



# Outsourcing in Life Sciences:

## A Pivot To Strategic Relationships

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June 11, 2020

### **Inside:**

Introduction: Outsourcing in the Life Sciences

Outsourcing Trends: Past, Present, Future

The Decision: Make vs. Buy

Staffing Considerations

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# Introduction: Outsourcing in the Life Sciences

Outsourcing in the life sciences continues to transform from a transactional sales relationship to a more intimate business partnership where both the client (sponsor organization/company) and CDMO work symbiotically for mutual benefit. Scientific advancement and technological innovation have integrated supply chain networks like never before as each party brings unique, complementary skill sets which, when combined, can lead to competitive advantage.

As a result, many Pharma companies have adopted outsourcing as a strategy. Many business models exist with options for full outsourcing to partners or utilization of a hybrid model enabling the addition of specific knowledge, specialized skills, and/or additional capacity to an organization's asset base. Companies need to tailor these relationships to capitalize on opportunities, select the right partnerships, and right-size staffing needs. Early and effective communication is key.

Communication starts with the bidding and contract processes (Eisenburg, 2020). When transparent discussions take place at these early stages, both parties will have a better understanding of the client's needs and whether the CDMO is a fit to meet these needs. The intensity of negotiations can also help the parties understand whether their interests are aligned, which will be absolutely critical in building and maintaining a healthy long-term relationship. Strong relationships will further lead to strong collaboration.

In our experiences, we have seen companies host supplier summits, bringing together all suppliers for key product lines to share information and best practices which aids optimal supply chain security and product integrity. As companies in the life sciences space continue to push the limits of existing technologies, they are recreating the future and writing their stories, communicating and working with suppliers to see if 'they want to be part of that story' (Prasanna, 2020).<sup>1</sup>

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<sup>1</sup> Outsourced Pharma (2020); A New Decade of Outsourcing: What Can We Expect? [Webinar]; retrieval date: 03Jun20 from <https://event.on24.com/wcc/r/2350926/11D2E34E659A8D20DE3E8407F1E50B76>

# Outsourcing Trends: Past, Present, Future

'To say the last 10, much less 15 or 20 years have seen a continual evolution in organizational outsourcing strategies by pharma and biotech companies is an understatement. One could even say that the outsourcing landscape has not only changed immensely over the last two decades but appears to be nowhere close to slowing down' (Science.com, 2019).

Historically, the pharmaceutical industry has been vertically integrated, utilizing internal capabilities in brick-and-mortar facilities to develop innovative technologies, which helps them gain or maintain a competitive advantage. This strategy worked well into the late 20th century as organizations were reaping the financial benefits of high-volume blockbuster drugs in the middle of their revenue-producing lifecycles, allowing organizations to continue to reinvest in developing pipelines. However, several headwinds in the early part of the 21st century started to create a shift toward outsourcing.

Nowhere are these shifts seen more clearly than in the emerging cell and gene therapy space which has shifted the focus from small patient populations to individualized medicine. Currently, there are 987 companies working on 1,066 products for more than 7,000 targets (Dasburg, 2020).<sup>1</sup> The individualized nature of these therapies is making large-scale manufacturing plants obsolete because the volumes do not require large scale operations and the time required to build such massive structures will phase companies out of the market, even as their competitors advance therapies at significantly faster rates.

Since speed is everything in this space, a new market has emerged for smaller labs for manufacturing. The current need is for over 1,000 labs; only around 100 are currently operating (Dashburg, 2020).<sup>i</sup> This has made suppliers a critical component of the supply chain. The labs currently operating must be efficient to drive both optimal capacity and delivery to patients. In many cases, the exact timing of drug delivery is required. So, for example, a supplier must receive a blood sample, manufacture the therapy, and transport cryogenically to a hospital in a matter of weeks.

