CLAIMS

1. A method for selecting a clonal cell line for use in production of a therapeutic protein, comprising:

   measuring, for a plurality of clonal cell lines, a product concentration of each clonal cell line;

   determining, based on the product concentration, product concentration profile data of each clonal cell line;

   inputting the product concentration profile data into a learning model comprising a modelling framework; wherein the modelling framework comprises multivariate latent variable modelling, multiway analysis structure, and evolving models structure;

   generating, using the learning model, an output indicating a production stability of each clonal cell line; and

   selecting, based on the output, a clonal cell line for use in production of a therapeutic protein.

2. The method of claim 1, wherein the multivariate latent variable modelling comprises at least one of Projection to Latent Structures (PLS) and Principal Component Analysis (PCA).

3. The method of claim 2, wherein the PLS comprises at least one of PLS-Discriminant Analysis (PLS-DA), PLS-Support-Vector Machines (PLS-SVM), PLS-Neural Networks (PLS-NN), PLS-Logistic Regression (PLS-LR), PLS-k-Nearest Neighbours (PLS-KNN), PLS-Decision Tree (PLS-DT), PLS-Naïve Bayes (PLS-NB), PLS-Random Forest (PLS-RF) and PLS-Gradient Boost (PLS-GB).

4. The method of any preceding claim, wherein the product concentration profile data of the clonal cell line comprises one or more of mean product concentration, standard deviation, skewness, kurtosis, differential, maximum product concentration, and maximum-minimum gradient.

5. The method of any preceding claim, wherein measuring a product concentration of one or more clonal cell lines comprises measuring a product concentration of each clonal cell line across a plurality of production runs, up to a generation number of 150 generations.

6. The method of claim 4 or 5, further comprising obtaining a generation number distribution for each production run.

7. The method of any preceding claim, wherein the evolving models structure comprises analysing the product concentration profile data of sequential production runs.

8. The method of any preceding claim, wherein the clonal cell line is a mammalian cell line, preferably a CHO cell line.

9. The method of any preceding claim, wherein the product concentration is measured at multiple bioreactor scales.

10. The method of any preceding claim, wherein the product concentration comprises the concentration of a monoclonal antibody.

11. A system for determining clonal cell line production stability or selecting a clonal cell line, the system comprising:

    a. an input for receiving clonal cell line product concentration profile data;

    b. a learning model to determine clonal cell line production stability or select a clonal cell line, the learning model comprising a modelling framework comprising multivariate latent variable modelling, multiway analysis structure, and evolving models structure;

    c. one or more processors for processing clonal cell line product concentration profile data with the learning model; and

    d. an output to provide an indication of clonal cell line production stability based on the processing of clonal cell line product concentration profile data by the learning model.

12. A computer program comprising instructions which, when the program is executed by a computer or data processor(s), cause the computer to perform operations according to the method of any one of claims 1-10.

13. A computer-readable medium comprising instructions which, when executed by a computer or data processor(s), cause the computer to perform operations according to the method of any one of claims 1-10.

14. The program of claim 16 or the medium of claim 13, wherein the instructions when executed implement (a) a learning model and/or any associated function and/or (b) a system to predict clonal cell line production stability.

15. The program or medium of claims 12, 13 or 14, wherein the instructions when executed output an output with an indication of clonal cell line production stability.