

### Fig. 3

#### US regulatory framework

The US regulatory framework is based on 4 white papers, which have been published in The Journal of Immunological Methods and The Journal of Pharmaceutical and Biomedical Analysis

A.R. Mire-Sluis et al.

*"Recommendations for the design and optimization of immunoassays used in the detection of host antibodies against biotechnology products"*

Journal of Immunological Methods 289 (2004) 1-16

D. Geng et al.

*"Validation of immunoassays used to assess immunogenicity to therapeutic monoclonal antibodies"*

Journal of Pharmaceutical and Biomedical Analysis 39 (2005) 364-375

S. Gupta et al.

*"Recommendations for the design, optimization, and qualification of cell-based assays used for the detection of neutralizing antibody responses elicited to biological therapeutics"*

Journal of Immunological Methods 321 (2007) 1-18

E. Koren et al.

*"Recommendations on risk-based strategies for detection and characterization of antibodies against biotechnology products"*

Journal of Immunological Methods 333 (2008) 1-9

Major analytics-related aspects were condensed in a FDA "Guidance for Industry" (Draft, 2009)

*"Assay Development for Immunogenicity Testing of Therapeutic Proteins"*

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM192750.pdf>

According to Dr. B. Liedert, Oct. 2010

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