

our R&D team is crushing timelines for ushering a new molecular entity to market—the market has taken notice and your team is recognized as a first-in-class organization for its scientific, medical and technical strategy and execution. The business team has just added two new assets to the pipeline and their trusted contract research organization (CRO) is showing signs it may not meet future expectations. The team hastily issues a Request for Proposal (RFP) at a moment of vulnerability, and the supply market knows it. Their desire to consider alternate CRO options raises the possibility the company is at risk of missing key development dates that could adversely impact the future of your young and emerging company.

This simple, and not unusual, example is just one of many "non-science" related areas that an emerging company must be able to address to be successful. A company should know how to deploy strategic sourcing techniques, negotiation tactics and internal teamwork to develop important market insight, product/ service options, service levels and pricing information to determine a productive path forward. A trusted sourcing and procurement colleague who understands the team's issues and requirements can help provide such important insight by managing the

supplier and negotiation process.

Below is an outline of five important activities a procurement professional can do to create a collaborative working environment with their colleagues to create value and manage risk. We use the acronym DICCE to make it easy to remember:

- **D**ocumenting current contract terms financial, performance/quality levels, remediation, etc.
- Identifying gaps between supplier performance and service requirements
- Coordinating internal briefing meetings to ensure the working team is aligned with executives
- Creating sourcing options through supplier discussions to uncover"hidden" options which may be more favorable to the team
- Establishing negotiation approach and roles to manage supplier communication

Whether a supplier provides the active pharmaceutical ingredient (API), packaging, CRO services, market research, IT hardware, or any of the hundreds of other services and goods a company

needs, all companies depend on suppliers to meet their business goals. Most emerging biotech companies spend, on average, 60-80% of their budgets on purchased goods and services as they try to keep a lean core staff and outsource significant R&D services.

How a company structures its procurement and sourcing function will dictate how well it can work with suppliers to meet demanding customer and regulatory requirements. Done right, a strong procurement and sourcing function provides the following benefits:

- Financial savings through negotiated pricing, payment terms and other business conditions;
- 2. Third-party risk management integrated with a company's enterprise risk process;
- 3. Employee productivity improvement through efficient workflow for supplier contracts, invoice management, financial accruals, and supplier management activities; and
- 4. Use of third-party data to support ongoing cost and risk analysis along with compliance reporting requirements.

To achieve the above benefits, we have found that successful emerging companies:

- Are agile and focus on simplicity;
- Align sourcing strategy with company growth;
- Align sourcing strategy with decision-making approach;
- Manage evolving supplier relationships; and
- Use a structured sourcing and procurement approach.

AGILE PROCUREMENT – FOCUS ON SIMPLICITY

Unfortunately, leaving the development of the procurement and sourcing process to individual departments often leads to inefficient processes, frustrated employees and suppliers, and the risk of inadequate supply and/or high costs. However, a company does not need to have a bureaucratic procurement process, which can also frustrate staff and suppliers, as well as lead to supply issues and high costs. To build a "fit for purpose" procurement process, it is important to break down the buying process into three activities: Sourcing, Procurement, and Payment (see Figure 1).

Although the scope of the above activities is relatively straightforward, too often matters are complicated by dividing these activities across different people and departments without coordination and alignment of the overall process.

ALIGNING SOURCING STRATEGY WITH GROWTH STRATEGY

Procurement polices need to align with a company's growth strategy. With an estimated \$1-2 billion in development costs for new drug and FDA approval, there is significant pressure to ensure a return on investment (ROI). While each company will have its own strategy to drive ROI, in general we outlined three growth strategies and their impact on a sourcing and procurement design (see Figure 2).

In the first strategy the founders and investors enjoy the entrepreneurial structure of their company and freedom from corporate bureaucracy to develop therapeutic treatments. While they may explore options to grow their company beyond NDA/BLA approval, their main intent is to develop

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therapeutic treatments and secure FDA approval before selling either the IP or the company. Further, the board knows that a strategic buyer has the resources to commercialize their treatment and provide the ROI acceptable to the investors. As a result, their investment in procurement staff, policies and procedures will be minimal.

In the second and third strategies, a company should consider how a procurement and sourcing function can help them accelerate their growth, manage risk and compliance, and control costs based on their organizational maturity and supplier dependence. Each strategy will require a company to invest time to develop formal processes, policies, systems, staff and metrics but the difference between them is the size of staff, as well as the extent of policies, procedures and systems.

ALIGNING SOURCING STRATEGY WITH COMPANY DECISION-MAKING APPROACH

A sourcing and procurement function needs to support the company's decision-making approach as well as its strategy. For example, consider the financial purchasing levels embedded in the delegation of authority policy and how it may need to change with rapid growth. If sourcing decisions were made by a few executives during the company's entrepreneurial phase, as the company rapidly grows and engages with more suppliers, these approval levels should be reviewed. Otherwise, these same executives will become overwhelmed by reviewing and approving significantly more supplier contracts.

Company growth creates a lot of excitement around commercialization of products, pipeline development, revenue and organization size. However, with this growth, a need arises to create supplier and procurement policies, procedures, processes and systems to manage a growing third-party cost structure and risk profile. This transformation creates tension by moving activities and decisions which were made in small teams quickly to larger teams which can be bureaucratic and slow as it relates to sourcing and procurement decisions.

