

**White Paper** | 2024



# Selecting a **Strategic Artwork and Labelling Partner**

**The why, how, and what to look for when considering outsourcing your pharmaceutical packaging artwork, labelling and associated functions .**

# Executive Summary

For over two decades, organisations around the world have been using business process service (BPS) organisations to improve service delivery and drive cost optimisation across their businesses.

The pharmaceutical industry is one of the most highly regulated industries in the world and one in which there is no room for error. Increasingly pharmaceutical organisations are outsourcing many downstream commercial functions, including those involving and associated with the artwork and labelling process. Outsourcing these functions and realising the full potential of subject matter experts can deliver economies of scale, increased flexibility, shorter lead times and remove the challenges of recruiting, training, and retaining teams.

Packaging artwork is highly complex, carries a significant level of liability and as such must be produced in a validated and highly compliant environment. Core to any organisation's business strategy, is the management of liability and risk, and as in any essential process artwork design and creation must be looked upon and managed in line with any organisation's core objectives.

Pharmaceutical artwork with mislabelling errors can be a major factor in product recalls, making the management of this process one of the riskiest phases of the product life cycle. Mistakes in artwork can result in incorrect or incomplete product information being presented to the patient due to several factors, including, for example, translation errors, incorrect specifications or the wrong information being placed on the pack version being used. Any of these issues can lead to a regulatory breach, a delay in getting a product to market, a product recall or even cause adverse patient reactions.

## However, with equal pressure to do things quickly and do things well, how can you ensure that you can achieve both?

Outsourcing enables pharmaceutical organisations to delegate some of their business processes to third parties or external agencies, allowing them to leverage the benefits of deeper subject matter expertise, greater resource optimisation, improved product quality and service innovation.

With up to two-thirds of pharmaceutical manufacturing now being outsourced, it is more important than ever to **choose the right partner**. Partners who:

- are GMP compliant.
- have a proven track record in delivering artwork and labelling subject matter solutions.
- are digitally centred with future-proofed technology.
- can demonstrate gold standard customer service.

With **the right partner**, a business unit can bring significant commercial advantage to their organisation, while at the same time maintaining management control and compliance across all aspects of the process and function.



## Do what you do best and outsource the rest.

**Dr Peter Drucker** –  
Management Consultant,  
Educator, and Author

In this paper, **Gabriele Iannizzotto**, Chief Business Officer, Perigord Life Science Solutions, **Michael Fleming**, Chief Operating Officer, Perigord Life Science Solutions, and **Pradip Advani**, Group Business Head, Tech Mahindra BPS, share their thoughts on why, how, and what to look out for when selecting a packaging artwork and labelling partner.

# 01 Why outsource your artwork and labelling to an SME?

As the world of health advances and as Life Science companies adapt their business models to meet the demands of the new market dynamics and focus on new ways to treat, cure, and manage the symptoms of a wide range of diseases and ailments, it is inevitable that more and more companies will reprioritise and focus their resources to areas that will deliver greater value. Increased competition, economic uncertainty, and globalisation are the primary reasons pharma companies outsource their packaging artwork and labelling, but there are many more.

## Outsourcing can deliver many benefits for your organisation.

### 1 Optimise operational efficiency and reduce costs.

Market forces impose a constant pressure to improve operating margins, increase productivity and deliver greater efficiencies. If you are seeking to reduce the cost and improve the effectiveness of numerous non-value-added functions outsourcing them could be the solution. When properly executed, outsourcing can have a defining impact on a department's budgets and enable them to deliver significant savings.

#### A business unit can increase productivity through various initiatives, such as:

- **Work allocation** – Sharing a set of activities across the team during peaks and troughs can help the team achieve more.
- **Knowledge management** – Improving productivity by reskilling resources and sharing knowledge.
- **Eliminating redundant activities** – Identifying and eliminating the redundant activities or re-distributing them to the right skill resource can help improve the overall throughput within the team.
- **Automation** – Digital transformation is a key driver of transformation in many global organisations and the Life Science industry and pharmaceuticals sector are no exceptions. With advances in artwork and content management systems it is critical that your preferred partner is utilising the most up to date technologies to deliver the economies and reporting you require.
- **Improved stakeholder management and collaboration** – with the right partner and correct subject matter expertise, stakeholder management and approvals between Regulators, Markets and Sites, CMO's and Print Suppliers will improve efficiency in the artwork process.



