

Contract Services' Crystal Ball

Developments in 2002 such as acquisitions, excess manufacturing capacity, and less funding for biotechnology will continue to affect the industry long into the new year

As we enter the new year, a number of developments from 2002 will continue to shape the contract services industry and will likely generate headlines in 2003:

Quintiles buyout effort. Dennis Gillings, founder and chairman of **Quintiles** (www.quintiles.com), failed in his effort to buy the company back from public shareholders, but the aborted buyout will result in substantial change at the company. The investment banking firm Morgan Stanley has been engaged to investigate strategic alternatives, which could include an outright sale or, more likely, a restructuring that will involve divestiture of some business segments. Financial investors as well as some other competitors are expected to bid on units that become available. Quintiles should emerge as a smaller, more focused, more profitable company.

Cardinal's acquisition of Magellan. The acquisition of **Magellan Laboratories** (www.magellanlabs.com) by **Cardinal Health** (www.cardinal.com) threatens to upset the competitive balance of the analytical and pharmaceuticals segment of the industry by bringing a large, well capitalized player into an arena inhabited mostly by small- and moderate-size private companies. The acquisition confirms that a strong development operation is now key for successful contract dose manufacturers

— a fact also reinforced by Patheon's efforts to grow its development services business.

Biotech financing problems. The bottom fell out of the biotech financial markets just as CROs (contract research organizations) and CMOs (contract manufacturing organizations) and started seriously courting biopharmaceutical companies as clients. The market for initial and secondary public offerings, which provide the cash to fuel Phase 2 and 3 development, has dried up. Uncertain about when they can raise their next round of funding, biopharmaceutical companies are cutting back discovery and development to focus on their most promising and advanced candidates. A continued funding drought could slow CRO growth and undermine the CRO industry's efforts to become less dependent on big pharma.

CMO capacity concerns. Most approved pharmaceutical ingredient (API) manufacturers were burned when exaggerated expectations of the new product pipeline gave rise to a boom in GMP chemical manufacturing capacity. Now the pharmaceutical chemical industry is wallowing in excess capacity, and contract biomanufacturers are feeling a sense of *déjà vu* as they watch biotech's late-phase product failures and fund-raising problems. Their traditional business model is to build capacity in expectation of future demand, but recent history may make them reconsider. Contract fill-finish manufacturers may be hit by a substantial surplus of lyophilization capacity.

EDC penetration. A senior official of **Novartis** (www.novartis.com) recently disclosed that 90% of its clinical trials are

being conducted using electronic data capture (EDC) and that the move to EDC will result in cutbacks in data management and site-monitoring staff as well as reduced outsourcing of clinical research. EDC strikes at the heart of the traditional clinical CRO business, but few CROs participate directly in the EDC industry, which is populated by many small, specialized companies. As EDC grows and the industry shakes out, large CROs will probably acquire the winners, and small CROs will respond with specialized niche services. Some CROs will try to avoid clinical research altogether and focus on their laboratory services offerings.

DSM comeback. In August 2001, **DSM Pharmaceuticals Inc.** (www.dsm-pharma.com), underwent an FDA inspection that resulted in a 18-point 483 citing problems with sterility assurance practices and quality oversight in the company's sterile manufacturing operations. It was the culmination of three years of regulatory and quality setbacks. Today, DSM (formerly known as Catalytica Pharmaceuticals) has put its regulatory problems behind it and is ramping up efforts to build its contract manufacturing business.

According to Terry Novak, senior vice president of commercial operations, DSM's business development efforts are built around its breadth of service offerings, including all major dosage forms (sterile, semisolids, and solids) and full development capabilities. The company is particularly interested in targeting midsized companies with multiproduct portfolios with whom it can establish a "manufacturing partner" relationship. **BPI**