TRISH MEEK and **ROHAN THAKUR,** of Thermo Fisher Scientific, discuss efficient outsourcing in the life science market. **Read on to hear how these partnerships can save you billions**

BILLION DOLLAR QUESTION

At the 2006 Drug Discovery Technology conference, a representative from a major pharmaceutical company estimated the cost of producing a successful drug at $1.2 billion and projected this figure to reach a whopping $2 billion by 2010.

Also in 2006, many brand-name drugs lost patent protection — the equivalent of about $12 billion. This trend is expected to continue as the total dollar amount of brand-name drug products slated to be off-patent is estimated at $45 billion by the end of 2010. What's more, once the patent expires, 80 percent of sales can vanish within a year as generic competitors reach the market.

To bolster their pipelines, pharmaceutical companies are looking beyond traditional small-molecule techniques to biopharmaceuticals — using biomarkers to better characterize the effectiveness of their therapies in the clinic. One way that companies are able to remain agile is through outsourcing some of these new techniques to contract research organizations (CROs). The specialized expertise of CROs allows for a competitive edge as well as an improved Return On Investment (ROI), not only in financial terms, but also in time savings.

THE CRO MARKET

North America accounts for a staggering 60 percent of the global CRO market. A recent analysis from Frost and Sullivan reveals that the U.S. CRO market earned revenues of $7.44 billion in 2006 and is likely to reach $19.35 billion in 2013.

While the highest concentration of CROs is in the U.S., there is also a strong and growing CRO presence in emerging markets of the Asia-Pacific region, especially in China and India, which attract an increasing number of foreign outsourcing contracts. In 2006, the combined Indian and Chinese drug discovery CRO market was valued at $7.3 billion and it was forecasted to capture 35 to 40 percent of the global market share. However, choosing the most suitable contractor within China and India can be a challenge due to numerous factors, primary among them being the ability to enforce adequate level of process validity required for a Good Laboratory Practice (GLP) study.

In the increasingly competitive life science market, where the pressure to reduce costs affects all parts of the pharmaceutical value chain, China and India offer a number of significant benefits — such as major cost savings, productivity gains and avoidance of capital outlays. For many years, Chinese and Indian CROs have focused their activities on the production of raw materials and, more recently, active pharmaceutical ingredients. As these countries gain experience and expertise, they become capable of undertaking the complete R&D process, from early-stage drug development to late-stage R&D and finished product manufacturing.

When done properly, a contract organization works in partnership with the sponsor company. This also facilitates the need for life science companies to carefully consider several factors when choosing a CRO.

"WATSON LIMS ALLOWS US TO AUTOMATE A SAMPLING SYSTEM PREVIOUSLY UNDERTAKEN MANUALLY. THIS HAS BEEN A SIGNIFICANT FACTOR IN OUR USE OF LABOR RESOURCES AND WILL ENABLE US TO INCREASE OUR CAPACITY."

– **John Allinson,** Director at Veeda Clinical Research

USING INFORMATICS TO CHOOSE A CRO

One important selection criterion is the informatics infrastructure of the CRO. CRO-created reports on new drug entities are subsequently used by the sponsor company to submit drug applications to the U.S. Food and Drug Administration (FDA). This needs to be a quick, smooth process and should meet compliance requirements in order to accelerate time-to-market.

Another filter for the time-to-market process is the Thermo Scientific Watson LIMS (Laboratory Information Management System). The Watson LIMS is currently used by 18 out of the 20 largest life science companies and 19 out of the 20 largest CROs — making it the de facto industry-standard. As a result, most major new drug submissions that are filed at the U.S. FDA have been exported from Watson LIMS.

It is certainly to the benefit of pharmaceutical and biotechnology companies to partner with a CRO that uses the same informatics solution that they do. Pharmaceutical companies can create their studies as they do today, and then send the complete study design to the CRO to import. This ensures that they will follow the study design as closely as possible. Such collaboration will also ensure agreement in the process validity required for a GLP study in terms of regulatory compliance. This also includes the 21 CFR Part 11 compliance standards instituted by the FDA to allow pharmaceutical companies to present their documents to the FDA in electronic form in place of paper. In order to comply with this rule, security of electronic records needs to be ensured to allow for electronic signatures to be treated with the same level of importance as handwritten signatures.

In line with this market trend, PRA International, a leading contract clinical development organization, has selected Watson LIMS to help manage its state-of-the-art Bioanalytical Laboratory.

Peter Ketelaar, Vice President of PRA International Bioanalytical Laboratory, said that 75 percent of LIMS in use in their pharmaceutical sponsors' laboratories are Thermo Scientific Watson.

"The data transfer between sponsor and PRA International is seamless within Watson LIMS since both sides can view the study and data in the same format," Ketelaar said. "As a result, now that we have standardized on Watson LIMS, our sponsors view the LIMS as an additional reason to work with PRA International."

PROCESS AUTOMATION IN PARTNERSHIPS

Process automation simplifies workflows, drives costs down and maximises efficiency. An appropriate informatics solution eliminates manual processes that are difficult and costly to implement.

John Allinson, Director at Veeda Clinical Research, an Anglo/Indian CRO with headquarters in Mumbai, said that Watson LIMS has allowed for automation within his facilities.

"Our Indian facility alone tests up to 200 samples per day per instrument and Veeda CR currently has three laboratories around the world which handle 4.5 million samples at present, moving towards 9 million samples per year," Allinson said. "Watson LIMS allows us to automate a sampling system previously undertaken manually. This has been a significant factor in our use of labor resources and will enable us to increase our capacity."

Through a shared informatics platform, communication is facilitated between the CRO and the sponsor. This ensures that the sponsor can monitor the progress of a study — in the same way that they monitor their internal studies — while benefiting from the cost-savings and productivity gains provided by the CRO. Once this level of communication is achieved, sponsor companies and CROs can elevate their relationship beyond the individual projects to a more strategic partnership. Sponsor companies can hand entire phases of the drug development process to the CRO and the CRO establishes steady work with a key sponsor. With a $2 billion figure on the horizon, companies must look to partnerships to remain competitive. FP

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