

# Strategic outsourcing options for speciality chemical start-ups

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**Christopher Kulp, executive vice-president at Richman Chemical, shows why the project management model may be the best way forward for most small companies in the speciality chemicals sector**

The development of novel speciality chemical products certainly requires talented researchers in the laboratory. However, successfully commercialising new compounds requires more than just technical expertise. Superior project management implementation is also an absolute necessity. For early stage companies in particular, good project management remains paramount for beating competitors to the marketplace.

Three principal non-chemistry challenges encountered by start-ups include protecting intellectual property (IP), securing adequate funding for product development and scaling up manufacturing to meet commercial requirements. This article will discuss these challenges and review a number of project management-based solutions.

## Key challenges

When commercialising products, companies must always balance the need to **protect their own IP** with the need to share their confidential process information safely with development partners. IP should be cross-referenced against existing patents, then protected during development and technology transfer.

Whilst in-house legal staff or contracted law firms typically conduct such due diligence, any perceived gaps may need to be addressed through additional laboratory work. Examples include conducting a Design of Experiments to evaluate substantive differences or similarities of target compounds, quickly synthesising competitive samples, preparing additional patent example compounds and identifying crucial trace contaminants. A start-up needs this work to be performed expeditiously to maximise future income within the limited patent life, protecting its unique technology.

There are many potential sources of **funding for product development**, but obtaining funding remains highly competitive. Each investor or funding organisation will have different requirements. Funding sources typically include venture capital (VC) groups, angel investor consortiums and grant opportunities through governmental agencies, such as nationally sponsored departments of energy.



## Several challenges must be addressed before commercialisation can begin

It is vital for start-ups to 'get in front' of VC and angel boards to pitch their novel technologies - preferably with strong proof-of-concept data in hand! In addition, external vendors and partners possessing existing relationships with such funding organisations are attractive avenues to pursue for young companies in need of capital. Start-ups must identify grant opportunities compatible with the technology in question and employ grant-writing experts when applying for these highly competitive sources of capital. Alternately, emerging companies can license their technology to commercial partners with synergistic or complementary technologies. In order to do this, however, robust proof-of-concept results are not only recommended, they are required.

Regardless of the route selected, comprehensive proof-of-concept data compilation and analysis must be conducted and presented in a convincing manner for potential investors to fund the company's subsequent product development activities. This is often the most expensive and difficult step for a speciality chemical start-up.

The early development stages of new compound development and research is usually based on small-scale batch synthesis. When **scaling up manufacturing processes**, however, obtaining raw materials and identifying appropriate and cost-effective manufacturing partners represents a significant challenge.

The successful transition of technology from the laboratory bench to the macro-level within a commercial production environment represents a major step. Start-ups must use production facilities that satisfy the requirements of timeliness, cost-effectiveness, regulatory compliance and sometimes geographical proximity.

Ideally, an identified manufacturing site will also be able to produce pilot or intermediate batches as a precursor to full-scale production. This capability not only minimises risk, but allows a consolidated location for crucial production activities in anticipation of the commercial introduction of any new product. If the proper manufacturing facilities and/or raw material providers cannot be located in an efficient manner, unrecoverable time and money are lost.

Finally, companies must confirm that any identified production site is compatible with the regulatory standards of the specified commercial market. While this could be covered extensively as a separate topic, it should be stressed that any outsourcing selection process must integrate relevant compliance requirements such as ISO or food grade, as examples



### **Kulp – Technical expertise not enough for commercialising new compound**

#### **Solutions**

The objective of any start-up is to commercialise its technology in the shortest amount of time and as cost-effectively as possible. Any lost time is irreplaceable as a start-up risks burning through existing funds. Even if successful, the time to profit under patent protection increases with each day the technology remains non-commercial. The optimal approach may be to outsource commercialisation requirements to experience specialists.

The most strategic reasons to outsource involve cost and time. The key drivers for this cost differential, which can be regarded as the underlying reasons for outsourcing, are access to production capacity and facilities, access to expertise (regulatory, scale-up, etc.), reduced investment in capital assets and fixed costs, access to reasonably priced raw material supplies and the ability to stay focused on core competencies.

