



Design of Experiments for Pharmaceutical Product Development pp 171–188

Design of Experiments for the Development of Biotechnology Products

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Abstract

The development of biotechnology products containing large molecules such as nucleic acids, monoclonal antibodies, hormones, etc., requires critical understanding of the product-specific quality attributes and close monitoring of the manufacturing process for attaining quality consistency without batch-to-batch variability. The conventional product development strategy using one factor at one time approach only provides limited solution without any significant influence on the product quality for attaining the robust performance. However, the systematic approach of using design of experiments (DoE) is very useful for minimizing the variability and improving the product performance. A score of literature reports are available which vouch the