MANAGING EVOLVING SUPPLIER RELATIONSHIPS

In the early stages of a company, relationships and agreements are often handled by the founders, CEO, CFO, chief scientist

Activity	Scope
Sourcing	Supplier evaluation and management Contract management process Supplier master data management Analysis of company's supply risk profile
Procurement	Defining buying authority requirements Delegation of authority for contract approval Integration of supplier master data file with payment approval process
Payment	Integration of supplier master data file with payment approval process Invoice management, segregation of duty in line with audit requirements Streamlining of supplier payment accrual process

Figure 1

Growth Strategy	Impact on Sourcing & Procurement Design
Pure R&D focus: Secure FDA approval and then sell the drug/ company to a strategic investor.	Minimal procurement functional size – typically includes small staff supporting clinical trials/FDA filings, contract management and AP activities.
Midterm approach: Build business around drug, demonstrate market potential over a 2-4-year period before looking for options to sell the company.	Need for a small staff, policies, procedures and systems to provide a potential buyer with confidence about supplier management, third-party risk management, and appropriate cost management.
Long term growth: Build a company around ongoing drug pipeline development and commercialization.	Need to scale a procurement and sourcing function in accordance with business growth.

Figure 2

and their small staff. Supplier sales teams get used to calling on this small group of executives and develop deep relationships that go well beyond a supply agreement's written terms. Consider that a supplier may propose adding resources to meet a deadline at no additional cost because of their personal relationship with a chief scientist or CEO. However, as the company starts to rapidly grow and the relationship changes, the strength of the earlier personal relationship between executives and suppliers can weaken.

As more people are hired and policies and procedures are created to manage activities such as contract approval and invoice processing, the previous strong connections can deteriorate. Understanding the changing nature of supplier relationships is critical to maintaining healthy relationships, which in turn maintain appropriate supplier management, risk management, and cost containment.

STRUCTURED SOURCING AND PROCUREMENT APPROACH

In *Figure 3*, we outline a framework to help emerging companies develop sourcing and procurement options to fit their strategy, stage of growth, and level of supplier dependence. Information about metrics, systems, etc. is only intended to guide discussions. Actual attributes need to be developed for each company's unique situation through a structured assessment and team building process.

Within each phase, companies use the levers seen in Figure 4

to efficiently manage the corporate buying process from sourcing to procurement to payment activities (Source-to-Pay).

By using this framework to develop and deploy a sourcing and procurement process, an emerging company is in a better position to answer the following questions.

Supply Risk

- 1. Where are the originating countries for our API and excipient materials? How does this impact our supply chain risk profile if our suppliers are located outside of the U.S.?
- 2. If there is an extraordinary event such as COVID-19 or natural disaster significantly impacting operations and our suppliers, can we analyze our supply contracts to understand the impact of force majeure clauses?

Business Growth

- How do we manage supplier relationships to maintain growth? What poorly performing suppliers can adversely impact our production, distribution, sales, research activities?
- 2. What suppliers and services do we need to develop into a strategic relationship to help us grow to the next level? What department and/or team member is managing the relationship?

Cost Management

1. What suppliers are driving most of our costs? What cost driv-

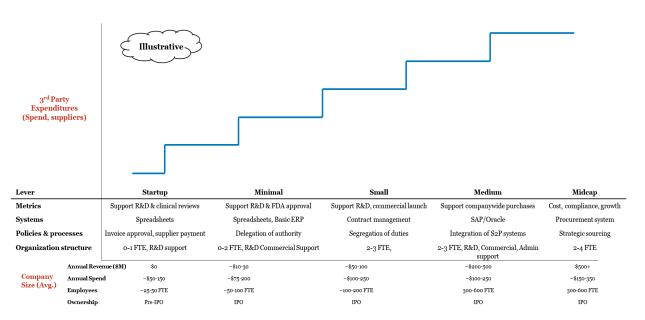


Figure 3

Lever	Scope
Organizational Structure	Procurement & supporting staff structure responsibilities needed to purchase goods & services
Polices & procedures	Steps, functions, policies and processes involved in the purchase of goods & services
Systems	E-procurement and other systems (ranging from point solutions to ERPs) needed to efficiently purchase goods and services
Metrics	Supplier performance, financial, risk and procurement metrics needed to efficiently manage the corporate buying process

Figure 4

ers does the buying team need to manage to control costs?

2. Are certain suppliers serving multiple departments? Can we leverage the spend with those suppliers to negotiate better terms?

Answers to the above questions provide an emerging company with the opportunity to create a sourcing and procurement process that supports their company's tangible and pressing needs, such as:

- Meeting critical development and launch timelines;
- Complying with FDA and other government reporting requirements:
- Managing cash and accurately reporting financial requirements to investors and the investment community; and
- Managing supply risk and meeting growing global environmental, social and government (ESG) reporting guidelines.

By having the right processes, information and analysis a procurement and sourcing team can collaborate with their colleagues to help manage suppliers and meet their company's business objectives. By following this approach, value (adequate supply, reduced risk, reduced costs, increased quality, and compliance) can be created through trust and partnership within an organization and with strong supplier relationships. **GP**



DAVE STOWE is a senior procurement and sourcing leader with global experience in the Life Sciences industry, including pharmaceuticals, biopharma, medical devices, medical diagnostics and healthcare. He has helped companies develop procurement organizations and led complex supplier negotiations with

multiple stakeholders across engineering, production, regulatory, legal finance and R&D. Contact Dave at david.stowe@tunnellconsulting.com.



JONATHAN HORN is a principal at Tunnell Consulting and has over 30 years of management consulting expertise in the areas of assessing, designing, and managing enterprise transformation initiatives, especially to help grow emerging companies. He has significant experience in multiple healthcare sectors, in-

cluding life sciences and federal health. Contact Jonathan at jonathan.horn@tunnellconsulting.com.