

LEVERAGING MAB CELL CULTURE PLATFORM TO PREDICT PRODUCT QUALITY

Chris Kwiatkowski, Biogen
chris.kwiatkowski@biogen.com
Alan Gilbert, Biogen
Christina Alves, Biogen
Rashmi Kshirsagar, Biogen

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Biopharmaceutical therapeutic development timelines can be reduced by quickly generating material to initiate clinical trials and begin the process of drug development in order to improve the lives of patients. One way Biogen has addressed these challenges is the generation of a high productivity host. The high productivity host enables the use of representative cell pools that produce sufficient material for toxicology studies faster than previous workflows which used an individual clone. In general, one caveat of using cell pools is the risk of generating material that may not be fully representative of the commercial process. As product quality may vary from clone to clone, a less productive clone may need to be selected in order to avoid repeating toxicology studies. Biogen has mitigated this risk through changes in the cell culture platform process in order to have more predictable product quality outputs across pools, clones, and products. Cell culture platform modifications to the host cell line, media composition, and process parameters have enabled a predictable quality profile for both clones and pools, thereby enabling a “fast to tox” strategy that is also consistent with generating a commercially desirable process