HEALTHCARE & LIFE SCIENCES

HOW A&M HELPS ASSET-LIGHT PHARMA COMPANIES OPTIMISE THE CMO NETWORK FOR GROWTH

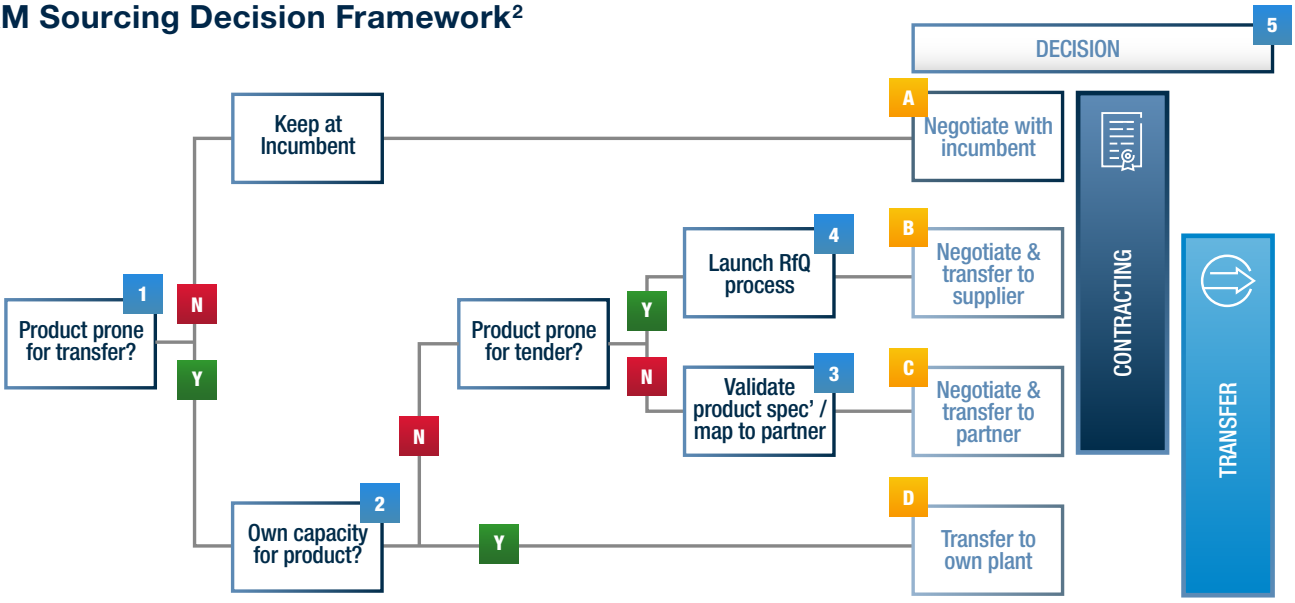
Introduction

A well-performing Contract Manufacturing Organisation (CMO) network is critical for asset-light pharma companies as the ability to supply is often the main hindrance to growth. Root causes of issues include becoming locked in with underperforming CMOs, not finding and building up alternatives, or failing to run transfers efficiently. In this article, we present the A&M Sourcing Decision Framework and show how we have practically used it to help our clients become more agile and structured to reshape their CMO network and support future growth.

The pharmaceutical industry in Europe is worth ~€250b in 2020 and is expected to grow at a compound annual growth rate (CAGR) of >5 percent until 2028[1]. It is widely acknowledged that small and mid-sized pharma companies play a decisive role as drivers of change and often respond to market changes faster than their larger competitors. Since many of the former are private equity-owned and want to remain asset-light, they rely heavily on CMO networks to enable growth. One mid-size pharma that we worked with had a CMO network of 35 manufacturing sites. The main challenge in this complex situation was how to mobilise the CMOs in a structured fashion and succeed with tech transfers.

Below is the action-oriented A&M Sourcing Decision Framework for marketed products that A&M applies to help asset-light pharma unleash their growth potential. We will demonstrate how to use it in adjusting the CMO network in a dynamic and coordinated way.

A&M Sourcing Decision Framework[2]



[1]www.grandviewresearch.com

[2]'Incumbent' currently produces the product, may be a licensor; 'Supplier' is a new supplier that is eligible to produce the product and is chosen after a Request for Quotation (RfQ) process; 'Partner' is an existing / positively known supplier that is eligible to produce the product.

Know yourself first: Can we transfer[1] and/or do we have own capacity for the product[2]

A robust understanding of the current state speeds up the process and helps focus efforts on the right products to reach optimal negotiation results. Before addressing transfer ability and internal production capabilities, our experts always review the contractual situation, to ensure awareness of licensing/lock-in scenarios and incumbent supplier relationships that may prevent changes as well as affect timing future decision points.