Dendron has developed a process for vein to vein drug delivery in four days (Dasburg, 2020).<sup>i</sup> With this comes a tremendous cost. Gene and cell therapy suppliers have a huge demand for their limited supply. In some cases, we have experienced greater than 12-month queues for highly-regarded suppliers. Additionally, the premium rates for these limited slots are increasing pricing pressure to payers as sponsors are passing costs through. As will be discussed at length below, the decision to build gene and cell therapy labs will be driven by an organization's culture- specifically, its historical preference, risk tolerance, and need for control - plus its cost, speed, and compliance, among other things.

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<sup>2</sup>Industry Trends (2019); An Overview of Outsourcing in the Life Sciences, Part 1: Seas of Change [Electronic Version]; retrieval date: 01Jun20 from <https://blog.scientist.com/2019/02/27/an-overview-of-outsourcing-in-the-life-sciences/>

# Outsourcing Trends: Past, Present, Future

An emerging trend definitely worth noting will be increased pressures for pharma companies to begin bringing supply chains closer to home after COVID-19 has exposed vulnerabilities. The COVID-19 pandemic has highlighted the risks associated with low-cost and high-risk supply chains driving pharma companies to re-analyze their existing strategies.

Organizations need to re-weigh the cost-benefit analysis regarding global sourcing locations, safety stock, and partner business continuity planning. Many companies will be looking to move manufacturing operations closer to key markets and customers while increasing safety stock levels. Both of these risk-mitigation items will lead to increased costs. There will be an up-front investment in tech transfers and/or building out new facilities in new locations, as well as probable increases to unit costing as companies move into locations with higher labor and tax costs.

Additionally, COVID-19 has changed the import/export landscape as governments all over the world are increasing tariffs and VAT to compensate for the decrease in foreign goods entering their countries and incentivize their manufacturers to sell goods at home. As a result, transport costs should carry a higher weighting in a company's supply chain cost-benefit analysis moving forward (Mark Ludwig, 2020).<sup>3</sup>

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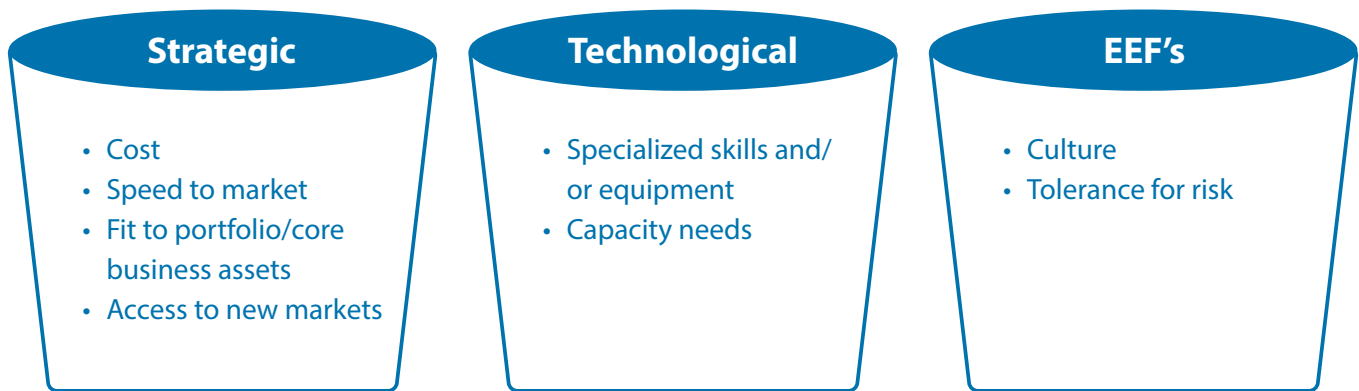
<sup>3</sup>. Iiii. Ludwig, Mark and Simon Kelly (2020): Life Sciences Supply Chains in the Wake of the Pandemic [Electronic Version]; retrieval date: 10Jun20 from <https://rsmus.com/economics/coronavirus-resource-center/life-sciences-supply-chain-considerations-in-the-wake-of-the-pan.html>

# The Decision: Make vs. Buy

The plan, conduct, and control procurements phases (supplier bid planning, analysis, selection and monitoring) for outsourcing involve a complex analytical process where an organization needs to evaluate the potential benefits of externalizing the product or service against using in-house resources. This process starts with the decision to make (internally) or buy (from an external supplier).

