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Leveraging process characterization, manufacturing process history and facility fit considerations to improve cell culture process performance

In commercial manufacturing of biopharmaceutical products using mammalian cell culture bioprocessing, variation in bioreactor product titer could have a significant impact on drug substance yield without having a significant effect on drug substance critical quality attributes. Variation in titer presents potential drug supply challenges to an organization and its patients. At commercial scale, applying any mitigation strategy to alleviate variation in bioreactor product titer faces technical challenges for manufacturing processes that utilize semi-defined production media, varying production scales, different process technologies and multiple manufacturing facilities. The contribution of raw material lot-to-lot variability in semi-defined production media on product titer is well-documented. Mitigating variation in product titer due to raw material lot-to-lot variability involves considerable in-house investment in time and resources as well as collaborations with vendors and external partners. In this presentation, we mitigated the impact of raw material lot-to-lot variability on bioreactor product titer by leveraging process characterization information, manufacturing process history analysis and facility fit considerations to improve bioreactor product titer by 10% while maintaining product quality.

Biography

Edward Crabbe has completed his PhD in Kyushu University, Fukuoka, Japan. He is a Senior Scientist in the Manufacturing Sciences and Technology Division of Bristol-Myers Squibb facility located in Syracuse. New York.

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