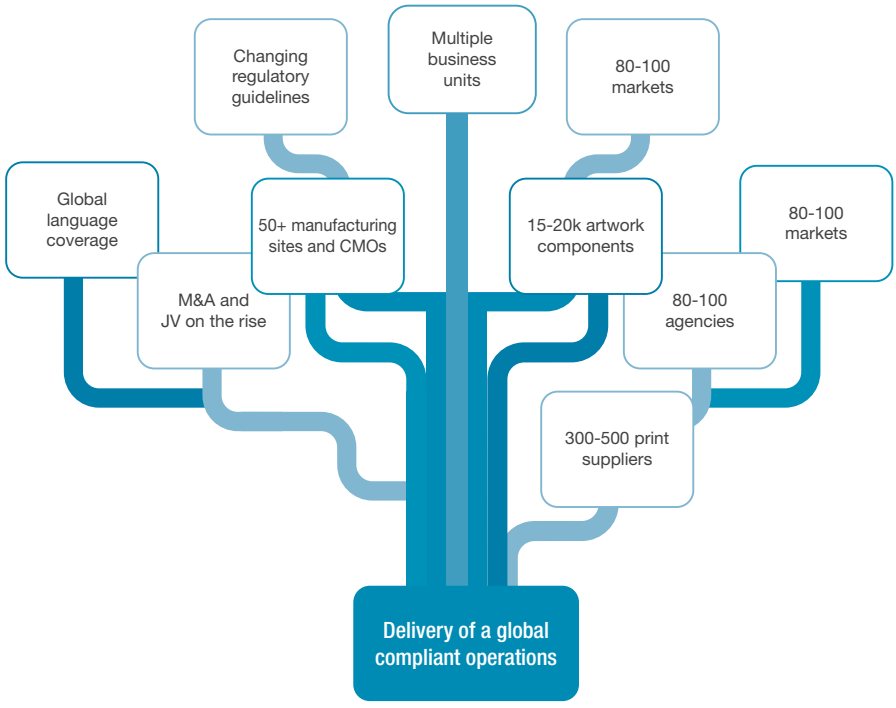
It's a complex world with significant liability

Most of the top 10 pharma companies have had product recalls or critical quality issues due to packaging artwork errors (contribute 30% of all recalls) YoY during the last 3 to 5 years. Each recall can cost millions of dollars in terms of direct costs alone.

A typical situation—a large pharma company for one of its large business division works with over 100 agencies, produces at least 15,000 artworks annually for 100+ markets, deals with multiple manufacturing sites and third-party CMOs, and supports a people organization of 150 to 200 FTEs or more (Figure 1). All this is to ensure they deliver a validated and highly compliant artwork management process. The result—most of the Top 10 pharma companies have had product recalls or critical quality issues due to packaging artwork errors (contribute 30% of all recalls) YoY during the last 3 to 5 years. Each recall can cost millions of dollars in terms of direct costs alone. Such costs include customer refunds, product write-offs, shipping and return costs, lawsuits and payment to victims and their lawyers, and finally costs of redesigning the product package.

Figure: 1

A typical situation in a large pharma company.



Packaging artwork is a complex and may often be an unseen aspect in the design and supply of pharma products. Unfortunately, when something goes wrong with the design or package information, the impact is felt across multiple parts of the organization and can have a significant effect on the company's brand image with regulators, patients, and physician community. However, despite these potential risks, packaging artwork operations is often regarded to be reactive rather than proactive. As the complexity of portfolios increases due to market expansion and newer ways of working besides line extensions, more and more companies are likely to feel the pain in their artwork operations. This is normally due to the cross-functional nature of the work and dependence on paper-based processes and individual knowledge.

Many companies have now started to discover and realize that there are processes, organizational and technology solutions to address these challenges and that significant improvements can be made, which can transform their current services to be a best-in-class operational unit.

Need for playing the game differently

In today's environment, the pharma industry is encountering numerous external challenges, especially with products going out of patent, cost pressures, and JVs, besides M&A. The complexity is further enhanced by the changing customer behavior and demographics, altering regulatory requirements, challenges in supply chain management, and the growing influence of private labels.

All these mean is that more packaging artwork needs have to be produced faster and in a very cost-effective manner than ever before and changes to packaging that took months are now expected in weeks. However, in reality, package, label design, and development are time consuming and often act as bottle-necks in accelerating time-to-market. The complexity arises out of lack of in-house expertise, absence of sophisticated tools and techniques, inability to share best practices, and the involvement of global multifunctional teams from various departments.

The ability to innovate, simplify, and standardize the operating model and deliver a more cost-effective, robust, and scalable business model that can run on a global scale is now a key requirement. Consolidating and optimizing spends on production and purchase of associated services—graphic design, artwork creation, repro, and print—is now no more adequate at a national or regional level, but needs to be done on a global scale.

