

## 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? / What is the purpose of the analysis? Please select:**

Process-specific ELISA                       Platform ELISA

Other. Please specify further: \_\_\_\_\_

**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 to 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 clinical phase of the drug product development?

---

What is the current status of process development?

---

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

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: \_\_\_\_\_

### 3. ASSAY DEVELOPMENT

#### 3.1 (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): \_\_\_\_\_

Concentration of the provided HCP-material (antigen): \_\_\_\_\_

Buffer composition (please specify): \_\_\_\_\_

# QUESTIONNAIRE – DEVELOPMENT OF HCP ELISA/ ANTI-HCP ANTIBODIES

## 3.2 ASSAY CHARACTERISTICS

**Should BioGenes perform cross-reactivity tests 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

## 4. ADDITIONAL INFORMATION

---

# QUESTIONNAIRE – DEVELOPMENT OF HCP ELISA/ ANTI-HCP ANTIBODIES

## CLIENT INFORMATION

Company/Institution name:

---

---

Contact person:

---

---

Address:

---

---

---

---

---

---

---

---

Phone:

---

---

Email:

---

---

Date:

---

---

## PLEASE SHARE SOME MORE INFORMATION ABOUT:

Planned timelines

---

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

---

How did you find BioGenes?

---

---