Expert Opinion

Technology versus products – what's the real driving force of interest for the pharmaceutical industry?

Thomas L Reiland
Drug Delivery Coordination, Global Pharmaceutical R&D, Abbott Laboratories, AP4A-4, D-R43D, 100 Abbott Park Road, Abbott Park, IL 60064-6122, USA

Keywords: products, technology, vision

Expert Opin. Drug Deliv. (2004) 1(1):1-2

It is intriguing to investigate all the truly innovative drug delivery technologies that have been in development over recent decades. Formulation scientists, trained in the area of dosage form design, can be like children in a sweet shop looking at all the new technology treats on display. It should not be surprising that drug delivery companies put such an outstanding effort into promoting the potential benefits of their novel approaches, as their very livelihood depends on it. Such promotion of new technology, besides being essential to the existence of the drug delivery companies, serves as a valuable educational tool for the pharmaceutical industry. However, what really drives their interest to get involved with the assessment and ultimate development application of a new drug delivery technology? Is it the intriguing technology presented, or the vision of a potentially new innovative, patent-protected and promoteable product?

On the intriguing technology interest side, there are formulation scientists from both the drug delivery innovators and pharmaceutical companies, and these are the people who must begin to make things happen. Ultimately to be successful, a drug delivery system must have some core intellectual property that needs to meet the patent office requirements of novelty and usefulness. Initially, this new concept is associated with a great deal of excitement from the innovative people involved in its conception with all the great visions about what it can accomplish. The drug delivery scientists must make the most of the limited preliminary data they have been able to generate. From the large pharmaceutical company perspective, the initial assessment tends to focus on understanding the delivery mechanism and revealing the usual extreme limitations inherent in the actual scientific proof of what can be done with the small amount of data available.

Looking back at pharmaceutical development over the past few years can be useful to illustrate the recurring pattern that is usually played out. A rather mature area now, which is an especially good example, is transdermal drug delivery. When first introduced, the excitement surrounding pushing drugs through the skin was contagious. All the potential advantages available with this new route of administration easily captured the attention of pharmaceutical companies. The novelty of the technology was obvious, although, at the beginning, the real true potential to produce marketable products was not understood from the visions promoted at the time. Even though there was some truth in those early dreams from the technology perspective, a look at the products that finally made it to the market place is revealing. The world record for the largest molecule delivered by passive diffusion through the skin on the US market, in a transdermal patch, seems to be fentanyl 337 MW. The barrier properties of the strateum corneum have become more clearly understood, as has the project killing impact of the development of irritation or sensitisation. All the different drug molecules ever commercialised as transdermal patches can just

about be counted on your fingers. The vision for which products can ultimately make it to the commercial stage is the crucial one. It is the nature of research that there are vastly more failures than successes, and the elusive target is to sort through the promoted visions for the technologies and capture the true product potentials that are realistically within reach.

Within large pharmaceutical companies, which end up funding the extremely costly clinical and formulation development processes, people have to evaluate which visions to pursue. There seems to be an unrealistic notion that large companies have big pockets full of unallocated funds just waiting for the right vision to be presented. The reality, however, is that there is a constant dynamic flux of activity related to the funding of internal projects. The endorsement and pursuit of any external drug delivery technology must compete with this ongoing internal financial review process. Someone within the company must become a champion for the technology if the vision is ever to take root, grow and produce a product that makes it to the marketplace. In the past, this has typically been achieved only when some members of a project team within a pharmaceutical company or someone in business development have been sufficiently interested (or frankly desperate) to try anything. There are several problems inherent in this approach, however, that should be recognised. A new dosage form development timeline from inception to market launch with a novel technology, not previously scaled-up and reviewed by international regulatory bodies, could be in the 5- to 7-year time frame. If a well-established drug delivery technology is utilised, significant development time savings can be realised; however, it still is an exceptionally lengthy process. Based on the vast majority of past experiences, it has been exceedingly difficult to get enough attention to life cycle management concerns in the 5- to 10-year strategic planning time frame that would be more optimal. It remains a challenge to get more than lip service to an effort to look for new product concepts far enough in advance.

Without the recognised need for a product, any internal champion will really struggle getting funding to explore a valuable new technology. So what is the solution to this dilemma? One suggestion is a hybrid approach pushing the need for new products with the benefits of new technologies. Why limit your argument to one old product at the end of its life? A review of a pharmaceutical corporation's pipeline by drug delivery experts can readily categorise the products into a limited number of areas for possible improvement that could be pursued. The most common example is the development of a controlled-release product that provides less frequent dosing and/or reduced side effects for real patient benefits. Improved bioavailability that allows a dosage reduction or being able to achieve a 'no food effect', or an alternate route of administration, such as transdermal or inhalation for an injectable product, are additional illustrations. Why not pursue a system that attempts to be aware of all of the needs of all of your products? Review everything you have and find out the overlapping areas of product improvement needs. From this sound basis, new drug delivery technologies become more readily recognisable for their potential impact in enabling new product development for a pharmaceutical company in meeting their life cycle management needs. After exploring technologies that are good potential hits with several of the drugs in your pipeline, you then have the benefit of both sides of the argument. As a result of this matching process with existing drugs, the pathway to new improved products will become more clear. That is, and should continue to be, a requirement for funding of external drug delivery technologies by pharmaceutical companies.

Affiliation
Thomas L Reiland PhD
Drug Delivery Coordination, Global Pharmaceutical R&D,
Abbott Laboratories, AP4A-4, D-R43D, 100 Abbott Park Road,
Abbott Park, IL 60064-6122, USA
Tel: +1 847 937 5079; Fax: +1 847 938 6569;
E-mail: thomas.reiland@abbott.com