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Workshop report

Non-Clinical Safety Evaluation of Biotherapeutics – Challenges, Opportunities and New Insights

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Abstract

New challenges and opportunities in nonclinical safety testing of biotherapeutics were presented and discussed at the 5th European BioSafe Annual General Membership meeting in November 2015 in Ludwigshafen. This article summarizes the presentations and discussions from both the main and the breakout sessions.

The following topics were covered in six main sessions:

(i) Challenges around use of PEGylated biologics, results of BioSafe survey

(ii) Unexpected side effects of biotherapeutics

(iii) Safety testing of cell and gene therapies including vector safety and integration site analysis and setting up a GLP facility in this field

(iv) Immunogenicity and PKPD including immunogenicity prediction or methodologies to prevent induction of anti-drug antibodies

(v) Current approaches applied to antibody drug conjugate (ADC) development