In this section, we will break down some of the high-level drivers (Team, 2010) that many organizations use as baselines for sourcing decisions. While there are many individual drivers, we have found that most can fall into the high level “buckets” shown in Figure 1.

**Figure 1: Key Evaluation “Buckets” for Make vs. Buy Analysis**



In most cases, there is an integrated decision-making process where multiple criteria are analyzed to determine the sourcing selection without a single factor being the sole criterion to make the decision. Many times, however, an organization will use a weighted analysis allowing higher-priority factors to have a greater influence on the organization’s decision.

For example, in our experience, new product or feature introductions prioritize speed to market over cost. For a first-in-class product launch, delays risk revenue loss as patent expirations are dated from the patent application, not the drug’s market approval. The high cost of pharmaceutical products means that even the loss of a few months (or even weeks) of revenue can impact an organization’s financial flows.

<sup>4</sup> LNS Research Team (2014); Thinking Outside the Box: 7 Drivers Behind Life Sciences Outsourcing [Electronic Version]; retrieval date: 01Jun20 from <https://blog.insresearch.com/blog/bid/197513/Thinking-Outside-the-Box-7-Drivers-Behind-Life-Sciences-Outsourcing>

# The Decision: Make vs. Buy

Additionally, many of today's new age pharma products are coming from publicly-traded companies, big and small. Even a delay in revenue recognition could impact a company's earnings reporting potentially risking investor flight, which could lead to future funding challenges. Lastly, when innovation drives a product improvement, companies also tend to prioritize speed to market aiming to maximize market penetration to capitalize on their new best-in-class technology for the greatest time period possible.

In all these cases above, the risk of lost revenues or threatened institutional capital generally far outweigh the minimal operational costs of things like spare equipment parts, back-up components, and staff overtime.

Let's take a closer look at some of the detailed factors frequently evaluated within each bucket. We have listed cost and speed to market in the strategic bucket but should highlight the crossover into the enterprise environmental factors (EEFs) bucket. As discussed above, in our experiences, the balance between cost and speed has generally been driven by the business's strategic drivers, prioritizing speed to market over cost based on the longer-term value the initiative can yield when completed on time.

Assumptions surrounding this insight are geared more to the commercial space where forecasts tend to be more stable and organizations can leverage multiple products and/or higher volumes during negotiations. However, an organization's culture, specifically its tolerance or appetite for risk, can drive cost decisions as well. Financial risk is viewed much differently in smaller companies with less cash flow.

A more risk-based cost approach is undertaken, especially when selecting an early-phase development CDMO partner because the longer-term outlook of the program is highly uncertain. Contractual terms become more critical than more traditional cost measurements, like unit cost. We have rejected CDMOs, choosing to pay more on a single batch basis, based on the financial risk imposed by the cancellation terms of a contract.

For example, it becomes impractical and cost-prohibitive to accept take-or-pay terms for a five-year period for a Phase 1 asset when forecast accuracy levels for early-stage assets are erratic as bioavailability data is being collected and clinical trials are being designed. The same is true when there is no sense of certainty that the asset will even be viable that deep into its lifecycle. In these types of situations, it becomes easier to justify cost overruns in risk-averse organizations than to articulate long term value (Eisenburg, 2020).<sup>i</sup>

Fit to portfolio, or an organization's core business, can be another strategic driver in the decision to outsource. Assuming for now that all else is equal in regard to technology and intellectual property security (these items will be covered below), the high-level SWOT analysis template shown in Figure 2 could help an organization make this determination.

# The Decision: Make vs. Buy

Strategic SWOT		Internal	
		Strengths	Weaknesses
External	Opportunities	Capitalize	Acquire
	Threats	Monitor	Divest

**Figure 2: Strategic SWOT Analysis**

This high-level governance structure can be customized to detail an Organization's core business functions ultimately aiding the decision to outsource.

