

QUESTIONNAIRE – DEVELOPMENT OF HCP ELISA/ANTI-HCP

ANTIBODIES

Please fill out this form as a prerequisite for planning and specifying the major steps of the respective project.

It will also be used as the basis for quotation and further discussion of project details.

All information provided including the client information at the end of this questionnaire will be treated strictly confidential. A nondisclosure agreement can be signed upon request.

1. INFORMATION ABOUT ASSAY PURPOSE

What is your specific request? / Which ELISA type do wish to be developed by BioGenes? Please select:

- Process-specific ELISA Platform ELISA
- Other, please specify: _____

What would be the estimated amount of antibody and/or number of ELISA 96-well plates required for the average lifetime of your drug product (10-15 years)? Please estimate:

2. INFORMATION ON CELL LINE AND PRODUCTION PROCESS

Cell line (or strain) used for drug manufacturing:

Do you have/ plan for further drug products to be produced by the same cell line/ strain?

- Yes No

The drug substance is/ will be gained from the following source:

- Cell lysate Cell culture supernatant Inclusion bodies

QUESTIONNAIRE – DEVELOPMENT OF HCP ELISA/ANTI-HCP ANTIBODIES

What is the current phase of clinical trials of the drug product development?

What is the current status of the process development?

Is there an HCP ELISA for testing of impurities already in place for this process?

No

Yes

If yes, what kind of assay? _____

3. DRUG PRODUCT INFORMATION

What kind of drug substance is to be detected? (Please specify):

Molecular weight of drug substance: _____

Drug product buffer: _____

Further information: _____

4. ASSAY DEVELOPMENT

4.1 (MOCK) HCP MATERIAL CHARACTERISTICS

Is the Mock HCP-material already available?

Yes

No

The HCP-material (antigen) is gained from:

Cell lysate

Cell culture supernatant

Capture eluate

Other, please specify: _____

QUESTIONNAIRE – DEVELOPMENT OF HCP ELISA/ANTI-HCP ANTIBODIES

Quantity of the provided HCP-material (antigen) [mg]: _____

Concentration of the provided HCP-material (antigen): _____

Buffer composition (please specify): _____

4.2 ASSAY CHARACTERISTICS

Should BioGenes perform cross-reactivity testing against the drug substance?

Yes

No

What kind of assay development services should be performed by BioGenes?

Complete HCP ELISA development including pre-validation

HCP ELISA development without pre-validation

HCP-specific antibody production only

Production of ready-to-use kits

Other services related to HCP analysis, please specify: _____

Which animal species is preferred for antibody generation?

Rabbit

Goat

Not decided yet

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5. PLEASE PROVIDE ADDITIONAL INFORMATION ON:

Planned timelines

Payment planned directly or via a purchasing platform (e.g. Scientist.com)

How did you find out about BioGenes?

Other information not previously covered

CLIENT INFORMATION

Company/Institution name:

Contact person:

Address:

Phone:

Email:

Date:
