

## **Cell Line Specific versus Generic Antibodies: Does my antibody need to be cell line specific or can I use a generic antibody?**

Our experience with CHO, *E. coli*, and many other mammalian cell lines is that the vast majority of HCPs are conserved from strain to strain within a given cell type. While it is possible that there can be some differences in a few HCPs from one strain to the next, most of the proteins must be conserved in order for the strain to survive. Furthermore, while growth conditions can have some impact on the quantity of certain HCPs, one can usually qualitatively find the same HCPs regardless of growth conditions. Understanding this, the most important issue for any HCP antibody or assay is not the strain or growth conditions used to obtain the HCPs for immunogen but rather how good is the antibody. Making antibodies can be a "hit and miss" proposition. If one attempts to make an antibody to a particular strain or growth process there is no guarantee that that antibody will be good enough. We have often seen that an antibody made specifically to a given strain may actually be less reactive with that strain, than another antibody developed from a second strain. In other words do not presume you need a cell line or growth process specific antibody because your efforts to develop such an antibody may not result in an antibody any better than existing antibodies. The proof of any antibody is in the assay developed with it. If the assay is sensitive enough to detect at least qualitatively most of the array of HCPs in your final product, then such an assay is good enough for not only process development but will also serve as a valid lot release test. Given the limitations of methods used to characterize antibodies such as western blot, it cannot be absolutely demonstrated that a given antibody recognizes all HCPs, nor is recognition of all HCPs an absolute requirement for the assay. The critical requirement for the assay is that it recognize a representative fraction of the various HCP found in a given sample type and that it have the sensitivity to detect those proteins in downstream samples and final product. Such an assay provides at least a qualitative indication of the relative purity of product and as such will be a very valuable method to determine relative HCP contamination from one batch to the next or from one purification process to the next.