



Custom Synthesis for Pharma and Agrochemical Companies

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The Market

In the chemical industry, custom synthesis describes the synthesis of non-commercially available molecules exclusively for a specific company. The amount thus produced tends to be small, ranging from a few milligrams to about 10kg or so – the production of larger amounts is usually called contract manufacturing. While the customer defines the quality of the required product, the synthetic route is developed by the custom synthesis provider. In such cases, the key challenge is not carrying out an established production process but rather developing it. Once such a process has been developed, it is far cheaper (possibly up to 90%) to produce more of the same material rather than to produce another material.

A recent analysis by the Chemical Pharmaceutical Generic Association estimated the global market for pharmaceutical custom synthesis at about US\$12 billion (2012), which makes for a total of about US\$15 billion if agrochemical custom synthesis is included. China's share of 12% in 2012 is forecast to increase to 19% in 2017 as the domestic pharmaceutical industry grows much faster than in the mature markets. This will make China the third biggest market for custom synthesis after the US (25%) and India (21%), which also has high growth rates.

Key customers for custom synthesis are pharmaceutical and agrochemical companies often for the purposes of new product development, regulatory compliance or analytical validation. Though the biggest of them have their own teams of synthesis chemists, they may also rely on external support if they temporarily need additional

resources or external parties that can reduce their overall costs. Smaller pharma and agro players – particularly startups - rely even more on custom synthesis providers as it allows them to avoid the high fixed costs of an internal synthesis team.

Key Success Factors

Successful custom synthesis companies share a number of capabilities, such as speed, high service level, moderate costs and of course broad chemical knowledge.

Customers expect the requested materials to be provided quickly. A typical timeline is 4-6 weeks after the order has been made. Therefore time pressure on companies in this segment is substantial. As mentioned above, the time consuming part of this work is the development of a suitable process rather than producing the material once the process has been established.

Customers also expect a high service level, which in particular means they want to be well-informed on the progress of their order. Successful providers communicate with their customers about once a week, letting them know about potential issues or just the smooth progress of the work. This allows the customers to integrate the predicted arrival date of the ordered molecule into their own planning. In the past, Chinese custom synthesis providers often lacked these communication skills, possibly due to the tendency of Chinese culture not to emphasize bad news.

A key resource for a successful custom synthesis organization is analytical support. Analytical techniques such as NMR, HPLC, MS and IR are utilized in order to understand if each step of a project is successful; and in order for a project

to progress smoothly and effectively, analytical instrumentation and experienced analytical chemists must be readily available. Furthermore, the qualitative and quantitative certification of custom synthesized analytical standards through the above techniques helps to further ensure customer satisfaction.

An important reason for hiring an external custom synthesis provider is cost. Consequently competitive pricing is important for success. Custom synthesis is not cheap – a 200 mg sample of a pharmaceutical impurity may cost between US\$1 500 and US\$15 000 – but this can still represent substantial savings compared to employing own dedicated staff.

Finally, a basic requirement is broad chemical knowledge, which also helps to achieve reasonable costs and high speed. Though software is available to assist in finding pathways to specific molecules, it still takes expertise to prioritize these pathways in order to increase the chance of success. Due to the broad variety of molecules ordered, custom synthesis providers are required to be specialists in many aspects of chemical synthesis. Specialization is required in areas such as process development, scale up, knowledge of esoteric synthesis techniques and an understanding in the application of the molecules (e.g. R&D versus use as pharmaceutical impurity). Companies also benefit from knowing about chemical trends, e.g., the focus of pharmaceutical research on specific types of molecules.

Market Trends in China

The pharma industry, the most important client base for custom synthesis, is projected



to grow at an annual rate of 14-17%, leading to a market size of between US\$160 and 190 billion by 2017. Drivers are government efforts to improve healthcare and insurance coverage, growth of average incomes and potentially a review of the list of reimbursed pharmaceuticals. As a consequence, the overall perspective for custom synthesis is very positive.

Some other factors are likely to further increase the market for custom synthesis in China. Agrochemical and pharma companies are likely to be subjected to stricter regulatory requirements in the future. This will force them to spend more on custom synthesis of impurities and metabolites. In addition, the Western trend of a fragmentation of the pharmaceutical value chain could also catch on in China and would lead to a larger number of smaller, research-oriented pharma entities which strongly rely on external custom synthesis providers.

However, not all custom synthesis

companies will benefit. Historically, many Chinese custom synthesis companies were very small and could only deliver low-quality services. Entry barriers were low, sometimes allowing individual graduate students to enter the markets. As environmental regulations are getting stricter, these entry barriers are increasing, some of the smallest players will likely have to quit the business, and the industry will consolidate. Another driver of consolidation may be the increasing demand for more complex molecules, which will require more knowledge and infrastructure on the side of the providers. Large custom synthesis companies which can offer a large portfolio of chemicals and synthesis services beyond traditional chemical synthesis techniques are likely to be the biggest winners of this trend.

In the longer term, an additional trend will be a location shift from Shanghai to slightly cheaper locations, though these will probably still be in Eastern China, where

the majority of customers are located.

Industry Outlook

As other industries in China, custom synthesis may be affected by increasing labor cost as salaries for qualified chemists and other staff increase - custom synthesis is not an area in which productivity gains can be achieved easily. Stricter environmental regulation for the custom synthesis companies themselves may also increase their overall costs. However, in the longer term a move away from classical chemical active ingredients and towards biosynthesis may be the largest threat for the industry in China as so far the local knowledge regarding these newer areas is still quite limited. However, in the next few years, the growth of the pharmaceutical market, the stricter regulation and a trend towards fixed cost reduction among clients will have a strongly positive effect on the Chinese market for custom synthesis. ■

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Scope of business

Planning & Consulting

■ Market survey

In-depth reports on the research of the silicon material sector
Annual reports on the monitoring of major silicon material products
Monthly reports on the monitoring of major silicon material products

■ Engineering consulting

Strategic planning
Analysis and research of investment opportunities
Feasibility study reports

Major research products

Metal silicon, siloxane, polysilicon, HCR, RTV, LSR, silicone fluids, silicone resin, silane coupling agents, chlorosilane, fumed silica, precipitated silica,

Media and publications

■ Weekly: China Silicon Industry Market Week (CSIMW)
■ Quarterly: Silicon Materials
■ Website: simuch.cncic.gov.cn

Conference activities

Green Silicon Conference

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