In the world of Life Science packaging artwork, labelling and marcoms asset creation and management, many of the world's leading organisations have already opted to outsource certain processes, functions, and responsibilities. We believe that as the market changes, as technologies evolve, and as the industry digitises more and more aspects of the supply chain, the trend towards outsourcing is set to increase. Additionally, patient support programmes (PSPs) are increasingly important for pharmaceutical companies. The ability to wrap services around their leading-edge therapies, to deliver superior patient outcomes, drive differentiation and strengthen patient and healthcare professional (HCP) relationships, will increasingly determine success in the future.”

**Gabriele Iannizzotto**  
Chief Business Officer,  
Perigord Life Science  
Solutions

**2 Access subject matter knowledge, expertise, and best practice.**

Outsourcing will enable your organisation to tap into and leverage a broader level of subject matter expertise and a wider knowledge base. It can provide your company with access to world-class capabilities and, with the right partner, ensure that the tasks and functional requirements are carried out in line with best practice. This will ultimately lead to better production, cost optimisation, and increased quality and reliability.

**3 Easily manage increasing and fluctuating demand cycles.**

Building, training and maintaining a team to manage fluctuating demand cycles is time-consuming, costly, and prone to waste. Product launches and regulatory changes cause internal resource crunches: outsourcing removes these headaches and delivers greater flexibility by providing access to additional resources not available internally, enabling you to scale up and scale down, as required.

**4 Mitigate risk and improve quality management.**

Achieving critical quality standards with consistency and transparency is certainly a prerequisite for any strategic supply relationship but, for Life Science organisations, it is a fundamental requirement and a key performance indicator when assessing the potential for long-term reliability and quality improvements. By delegating responsibilities to the right external partners, you can improve compliance with internal policies and control, manage and deliver better quality outcomes by avoiding internal roadblocks, and having one central point of reference.

**5 Accelerate your route to market.**

The more directly and succinctly a drug manufacturer can manage a drug's launch timelines on the way to market, the more successful the product will be financially, both in the short and long term. Outsourcing can speed up the process, saving your organisation money, giving you the competitive edge, and helping you to get your products to the patients who need them even faster.

**6 Drive continuous improvement.**

Outsourcing to a strategic partner that is constantly focused on continuous process improvement (CI) can drive many benefits. Partners with experience, vision, and focus on CI can bring intelligent, future-proofed solutions that will deliver greater efficiencies for your organisation over the longer term.

**7 Gain access to a consistent supply chain.**

A strategically important supplier must be able to provide reliable access to well-executed, quality-driven, and scalable solutions. How well they manage their own process and business activity is a good indication of their ability to deliver this. Any disruptions in your partner's process and your product delivery may be delayed.

**8 Gain the freedom to focus on core business and value-adding activities.**

Outsourcing non-core activities to external suppliers enables your organisation to become more agile by freeing your teams up to focus on their core business and concentrate on those activities that deliver a greater return.



In today's dynamic and evolving pharma landscape, packaging operations are being looked at as a specialised service that is no longer considered CORE but as a process that is repeatable, trainable and delivered using trusted partners, driving change management, technology innovation, and process excellence while helping reduce the complexity across the stakeholder ecosystem. The advantages are distinct and realistically achievable. The global delivery setup can provide a cost advantage as opposed to the traditional ways of working."

**Pradip Advani**  
Group Business Head, Tech Mahindra BPS

# 02

## How to go about it.

Successful outsourcing and outsourcing that drives transformation and helps achieve broad strategic goals of an organisation, requires companies to follow a disciplined process that keeps them focused on taking the right steps and making the right decisions.