In general, strengths and weaknesses tend to be internal to the organization while opportunities and threats come about from the external marketplace (i.e. what one's competitors are doing, what the customer wants, etc.) When a company has a strength and a market opportunity presents itself, the company should set activities in motion that will exacerbate the positive risk so that it can capitalize.

A great example is how packaging and labeling CDMOs responded to governmental mandated serialization requirements. Many of the players in this space quickly adapted by becoming subject matter experts in both the regulations and technology associated with the new requirements. They also procured the necessary equipment enabling them to provide a turnkey solution for both larger pharma companies, which may not have acquired the knowledge to implement an in-house solution, as well as smaller pharma companies, which did not have the cash flow or product volumes to justify equipment procurement.

# The Decision: Make vs. Buy

Organizations looking to capitalize on a market opportunity with one of their strengths would tend to leverage internal capabilities to maintain control over both the capability and the optimization of the opportunity. On the other side of this is when an organization has a weakness and there is a market opportunity or threat. In a situation where there is a threat, the company would look to divest. If there is an opportunity or the capability cannot be fully divested (i.e. the product or service is a loss leader for a larger portfolio of products for a key client), the organization should look to outsource or even enter into a business alliance or partnership.

An example of this could be when smaller organizations sell off global rights to larger pharma companies in order to leverage a broader commercial team to maximize global revenue streams by accessing new markets. Lastly, we want to look at when there is a threat to a company's strength or core business functions. In this case, the organization may not want (or even need) to act but rather create risk response plans for implementation if needed. A simple, high-level example of this could be the launch of a competing product.

Capacity and capability often play a significant role in outsourcing decision making. Many times, it is part of the holistic strategy. Organizations that follow a full outsourcing model, for example, have a high degree of subject matter expertise for their specific product. However, they are completely dependent on their outsourcing partners for capacity and are highly reliant on them for more generalized subject matter knowledge expertise (i.e. equipment operation and other operating procedures). The smaller the organization is, the more dependent it becomes on developing the relationship into a partnership.

Traditionally, the relationships have been built by having boots on the ground. Heavy on-site presence from the sponsor organization is generally required prior to and during the site selection process to ensure that the chosen CDMO has adequate technical knowledge, efficient and underloaded capacity, and complementary processes, systems, and culture as well as person-in-plant during execution activities to monitor compliance and production process. Many organizations are evolving and turning toward a concept termed technology-aided transparency (Spes, 2020)<sup>i</sup> as the world evolves to support alternate means of business continuity following the COVID-19 outbreak.

This form of virtual relationship-building utilizes video-conferencing and other forms of virtual reality to maintain and even create new relationships. In its infancy, the concept of physical auditing has become a point of contention in the gene and cell therapy space as suppliers are less likely to allow sponsors to physically enter their production suites due to concerns for product integrity and intellectual property, while physical audits are what the small molecule and biopharma industries as a whole are historically accustomed to. While many believe that COVID-19 has fast-forwarded a growing movement for virtual work, it will be interesting to monitor the evolution of these traditionally infrastructure-based activities, like auditing, over the next few years to see if the changeover to camera or other virtual reality methods will ever be fully accepted by the industry and its regulatory oversight bodies.



# The Decision: Make vs. Buy

Larger companies, which both house internal operations and have external manufacturing capabilities, require a more robust decision-making process. There is generally more of a choice here and several variables that should be considered.

As introduced above, if the technology is an internal strength, the holding organization will tend to go in-house for control and security of intellectual property. Conversely, if the technology is the strength of a CDMO, it generally makes more financial sense to outsource than to hire the necessary resources. This still adds the deep knowledge breadth of the CDMO to the sponsor organization's asset base.

Additionally, it is generally cost-prohibitive for a sponsor to procure equipment needed for specialized technologies, as these products many times have low throughputs. CDMOs can utilize the equipment across a network of clients, absorbing the depreciation and driving down the unit costs.