Ability to transfer products and technology

We continue with considering the ability to transfer technology to third parties (e.g. CMOs). As a rule of thumb, the total payback time should not be more than two to three years for a tech transfer and transfer risk assessed as low-to-medium; otherwise, remaining and negotiating with incumbents is likely the preferable option. To reduce the risk of failed transfers, basic transfer ability includes the following:

- Generate good baseline data and forward vision, enabling swift decision-making. Product documentation (dossier) must be in English and detailed thoroughly.
- Keep an up-to-date pool of reliable CMOs by geography and technical capability who are capable to pick up transfers and produce products in a robust and reliable way.
- Secure resources and competencies that can drive transfers at pace, triggering stage gates from (virtual) supplier audits to commercial production within the required timeline. This refers to transfer/project managers but even more to availability of specialist competencies such as quality or regulatory affairs.

Clarity on internal production capabilities

If possible, it is preferable to transfer products in-house to fill spare capacity and increase asset utilisation to the extent it does not require substantial build-up of new capabilities and capital expenditure (CapEx). This would go against the asset-light strategy and add risk of poor quality, late deliveries and cost overruns. Make and buy decisions should be based on a solid understanding of current state and include risk-assessed models of costs and efficiency improvements, involving stakeholder functions.

Validate product specification/map to partner[3]

Should there be no suitable in-house availability, which will often be the case for asset-light firms, the next preferred option foresees reviewing the existing network of preferred suppliers and evaluating them against key product criteria such as dosage form, required technology, volume or special regulatory or analytical capabilities.

If preferred suppliers (i.e. true partners with which we have built a trustful relationship in the past) appear suitable, we do a quick tender and, if an open-book agreement or basic cost value analysis suggest the quotation is competitive, we may pre-contract and trigger transfer activities to a partner from our preferred CMO network. A clear advantage with this approach is the short lead time, and that tech transfers usually run more smoothly with established partners who are equally eager to establish long-lasting strategic partnerships that align with their goals around horizontal and vertical integration, global expansion, new technologies and so forth.

If we lack suitable partners, the quotation of the preferred partner is not competitive, or the product has high commoditised portions, the product is more suitable for a request for quotation (RfQ) process.

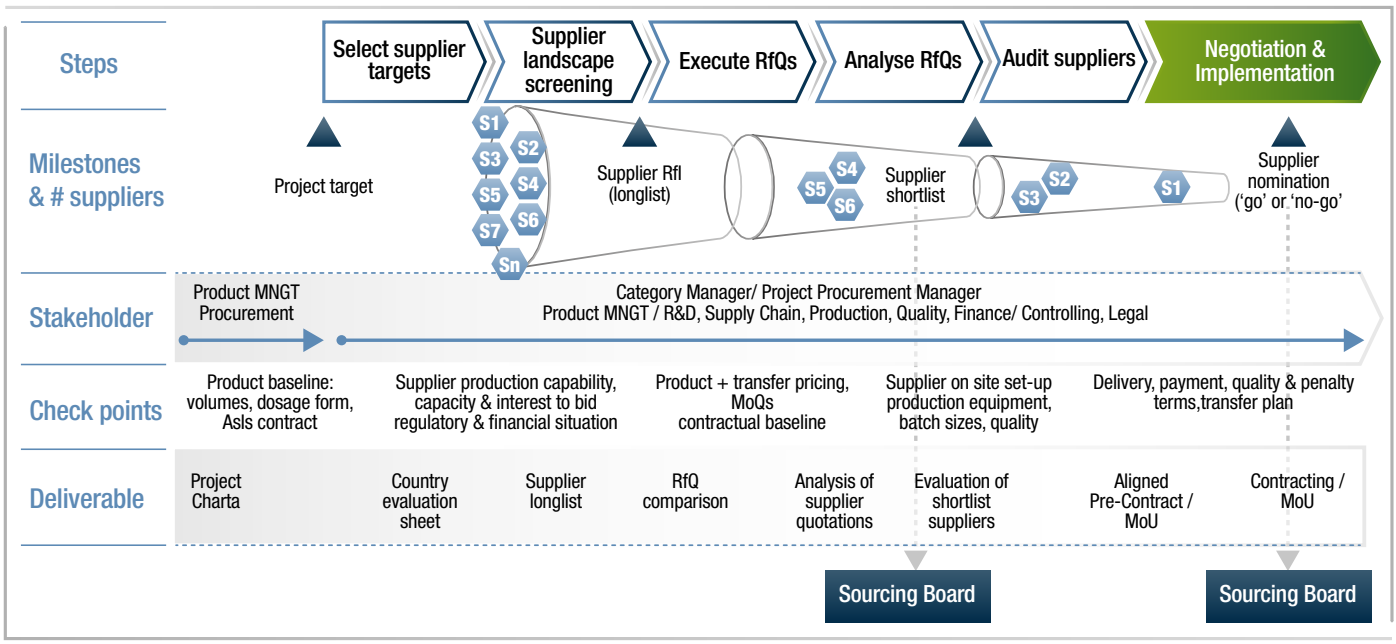
Launch RfQ process[4]

Running an RfQ aims to identify the most competitive supplier for the product keeping 'Best Cost Country' in mind. In a full scope supplier assessment and selection process, we start with reviewing our CMO database; for specific scenarios, we also involve research agencies.

