

ARTICLE

CHARACTERISATION OF BISPECIFICS CURRENT APPROACHES TO ADDRESS CMC CONSIDERATIONS

Abstract

Bispecific antibodies comprise of at least two specific antigen binding elements within one single bispecific antibody (bsAb) and they have the potential to provide a viable alternative to combination therapy involving two mAbs (or mixtures) for therapeutic applications including cancer, chronic inflammatory diseases, autoimmunity, neurodegeneration, and infections. The activity, efficacy and immunogenicity of bispecifics (bsAbs) are influenced by molecular structure and properties and so understanding and control of these should be demonstrated during development and manufacture. Structural characterization of bsAbs requires multiple analytical approaches to assess all expected properties in line with ICH guidelines.

In this article, Intertek's experts Michael Walker and Tom Miles describe key considerations for the characterization of an asymmetric heterodimeric bsAb including structural characterisation, purity/impurities and potency.

Click the button below to download the full article.

DOWNLOAD ARTICLE