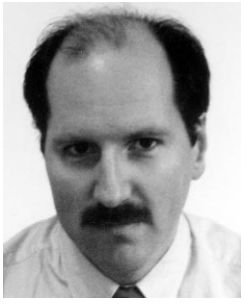
Virtuality: the tide floods from the West



'…to in-license, add value and sell on'

The new environment for pharmaceutical R&D is not overburdened with clear terminology. 'Biotechnology' for one is a name that inadequately identifies what is now becoming a diverse group of new companies in the industry. But there has been at least one attempt to provide better understanding by partitioning the sector into the technology provider (combinatorial chemistry or genomic company for example) and the multidisciplinary biopharmaceutical company. The equally evident trend in the industry towards out-sourcing has been captured in the so-called virtual company, a name that confuses by its association with 'virtual reality', and signifies to many a company without formal basis, when in fact it may well subsume the essence of large company pharmaceutical R&D. In only one sense, as suggesting technological radicalism, does the word 'virtual' signify a new approach to pharmaceutical R&D. So, is this a fair assessment?

Radical or hype?

Virtual companies rely almost exclusively on out-sourced activities; but the trend towards the use of out-sourced work is running feverishly throughout the pharmaceutical industry. From large multinationals seeking ways around resource bottlenecks in their development pipelines, to biotechnology companies reaching out for new technology to advance their research efforts; even the partnerships between large pharma and technology providers are good examples of outsourcing. By this analysis, virtuality is not as radical as it may appear. Virtual companies are in essence project management specialists; and project management is the essence of pharmaceutical R&D, insofar as this is its defining principle. Again, nothing remarkable here.

Virtual companies promise lower pharmaceutical development costs by virtue of reduced infrastructure overheads. While experience is still being accumulated, emerging signs are that this is possible. CollaGenex (Wayne, PA, USA) developed a new treatment for periodontitis from work emanating from the State University of New York (SUNY) through to an NDA for $6.2 million, with an in-house team of no more than half a dozen people. There are a host of new companies, largely in the USA, hoping to ape this strategy. Many of these companies, such as Triangle Pharmaceuticals (Chapel Hill, NC, USA), Delta Pharmaceuticals (Research Triangle Park, NC, USA), Sensus Drug Development (Austin, TX, USA), Pozen (Chapel Hill, NC, USA) and BioMedicines (Alameda, CA, USA), have based themselves on being able to in-license drugs from large pharmaceutical companies. Indeed, building on prior research is a major part of the strategy; they aim to in-license, add value and sell on. Others include The Medicines Company (Cambridge, MA, USA), with Hirulog as an anticoagulant alternative to heparin, Zarix (San Diego, CA, USA), developing oncology products for European markets, and EntreMed (Rockville, MD, USA), with various cancer treatments based on anti-angiogenesis, all adopting a variety of ways of enhancing the value of a product. The value added may not be just in longitudinal development. Alternative strategies invoke development for additional therapeutic indications, or for more complete global coverage. The real virtue of virtuality is in its ability, through reduced costs to play into niche areas that are (rightly) overlooked by traditional methods of pharmaceutical R&D, using traditional financial bases for portfolio management.

Radical changes in the modern pharmaceutical market rarely arrive through finding a dramatically improved treatment in a well-covered area; instead they usually enlarge the overall market by addressing an area that was previously completely untreated, or involved other methods (e.g. surgery). If reduced costs render such niche areas commercially viable, radical changes in the overall marketplace are indeed possible. The new breed of virtual company is flexible in its aims, willing to enter into areas without concern for a large overall strategy. At Arachnova (Cambridge, UK) we are working on a new treatment for an orphan indication on the back of a low risk, low cost and relatively short development programme for a drug for animal treatment.

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Impact on large pharma

The multinationals have not ignored this trend. Roche has set up Protodigm (Hemel Hampstead, UK) as a wholly-owned, 10-member, independently operated subsidiary. The company has tendered for development projects for compounds from its parent company in competition with in-house alternatives. It is therapeutically and developmentally diverse, having three projects currently ongoing, and is able to make decisions much more rapidly than most large companies. When Protodigm was established, its goals were to develop compounds 40% quicker and 40% cheaper than Roche's benchmarks for internal programmes; three years on, these goals are being achieved. Protodigm may offer many of the advantages of virtuality to Roche, but a key question remains whether it is better to retain a very talented group of executives in a subsidiary or as a separate entity. One of the additional advantages of a separate company is the ability it has to raise its own money for financing development. Moreover, the full advantages of the more heterogeneous environment created by multiple separate companies include those derived from competition. A subsidiary of course cannot act in competition with its parent.

As well as addressing new markets, virtual companies may be radical in a more far-reaching way. The opportunity for groups of highly talented, risk-conscious, multi-disciplinary and commercially aware individuals to break into this high-risk, high-cost game will challenge more than ever the occupation of the centre ground of pharmaceutical R&D by the large multinationals. So long as new molecular entities come with a $600 million price tag and a chance of success of one in 10,000, huge investments and oligarchic business practices are inevitable. But if costs can be reduced by two orders of magnitude and risks arbitraged by sophisticated in- and out-licensing strategies, a more inhospitable and competitive environment beckons. Large multinationals will not go away, their global marketing activities are likely to be evermore important, just as the automotive industry is dominated by a few big players. But if this prognosis is true, we need a better motif than 'virtual' to describe a radicalism soon set to become a reality.

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