

## **Of Peptides and PANDAS: Innovative Preclinical Assessment Tools for Safety and Efficacy of Protein and Peptide Therapeutics**

The FDA recently released a new draft guidance defining the equivalence of a rDNA peptide product and a synthetic peptide product. The draft guidance enables generic manufacturers of peptide drugs to file an Abbreviated New Drug Application (ANDA) for synthetic peptide drug products that refer to listed drugs of rDNA origin. Since the processes for manufacturing the generic and reference drug (RLD) are not equivalent, peptide drugs can be associated with impurities. Impurities can result from changes in the sequences due to deletions, insertions, integration of incorrect amino-acids and modifications and also impurities related to the synthetic production. The FDA draft guidance requires manufacturers to prove that the synthetic peptide product does not contain impurities that have an increased affinity

for major histocompatibility complexes and potential for engaging immune response, which may drive undesired anti-drug antibody development. We have used both immunoinformatics-driven analysis and in vitro validation assays to perform immunogenicity risk assessment of peptide generics. This combination of in silico and in vitro tools is referred to the PANDA assay which can be used to support generic peptide drug equivalency in an ANDA application. This presentation will provide insight as to the process of performing the PANDA assay, illustrating the process with two case studies (such as Calcitonin and Teriparatide).

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