



## The Need for Development Advisory Boards in Small Pharma

The past fifteen years has seen the formation (and demise) of a number of small pharmaceutical companies, seeking to exploit a technological breakthrough in a niche therapeutic area and to establish themselves as viable businesses. Many of these companies are founded by leading academics, with little or no knowledge of the drug development process, outside their own area of technical expertise. Some of the others were formed as a result of a downsizing exercise in one of the pharmaceutical majors, in which redundant team members joined forces to seek to exploit unwanted technology.

Recent estimates have put the total cost of bringing a new chemical entity to the marketplace as high as \$850 million; this represents several hundred times the market capitalisation of many of the small players in what is acknowledged to be a high-risk high-return industry. Furthermore, only one in four new drugs launched actually goes on to recoup the investment that went into its development. Even the pharmaceutical majors are baulking at this level of investment and risk.

Many of the emerging companies have recognised the benefits of outsourcing the development and manufacture of their clinical drug candidates; it is considerably cheaper to rent time and personnel within contract facilities than to carry the burden that goes with this infrastructure, particularly given the high risk that accompanies such projects. If a project should fail in development, then the virtual company can terminate its development contracts and so limit its financial exposure.

In order to maximise the return on investment whilst controlling costs, companies must fully exploit the intellectual capital that exists within their organisations. The infrastructure costs of the majors are prohibitively expensive for the emerging pharma companies, who must find alternative ways to access the technical and managerial experience needed to shepherd a new chemical entity through the drug development process. One way to achieve this is through the use of consultants.

Many companies have adopted the strategy of employing a scientific advisory board, comprising industry experts in relevant technical fields, when conducting a portfolio review of research programmes. It would be a logical progression to extend this concept to cover the drug development arena. In this case, the advisory board could be comprised of chemists, biologists, pharmacists, pharmacologists, toxicologists and clinicians with the expertise to cover the spectrum of drug development activities.

This represents an opportunity to call upon the knowledge of a number of seasoned industry experts and would be expected to significantly improve the chances of getting a drug to market in the shortest time, through the avoidance of pitfalls and learning from this collective experience.

Senior managers with experience of the development process command high salaries. This expertise is expensive if it is not in constant use and the manager is involved with a lot of low

added-value activity. The ability to “rent” the expertise only when needed is an attractive alternative.

## About This Article

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## About The Author :: Paul Madeley

Paul Madeley began his career with Boots Pharmaceuticals in 1977. Later, following his PhD studies, he worked as a development chemist with Courtaulds and then Abbott Laboratories. Since 1995 he has worked in the virtual pharmaceutical arena, first with British Biotech and then with OSI Pharmaceuticals, where he was Senior Director of Chemical Operations, with responsibility for outsourcing, technology transfer, chemical development, scale-up and validation. He has also managed analytical and pharmaceutical development functions at various times.

Dr Madeley has worked on over fifty API programmes, covering more than two hundred synthetic process steps. He set up Synth-Isis Ltd in 2004 to provide consultancy services to small pharmaceutical and biotechnology companies.