Following an initial request for information, checking basic supplier capability and nondisclosure agreements (NDAs), the actual RfQ is initiated, accompanied by detailed technical requirements and dossiers. The suppliers (including the incumbent) are usually evaluated in two to three rounds and down-selected according to their ability to deliver, price, quality, lead times and so forth. Prior to final negotiation and contracting, the technical capability is validated via an on-site supplier audit.

While the supplier selection through an RfQ takes two to three months longer than going to a preferred partner, it does give confidence that the process is guiding us towards the most competitive price point considering key dimensions such as batch sizes or minimum order quantity (MOQ); in a highly commoditised scenario, this can be further enforced through running an auction.

Supplier assessment and (pre-)selection



While the RfQ is designed to find the lowest price point and ensuring suppliers' technical capability to deliver the product, it can also be used as starting point to establish a trustful relationship. In line with that aim to set the right tone by sharing and adhering to communicated timelines as well as providing technical data and giving commercial guidance without sharing competitor details.

On a more detailed level, success factors for the RfQ process include:

- Start a Request for Information (RfI) timely, involve a wide group of potential suppliers given their current situation, hunger for new work may be different from your expectation.
- Ensure early that the RfI (and later the RfQ) have landed with the right team at the supplier and are picked up and worked on.
- Have your data (dossiers, etc.) ready to be shared once NDAs are signed.
- Set a challenging but achievable timeline; if suppliers communicate delays and/or asks for extensions, properly grant an extra week at a reasonable advance time.
- Share information, answers to questions, extensions with all suppliers, ultimately giving all parties a fair chance to win the new business with you.

Decision: Contracting and Transfer[5]

Remaining actions have one commercial stream where we complete negotiations, detail remaining contractual terms and execute actual contracting. Often in parallel to this, transfer planning proceeds. Unfortunately, we often experience that, while the business case is positive and clear, the tech transfers miss targets due to not being fully costed or because of over-costing them for political reasons.

Therefore, A&M strongly advises to request detailed transfer cost (usually in a second RfQ round) from short-listed supplier/product combinations and include that early in the decision process. Secondly, the transfer process/project needs "de-mystification". Even though one characteristic of the process is that it requires input of sparse experts with a quality management or regulatory background and has approval blocks outside the company, most of these are known. A stringent project planning with input from relevant stakeholders and an experienced transfer manager can ensure that the transfer stays within the timelines underpinning the business case and that the change really stick. See sidebar/box.

An advantage when negotiating with partners is that communication is already established and many insights about each other are already known, which will speed up the process.

In our experience, investing additional time during the negotiations to ensure that technical requirements and expectations are aligned reduces later problems and supports a faster tech transfer protecting the expected timeline and kick-in of savings.

Conclusion

The point of departure was how A&M has helped asset-light pharma optimise the CMO network for rapid growth – by being both agile and structured thanks to the sourcing decision framework. Without the latter, the sourcing initiatives risk being uncoordinated and thereby less impactful. We have also touched on challenges around tech transfers to help "de-mystify" this and encourage asset-light pharma in proactively shaping their CMO network.

Please contact us if you would like to learn more about unlocking the full potential of your CMO network to fuel growth.

Tech Transfer Lessons Learned

- Develop a playbook with templated deliverables to standardise the process, enact governance structure, define roles and responsibilities, reporting and key performance indicators (KPIs).
- Clear and aligned accountability and effective coordination between sending and receiving sites and regulatory are critical for the transfer of product and process knowledge and establishing transitionary supply tactics and inventory holdings.
- Recognise that different incentives are at work amongst the parties, which may result in very different views on required costs and timelines. Incentives are typically most strongly aligned when the receiving site drives the process.
- Review documentation early and address any gaps, particularly when working with older regulatory dossiers.
- Develop a master transfer plan that combines the timelines from all functions involved. Local regulatory intelligence is critical for obtaining an accurate picture of market approvals.
- Resource the master plan to forecast and plan for constraints, particularly scarce resources thinly spread over multiple programmes.
- Take the opportunity to rationalise stock keeping units (SKUs) and bundle other changes as part of regulatory submissions.

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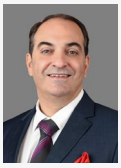

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