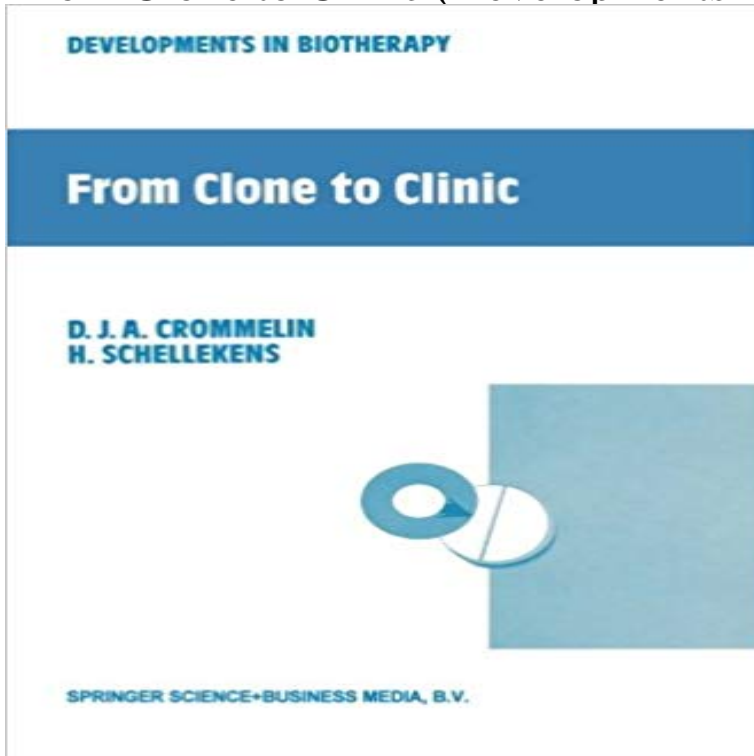


From Clone to Clinic (Developments in Biotherapy)



This book contains a selection of the papers presented at the meeting Between Clone and Clinic which was organised in March 1990 in Amsterdam by the dutch Organisation for Applied Research, TNO, and the University of Utrecht. The scope of this meeting was the development of biotechnological pharmaceuticals mainly made by recombinant DNA technology or monoclonal antibody techniques. All aspects concerning the development of the products after host cells producing them are obtained where discussed. The meeting was attended by twohundred specialists from all over the globe, including pharmacologists, toxicologists, registration experts, Quality Assurance managers, production en gineers and physicians. Biotechnological pharmaceuticals are in general large and complex protein molecules. Bringing these products to the market poses other problems than encountered with the classical chemical drugs. The source of biotechnological pharmaceuticals are living cells. The function of cells are depend ent on many factors and the stability of production may be a problem. Good Laboratory and Manufactory Practices with Quality Control (GLP and GMP) are of paramount importance and are discussed in a number of papers. The products of the new biotechnology are often highly specific and only active in the human species. Also the side effects can only be studied in the clinical setting. Even when the product is active in animals there is the problem of antigenicity. During treatment the animals will produce antibodies which neutralise the activity. So safety testing may prove difficult.

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