

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 you 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: _____

Biosafety level: **1** **2**

If the drug substance is a genetically modified organism, please specify:

For BSL2 (biosafety level 2 according to Biological Agents Ordinance https://www.gesetze-im-internet.de/englisch_biostoffv/englisch_biostoffv.pdf please provide risk analysis.

If samples submitted are GMO, please attach Formblatt Z or relevant documentation. The final risk assessment and security level for GMO organisms will be finalized by Biogenes in accordance with the German law since regional differences may occur. (Genetic Engineering Safety Ordinance – GenTSV) <https://www.bmleh.de/SharedDocs/Gesetzestexte/EN/GenTSV-E-en.html>

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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: _____

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

Other services related to HCP analysis, please specify: _____

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If the complete assay development incl. pre-validation is requested, how should the assay be produced?

Delivery of ELISA reagents (capture antibody, detector antibody, standard, control sample) as single-use vials

Production of ready-to-use kits

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: _____

Ordering 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: _____