

PHARMACEUTICAL

Paul Corral examines the role of outsourcing in the pharmaceutical industry.

Pharmaceutical industry

The pharmaceutical industry is constantly undergoing change. In the past pharmaceuticals had a different strategy; companies used to build all the products internally and confine access to information or resources to third parties.

Pharmaceutical companies are now outsourcing many key business functions. The use of contract research organisations (CRO) in the industry is widespread to assume various aspects of the clinical research process (i.e. to conduct clinical research trials on behalf of the client).

In an industry with a high overhead and cost structure, and where, according to research firm Frost & Sullivan, it can now cost up to £1bn to bring a drug to market, outsourcing helps companies involved save money.

Pharmaceutical – 2011 overview

Business process outsourcing and the use of contract research organisations are commonplace in the pharmaceutical industry, as the sector is always keen for any development that will speed up time to market. With the long research and development cycle of pharmaceuticals, outsourcing of tasks such as sales force automation and back-office functions – anything that will get the drug on the shelves quicker is readily accepted.

Duncan Aitchison, Partner & President, EMEA, TPI, said: “The costs associated with healthcare reform and expected revenue loss when patents expire have been strong motivating factors for companies to build up and speed

up new product development pipelines. Companies in the drugs and biotechnology sector tend to invest more heavily in BPO services, particularly industry-specific solutions. Take up of BPO outsourcing in the pharmaceutical industry is led by finance and accounting followed by HRO and then procurement. Other activities include specialist business processes such as clinical trials and lab automation.”

Sanjiv Gossain, Cognizant Senior Vice President and Head of UK and Ireland, agrees about the prominence of outsourcing in the pharmaceutical industry.

“From managing large scale R&D projects – testing product safety, monitoring reports, clinical data management and clinical development activities – and from supply chain networks to even leading on customer service, outsourcing has become an integral part of the way large, multinational pharmaceutical companies are run.”

Despite the omnipresence of outsourcing in the industry, the TPI Index 2011 shows that investment in pharmaceutical outsourcing is down from the impressive \$6.3bn Total Contract Value at the end of 2010. At the end of 2011, the figure of \$5.7bn is comparatively low and well under the prior five-year average for the industry.

Amneet Singh, Vice President, Global Sourcing, Everest, said: “The spike we saw in 2010 was largely the result of pent up demand from the recessionary economy. However, the business drivers for outsourcing adoption remain and continue to evolve. Cost pressures, a changing pharma ecosystem, emerging markets and other market forces are continuing to

drive the market. Moving forward, we expect to see an increase in sourcing of drug development and research, supply chain, data management and analytics functions.”

Historically, U.S.-based pharmaceutical companies drove demand for outsourced services; however, European companies have dominated contract signings over the past three years.



Legislation, research and development

The pharmaceutical industry is heavily legislated, and these regulations frequently change. Outsourcing business functions reliant on strict legislation means a company does not have to worry about staying abreast of, and managing these changes. Suppliers are able to offer both flexible structures and cross-industry expertise to succeed in a heavily regulated environment.

The increase in regulation along with research and development outsourcing has seen a rise in a number of CROs and pharmaceutical-specific service providers such as Covance, Advinus, inVentiv Health, PDI, Publicis Touchpoint Solutions and ZS Associates.

These companies offer various development services in an assiduously monitored legal environment, which include project management, clinical monitoring, site management, regulatory affairs, medical writing and biometrics.

A report by Deloitte and Thomson Reuters found that among the dozen companies which are the biggest global spenders on developing new drugs, the average cost of successfully bringing a product to market jumped by more than 25% from \$830m (£526m) in 2010 to \$1.04bn in 2011. Yet their research also suggested that the average commercial value of each asset was unchanged from 2010. That, along with rising costs, contributed to the internal rate of return on research and development sliding from 11.8% in 2010 to 8.4% 2011.

Pharmaceutical companies collect and analyse vast quantities of research data, generated in-house and externally, in order to find new drugs to develop – and the pressure to find new products is intensifying. The sector seems to be struggling to make sense of the amount of scientific data that it collects and this is certainly something, which if regulated correctly, the outsourcing industry could help streamline.