An example is the Groeninger syringe labeler, which has an initial investment north of \$1 million. With the emergence of Fortune 500 pharma companies entering the rare disease space, many times, even with product portfolios of 10 or more assets, these companies still do not have adequate volume to maintain enough uptime to make the procurement and maintenance of these high costs pieces of equipment financially viable. Instead, they chose to outsource. The drawback is that outsourcing comes with less control and thus decreased flexibility to meet any rapid changes in market supply demands.

Here again is where relationship building, partnering, and negotiation become the key drivers to a successfully outsourced supply chain. In some cases, we have seen situations where speed-to-market trumps cost for key product lines. The sponsor organization will actually pay for the procurement, installation, and maintenance costs of the equipment even if the equipment only runs a few times or even once per year (i.e. auto-injector space).

It will also pay the CDMO to house the equipment and for the idle line time. The sponsor organization, in a sense, buys a portion of the CDMO and absorbs all overhead as if internalizing the supply chain. In these cases, the risk (value, reputational, or cultural) makes the costs a non-factor in choosing to completely eliminate the risk of market shortages. In some cases, the sponsor organization will sell its idle capacity to help offset costs. However, intellectual property concerns sometimes lead risk-averse companies with deep pockets to absorb the overhead as a sunken cost of doing business.

An organization's cultural risk appetite plays a role in driving outsourcing decisions as well. Organizations less willing to take risks will keep product technologies as close as they can until some driving force - portfolio growth, capacity constraints, and so forth - makes internal operations no longer viable. So organizations need to choose whether to dual source a key product line to multiple suppliers or source to a single supplier. There are advantages and disadvantages to both.

# The Decision: Make vs. Buy

Dual sourcing increases both complexity and cost as it effectively doubles your network, possibly resulting in disbursement struggles and the need for additional staff for proper oversight, among other issues. Perhaps both CDMOs will try to negotiate minimum order quantities or take-or-pay clauses in contracts.

While single-sourcing alleviates many of these issues, it presents a supply chain security risk as 'all eggs are in one basket' so any disasters - natural, governmental, force majeure, etc. - can cause irreparable damage to a supply chain. As we are quickly learning the reality of these cataclysmic situations, this threat becomes much clearer.

With the globalization of the CDMOs as well as a growing presence in the research and development spaces, there is another emerging opportunity for pharma companies to leverage. Dual sourcing at multiple sites within the same CDMO allows for an organization to effectively mitigate the risks of a single source while leveraging global contracts to keep pricing and other constraints in line.

# Staffing Considerations

As organizations finalize their business strategies around outsourcing, the next strategy to be developed is staffing needs for the chosen model. While the levels of staffing are proportional to the amount of reliance on the CDMO (i.e. companies that outsource most or all of their work will tend to have a larger staff overseeing the external manufacturing work), the ideology remains consistent. In other words, organizations 'right-size' their staffing for the scale of operations outsourced.

We have seen 4 high-level models when it comes to staffing external manufacturing business units.

**Figure 3: Outsourcing Staffing Models with associated Advantages (A) & Disadvantages (D)**

		Cost	Communication	Subject Matter Expertise	Complimentary Skillset	Transparency in Supply Chain	Career Development
<b>Regional</b>	Refers to a model based on geographical dispersion of staff in relation to CDMO location (i.e. utilizing EU staffing to manage local European suppliers)	A	A	D	D	D	D
<b>Nodal</b>	Can also be referred to as technological Refers to setting staffing to manage specific nodes of the supply chain (i.e. the focus is API or Aseptic fill finish regardless of product category)	D	A	A	D	D	A
<b>Product</b>	Refers to staffing a product line (i.e. a staff member manages the end-to-end CDMO network for a product line)	D	D	A	D	A	A
<b>Hybrid</b>	Refers to any combination of two or more of the three distinct models above	A	A	A	A	A	A

# Staffing Considerations

Regional staffing models put the external site managers in close geographic proximity to the product or service supplier. The benefits of this staffing model are mostly administrative. Localized management facilitates communication in a few ways. It minimizes the disruption of partners being in different time zones plus enables more frequent opportunities for face-to-face interaction. It creates additional cost savings on the S&G expense line as travel expenses are lower since employees are driving and taking local flights or trains rather than trans-oceanic or trans-continental business class flights.

