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"Pre-Clinical Research with Biotechnology Products"

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The process of drug development has seen major changes over the last two decades with the movement away from standard small molecule drug discovery programs, through computer-assisted drug design methodologies towards biotechnologically derived products.

The aim of duplication of endogenously active materials to be administered exogenously has enormous impact on development practices and evaluation of safety. In particular, simple chemical toxicity is less of an issue today than it was a few years ago, whereas exaggerated pharmacological response and immunological response is now of prime concern.

The commercial value of the biotech products is also 'high-end'. Complex and expensive molecules with high biological activity and potency are extremely effective pharmaceutical products that can command premium market prices in the wealthy developed countries (and are straining the resources of those countries with a socialized medical support infrastructure).

The discovery and early development of products has moved away from the domain of big pharma to the biotech companies, small focused and energetic companies who pursue high value for their products. Now more than ever drug discovery is commercially driven. Business planning and intellectual property issues have become of paramount importance even before the identification of a product

Issues facing the developer of biotech products include questions regarding the reliability and ease of production of the new biopharmaceutical, expected human toxicity versus toxicity in laboratory test species, cross-reactivity and complications arising from immunogenicity. The identification of metabolic pathways becomes extremely complex

with the difficulty that analytical methodologies may have in identifying endogenous and exogenous substances. These difficulties have been and are being addressed through the development of new and powerful technologies in the biological sciences and is paralleled by a changing regulatory environment (particularly in the US) where scientific understanding by regulatory authorities of the products that are being approved has never been so high.

The presentation will address a number of development issues in relation to development of biotechnologically derived products with particular emphasis on pre-clinical issues.