### A strategic approach to outsourcing.

#### 1 Clearly define and validate your requirements.

The goal of requirement/model validation is to identify your target model, the stakeholders experiencing the most significant pain and areas that need the most improvement. Through this process you identify the gap between what constitutes a total solution and what minimal functional support you can realistically require. That gap represents your partnering roadmap and identifies where you need to partner to deliver the total solution.

Model validation, therefore, is the first action to be taken in any strategic alliance strategy.

**Service delivery modelling** and analytical tools can be used to help organisations quickly understand the current state of functions and create a best practice vision of a target state, both in the short and long term. This approach measures the maturity of an organisation under four key headings and associated capability areas, as illustrated below. Using key stakeholder input to rate the service delivery on a ranking scale, an organisation can assess a function's current state and create a road map to an ideal future state. Armed with this assessment, the business can develop a multi-year plan to generate additional value by increasing its effectiveness in the appropriate capability areas, be that inhouse or by outsourcing the function.



Outsourcing enables companies to review spending, increase efficiency, underwrite quality and stay abreast of the latest technologies. With the right focus on innovation and continuous improvement, a strategic partner should always seek ways to improve your process and drive efficiencies and do this with the dedication of a partner, not a vendor. With the growing importance of contract Business Process Services and a growing number of providers, it is more critical than ever to make the right choice.”

**Michael Fleming**  
Chief Operating Officer,  
Perigord Life Science  
Solutions



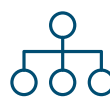
#### Strategy

- Mission/Vision/Values
- Scope of services
- Location of services
- Business planning



#### Service delivery

- Performance management
- Compliance and issue resolution
- Customer relationship management
- KPI identification and reporting
- Continuous improvement



#### Organisation

- Organisational structure
- People management
- People development
- Culture
- Recruiting



#### Organisation

- Process
- Technology
- Controls
- Program management
- Facilities and infrastructure

All assessments would include a cost-benefit analysis.

## 2 Develop partner selection criteria.

Firstly, decide if your outsource partner needs to be GMP compliant to fulfil the obligations under any outsource contract. The better you know what attributes you are looking for in a partner, the easier it will be to determine who is the best fit. It is important to sit down with your management team and identify the most important selection criteria. Having undertaken the correct analysis and modelling, as outlined above, you should be able to identify the core needs and associated attributes you require from a strategic partner.



### GMP Outsource Recommendations:

#### General

- There should be a written Contract covering the outsourced activities, the products or operations to which they are related, and any technical arrangements made in connection with it.
- All arrangements for the outsourced activities including any proposed changes in technical or other arrangements should be in accordance with regulations in force, and the Marketing Authorisation for the product concerned, where applicable.
- Where the marketing authorization holder and the manufacturer are not the same, appropriate arrangements should be in place, taking into account the principles described.

#### The Contract Giver

- The pharmaceutical quality system of the Contract Giver should include the control and review of any outsourced activities. The Contract Giver is ultimately responsible to ensure processes are in place to assure the control of outsourced activities. These processes should incorporate quality risk management principles and notably include:
- Prior to outsourcing activities, the Contract Giver is responsible for assessing the legality, suitability and the competence of the Contract Acceptor to carry out successfully the outsourced activities. The Contract Giver is also responsible for ensuring by means of the Contract that the principles and guidelines of GMP as interpreted in this Guide are followed.
- The Contract Giver should provide the Contract Acceptor with all the information and knowledge necessary to carry out the contracted operations correctly in accordance with regulations in force, and the Marketing Authorisation for the product concerned. The Contract Giver should ensure that the Contract Acceptor is fully aware of any problems associated with the product or the work which might pose a hazard to his premises, equipment, personnel, other materials or other products.
- The Contract Giver should monitor and review the performance of the Contract Acceptor and the identification and implementation of any needed improvement.
- The Contract Giver should be responsible for reviewing and assessing the records and the results related to the outsourced activities. He should also ensure, either by himself, or based on the confirmation of the Contract Acceptor's Qualified Person, that all products and materials delivered to him by the Contract Acceptor have been processed in accordance with GMP and the marketing authorisation.