For us, the risks associated with this model outweigh the administrative benefits. Many times, organizations utilize staff members that are already in place and effectively retrofit the staff to the new supplier, technology, etc. In the best case, there is a learning curve for the employee to get up to speed managing the new supplier and learning the new product and its associated technology. This can lead to a slow or 'rocky' start to the new business relationship at a critical time when strong collaboration is needed.

In the worst case, the employee does not have the necessary skills to manage the new unit. This will strain and eventually erode the relationship, placing an extended risk on the supply chain. Companies must ensure that the staff members selected to manage outsourcing partners have the necessary skills to perform the job adequately, are properly trained, and/or have the needed support resources to enable success. One last drawback of this model is that it can limit staff development because assignments are based more on where you are located rather than your background, skills, and career interests.

Nodal, or technology-based, staffing models base staff assignments on a specific node of the supply chain with the major buckets being API, drug product/fill finish, and packaging and labeling. Let's take a hypothetical example of a medium-sized product portfolio containing three small molecule products.

In our example, the supply chain is efficient and the technology allows for all three APIs to be dual sourced from the same two suppliers. In this case, one staff member would likely be assigned to oversee all API activities for these two suppliers. One benefit of this model is that it provides a single point of contact for the supplier. This clearly identifies for the supplier who it can go to resolve problems, especially surrounding product prioritization.

When there are multiple interfaces with a CDMO, everyone believes that their issue is most critical and needs to be resolved first. Having a single point of contact eliminates this bias as one person is accountable for the portfolio of products rather than a single product, so they are making decisions from a holistic organization view rather than a narrower product view.

Let's now add a biologic-based product to this medium-sized portfolio. In this case, it is likely that the organization would need to add another API supplier to its asset base as this is a different technology than currently exists in the portfolio. Many times, the organization would expand its staffing to include personnel with a stronger background in biologics. The advantages of this nodal model are that staff develops deeper expertise in their node. It also provides staff with career growth as they learn the various aspects of supply chain functions, enabling them to ultimately grow into more prominent positions throughout the company.

# Staffing Considerations

One aspect to monitor in this model is the need for both business and technical aptitude of the managing staff. These two skills are not always complimentary. Those with technical expertise cannot always work well with people and, conversely, great collaborators do not always translate into great scientific minds. So again, training and supporting resources become critical for success in this model.

Product-based staffing models set staff to 'own' a product end-to-end, meaning that the staff needs to understand the intricacies of the product and its supply chain. They must have, at a minimum, a high level of understanding of all supply chain nodes. A major advantage of this model is transparency in the supply chain. By having visibility to a product's end-to-end supply chain, the manager can anticipate delays and start creating risk mitigation plans to ensure uninterrupted supply.

For example, if a batch of API material is delivered a month late, the manager can begin working with the drug product and packaging/labeling sites to crash activities to keep the final product release on schedule. This can be managed with the other models listed above but is reliant on robust, formalized communication processes like tier meetings or other frequent production update meetings.

We have, in our experiences, been frequently blind-sided by late API or drug product deliveries while using the nodal staffing model. This led to cost overruns and strained relationships with downstream suppliers as the need to expedite quickly turned into a standard way of operating. This staffing model does allow for career development. As it contains both a business and technical core competency, staff can move into business positions managing more aspects of the product (i.e. lifecycle management, marketing, etc.) or can dive deeper into a technical role associated with the product.

Additionally, not all products are created equally, so there is always the opportunity to move laterally and run operations for a new or higher profile product. This can help the manager become recognized at higher levels of the organization, which can lead to future opportunities to grow.

