



Preclinical Technologies

FACTSHEET



Applied Immunology

Immunogenicity

Biotherapeutics have the potential to elicit an unwanted immune response and a strategy to characterise this response must be in place for clinical trials. Indeed, consideration of immunogenicity is initially developed in the pre-clinical phase in order to assess the potential effect such a response may have on drug activity and PK. Aptuit engage a three stage approach as recommended in the EMEA guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins (EMEA/CHMP/BMWP/14327/2006).

Screening for Anti-therapeutic antibodies

Multiple arms of the immune system are involved in an anti-drug response and antibody formation is a useful way to detect immunogenic activity. Screening for anti-drug antibody formation is accomplished using either a bridging or 'direct' ELISA.

Confirmation Assays

Positive anti-drug antibody responses found in samples by the screening assays are then subject to further analysis by a confirmatory assay. Typical approaches include:

- inhibition assays
- competitive immunoassays
- bridging assays
- protein blotting

Neutralizing activity assays

The anti-drug response, if confirmed, is then assessed for interference in the drug's action by using a functional model such as a cell based bioassay. Examples include assessment of a number of parameters, such as:

- enhanced/diminished cell growth
- cytotoxicity
- attenuated/enhanced enzyme activity

Each stage of Immunogenicity testing is continually evolving and as such Aptuit incorporate the latest recommendations for assay development and validation as indicated in the FDA draft guidance for industry (2009) implemented by our expert immunoanalytical group to provide an efficient and effective immunogenicity monitoring program.

Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

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Engineering a better drug development process
through scientific excellence.