### The Contract Acceptor

- The Contract Acceptor must be able to carry out satisfactorily the work ordered by the Contract Giver such as having adequate premises, equipment, knowledge, experience, and competent personnel.
- The Contract Acceptor should ensure that all products, materials and knowledge delivered to him are suitable for their intended purpose.
- The Contract Acceptor should not subcontract to a third party any of the work entrusted to him under the Contract without the Contract Giver's prior evaluation and approval of the arrangements. Arrangements made between the Contract Acceptor and any third party should ensure that information and knowledge, including those from assessments of the suitability of the third party, are made available in the same way as between the original Contract Giver and Contract Acceptor.
- The Contract Acceptor should not make unauthorized changes, outside the terms of the Contract, which may adversely affect the quality of the outsourced activities for the Contract Giver.
- The Contract Acceptor should understand that outsourced activities, including contract analysis, may be subject to inspection by the competent authorities.

**Source:** European Commission (2012) 'EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines', Chapter 7 – Outsourced activities', pp. 2-3. Available at: [https://ec.europa.eu/health/documents/eudralex/vol-4\\_en](https://ec.europa.eu/health/documents/eudralex/vol-4_en)

### 3 Identify and prioritise partner candidates.

From the gaps you identified in your validation work in step one, start identifying companies who possess your missing capabilities. Seek advice and introductions from other stakeholders in your organisation, watch out for webinars around the core function or competency you would like to outsource, search the web using the keywords and attributes you require. Identify who industry analysts say are the important companies in the space you are targeting. Add these companies to your recruitment target list. Using the criteria, you identified in step two, prioritise your target list to decrease it to a manageable number of companies to approach.

#### Potential Strategic Consideration Points:

- If it has been previously decided that a proposed partner must operate to GMP, can they demonstrate GMP in action?
- Does your potential partner have the correct business profile and experience in the relevant industry?
- Can they support your needs locally, regionally and Globally?
- Do they have the correct skill set, would it be available where and when you need it?
- Do they operate to the same standards as your organisation?
- Do they have the right quality certification to support their claims?
- Does their business culture and policies align with yours?
- Do they have a detailed implementation process?
- Do they have the financial strength to support your needs over the long term?
- What extra benefits can they bring to the table?
- Can they support their claims with relevant client references?

### 4 Prepare “Partner Proposition Worksheet”.

Prepare a “Partner Proposition Worksheet” for each partner prospect and list the core attributes you need to see from them. Outline the scope of the opportunity, clearly detailing the range and mix of work, task, delivery times, language report templates, KPIs, quality certifications and operational models you are looking for from the potential target partner. Do your homework. Understand the target company's market position, longer-term objectives, and strategies. Think through what your ideal value proposition to your organisation would be. Identify a compelling vision for the opportunity and articulate the impact of that vision on your business. Finally, clearly articulate your needs and be as specific as possible.

## 5 Conduct a screening call(s).

Once you have laid the groundwork, you are now ready for that initial call. Depending on the size of the firm, your target stakeholder needs to be either a Director, VP or Chief Business Officer of Sales, Business Development or Operations, or an existing account manager for other services your business uses. Use your network to identify the right contact and perhaps get an introduction. Send them a copy of your completed Partner Proposition Worksheet and walk them through it.

## 6 Conduct due diligence audits.

Now it is time to evaluate the “partner fit.” The depth, scope, and criteria of the due diligence should be risk-based and address all relevant risk areas. But first, before you start, you will need to assess if your potential partner is audit-ready.



**Here are some key questions you will need to ask, to assess the risks involved:**

**Supply Risk:** Is there any risk that the services provided by the partner could have a negative impact on the supply of our products?

**Financial Risk:** Is there any risk that the partner could not fulfil its financial liabilities resulting from the provision of the proposed services or any subsequent failure to meet services obligations or failures in compliance?

**Quality Risk:** Is there any risk that the services provided by the partner could have a negative impact on the quality of our products or delivery timelines?

**Legal Risk:** Does the nature of the services provided by the partner require an extensive contract (e.g., distribution and/or service agreement)?

**Reputation/Social/Ethics Risk:** Are there any indicators that an engagement with the partner could negatively impact our reputation?

