

Sartorius introduces assays for testing biosimilarity of three leading biologics

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The new assays, launched by SSB's subsidiary Sartorius Stedim BioOutsource, will allow biopharma manufacturers to generate accurate comparability results rapidly and cost-effectively.

Utilizing its extensive expertise in the development, optimisation and qualification of a wide range of different types of binding assays and immunoassays, the ready-to-use assays have been developed to ensure accurate comparability results for biosimilars to Actemra, Stelara and Lucentis. The new assays available include: Actemra IL-6R neutralization Bioassays; an Actemra IL-6R Binding ELISA; Stelara IL-12/IL-23 Binding Assays; a Stelara C1q Binding Assay; a Stelara neutralization bioassay; Lucentis VEGF Binding Assays and a Lucentis VEGF neutralization Bioassay.

These pre-developed assays complement BioOutsource's existing portfolio of assays and expands the number of molecules the company can now support to more than nine molecules. The availability of pre-qualified off-the-shelf assays provides biosimilar developers the opportunity to quickly and cost effectively test a wide range of biosimilars utilising assays from just one trusted supplier.

Additionally, as BioOutsource has its own in-house R&D department, it is continually adding to its portfolio of assays. Therefore, if an assay is not listed, scientists can contact the firm to discuss its availability, or use the company's expert services to configure an assay to meet their specific requirements.

Dr Daniel Galbraith, chief scientific officer of Sartorius Stedim BioOutsource stated, "We're delighted to bring new assays for testing Actemra, Stelara and Lucentis biosimilars to market. This means we can now offer biopharma companies a comprehensive range of ready-to-use assays, which they can trust to determine precise comparability results and accelerate their biosimilar drug development."