SYSTEMS ANALYSIS AND DESIGN FOR ACCELERATING PROCESS AND CELL LINE DEVELOPMENT

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This presentation will highlight our work on integrating genomic science with systems analysis for cell culture engineering. Advances in computational and analytical tools in the past fifteen years have altered the landscape of process engineering. The traditional experimentation based process development is greatly augmented by data and model driven approaches. The availability of vast amount of bioprocess manufacturing data allowed us to gain valuable process insight through data mining. Those insights have led to genomic exploration and mathematical model development that provided mechanistic understanding of pivotal process features and aided in devising a better control of the process and product consistency. The data and model driven approach will also play a key role in a design based cell engineering for the development of production cell lines. A scenario of integrating data on genome stability and accessibility with model assisted cell engineering for cell line development will be presented and the potential and limitation of such an approach will be discussed with technical and regulatory considerations.