

MAINTAINING PRODUCT QUALITY FROM EARLY TO LATE STAGE PROCESS DEVELOPMENT

Jason Goodrick of Genentech, Inc.
goodrick.jason@gene.com

Maintaining product quality of a monoclonal antibody through all phases of clinical development creates many challenges. Changes in cell line, cell line host, media and process conditions can all affect product quality attributes as a product moves from early to late development. All of these factors must be balanced with the desire to maintain protein production levels. Product quality attributes can be impacted by a number of these factors. A case study will be presented on the efforts to maintain product quality when switching cell lines from early to late stage. The effects of media composition and process conditions on product quality attributes will be examined.