Special Concerns for Preclinical Evaluation of Biotechnology Products

Although many assume that biotechnology is a recent concept, the application of this science has been understood for many years and utilized in its simplest form in the fermentation of beer, wine, and bread by microbial agents. Modern biotechnology can be divided into three research and development areas: recombinant DNA technology (rDNA), monoclonal antibody technology, and bioprocess technology (Mackett, 1993; Malinowski, 1999). The commercialization of these three processes is based on the premise that biotechnology can cost-effectively produce large quantities of a highly purified product.

Biotechnology as a promising source of new and more efficient source of more targeted therapeutics has been with us since the mid-1980s (Maulik and Patel, 1997). While (as one should expect) some of the early promises have not quite been met, biotechnology has turned out to be a valuable source of new and valuable therapeutics and currently accounts for one-third of all new therapeutics entering the marketplace. Table 1 lists the proteins approved in 2007 that have more than a billion dollars a year in global sales.

Protein and other biotechnology-derived therapeutics have some fundamental differences from traditional small (synthetic organic) molecules and so require modified or different approaches to characterize their toxicity and evaluate their safety. Table 2 presents a comparative summary of these differences.

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