

Unlocking the Power of Analytics in Support of QbD in Development

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In preparation for commercialization, Regeneron typically introduces a new high titer cell line and optimized production strategy for improved plant capacity and cost-of-goods while meeting or exceeding quality from first in human manufacturing process. For this work, the principles of Quality by Design is leveraged for targeted, rational development. The presentation will provide examples of how analytical support is applied to serve a persistent focus on critical quality attributes to drive this development effort.