

A Customer Case Study in Strategic Outsourcing: Key Decisions and Processes

By Argonaut Manufacturing Services

Executive Summary

This case study outlines the decision-making process a new Argonaut client used to determine the best cGMP manufacturing solution for their applied market NGS kits. Faced with the need to quickly scale, their options were to expand internal manufacturing capabilities or outsource. Ultimately, outsourcing was chosen, as it had the lowest risk to the company and was their fastest route to market. Their primary concern over costs was overcome by engaging the Argonaut Ecosystem. Rather than retaining pieces of the manufacturing path internally, a turnkey solution was chosen to maintain company focus.

The Problem

The NGS company was facing a growth opportunity challenge when they contacted Argonaut. They had developed a successful kit for research use only (RUO), but it was now gaining early traction in new areas. These new markets required a higher level of quality and regulatory compliance than internal manufacturing was currently delivering with their RUO product. Timelines were a factor, as well. The company's first major client needed product within three months, and the possibility of capturing a second, larger, client was becoming more real by the day. The team was excited, but understandably anxious whether they could fulfill the manufacturing needs of the first client, much less the expanded scale and scope of the second. To further exacerbate the situation, competitive price pressures in the NGS market had the potential to force them into low margins if manufacturing costs were high.

The team needed to make a decision, and fast. Should they expand their internal manufacturing capabilities or outsource to a reagent contract manufacturer? And, if they did outsource manufacturing, to what extent? Did it make sense to retain control of purchasing, quality control or fulfillment? They quickly launched an effort to compare the available options.

Option 1: Expand Internal Capabilities

For this customer, the appeal of adding internal capabilities centered primarily on being able to leverage a larger manufacturing team. Internal manufacturing would enable easy

transitions of new products while allowing greater control of manufacturing and visibility into costs.

The team also identified three primary drawbacks to expanding internal manufacturing:

Speed- They would need to not only build a cGMP manufacturing suite, but also acquire educated staff to implement and maintain it. With long lead times necessary to expand the facility and obtain new equipment, a proper validation would be a prolonged and demanding process.

Scale- Another problem facing the team was not knowing what scale facility to build. While the second client would be exponentially larger than the initial client, the scaled costs would also be higher. And, there was still no certainty the second client would sign. Should the deal fall through, they could be left with a large facility sitting dormant.

Opportunity- A buildout to implement cGMP would likely disrupt current operations. With resources already strained, there was a risk of cannibalizing key personnel to staff the new manufacturing line.

Option 2: Outsource Manufacturing

Outsourcing could provide a number of advantages to the company, but would also mean relinquishing some control over the manufacturing process. However, the primary concerns this team identified with outsourcing were cost and time to delivery. If these concerns could be overcome they would gain:

Flexibility- Contract manufacturers offer “right-sized” processes and already have installed the necessary equipment to scale up. Operations could scale easily with an outsourced solution if they captured the second client, rather than paying up front for larger facilities they might not need.

Reduced Risk- A large buildout for internal manufacturing capabilities risked capital and possible overexpansion. Outsourcing offers variabilized costs that are more palatable.

Focus- Managing a cGMP facility was not an area of expertise for the company. In order to scale their manufacturing and meet the new regulatory requirements, they would need to bring in new talent. The team strongly preferred to stay focused on building new products and commercialization efforts rather than spreading themselves thin.

The CMO Selection Process

After comparing the options, the NGS company decided to outsource their manufacturing and began screening potential contract manufacturing organizations (CMO's). Primary decision criteria's they looked for were knowledgeable teams, demonstrated performance, and stability of the supplier. They strongly suspected that cost would become a factor, but initially deprioritized this believing that costs would improve over time as volumes increased.

An unexpected roadblock was that the team had difficulty obtaining apples-to-apples quotes from the various providers. Some proposals had costs that were hidden, while in others

the benefits (e.g. QC testing) were baked into overall prices and not broken out. The team found it difficult to make comparisons, as some quotes also did not include terms. Argonaut has since written a [guide to comparing contract manufacturer proposals](#), which can help teams in similar situations overcome opaque pricing models. In order to streamline the later phase of decision-making, the competing pool was reduced to two finalists.

