

R&D

open verdict?

As pharmaceutical companies begin to shift from in-house R&D to external partnerships and 'open innovation', the traditional drug discovery model may soon be a thing of the past. In this article we explain what is driving these changes and what the implications are for the R&D workforce.

The pharmaceutical industry has adhered to a 'closed' model for drug discovery and development for many years. Individual companies plough millions into in-house R&D in a bid to discover new molecules with therapeutic properties. Only a tiny proportion of those that show potential will run the gauntlet of lab-based testing, clinical trials and regulatory hurdles. Those that emerge, blinking, into the light of the market will be exclusively owned during the period of patent protection – and are heavily promoted to maximise profit and recuperate the prohibitive costs of R&D.

This strategy of 'betting' on in-house R&D to find potential medicines making it to market has paid off handsomely for shareholders for many years. But could the tactics of big pharma be set to change forever? Some experts certainly think so, pointing to a number of factors conspiring to bring this once stable model of 'closed' development into question.

Patently obvious?

New drugs are the life blood of the pharmaceutical business. Without new therapies to sell, the industry is in limbo, relying purely on the strength of ageing brands. But with the patents on many 'blockbuster' medicines launched in the glory days

of the 1990s due to expire over the next few years, big pharma is starting to feel very exposed.

According to Barbara Ryan, an analyst at Deutsche Bank, patents worth a projected \$30 billion in revenue are due to expire between 2010 and 2013. With the ensuing rise in generics flooding the market, pharma companies will need to raise their productivity in order to keep profits flowing.

So it is a worry for the industry that the drugs pipeline, at least in some quarters, appears to be running dry. While pharma R&D spend has increased, the number of new drug approvals has remained relatively flat.

In its 2007 report *The Innovation Gap in Pharmaceutical Drug Discovery and New Models for R&D Success*, Northwestern University's Kellogg School of Management, based in Illinois, US, suggests three potential factors behind this crisis.

The first is over-saturation. Have pharmaceutical companies made all the breakthroughs they can with current technology, ask the researchers. Secondly, the authors cite increased risk taking. In recent years the pharmaceutical industry has shown a greater appetite for investments that have proven less than safe. For example, focusing on biologics and genomic-based therapies, which are often harder to develop and can struggle to receive regulatory approval.

By Dr Kay Wardle

Finally, it suggests that excessive growth and corporate stagnation could be to blame. Have pharmaceutical companies, and their R&D processes, become too big and set in their ways to produce true innovation?

Whether it is one factor, or a combination of them all, the cost of R&D is increasingly becoming a burden as innovation and the associated pay off from new drugs fails to materialise.

Developments rising

It is not just the dearth of new products hitting the market that is a cause for concern for the industry. The cost of R&D is increasing too. Together with expiring patents, this represents a potential time bomb for R&D divisions across the industry.

The recent PricewaterhouseCoopers report *Pharma 2020: Virtual R&D, Which path will you take?*, highlights the issue: "If pharma is to remain at the forefront of medical research and continue helping patients to live longer, healthier lives, it must become much more innovative, as well as reducing the time and money it spends on developing new therapies."

And it goes on to claim that incremental improvements are no longer enough, stating: "The industry will need to make a seismic shift to facilitate further progress in the treatment of disease."

Offshore and more

How can pharmaceutical companies achieve this seismic shift in R&D practise? In several companies we have already begun to see part of the answer: outsourcing.

The sector is likely to see an increasing reliance on contract research organisations (CROs) in both preclinical and clinical R&D. These organisations frequently use heavily automated, bioinformatics-based experimentation systems to develop new potential therapies.

Outsourcing is proving to be a common strategy, particularly in developed Western economies that are expensive in which to operate. RSA has seen a rising trend of terminating researcher contracts when projects end. These skilled workers are being replaced via outsourcing, or through the creation of new R&D departments in countries where labour is cheaper.

According to Reuters Business Insights, 15% of pre-clinical drug research operations are now outsourced. And this is set to rise. For example, the UK Life Science Leaders Survey 2010*, carried out by the Science Technology & Innovation Partners and sponsored by RSA, revealed that

57% of supply chain managers in UK life science business expected offshoring to increase in the next two years.

Yet offshoring as a purely cost-saving measure may not be a long term solution: for it to be sustainable, wages must remain low – which is not a given – and it carries other risks such as hidden costs related to differences in culture and loss of control over IP.

