IT Solutions Focus

NEW AUTOMATED END-TO-END APPROACH SPEEDS UP BIOEQUIVALENCE STUDIES WHILE MEETING FDA ANDA GUIDELINES

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Rapid market growth in generic drug manufacture is driving the requirement for fast efficient bioequivalence studies to meet FDA ANDA (Abbreviated New Drug Application) guidelines. Bioequivalence studies are a critical component of ANDA submissions. The purpose of these studies is to demonstrate pharmaceutical equivalence between a generic drug product and the corresponding reference listed drug. Establishing bioequivalence allows for a regulatory conclusion of therapeutic equivalence [1].

According to IMS Health, global generics sales are increasing by 19% per year [2]. A generic is the bioequivalent of an original pharmaceutical product, whose patent has expired. Generics are much cheaper to produce than the original brand on which they are based. Once a product has lost patent protection, it is replaced almost entirely within six to twelve months by generics, which are sold at 85% to 90% less than the original products [3]. This compression of the time-to-market for generics, and the extreme price sensitivity of final generic drugs means that speed and cost are major drivers for customers. The urgency to remove stages from the manufacturing process of generic drugs is more compelling than ever in order to ensure improved throughput and much easier regulatory compliance.

[1] http://www.fda.gov/cder/guidance/3615fnl.pdf

[2,5] Milena Lzmirlieva, "Regulatory Efforts to Promote the Use of Generics – Government Versus Big Pharma", Business Briefing: Pharmatech (2003).

[3] Exel, "Role of Pre-wholesalers in Generic Pharmaceutical Manufacturers' Demand Chain Management Strategy", Business Briefing: Pharmagenerics (2003).

[4] Dr. Richard G Frank and Erica Seiguer, "Generic Drug Competition in the US", Business Briefing: Pharmatech (2003).

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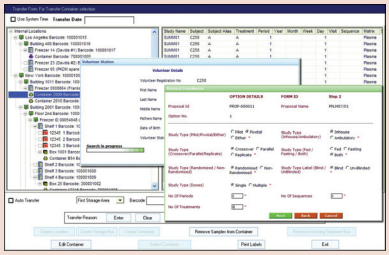
Keeping pace with the times, Thermo Fisher Scientific, the world leader in serving science, and Megaware Inc., a life science technology organization based in India, have joined forces to deliver a new complete bioanalysis/equivalence solution and support services for pharmaceutical, biotechnology and Contract Research Organizations (CROs). This strategic collaboration brings together bioanalytical and life sciences expertise to serve an established customer base in contract research and pharmaceutical companies initially in India and thereafter across the Far East and other markets. In India, the market for clinical trials is growing rapidly because the average cost of trials is significantly lower than in the United States and Europe. The consultancy firm McKinsey estimates that US and European pharmaceutical companies will spend US $1.5 billion per year on clinical trials in India by 2010.

Under the terms of the new collaboration between Thermo Fisher Scientific and Megaware Inc., the two companies will sell, market and support the first comprehensive, end-to-end software solution to provide bioequivalence functionality on a single platform to help speed up and manage critical and regulated clinical trials. Time and administrative burden will be eliminated from the bioequivalence challenge.

The Thermo Scientific and Megaware software solution automates the entire bioequivalence process end-to-end, starting from volunteer management through management of clinical studies, protocol management and into bioanalytical applications right through to reporting. Traditionally, bioequivalence studies were processed manually using single point solutions, but customers carrying out bioequivalence studies are looking to speed this process up. Automating the process allows customers to improve their throughput of studies.

By taking time out of the bioequivalence process, Thermo Fisher Scientific and Megaware allow customers to be highly competitive in bringing generics to market faster – the benefit of this under the Hatch-Waxman amendment is a major commercial advantage to the first-to-market player. The Hatch-Waxman Amendment specifies that the first generic manufacturer to submit an ANDA successfully challenging the validity of the brand manufacturer's patent gets 180 days of marketing exclusivity [4]. This 180-day period can be extremely profitable. Indian generic manufacturer Dr. Reddy's Laboratories Limited, for example, made US$60 million from US sales of a generic version of Eli Lilly's antidepressant Prozac® in the six months of marketing exclusivity.



As a result, the last five years have seen rapid growth in the number of bioequivalence studies undertaken per annum. Globally, the number of studies has leapt from under 200 studies in total to more than 100 studies being conducted annually by some of the larger CROs alone. The market for bioequivalence studies in India and the Far East is growing particularly rapidly. As a consequence, automation is becoming more and more critical.

The bioequivalence process lends itself well to automation. The new solution will be an open system capable of integrating with third party instrumentation and applications. This is a prerequisite since pharmaceutical, biotechnology and CROs implement a mixture of instrumentation and applications and, therefore, require flexible, adaptable software solutions.

Driving the new solution is an innovative platform that has been designed specifically to foster automation in the laboratory. The platform incorporates a powerful toolset that can be leveraged to build organization specific solutions that can meet the unique functionality, workflow and automation requirements of departments and laboratories.

This unified software solution will aggregate disparate software systems for organizations that need to harmonize processes and avoid loss of data. The solution will also address the varied needs of bioequivalence laboratories from patient registration through to achieving greater levels of regulatory compliance and standardization of bioequivalence processes.

Combining multiple bioequivalence capabilities on a single platform, the new software takes a user-centric approach allowing for complete, targeted configuration to fit specific processes and approaches.

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