CROs offer efficient outsourcing

By **Dave Champagne**, Vice President and General Manager, Informatics, Thermo Fisher Scientific.

With investments nearing 15 years and costs approaching $2 billion by the year 2010 to bring a new drug to market, pharmaceutical companies are increasingly in search of internal and external processes which help them deliver a return on investment (ROI) during the patent life of the drug.

Big pharma has been moving towards a crossroad and faces the prospect of no longer having blockbuster drugs as their mainstay product. Instead, pharmaceutical companies are investing in biologics to fill development pipelines, consolidating R&D efforts in similar therapies through mergers, purchasing generics companies in countries like India, while continuing to invest in their core expertise and meet ever increasing regulatory approval standards.

One way to improve the odds of discovering the elusive blockbuster is to increase the number of promising drug candidates under investigation. Outsourcing to a contract research organization (CRO) with specialized expertise can provide the necessary ROI in financial terms and in time savings.

Using informatics

North America currently accounts for 60 percent of the global CRO market, and there is simultaneously a strong and growing CRO presence in emerging markets, especially in China and India (combined market value of $7.3bn). These Asia-based CROs offer a significant financial advantage to pharmaceutical companies seeking capacity in the drug development process. Data obtained and used for determining critical toxicokinetic and pharmacokinetic parameters should be compatible for CROs and sponsors so that final reporting to regulatory authorities is not at risk.

Working with CROs, it is important that full compliance with industry regulations such as GLP and FDA 21 CFR Part 11 is maintained. 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.

For those companies utilizing the services of CROs, the need for secure and reliable bidirectional data review is now a strategic part of global growth plans, as this determines how CRO and sponsor will work together and how successful the relationship will be.

Sponsor and CRO alike need a solution that delivers purpose-built functionality, making their workflow as efficient as possible. They need a solution that facilitates reliable and secure communication of data, so that study results are not in question when final reports are submitted to regulatory agencies. Improved and secure data transmission between the CRO and sponsor company, reduced costs from stored inventory and improved time to market result. This secure exchange of digitized data on a global level improves business decision-making.

John Allinson, Director at Veeda Clinical Research, an Anglo/Indian CRO with headquarters in Mumbai, comments: “Our Indian facility alone tests nearly 200 samples per day per instrument and we currently have three laboratories worldwide which handle 4.5 million samples, moving towards 9.0 million samples per year. 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.”

Thermo Scientific Watson LIMS is used by 18 of the top 20 largest life sciences companies, so most major drug submissions filed at the US FDA have been exported from the standard reports provided by Watson, which is recognized as the de-facto industry standard.

Conclusion

Pharmaceutical and life sciences sponsor companies that utilize the services of informatics-compatible CROs in the emerging markets of India and China position themselves to manage costs and improve their time to market, and increase their chances of finding the next blockbuster.

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Sponsor companies and their CROs utilizing Watson LIMS take a major step towards reducing the barrier to entry for working and selling into these emerging markets. With a long-standing history of successful compliance and use by the top pharmaceutical companies, the FDA will accept more easily the checks and balances for ensuring compliance that are automatically in place with Watson users. Without this secure data capture and transmission process in place, a new drug submission can be denied by the FDA, wasting millions of dollars of research and inventory.

For more information about Thermo Scientific informatics solutions, please visit www.thermo.com/informatics. ■

http://www.contractpharma.com/articles/2008/03/cro-market-view