Last year, Swiss drugmaker Roche’s Chief Finance Officer, told a conference that the company’s data is doubling every 15 months. “I don’t think we are increasing our know-how every 15 months, far from it,” Erich Hunziker said. “I’m scared that a lot of this data is just spam. We don’t know how to filter it.”

Medical writing

Medical writing is another fast developing discipline within the industry and involves writing on topics useful for the medical fraternity and drug development. In the pharmaceutical industry, the demand for high quality documents is increasing as the difference between poor-quality and high-quality medical writing can result in a speedy drug submission approval, or a rejection.

Many pharmaceutical companies are now opting to outsource their medical writing in order to meet deadlines, maintain high quality, and reduce costs. Outsourcing to companies that have staff with medical background and technical knowledge of the regulations increases the speed of this product development work.

Globally, many pharmaceutical companies are turning to India in order to tap the medical writing skillset of the country. A large number of qualified and experienced professionals, cost effectiveness and wide use of English are some of the advantages that make India a dream destination for outsourcing medical writing.

India has a pool of qualified, talented and experienced medical scientists who graduated from one of 200 medical schools. Many Indian professionals have thorough knowledge of good clinical practices, drug development, experience with basic and clinical sciences and good writing skills. Many of them also possess industry experience and consequently know how to put together reports and analyse safety data.

Cognizant, provider of information technology, consulting, and business process outsourcing services, is tapping into this talent pool to deliver a multi-year agreement with AstraZeneca, to provide medical reporting services and comprehensive biostatistics to generate clinical study reports.

Under the agreement, Cognizant will provide medical writing, centralised statistical programming, statistical analysis, and document publishing services, spanning the entire chain of clinical data reporting from case report forms to clinical study reports.

“Cognizant will help us streamline our clinical development operations. This is key to our business transformation aimed at achieving greater efficiency, agility, flexibility, and global competitiveness – all of which are crucial to clinical trials and development of new drugs,” said Karin Wingstrand, Vice President and Head of Clinical Development at AstraZeneca.

Offshoring and emerging markets

The increased cost of drug development has encouraged pharmaceutical companies to seek better opportunities offshore to successfully develop their products on a global scale. The big pharmaceutical companies have traditionally invested in countries such as India and China, which offer advantages such as an intellectual talent pool, cheap land and labour, and investor-friendly governments.

Pharmaceutical suppliers have also been taking advantage of the many benefits central European countries can offer. Czech Republic, Slovakia, Hungary, Poland, Romania and Bulgaria and three Balkan states: Croatia, Serbia and Slovenia are leading the surge in European pharmaceutical contract manufacturing and active pharmaceutical ingredient (API) sourcing. These countries all developed a specialised area of operations and mature product and service portfolio.

Within the next decade, Asia is expected to overtake Europe in pharmaceutical sales, driven by growth in key emerging markets. For example, China is predicted to be the second largest pharmaceutical market after the United States by 2015.

Pharmaceutical companies are having to radically change their practices when it comes to tackling emerging markets such as China, India, Russia and Brazil. This is being achieved by adopting a regional approach – by moving beyond the use of contract research organisations and marketing of established products to include early-stage research aimed at specific medical needs of patients in these regions.

“Eighty-five percent of the world’s population lives in the emerging markets, and during the past 5 years, all real economic growth has come from these markets,” says Patrick Keohane, Vice President for R&D Asia Pacific at AstraZeneca.

“With companies focusing on emerging markets, pharmaceuticals would need to address the varying medical requirements of each of these markets,” says Frost & Sullivan Research Analyst Swetha Shantikumar. “Therefore, there will be an overall shift in the pharmaceutical industry from a very Western centric model to a global one.”

