

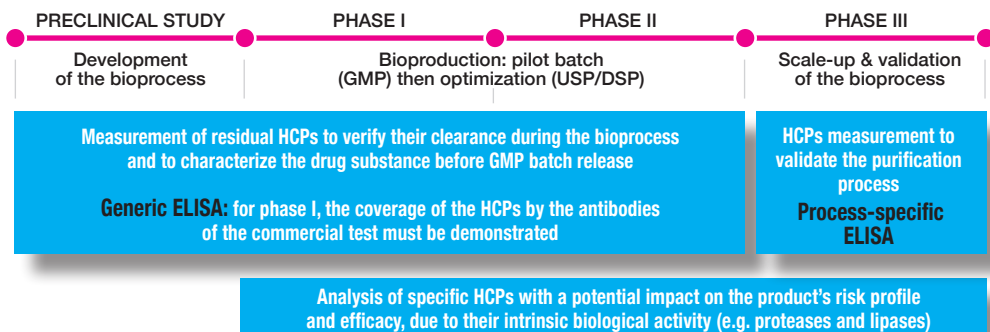


PATIENT SAFETY AND THE EFFICACY OF THE MEDICINAL PRODUCT



Biotherapeutics must be free of bioprocess-related impurities, including protein contaminants derived from the host cell used as the expression system (bacterium, yeast, mammalian, insect or plant cells). HCPs fit the definition of Critical Quality Attribute (CQA) due to their potential to **affect** product safety (**immunogenicity risk** for patients) and **efficacy**. Regulatory guidelines therefore require manufacturers to monitor the removal of HCP impurities in order to manage these risks.

REGULATORY REQUIREMENTS FOR HCPs MEASUREMENT AND CONTROL



OUR CUSTOM SOLUTIONS

HCPs QUANTITATION

- > Assistance in choosing the commercial generic ELISA kit best suited to your process, depending on test antibody coverage
- > Custom ELISA development for:
 - Bioprocess-specific (for phase III and atypical processes – recommended from phase I if commercial kits are unsatisfactory).
 - Specific high-risk HCP
 - Anti-HCP antibodies
- > Cross-validation with an orthogonal method
- > Sample bioanalysis (non-GLP)

HCPs IDENTIFICATION

- > Generic identification of all HCPs in preclinical and clinical batches
- > Analysis of the physicochemical characteristics of each HCP (aa sequence, MW, pl, hydrophobicity, etc.)
- > Control of HCPs clearance between each purification step
- > Characterization of a specific HCP of interest (e.g. an HCP co-purified on the protein A resin)
- > Comparability testing when the process is modified (scale-up)

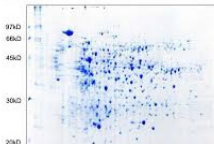
IDBiotech YOUR PARTNER OF CHOICE

To de-risk
your drug substance

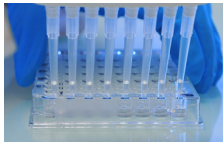
To optimize
your bioprocess

The challenge HCPs pose is reflected in the growing number of publications and scientific conferences devoted to these impurities. The complexity of HCPs analysis arises from their heterogeneity. Biopharma companies are therefore advised to manage this risk right from the early phases of the candidate biopharmaceuticals lifecycle development, and to generate a sufficient knowledge to demonstrate control before submitting regulatory filing.

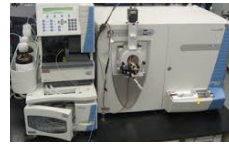
PROVEN EXPERTISE AND COMPLEMENTARY TECHNOLOGIES TO SUPPORT YOUR INNOVATIONS



Western blotting
and 2D gel
electrophoresis



ELISA



HPLC and mass
spectrometry
(orthogonal method)

A COMPREHENSIVE APPROACH TO IMMUNOASSAY DEVELOPMENT

Context
analysis and
consultancy

Preparation
of
bioanalytes
(Ag and antiserum)

Test
design

Assay
development
& validation

Technology
transfer
(sponsor or CMO)

Supply of
kits or testing
services
(non-GLP)

HIGH ADDED VALUE SUPPORT FOR YOUR PROJECTS

★ **De-risking** entry into the clinical phase (drug substance characterized, safety controlled).

☑ **Ensuring compliance** of your CMC documents with health authority requirements (FDA, EMA).

➤ **Accelerating** your pharmaceutical development stages by supporting the optimization of your bioprocesses.

👤 **Helping** valorization of drug candidate at various steps (IP, fundraising, licensing)