iCOP™: Bioprocess Optimization

Third in a Series of Application Notes on the integrated Cellular Omics Platform

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Understanding the system

Current methods for process optimization are very time consuming, expensive, and labor intensive and only lead to incremental improvements. Traditionally, process optimization for media and cell culture conditions is achieved either through Design of Experiment, experience, or trial-and-error approaches. Most importantly, these practices must be repeated for every new production cell line and associated protein product.

At best, they result in a highly variable and unpredictable process, both in terms of productivity, as well as product quality. These heuristic approaches lack the mechanistic understanding of how and why process conditions, or any implemented changes, bring about the desired outcome.

iCOP: integrated Cellular 'Omics Platform

iCOP is a Systems Biology platform. It relies on high-throughput 'Omics technologies to provide a system-wide characterization of the cell's DNA, RNA, proteins, and metabolites. Following the QbD philosophy, iCOP is a data driven approach that generates mechanistic insights into the production host physiology and metabolism.

Application to Bioprocess

Implementation of the iCOP platform produces a systems-wide *in silico* cellular model of the production host that is constantly tested and refined during each iteration of the platform. The result is a model that is robust, accurate, and can be used for prediction of cellular behavior in culture. Process targets are identified for immediate optimization and capitalized on in the engineering phase. Additionally, any adverse metabolic reactions related to any of the processes can be characterized and identified for modification, for example to optimize central metabolism efficiency and maximize cellular productivity. Furthermore, improved process understanding, as outlined by QbD, requires the comprehensive and integrated analysis of process data and phenotypic cellular-level data. ArrayXpress' data analysis pipelines are designed to allow for the integration of these intrinsically distinct but relevant datasets. The integration of PAT data with systems-wide molecular data allows for the identification of early biomarkers and process parameters indicative of final production phenotypes. These biomarkers and process parameters can be utilized during biomanufacturing as early process indicators that can be surveilled in real-time for process monitoring, quality control, and troubleshooting.

Efficient Resource Allocation

The iCOP platform offers a distinct advantage that allows cell development scientists and process engineers to work synergistically, accelerating and streamlining process optimization. At the same time, existing client capabilities are identified and complemented with ArrayXpress' expertise to maximize resource allocation. Contact us to discuss how iCOP can be used to optimize your bioprocess.