



BioGenes' strategy for specific HCP ELISA development

Host cell proteins (HCPs) are a mixture of proteins which occur during a biological drug manufacturing process. An efficient decrease in HCPs must be achieved during the purification process to guarantee the removal of undesired proteins in the final drug bulk.

The remaining HCPs bear potential risks for patients as they might exhibit immunogenic or other undesired activity in humans. Thus, the purity of the final drug substance is of high importance for increasing the clinical safety of biologicals.

EMA and FDA, two major regulatory bodies, have released a set of guidelines to regulate the control of HCPs during the production process. The key points of these guidelines are:

- To use highly sensitive methodologies
- To routinely test for residual HCPs
- Not exceeding the permitted amount of HCPs in final drug bulk (<1-100 ppm)

Currently, a set of methods is available to monitor the decrease in HCP during drug manufacturing, with the ELISA method being the gold standard. The ELISA method has the advantage of combining high sensitivity and high throughput without the need for cost-intensive instruments.

Commercially available generic HCP ELISA kits are broadly used for the monitoring of HCP decrease in biologicals during pre- and early clinical phases. However, the use of a generic kit makes you dependent on a certain company, and the performance may vary from batch to batch. Thus, for drug approval, the development of a process specific ELISA is generally unavoidable. Only a specific HCP ELISA can meet the requirements, such as providing reliability regarding performance and availability. Moreover, the selection of a specific development ensures you a sufficient amount of antibodies for the complete drug production phase.

BioGenes has developed process-specific HCP ELISA since 1999. Having finalized more than 150 projects using different cell lines, BioGenes has become a leading global specialist in this field. Supported by a staff of highly skilled scientists and a pro-active project management team, BioGenes is equipped to provide a full-service portfolio. Our experience has led to a cutting-edge specific HCP ELISA development approach that is appreciated by our customers worldwide.

The ELISA development process is very time-consuming and might take up to 1.5 years. Thus, BioGenes recommends starting a project at an early stage.

Below, the general workflow for the development of a specific HCP ELISA, as offered by BioGenes, is depicted. In brief, two immunization cycles are performed, including distinctive features at various steps to ensure the best outcome and performance of the resulting ELISA for our customers.

