

Transforming the chemical industry

In the past decade, fine chemicals suppliers have changed to meet the needs of pharmaceutical production. Further changes will be necessary for the industry to realise its vision for the drugs of the future.

During the 1990s, the concept of outsourcing the manufacture of intermediates and active pharmaceutical ingredients (APIs) became a reality for the pharmaceutical industry. Pharmaceutical houses realised that they could achieve significant gains in speed to market, economics and the ability to leverage their own productive assets, and outsourcing became a strategic tool of great importance for the industry.

A decade on, the chemical industry has been transformed, both in terms of capability and culture. On the capability front, the need for complex, multi-step synthesis based around key technologies has been mastered. From a culture standpoint, suppliers have become hybrid organisations, combining the disciplines of the pharmaceutical industry in the manufacture of regulated materials with those of the traditional chemical industry and its emphasis on high levels of efficiency.

Outsourcing as a tool for pharmaceutical companies has changed from a general practice to a finely tuned instrument to achieve specific goals. The basis for making outsourcing decisions has also evolved (see Table 1). Today, service, quality and innovation are the core components of an outsourcing relationship. Underrated during the first decade of outsourcing, responsive service is now required throughout all phases of a project. Quality is also redefined. Clariant Pharmaceuticals has established two primary current good manufacturing practice centres of excellence that serve as standards for its manufacturing effort. These standards will be replicated globally. But, more than that, says the company, the quality orientation of these sites will infuse all of its activities, across the board.

Innovation needed everywhere

Today, the role of innovation has expanded into every facet of the customer/supplier dynamic. In the area of technology, pharmaceutical organisations are looking for differentiating, world-class technologies that can achieve synthesis targets and add value in the critical steps of a manufacturing process. Clariant is responding to this need with work in areas such as organometallics, nucleosides, versatile chiral production and new processes for work with halogens and butyl lithium. However, technological innovation goes beyond specific chemistries, and new

Table 1. Quality, innovation and service: Transforming the outsourcing partner

- Development services
- Rapid delivery of small scale at all phases
- Differentiating, world-class technologies
- Integrated ancillary technologies
- Pharmaceutical culture
- Broad cGMP capability
- Clean regulatory track record
- Integrated global supply chains
- Experience with late-stage APIs

Table 2. Requirements of the transformed outsourcing partner

- Long-term reliability/stability
- Superior project management
- Shortest response time
- Parallel projects on several sites globally
- Ability to handle complex projects
- Access to broad technology
- Tailor-made e-business tools
- Tailor-made customer interface
- European/US cGMP production
- Best practices globally

approaches such as microreactor technology are developing better process solutions for difficult synthesis challenges.

Continuing transformation

Over the next decade, Clariant will continue to transform itself to become a better partner for its pharmaceutical customers, enabling the industry to realise its vision for the drugs of the future (see Table 2). Its presence will be felt particularly in early-phase manufacturing and process development services, in global manufacturing strategies that ensure quality and reliable supply at cost targets, and in late-stage manufacturing strategies that maximise customers' return on their intellectual property. ■

COMPANY PROFILE

Clariant Pharmaceuticals, a business unit of the global Clariant organisation, is a commercialisation partner for the world's leading pharmaceutical companies, providing custom synthesis, a range of development services and world-scale production of bulk generic pharmaceuticals. Clariant Pharmaceuticals is a leader in developing chemistry for some of the industry's most important and difficult to manufacture APIs.