**Other Risks** (if applicable) ( e.g., Commercial Risk, Innovation/Technology/IP Risk): Can the partner properly protect your IP and Trademarks?

Effective international business partner due diligence requires that you gather meaningful information, assess the potential risk of project failure, and include risk mitigation strategies as part of the due diligence process.

## 7 Negotiate a mutually beneficial partnership agreement.

The discussion process effectively starts when you make your initial call to the target partner. You should be continually monitoring the potential value a prospective partner can bring throughout the process. Prepare a business terms document first, defining the general business terms. Get agreement from the business sponsors on the business terms before you engage the attorneys.

## 8 Develop a partnership plan.

You now need to work with your new partner to develop a plan that outlines partnership goals/objectives, action plans, rules of engagement and checkpoints, and you will need to assign a partner manager to manage the relationship and execute the plan.

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## What selection criteria to use when choosing a packaging artwork and labelling partner.

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As packaging artwork and labelling contracts typically last over five years, choosing the right partner(s) is essential. Depending on the business process to be outsourced, the criteria may vary, but we have identified several key areas for investigation that will help you make the right decision.

### A strategic approach to outsourcing.

#### 1 Clearly define and validate your requirements.

One of the main advantages of setting up a packaging artwork and labelling partnership is the value that will be derived from the dedicated vendor's knowledge and expertise. Building on that knowledge will permit an increase in the quality of the function's output and, in time, deliver the desired cost savings. Therefore, when choosing a partner, it is important to assess their level of experience.

#### 2 Quality – 98% RFT is a minimum requirement.

As the goal of the pharma artwork process is to deliver Right First Time (RFT) artwork into the print production cycle, there really is no room for error. It must be 100% right 100% of the time but is this achievable given the number of variables in the process? Increasingly it is becoming vital that Life Science companies manage and maintain their artworks in a fully compliant and audit-ready environment, and to do this they need to ensure their processes and systems are fully aligned. We also know that when the process generally works 'well', having a RFT of 98% is a minimum requirement with anything less being unacceptable, and 99% being a realistic goal.

#### 3 Flexibility.

If your business expects a growth or a temporary surge in the quantity of output required, it is important to ensure that your partner will be able to keep up with your requirements. Make sure to check whether the provider's pricing models allow for flexibility and if they can support any changes in demand.

#### 4 Implementation planning.

Make sure that the potential partner has a detailed implementation plan, proven methodology and key stakeholder engagement strategy that aligns with your needs and preferred operating model. The core of the plan will have to be agreed upon and included as part of the contract, with the detail developed together at the start of implementation.

## **5 Digitisation/innovation.**

As well as investigating the potential partner's current technologies, it is also crucial to ascertain their future development plans in terms of technology and capability. This is especially important, as packaging artwork and labelling contracts span several years, therefore, at a time of such a rapid technological shift, it is important to scrutinise the market to identify potential disruptors.

## **6 Location.**

It is also important to consider the partner's current location(s). Are they present in the country or regions where you operate? Do they have the account management expertise to handle an account of your size? Do they understand the regulatory requirements of your business?

## **7 Compliance/security.**

As your chosen partner will most likely gain access to protected data, it is vital to ensure that they are compliant in all aspects of data security. A non-compliant partner will put your whole organisation at risk. Are they aware of and prepared for upcoming regulation changes and do they have appropriate security certificates and systems in place? What is the timeline to implement them?

## **8 Strategic development plan.**

Your partner's strategic development plan for the next five years should also be assessed. Does it seem achievable? Is there any chance that the level of services provided will decrease over time because of the vendor's decision to free up resources to focus on other strategic projects?

## **9 People management.**

A critical key to any successful outsourcing initiative is people – any potential partner will need to demonstrate their ability to recruit, train and retain the right people, with the right skill sets in the right locations. Having a well-documented and robust HR structure and employee welfare programme is essential. Any due diligence of potential must include a review of the vendors HR policy.