Open innovation

Many experts are now arguing that for the industry to adapt to these rising development costs, new approaches towards innovation itself are needed. Such is the need for a step change in the discovery model that pharmaceutical giants are now willing to break their long established inward-looking mentality, in favour of a more collaborative system of drug discovery and development.

Such open collaboration has the potential to benefit the industry as a whole. The process is often called 'open innovation' – a term coined by Henry Chesbrough, Professor and Director at the Centre for Open Innovation at The University of California, Berkeley, US.

'Open Innovation' means recognising the value of external ideas, and using internal R&D to add value to them and take them to market for profit. The model encourages sharing IP between companies, in order that they can be employed in the best possible way.

In the technology industry, the open source movement, where permission to use intellectual property is freely available to all, has enabled some companies to benefit from the wider knowledge base, before specialising and working with ideas and before taking their product to markets.

Another industry where an open collaborative approach has blossomed is Hollywood. Studios do not own the entire process of creating and releasing a film: many smaller companies, from talent agencies, to special effects, to scriptwriters, are involved in the many separate constituents that must come together to produce a successful film.

Indeed, some pharmaceutical companies are already forming partnerships with smaller biotechs to boost early stage discoveries. Open innovation doesn't only mean looking to start-ups. Academia is a huge resource of innovation and development capability with which the pharmaceutical industry is increasingly forming partnerships.

Pharmaceutical companies are hoping that this more open, partnership-based approach to drug discovery will finally lead to further innovation with realistic costing models.

Evolve or die

Ultimately, the increased use of offshoring is likely to result in job losses within the UK pharmaceutical industry. As global leaders in life sciences Executive Search and Interim Management, RSA has begun to see a movement of staff displaced from the pharmaceutical industry to the CRO sector – and this is likely to continue.

Several R&D sites across Europe have closed – and more are set to close in the coming months. On a positive note, some of these sites have been sold to CROs in their entirety, with many of the staff being offered jobs as part of the deal. For example, the GSK site in Verona was sold to the CRO firm Aptuit. Similarly, Merck's research site in Rome has also become a CRO. Indeed, many pharmaceutical companies are promising two to three years of business to the purchasing CRO as part of the sale. This generates stability for the first few years until additional clients and contracts can be secured.

The net outcome is that the CROs are getting greater access to highly skilled staff – something that has been a criticism of CROs in the past. However, while the roles within CROs and in-house R&D groups may be similar, salaries are often lower. More forward-thinking staff may move to organisations which develop the technologies that are used by CROs to facilitate the R&D processes.

Not all staff will move to CROs. Others will adopt a more entrepreneurial approach, joining forces with like-minded colleagues to acquire and develop IP that they have worked on prior to a site closure. While there are plenty of vacant research laboratories and redundant equipment, the real challenge for these individuals will be securing funding within a still-cautious environment in which venture capitalists and business angels are reluctant to invest in life science organisations.

Nor will all sites become CROs. For example, the former Roche site in Welwyn Garden City, UK is now a thriving Biopark which will nurture fledgling research companies with the hope of creating further job opportunities.

For the staff that remain within pharmaceuticals, demonstrating their value and showing that they have the skills and competencies above and beyond those that exist in CROs is crucial – or their activities will be outsourced and roles eventually made redundant. To survive, they must remain at the forefront of their science.

Despite these changes, increases in a collaborative approach to R&D have the potential to create more opportunities, should smaller, more innovative companies find their niche in the industry.

The skill sets that in-house staff will need is also likely to change to meet the needs of this newer, more collaborative approach. The ability to manage external partnerships, often from a distance, will become critical. This will require excellent communication and time management skills, plus the ability to operate across cultural and language barriers.

Future choice

Outsourcing routine tasks will enable staff within pharmaceutical companies to concentrate on a more focused, expertise-driven approach to drug discovery.

For the smaller, more innovative biotech and research companies, a move towards open innovation in the sector could herald new business opportunities and subsequent employment opportunities. For big pharma, a collaborative approach to R&D has the potential to break the deadlock we are seeing in R&D innovation, and generate the blockbuster brands of the future.

* The UK Life Science Leaders' Survey 2010 was conducted among 390 key leaders working in the global life sciences industry. Data was collected in July 2010. **DDW**

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