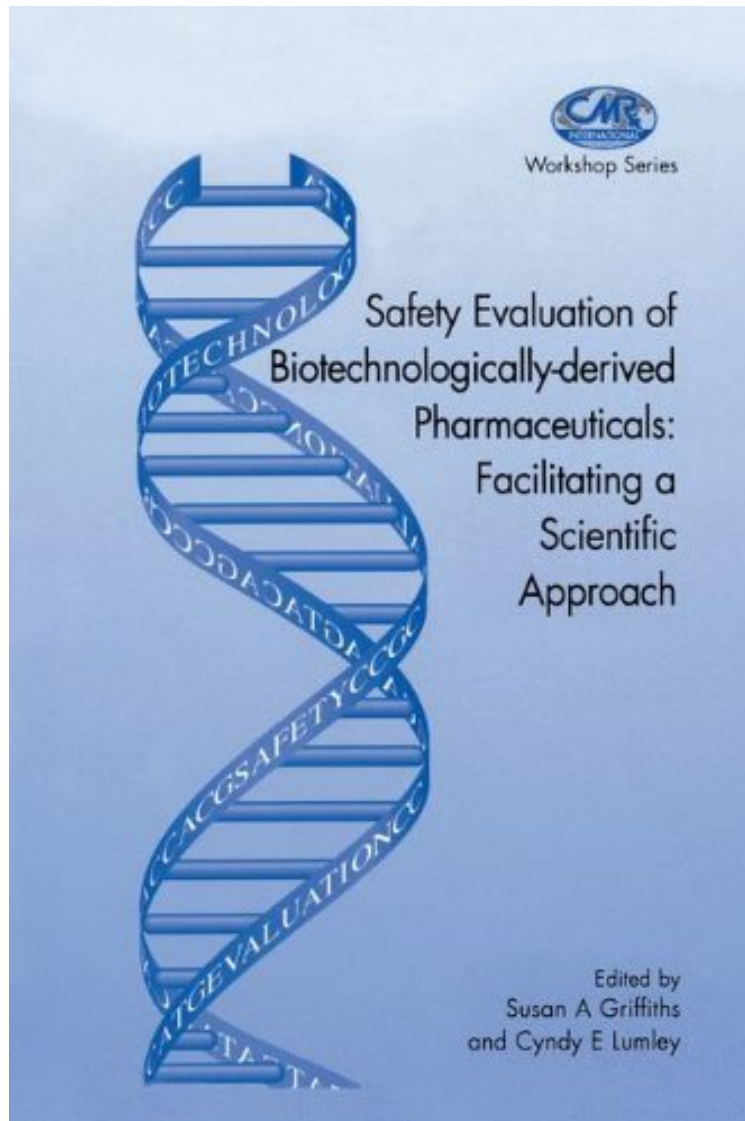


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## Facilitating a Scientific Approach (Centre for Medicines Research Workshop):

Considerable investment has been made by both pharmaceutical and biotechnology companies in pharmaceutical products of biotechnology. However, because relatively few of these products have been marketed, lack of relevant experience means that uncertainty still surrounds the most appropriate strategy for their safety evaluation. The 13th CMR International Workshop, held in February 1997, provided the opportunity for regulatory authority and industry experts from Europe, Japan and the USA to share their experiences of designing safety evaluation programmes for specific product classes: colony stimulating factors, growth factors, hormones, interferons, interleukins, monoclonal antibodies for therapeutic use, and gene therapy products. Participants worked together to recommend those studies that should be considered for such safety evaluation, and those that may be unnecessary. These recommendations subsequently made a valuable contribution to the ICH guideline 'Safety Studies for Biotechnological Products', which was finalised at ICH 4 in Brussels in July 1997. The Workshop proceedings not only describe the recommendations but also provide the reader with an appreciation of the science behind safety evaluation strategies used by experts, the influence of different regulatory systems on these strategies, and the type of data required by both toxicologists and clinicians before they have sufficient confidence to administer pharmaceutical products of biotechnology to humans.