

One-Stop Shops

Contract research organizations that provide multiple services look appealing again to big biopharmaceutical companies

The “one stop shop” strategy, thought dead just a few years ago when its leading proponent declared bankruptcy, may be making a comeback.

A one-stop-shop CRO is a single-source provider of multiple services across multiple development stages. The client signs a single contract, and the CRO does all or most of the development work and assumes most of the responsibility for project management. In a typical arrangement, the CRO might oversee preclinical studies, development and testing of analytical methods, product formulation, manufacture of clinical trial material, and maybe even clinical research through phase 2/3.

For the sponsor, one purported benefit of the one-stop-shop relationship includes faster project completion, thanks to better coordination and fewer hand-offs from one CRO to another. In addition, transaction costs may be lower because there is only one contract to negotiate, fewer sites to audit, and better communications between sponsor and CRO. However, the sponsor gives up the opportunity to contract the best-in-class service provider. Also, the sponsor may find that the CRO has neither the experience with the drug development process nor the project management skills to pull it off.

The one-stop-shop model created a lot of buzz in the late 1990s when it was being heavily promoted by **Oread**, the Lawrence, Kansas-based CRO known for its lavish marketing and promotion efforts. Starting

out as an analytical lab, Oread added capabilities for preclinical testing, formulation, clinical packaging, and dose and API manufacturing, mostly through acquisition. In an arc strikingly similar to the dotcoms, the company grew to more than \$100 million in revenues, but found profitability elusive and ran out of cash. Its bankruptcy and dismemberment set back many client development programs.

For a CRO, the strategic rationale of the one-stop-shop model remains powerful, and several major CROs, including **MDS Pharma Services** and **AAI International**, have made it part of their business strategy. By pursuing this strategy, a CRO can maximize the return on its marketing effort by obtaining more of a client’s development budget. This strategy also is appealing to a CRO that cannot compete as a market leader in any one service area but is able to offer a broader package of services. The model is especially attractive in the current industry environment because it offers an escape from price-based competition by promising more value to the client, thereby justifying a greater profit margin.

MDS Pharma Services is trying to shift its business model from project work to program work, according to Nigel Brown, senior vice president for strategic business and technology planning. “The traditional CRO business has degenerated into a low-margin, price-competitive bid-and-tender business,” said Brown. MDS is looking for ways to benefit clients while also improving its operating margins.

According to Brown, MDS has been focusing its strategy on target client groups rather than specific service areas. Key segments include small- to mid-size

biopharmaceutical and pharmaceutical companies as well as generics companies. The service package spans late-discovery services through phase 2b. A key to this approach has been the involvement of an experienced drug development veteran who has taken several products through to new drug application filing and approval. That person works with the client to develop a product development plan and coordinate the development activities within MDS.

Brown said that the MDS one-stop-shop effort (although that’s not what they call it) has been met with strong market acceptance. The group sold five programs in the first eight months of the initiative and now has at least 10 programs under way. MDS is also developing partner relationships with other vendors to fill the gaps in its development offerings and recently announced an alliance with **Patheon** for certain formulation development and clinical trial material manufacturing services.

Quintiles Update

By the time this column hits your desk, the fate of **Quintiles Transnational Corporation** may have been decided. Following the rejection of founder and chairman Dennis Gillings’ bid to buy back the company, the Quintiles board of directors engaged investment bank **Morgan Stanley** to help it explore its options. Although the board could have chosen to restructure the company and sell off pieces, it apparently decided that putting the whole company up for sale was the best option. Bids were due in early January, and the word on the street is that Gillings and his backers are again among the bidders, along with several private equity groups.

Patheon Closes on Cincinnati Site

Contract dose manufacturer **Patheon, Inc.** expects to hit revenues of CDN \$600 million (U.S. \$395 million) in 2003 — almost 50% more than its 2002 performance — with its acquisition of the **Aventis** manufacturing and development facility in Cincinnati, OH. The U.S. \$16 million acquisition closed on 31 December 2002. Patheon will continue to manufacture the Aventis products produced at the site as well as the products produced under contract by Aventis for other parties.

Other factors that will affect its 2003 revenue performance are the start-up of the new lyophilization units at Patheon's Monza and Ferentino, Italy, facilities and the manufacture of an undisclosed new product that FDA approved in October 2002.

Patheon also reported strong 2002 results. Revenues were CDN \$418 million (U.S. \$275 million), a 31% increase from 2001. Manufacturing revenues were up 27% overall. Growth in European operations was 9%, the net of currency effects. The company's pharmaceutical development services segment was a major success story, with revenues up 62% to CDN \$54 million (U.S. \$34 million).

Other Developments

MDS Inc., reported that revenues at MDS Pharma Services rose 18% to CDN \$508 million (U.S. \$340 million) during the financial year that ended 31 October 2002. MDS management expects revenue growth at a similar rate in 2003.

Akorn, Inc., a provider of contract sterile manufacturing, is still wrestling with financial and operating problems. The expected reinspection of its Decatur, IL, manufacturing facility (required to review changes the company made in response to a warning letter received in 2000) has been delayed, and delays in reopening a production suite have affected client development programs. John Kapoor resigned as CEO, although he remains chairman of the board of directors, and the company effectively is being run by an outside consultant that the company was required to hire under terms of a forbearance agreement with its senior lenders. **BPI**

Don't Blink: FDA Renaissance Gets Fast-Track Authorization

Significant changes in philosophy, policies, and personnel at FDA are happening rapidly and dramatically.

Notable FDA renovations, arising from the agency's ongoing initiative to modernize the regulation of pharmaceutical manufacturing, include

- reorganizing staff and duties between CBER and CDER
- releasing a draft guidance clarifying the scope and application of 21 CFR Part 11
- releasing a draft guidance on comparability protocols for certain manufacturing changes that may not require a prior approval supplement
- planning workshops to solicit public input on scientific aspects of the initiative
- issuing a progress report on improving dispute resolution
- clarifying the language used to communicate deficiencies — "to better describe the purpose and effect of the investigator's observations"
- hiring scientific experts for inspection teams and for its collaboration with academic groups, industry, and other experts.

FDA inspection resources are to be "focused on areas that could have significant health impacts, such as sterile drug manufacturing." These "smart regulations" are part of HHS Secretary Tommy G. Thompson's effort to improve and streamline regulatory processes and FDA Commissioner Mark B. McClellan's "risk-based" and "least burdensome" pharmaceutical manufacturing regulations for the 21st century announced in August 2002. "Using state-of-the-art approaches in FDA's many critical review and inspection activities will encourage innovation and continuous improvement in drug manufacturing to minimize production problems," McClellan said.

FDA released its six-month progress report on this initiative 20 February 2003 and held a teleconference to discuss the progress in its two-year program. The agency expects to "publish a comprehensive implementation plan for this CGMP initiative by mid-year."

More information on the changes and current thinking about 21 CFR Part 11 regulations on electronic records and signatures can be found on page 54. **BPI**