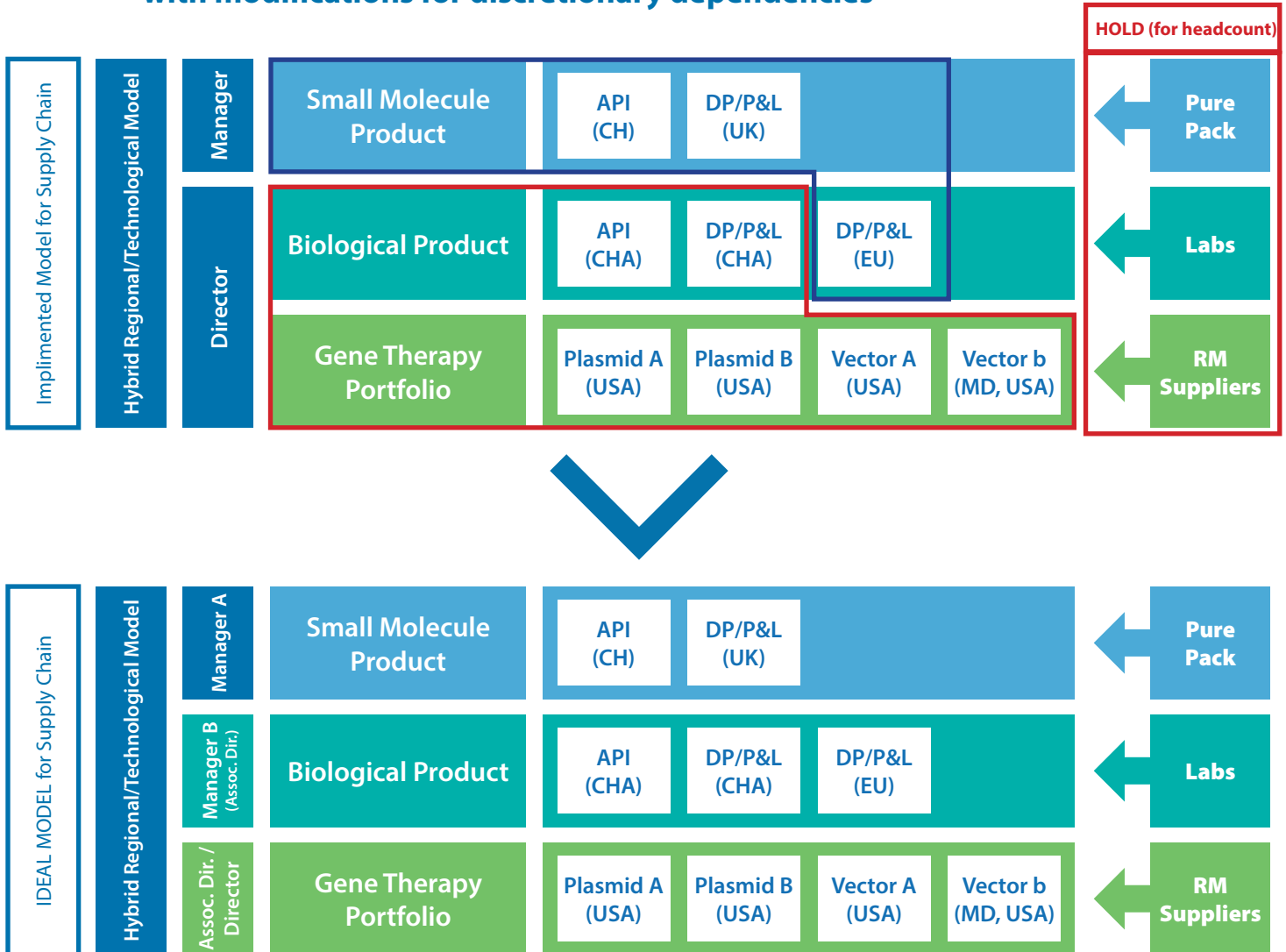
Probably the biggest disadvantage of this model is communication barriers. These models may not be geographically desirable since so many supply chains and product portfolios are global. As a result, the logistical communication gaps mentioned below could be present. Moreover, in multi-product organizations, a supplier could have multiple stakeholders from the same organization who all have competing priorities.

