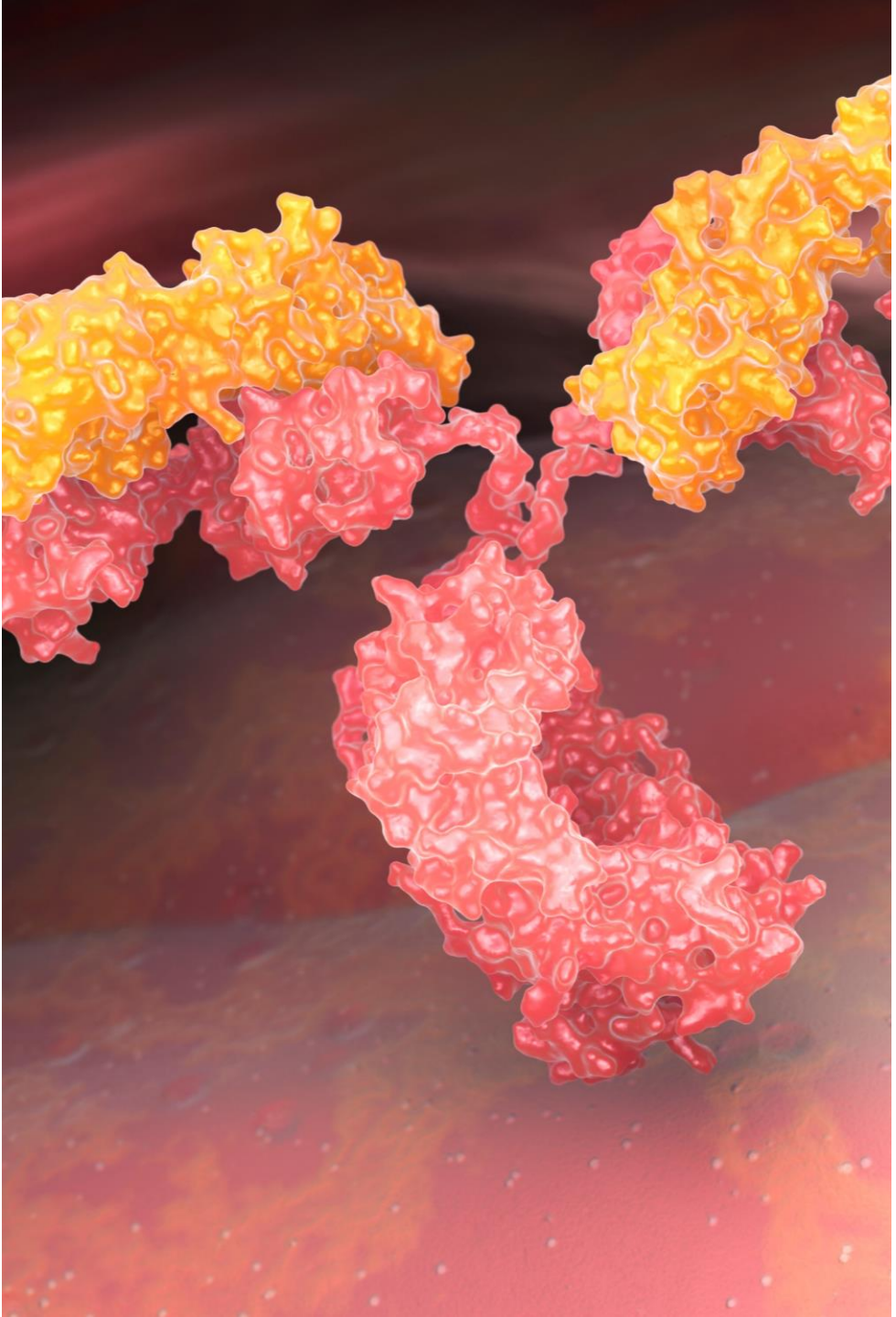

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ARTICLE

mAb STRUCTURAL CHARACTERISATION CHALLENGES

ADDRESSING CRITICAL QUALITY ATTRIBUTES

Abstract
In 2018, twelve antibody therapeutics were awarded first approval in either the European Union (EU) or United States (US) and it is forecasted that another twelve may enter regulatory review in 2019. The activity, efficacy and immunogenicity of mAbs are influenced by primary structure, post-translational modifications and higher order structure and control of these should be demonstrated during development and manufacture. Analytics required for structural characterisation, in line with regulatory guidance, are required, with suitable development, to drive a deep understanding of all sources of variation which may impact CQAs such as glycosylation pattern, charge variants, aggregates, and fragments or low-molecular-weight species to enable identification of potential deleterious variants and allow assessment of product heterogeneity.

In this article, Michael Walker, Technical Expert, Biologics Characterisation Team, Intertek Pharmaceutical Services, discusses the challenges for monoclonal antibody analytical characterisation.in a GMP environment and typical challenges which must be overcome.

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