

Questionnaire development of HCP ELISA/anti-HCP-antibodies

What is your need:

- 0 - Process-specific ELISA
- 0 - Multi-product ELISA
- 0 - Generic ELISA
- 0 - other _____

Estimated number of ELISA kits per year needed during the life time of the product:
In total (per year x life time of the product): _____

Cell line (strain): _____

Product produced by the cell line: _____

Do you have/or plan other products produced by this cell line (strain): Yes / No

The product is gained from:

- 0 - a cell lysate
- 0 - a cell culture supernatant
- 0 - inclusion body

Status of the product's clinical phase: _____

Status of the process development: _____

Is a HCP ELISA in place that you already use? Yes / No

If yes, what kind of? _____

HCP-material is already available: Yes / No

The HCP material/antigen is a gained from:

- 0 - capture eluate
- 0 - cell culture supernatant
- 0 - cell lysate
- 0 - other

Quantity: _____

Concentration: _____

Buffer: _____

Should BioGenes perform cross reactivity tests against the product (API)? Yes / No

What service should be performed by BioGenes?

- 0 - Complete ELISA development including pre-validation
- 0 - ELISA development without validation
- 0 - Only antibody production
- 0 - Studies to test and select suitable HCP antigens
- 0 - Production of ready-to-use kits
- 0 - Usage of the ELISAs by BioGenes in Analytical testing/Release testing
- 0 - Other HCP analysis related services

Required animal species:

0 - rabbits

0 - goats

0 –not yet decided

Time schedule: _____

Are there any additional requirements and/or questions?

Company _____

Contact name: _____

Address: _____

Phone: _____

Email: _____