For example, we managed a pure packaging and labeling site with nine commercial products across three technical divisions, plus twelve active projects. Using the product-based staffing model, this could have led to the supplier having to take guidance from almost two dozen stakeholders!

Lastly, hybrid models tailor the organization's staffing model, combining the features of the above models which will best optimize cost and human resource allocation. Let's talk through a case study for a mid-sized Pharma organization as diagrammed in Figure 4.

# Staffing Considerations

**Figure 4: Case Study highlighting use of Regional & Technical Hybrid Model with modifications for discretionary dependencies**



The case study is for a mid-sized Biotech company headquartered in the US having a large satellite presence for operations in the UK as well. The organization had one commercial asset available in the US and parts of the EU, which was a small molecule product with a single supply chain for all markets procured from suppliers in Switzerland and the UK.

The second asset was a late-stage biologic manufactured fully in China (API through P&L). Drug product finish and P&L activities were in the process of being tech transferred to a supplier in the EU; this activity was scheduled for completion after the product's launch. This product also had an associated chaperone, which was a small molecule commodity sourced from the US. Lastly, the organization acquired a gene therapy portfolio of very early-stage assets and was building out the supply chain architecture.

# Staffing Considerations

While the split in our case study theoretically fit nicely into a regional and nodal/technological hybrid model, three specific constraints created the need to customize specifically for the organization. First, the organization's management team had a heavy bias toward the existing straight regional model. There was limited flexibility in their thinking.

The second constraint was that the model was initially set with the assumption that the department would be granted three resources. However, only two heads were approved for the budget. Lastly was the presence of minor suppliers and the addition of suppliers needing to be managed by the team in the long term. As a result, the staffing was configured for growth setting an interim plan with a two-year plan to establish the ideal model.

We stayed with the regional and added aspects of the nodal hybrid model with a few short-term improvisations. The manager out of the UK office was given responsibility for the small molecule product technology and associated suppliers in Switzerland and the UK. Additionally, the manager was tasked to oversee the successful tech transfer of the biologic product from the Chinese to the EU supplier. This structure provided the localized oversight that the management team was looking for yet also provided a gateway for the employee to own a critical, highly visible activity and advance their knowledge by undertaking activities across multiple technological disciplines.

The area director, located in the US headquarters, then had to take direct responsibility for the API processing for the biologic product as well as ownership of setting up the gene therapy supply chain. This split made sense as the manufacturing processes and technologies for biologics API and gene therapy products are more aligned with each other than with chemical synthesis processing of small molecule API products.

This again provided regional management as per the initial guardrails set by management. Please note that there were no employees located in China so this supplier could not be managed regionally. The area director also passively oversaw the procurement of the small molecule chaperone.

This interim model was created as a bridge to acquire staffing for the ideal model. An additional headcount was requested for the next fiscal year, which would allow for full realization of the model. A business case was created for the additional headcount based on the addition of suppliers to the base.

As stated above, there is currently hands-off, passive management of the chaperone procurement. As the biologic product advances toward commercialization, this commodity item becomes more critical and would require a much more formalized management.

For example, the material needed for the clinic was ordered then stockpiled and discarded as it expired. Not only is this a cost-inefficient way to run a commercial supply chain, but it introduces a huge amount of risk if this material is not available when needed. Imagine having to backorder a rare disease biologic, which takes almost a year to make with a CoG's of almost \$1 million per batch, because there was a breakdown in the

# Staffing Considerations

supply chain for the commodity chemical, which costs a few cents per kilogram. This would have financial as well as reputational ramifications.

Additionally, the area agreed to begin managing the relationships with analytical labs as their number and importance increased along with the commercial product portfolio. Lastly, the secondary P&L sites for the gene therapy products needed to be established in the long term as none of the vector suppliers were currently performing these activities.

One last, valuable aspect of the model is the opportunity for staff growth. As you can see, the model is broken down to increase responsibilities and aptitude providing a progression and career path for employees. For example, a manager can enter the organization supporting the small molecule/P&L business unit and advance through the Biologics/AD business unit, and finally, into the high profile gene therapy space.