The advantages to outsourcing far outweigh any perceived disadvantages. In order to mitigate any loss of control over functions, however, it is important to ensure that corporate cultures mesh, processes are transparent, communication is open and performance objectives are closely monitored.

#### **Outsourcing models**

Various outsourcing models can be used depending on specific need, company philosophy, and/or time and financial constraints. In a **partnership** model, for example, a company may choose to partner with one specific vendor for certain aspects of product manufacture.

Usually this is a contractual relationship, and the risk is shared so that the outcome is equally important to both parties. The vendor who participates in this type of business relationship has a keen interest in seeing the project through to a successful conclusion and payment is at least partially contingent on a successful outcome.

Whilst this strategy can be very successful, it is severely limiting in terms of scope, capabilities and often capacity. Ideal partners for one stage of the product development process may not be optimal for later stages of the outsourcing process. Furthermore, negative external factors affecting one of the partners will often affect the partnership as a whole



### **The partnership model is popular but can be limiting**

Many companies maintain extensive data on past and present suppliers, with details of capabilities and performance levels, which makes **pre-qualified vendor selection** another option. Companies may use an outsourcing department to assure an appropriate match for a particular project can be made with regard to a potential supplier's capabilities, past performance, and business model. If not on record, this information can also be generated on a case by case basis for evaluation purposes.

Most companies pre-qualify potential suppliers and set up preferred provider relationships, pre-defining outsourcing strategies for particular areas within the company. This model typically works well, but it is costly in terms of manpower & economic expenditure.

In the **vendor competitor** model, multiple vendors with similar capabilities compete for business. Vendor selection is generally based on time and cost, although cost is frequently the overriding factor. Many start-ups think multiple vendors will drive costs down. Usually the opposite applies. Many potentially good vendors drop out of bid requests that have too many participants. When they perceive poor odds of winning the bid, they do not want to waste time and money preparing one. Even the successful bidder may not be the best choice if their low cost comes with inadequate support and incentive to support the project properly.

With the **principal vendor** model, the company uses one principal outsourcing vendor with the understanding that the vendor will be further outsourcing parts of the project to others. The principal vendor is still the supplier of record and is the responsible party for due diligence and compliance with regulations.

This is a somewhat complex arrangement, and it effectively places all outsourcing requirements (contracted and sub-contracted) into the hands of personnel who may be inexperienced with project management arrangements involving third parties. Significant attention is allotted to the principal contract work and sub-contracted efforts may suffer due to a lack of experience and/or an absence of long-term client-vendor relationships.



### **The project management model brings access to multiple partners**

Finally with the **project management** model, a company is hired to provide project management services for the project being outsourced. The project manager (PM) does not conduct the actual physical manufacturing within the company's own facilities but instead provides access to a specialised network of suppliers with whom it maintains established relationships.

Enlisting the services of a PM effectively expands the potential sources for any company engaging in outsourcing. The PM provides industry vendors, such as CROs and CMOs, with technical competencies, scope of capabilities, track record, business culture, available equipment, manufacturing capacity, scalability and reliability. A PM is assigned to the client in need to handle its specific requirements, functioning as its de-facto outsourcing department but without the internal cost.

A competent PM should provide extensive technical and manufacturing experience leading to compressed timelines, lower costs and increased technical capabilities. This allows for improved focus on new technology development and sales and marketing efforts. Furthermore, PMs can facilitate the provision of auxiliary services as needed, including product development, raw material sourcing, logistics coordination and regulatory support.

Within the parameters of this model, the outsourcing client depends significantly on the expertise of the PM to provide compatible service offerings. However, the model itself is based upon a cooperative, risk-sharing foundation between the client and the PM. It is not uncommon to invoice for services rendered only after the project has been successfully completed.

## **Conclusion**

The proliferation of start-up firms within the speciality chemicals market highlights the need for competent, highly skilled vendor partners capable of handling custom chemistry projects. Effective outsourcing to CROs and CMOs provides a significant opportunity to accelerate product development, maintain operating budgets and use internal resources effectively for the industry as a whole.

A wider acceptance of the benefits of such a relationship can only be gained by fostering a greater understanding of the outsourcing process. Start-up organisations may find that, in many cases, the project management model offers the most benefits when it comes to commercialising technology within the shortest amount of time.

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