Overcoming Costs through Strategic Ecosystem Sourcing

Initially the quotes from both finalists were higher than the company was able to take on, especially considering that pricing pressure in NGS is anticipated to worsen. The source of the issue was that numerous expensive enzymes and buffers were dominating the COGS. Collectively, four enzymes were driving a significant component of total costs. If the material COGS (mCOGS) could be reduced, margins would improve and outsourcing would continue to look attractive and Argonaut's proposal would become the obvious path forward. Situations like these are why Argonaut chooses to maintain "ecosystem partners"; a network of trusted companies that provide complementary service offerings. One ecosystem partner was able to supply all of the required price-sensitive materials at a substantial cost savings. The substitution materials were tested and it was found that all met specifications. As an additional benefit, three of the four had variants available that actually exceeded the existing specifications, allowing less reagent to be used in each reaction and enabling further cost savings.

By substituting key raw materials sourced from the ecosystem partners, the sticker price savings and reduced enzyme volume enabled Argonaut to improve the project mCOGS by an astonishing 40%-60% (dependent on batch size).

Evaluating Turnkey Solutions

With such a large improvement in material COGS, the company next decided to explore a full-service solution with their savings. In this model, Argonaut would provide not only the manufacturing but also handle the purchasing, packaging and shipping. The company also considered supplying the materials themselves ("consignment") as an option to help drive down costs, but had two primary concerns about a consignment model: Purchasing and Staging.

Purchasing- Relying on their internal RUO manufacturing team to purchase custom bulk reagents with demanding QC criteria was a risk. The new regulatory requirements exceeded the experience of their internal staff. Any errors in purchasing the large lots would be very expensive.

Staging- With their clients demanding an aggressive delivery schedule, the leadership team was concerned about providing raw materials to Argonaut in a timely fashion. Materials purchased too early were a waste of capital and could expire, while those purchased too late impacted delivery and could cause backorders. Further, delayed materials could potentially cause harmful damage to the CMO's production schedule if a build is missed as a result.

The overall consignment purchasing risk was eventually deemed too high, and it was decided to outsource procurement to Argonaut.

Packaging and shipping also required the team to weigh pros and cons. The NGS kit would be white labeled for their clients instead of using their own branding. With multiple types of boxes, inserts, and labels to keep track of, it was far easier to outsource the packaging to Argonaut. Deciding to handle shipping logistics in house would mean dedicating a large amount of space for ramp-up capabilities, which might not be needed. The need to conserve space, combined with the favorable bulk pricing Argonaut was able to achieve with shipping partners, made the choice to outsource shipping easy.

The Final Decision

When the executive team met to make their final CMO selection, it was clear that every stakeholder had a different priority. The CEO was most concerned with keeping costs reasonable and choosing a strong partner. The CSO prioritized the product's functionality and user experience improvements that could be realized with the right CMO, including higher-performance enzymes and lyophilization. For the CCO, delivery time commitments were paramount. With all of these priorities combined, Argonaut pulled ahead as the clear winner. Their efforts to trim costs had demonstrated flexibility and a client-first attitude, as well as the value that their ecosystem partners could provide. Further, their available supporting services like lyophilization and commitment to a rapid delivery schedule satisfied the team. Overall, choosing Argonaut was a decision the team felt confident in.

Lessons Learned

Engaging contract manufacturers and comparing costs was not as straightforward as the team initially planned. Both CMOs and raw materials vendors struggled to provide quotes in a timely fashion, and when pricing was finally received it was often opaque. The team needed to be diligent in assessing gaps between quotes from different vendors. As an example, one potential vendor did not include NGS kit assembly in a DNase free environment; this would be an additional charge. Quickly narrowing down to only two potential manufacturers allowed deeper conversations, and gave the team a sense of each CMO's working style.

Summary

Every company will have a different journey as they evaluate whether outsourcing is the right strategy for them. In the end, this client decided a turnkey solution from Argonaut was the best approach. Choosing Argonaut to manufacture for them required the least capital outlay, was the lowest risk to quality, and assured their timelines would be met. For this client, working with Argonaut was a guarantee of Reagents Made Right.

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