The Triple "S" Approach–Strategize, Simplify, and Standardize

Since the regulatory environment is becoming increasingly stringent across many countries and given the fact that there is an increase in the number of product recalls (as per the FDA), most pharma companies need to focus and adopt a long-term strategy on their packaging operations. The need is to drive down costs of producing the artwork, reduce process variations, and deliver a global standardized process with high quality compliance.

In the changing environment that most pharma companies are adapting to, some companies have shown proactiveness and therefore are ahead of the curve in terms of their agility and flexibility to develop newer and efficient methods of working, whereas there are others who are still evolving in their thinking on how to make their current operations more competitive.

In order to deliver robust packaging operations, some of the key attributes that beg consideration are:

- **Long-term view–** The business has to see value in creating a long-term strategy on what they need to do in order to achieve **"best-in-class"** presence in this space. This includes relooking at what their current operations are and how that will change based on the future needs of the organization with respect to their product portfolio, technical and domain expertise, cost of service, internal vs. externalization of production and services, intervention of technology to enhance the user experience, as well as building the long-term brand image. The resultant changes

Figure: 2

Service consolidation model across industry.

*Business As Usual

have to ensure achievement of patient safety norms primarily, besides complying with the ever-changing requirements of the regulatory bodies globally. Successful companies have developed this up over a 3- to 5-year planning phase and implemented changes addressing the changing dynamism in the marketplace. A top global pharma company has reduced recalls from 2 to 3 per year to ZERO during the last 5 years—annualized savings and benefits of US$ 25 MN.

- **Validation of a global single process–** The pharma industry can barely breathe without mentioning any number of acronyms that govern—and in some cases ease—the packaging process. For example, 21 CFR Part 11, GxP's, EMEA 2011, ASTM E2537 Guide (for Application of Continuous Quality Verification for Pharmaceutical and Biopharmaceutical Manufacturing), etc. are just a few of the acronyms that are the part of the complicated process called validation. Simply stated, validation means that the pharma companies must document each step of the manufacturing process including packaging so that they know exactly what they are supposed to do each time. This ensures the safety and quality of the medicines. Validation ensures that the right product is in the right package, the product has been properly prepared, and it has the right label. Everything can be traced back for each of the lot numbers. What makes the process more complicated is the fact that there are no clear guidelines that specify exactly how validation is to be done. It is therefore the responsibility of each pharma company to develop its own program to respond to the regulatory guidelines (eg, FDA), and no matter how they choose to respond at the end of the day, they are the ones responsible for compliance. It is imperative, therefore, that the process of validation needs to be well documented with procedures and guidelines for each step of the process, which once ready has to be communicated through initial as well as on-going refresher training to the entire packaging operations group. The continuous tracking and adherence to such a process with minimal deviations can ensure a robust and efficient packaging service. A positive impact for one of the pharma companies

was reduction in lead time of processing the change request from an average of 5 months to 6 weeks.

- **Competency in people–** Contrary to belief, human capital still continues to be a top driver in developing, changing, and adapting newer ways of working. Knowledge creation going forward will be a huge differentiator in the market place for pharma companies. It is therefore important to ensure that all individuals are competent to carry out the activities required by them and that they are clear on their accountabilities within the process. They have the right tools and environment to perform their tasks. This is particularly important for activities such as proofreading and artwork creation. Further, the pharma company needs to establish a continuous improvement culture that values errors as a learning opportunity to improve the existing process. A critical part of reducing recalls in this area is identifying, learning from, and eliminating out the minor errors and near misses. Artwork effort has a very clear and visible impact on patient safety, which is clearly understood by the people who work in this space and is a motivator to generate a zero-error culture.

- **The technology intervention–** The advent of technology in aiding or assisting processes to be seamlessly delivered across the globe is no more a phenomenon but a growing business reality that most pharma companies have come to accept. There are validated platforms like Agile PLM and Kodak, to name a few, that are compliant to deliver a global packaging process with a single view for all parties concerned. These tools not only enable faster access to existing artwork and tracking the changes thereof but also help in traceability for audit and compliance requirements through digital archival and repository of information that can be retained for decades.

- **Offshoring and multi-shore delivery model–** The cost pressures that most companies are facing are no secret anymore. The time has come to invest, trust, and build relationships with partners who can provide the cost advantage with a multi-shore delivery capability. The ability to service global demands in a 24 x 7 work environment and constantly innovating themselves with the changes in the industry are some of the features that pharma companies need to consider and execute appropriately.

Packaging operations is being looked as a specialized service that no longer is CORE but a process that is repeatable, trainable, and deliverable using technology, knowledge base, and external partners with a global hybrid operating model, besides reducing complexity through process simplification and standardization.

