

## **204a Assessing Robustness for Cell Line Selection**

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Robustness is among the most desirable features of a cell culture manufacturing process, which is tightly linked to the robustness of the production cell line. Process robustness is often assessed after the selection of the production clone. Screening multiple process parameters on multiple production clones can yield a model that predicts the robustness of each clone with respect to the parameters tested and the ability to control those parameters in a manufacturing environment. The statistically designed screening experiment first yields a model of the desired output (e.g. titer) as a function of the screening variables (e.g. pH, temperature, media conditions). This model is then used, with the knowledge of the capability to maintain set point at manufacturing scale, to provide a robustness index for each cell line. Final selection of the clone is based on the ability to meet the target productivity, optimization potential, and robustness.

Multiple clonal cell lines were assessed for productivity and robustness for two independent clinical antibodies expressed in a CHO host. The experimental methods and robustness analyses of these multiple cell lines will be presented.