Emerging opportunities

Early in 2011, David Cameron highlighted in a speech, the critical importance of high-tech industries, and specifically the pharmaceutical sector, in leading Britain back to economic health. It was only a few weeks later that Pfizer, the pharmaceutical giant, announced the closure of its research facility at Sandwich in Kent, at a loss of 2,000 jobs, which sent shockwaves through the industry – and through Whitehall, too.

Business Secretary Vince Cable said the firm’s decision was not about the UK as a location for pharmaceutical research; however the closure seemed to serve as a catalyst for the government to take a stronger stance to incentivising pharmaceutical outsourcing within the UK, along with research and development through a number of key measures.

The first positive step was the recommendation from the NHS Chief Executive for Sir Ian Carruthers OBE, (Chief Executive, NHS South West), to lead a review on his behalf on how the spread of innovations can be accelerated across the NHS and inform the strategic approach to innovation in the health service.

Following the release of the innovation review – Innovation, Health and Wealth, the government has decided to invest £180m into a new “Catalyst” programme, as part of its strategy for Life Sciences, which will help finance the crucial stage between discovering a product and its commercial success.

While some might argue that pharmaceutical companies should pay for this themselves, this seems a justifiable use of tax-payers’ funds taking into account that after many years of bringing home massive profits, the industry is facing tougher times, now that the patents on the most lucrative products are running out, and the market is flooded with cheaper copies.

David Cameron has also highlighted a consultation on changes to the use of NHS patient data which will have a direct effect on the UK’s pharmaceutical industry and the use of outsourcing. The proposal is for patient information to be shared with private healthcare companies and data automatically included in clinical research unless individuals opt out.

In his autumn review, Chancellor George Osborne reiterated Cameron’s point that the pharmaceutical research

and development in the UK would benefit greatly by the release of the UK’s detailed, anonymised medical data

A statement released by the Department of Health stated: “The UK is uniquely placed as being one of the few countries to have a universal ‘cradle to grave’ health system boasting some of the most detailed, anonymised information on patients. We have the potential to lead the world as a location for data-enabled health research with direct benefits to patients, via the Clinical Practice Research Datalink.”

The government now has high hopes for the new measures, which were developed in collaboration with almost 120 existing commercial enterprises, including GlaxoSmithKline, Experian and SAS UK.

Prime Minister David Cameron said: “We can be proud of our past – but we cannot be complacent about our future. The industry is changing; not just year by year, but month by month. We must ensure that the UK stays ahead. Yes, we’ve got a leading science base, we’ve got four of the world’s top ten universities, and, we have a National Health Service unlike any other. But these strengths alone are not enough to keep pace with what’s happening – we’ve got to change radically – the way we innovate, the way we collaborate, the way we open up the NHS.”

GlaxoSmithKline, one of the world’s leading research-based pharmaceutical and healthcare companies, said: “The government’s strategy for Life Sciences is a very important next step on the journey to make the UK the best place in the world to locate pharmaceutical investment. The actions on research and manufacturing will further strengthen the attractiveness of the UK and most importantly the results of the Innovation Review should ensure that the NHS is a stronger adopter of innovative medicines and technology, ensuring that all patients can benefit from cost-effective treatments and interventions approved by the National Institute for Health and Clinical Excellence... to make the UK a world class environment for life sciences.”

Dr. Vivienne Nathanson, head of science and ethics at the British Medical Association, offers a cautionary note: “The use of anonymised health data could benefit patients, but we are concerned that elements of the government’s proposals could, if implemented, undermine patient confidentiality.

“We are especially worried by recommendations that would grant researchers, possibly from large commercial companies rather than the patient’s healthcare team, access to patient records. This could mean that details of an individual’s health status and treatment will be revealed if researchers are able to search through records and identify patients in order to contact them.”

Ultimately outsourcing is an integral part of the pharmaceutical industry and the partnerships which are formed allow companies to establish consistency and efficiency across sprawling international networks of commercial, supply chain and manufacturing organisations. Outsourcing and the government’s initiatives to support and reinvigorate the industry, if managed and executed strategically, has every potential to improve patient care, add value to the shareholder and keep the investor community happy – throughout 2012 and beyond.