

Paper 285-2009

Use of DOE to Determine the Critical Parameters and Design Space for Production of Biotherapeutic Proteins

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ABSTRACT

Biolex Therapeutics uses a novel biomanufacturing platform, the aquatic higher plant *Lemna minor*, genetically engineered to produce recombinant biopharmaceutical proteins. Using SAS® JMP® Design of Experiments (DOE) software, results will be presented to show:

- The identification and optimization of critical parameters that affect the yield and quality of recombinant protein.
- The use of a small scale process model to define the design space in which consistent yield and quality are achieved.
- The relevance of the small scale process model to the large scale production process and equipment.

Significant parameters controlling the upstream process were identified using the Parameter Estimate Report of the Analysis of Variance. The DOE results clearly defined important interactions between critical environmental parameters. The use of the Prediction Profiler and Contour Plots were instrumental in defining our design space and the technical transfer of the upstream process to GMP manufacturing.

No paper was submitted for publication.

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