## **10 Financial health.**

You will also need to assess your potential partner's financial health and evaluate their risk of not being able to fulfil their financial obligations under the terms of any proposed contract. Do they have a debt ratio? Are they profitable? Do they have liquidity problems? Are they part of/backed by a big group that could provide financial help if threatened by bankruptcy or liquidity problems?

# Final Thoughts: The Advantages for Pharmaceutical Companies

In the fast-paced, highly regulated, competitive and increasingly demanding environment requiring continuous change, the pharmaceutical industry needs to continuously seek new and better ways to do things or manage processes. Choosing to outsource can bring many quick wins, more control and greater efficiency to many of the non-core activities required to bring products to market.

Taking the right approach to identifying the right opportunities for outsourcing is not a task that should be taken lightly but with the right strategic position and by selecting the right partner the impact of outsourcing can bring benefits almost immediately and position an organisation for growth into the future.

Once you understand the strategic objective of your organisation, taking a Triple-S review of all your functions and processes, will help you standardise, simplify, identify and strategise, what processes and functions that you could outsource and the approach you need to take in that journey.

As experts in all the business processes that surround the packaging supply chain including artwork and labelling, Perigord are delivering significant cost savings, greater efficiency and improved compliance for some of the world's leading pharmaceutical organisations.

Talk to us today and let us demonstrate how by outsourcing to Perigord we can help you and your organisation.

## About the Contributors



**Michael Fleming**

Chief Operating Officer, Services Division

Michael has over 25 years of experience in artwork and packaging, and was at the helm of the day-to-day activities in Perigord's European Operation for nearly eight years before taking on the responsibility for Global Operations in 2014. As Perigord's COO, Global Services Division, Michael has operational responsibility of all of Perigord's Global Centres of Creative and Packaging Excellence and the services they provide every day to our customers. Michael is a versatile leader with good technical skills who is able to develop and motivate others to achieve targets, and can demonstrate a strong ability to manage projects from conception through to successful completion. He brings a wealth of knowledge in relation to artwork and services solutions and is at the forefront of making sure that the solutions Perigord provide are innovative and efficient.



**Gabriele Iannizzotto**

Chief Business Officer

Gabriele oversees all activities related to Sales and Business Development, globally, as Perigord's Chief Business Officer. He also proactively works on building and maintaining strong, long-lasting customer partnerships by solving client's problems and through identifying and delivering value-add customer solutions. With a career spanning almost 25 years, Gabriele has worked with most of the world's leading Pharmaceutical and Biotech companies. Gabriele's passion for innovation and his understanding of its role in the packaging supply chain has positioned Gabriele as a leading packaging authority within the Life Science industry. Gabriele's advisory role, will enhance compliance, concordance, and patient-centred care such as PSP (Patient Support Program).



**Pradip Advani**

Group Business Head, BPS

A senior leader with over 25 years in the services industry, Pradip who leads the HLS BPS practice as a Group Business Head has worked in this space for the past 18 years across the commercial, regulatory and safety, patient support and supply chain services portfolio, having delivered specialised and niche capabilities and outcomes. With experience across the spectrum, Pradip brings strong expertise and acumen of business strategy and consulting, migration and implementation, ensuring success and value creation for the customer.

*Authored by Robert Saunders, Global Commercial Director.*

## We are here to help.

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At Perigord, we know the pharmaceutical industry extensively. We work closely with 15 of the top 20 pharma companies worldwide so we understand the unique challenges they face in getting their products to market and how to overcome these challenges.

Whether you are an established global pharma business, an emerging small pharma company preparing to launch your first product, or a CMO managing multiple products for multiple clients in different markets across the globe, we have the experience, expertise, and insights to guide you.

Perigord provide full business process services supporting.

- Market coordination
- Artwork coordination
- Artwork production
- Creative design and digital delivery
- Independent Packaging and Labelling Inspection Service
- Translation management
- Change control management
- Workflow management
- Artwork production
- Managed Services

Perigord can help businesses focus and efficiently manage resources and non-core activities by supporting and managing large non-core multi-disciplinary supplier relationships.



To find out more about how Perigord can help,  
visit [www.perigord-as.com/strategic-outsourcing](http://www.perigord-as.com/strategic-outsourcing)

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