- **Decoupling model–** Historically, each country, region, or brand has a local agency that looks after the strategy, creative, and production work. Even though with the comfort of having the agency service at the door, high costs spent on creative production cannot be justified as there is wastage in time and reinventing the wheel again and again. The de-coupling model facilitates the needs of the brand across regions and delivers with savings in cost and time, thus allowing for flexibility and standardization.

Organization Gains—Staying Ahead of the Competition

Packaging operations is being looked as a specialized service that no longer is CORE but a process that is repeatable, trainable, and deliverable using technology, knowledge base, and external partners with a global hybrid operating model, besides reducing complexity through process simplification and standardization. The advantages are distinct and realistically achievable as long as the organization is willing to acknowledge and drive the change management diligently.

- **Cost savings–** This varies between 30% and 50% YoY (offshore model) assuming the programs are scalable with well-defined processes and technology interventions. Consolidation of services alone can generate a 10% to 15% improvement in ROI in the short to medium term. Working with one of our customers presently, the capability to combine multiple services under one team has given them a huge advantage in terms of reducing project management costs, improvement in processing time with lesser rework, besides the labor arbitrage.

- **Productivity–** Given the shrink in annual budgets and spend, the need to do more with less is almost evitable. The pharma companies have to tap into resources that offer an improvement of 10% to 15% over their existing resources. Speed to market and schedule adherence are demands that most markets will continue to exert, which in the long run can be a likely differentiator in the market place for any pharma company. Players like Indegene partner with their customers driving such initiatives successfully. The focus on training and process specialization helps us in hiring the right skills to deliver better-than-expected results.

- **Improved serviceability–** With an increase in global coverage, especially emerging markets, overall increase in product portfolio across prescription medicines, OTC, consumer and generics (both branded and through tie-ups) sold with different components and language specifications, and a need to supply faster, better, and cheaper drugs to patients, it is almost predictable to say that most pharma companies will gain significantly in providing the packaging service using a shared services model that cover global time zones with local presence, besides leveraging other improvement and efficiency gains. One of the top three pharma companies, for example, has gained significantly using a similar model by expanding the service to multiple business units and newly acquired companies. The ability to migrate the data to newer ways of working becomes much more simpler and easier to adapt.

- **Access to skilled manpower–** There are service providers specializing in providing this service to the pharma industry that are available onsite, near, shore, and offshore. One does not have to continuously develop this capability in-house. This model is especially beneficial where requirements for certain languages (eg, Oriental languages) become an increased need and the same cannot be sufficed within the organization. The cost for hiring and retaining such talent is significantly lower.

- **Increased competitiveness–** Enhancing the overall operational efficiencies helps the pharma companies reduce the cost per artwork significantly, thereby staying ahead of the curve. Benchmarking with other top pharma companies, one of the global top five pharma companies implemented this strategy almost 10 years ago. The company stood out on process compliance, percentage of recalls as opposed to total volumes delivered, and high stability in terms of job processing (request of change to product of shelf).

Quality of service is all that matters

Delivering a high Right First Time (RFT) on a consistent basis is clearly one of the top three focus initiatives for any large pharma company. Experience will tell us that if ever in doubt, one would always compromise speed and productivity over quality because that is what a large centralized packaging operation should commit to deliver. Ensure that the basic process revolves around two essential steps. Firstly, define and agree upon what is required, the 'Brief'. Secondly, execute the change and verify that what has been done adhere to the Brief.

Pharma companies emphasize quality in all aspects of their operations and extend that philosophy to include their suppliers as well. The expectation is that the supplier will perform to the same level of quality as the pharma company demands of itself.

It's time to separate the myth from reality. The overall packaging space is definitely seeing a shift in the traditional ways of working and will in years to come be a key process in driving lower costs, increasing efficiency and quality, and be one of the catalysts in the simplification program that most pharma companies are embarking upon. The question to ask is how much and how soon. This part of the supply chain process is highly knowledge intensive and will be best delivered if there is a proactive strategy and execution plan in place, which in turn would lead toward a world-class service for the pharma companies.

About Indegene

Indegene is a leading global provider of R&D, commercial, and marketing solutions to global pharma and health care organizations. We partner with clients to drive both productivity and revenues by delivering better patient outcomes, optimizing cost, enhancing R&D agility, and improving sales and marketing effectiveness. We apply deep scientific knowledge, flexible delivery models, proprietary technology, and a client-centric approach to drive transformational initiatives.

With offices in the United States, Europe, China, India, and Australia, Indegene can partner globally with clients; leverage a global talent pool of clinicians, technologists, Labeling specialists, domain experts, and business process specialists; leverage global infrastructure; and harness global pharmaceutical expertise to solve client challenges.

indegene™

Scientific Insights. Transformational Solutions.