

SUBSTRATE KINETICS SCREENING METHOD FOR MITIGATING LOW TITER YIELDS AT LARGE SCALE PRODUCTION

Beril Ereren, Genentech
Fikret Kulenovic, Genentech
Semsî Ensari, Genentech
Dave Stewart, Genentech

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The use of chemically undefined peptones in the media is known to increase the variation of product yield beyond inherent lot-to-lot variation. Here we present a case study demonstrating risk mitigation for low titer yields seen at large scale production by minimizing lot-to-lot variation of a chemically undefined peptone used in Chinese hamster ovary (CHO)-based cell culture process. The peptone, which is categorized by copper concentration, is used in two different media during the production culture. The cell culture was initially screened at different peptone concentrations to find the optimum concentration where the resulting difference for titer and specific productivity were the greatest between the lots. Subsequent studies were performed using a 4x4 factorial design to screen, analyze, and recommend the lot usage designations and combinations to mitigate the risk of low titer yields. This presentation will discuss the results of this case study, and its implications to production media design.