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
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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: ___________________________________________
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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: