

From R&D to Industrialization of pharmaceutical research Scale up of plant cell culture technology for paclitaxel production

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Although pharmaceutical industry is recognized as high value return field, companies involved in the business always face on the pressures to reduce cost, time and risk in pharmaceutical R&D, and clinical attrition rate. Recently pharmaceutical research incorporates standardized and repetitive methods to identify disease-related genes and their protein products, and to make and test the chemical compounds used to target them. At the same time, the common industrialization methods, such as process optimization, quality management and knowledge management systems are applied to the industry. In order to succeed on the drug competition, both research side and developmental side have to be rigid to complete the commercialization of a drug.

This article focuses on the process development part, which can be considered as a bridge between research and commercialization. Developmental case of Genexol, plant cell derived paclitaxel, will be presented including verification of technology, optimization, technology relocation, qualification and validation.