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Development of a biosimilar CMC strategy for the identification of critical quality attributes

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To support a claim of biosimilarity, the EMA and FDA are interested in the 'totality of evidence' where the molecule and its physicochemical and biological attributes are assessed from the perspective of clinical relevance. The assays used in these assessments need to have the ability to identify where changes in the molecule are key to clinical efficacy. There is no type of assessment which alone is capable of verifying biosimilarity. As such an orthogonal approach combining physicochemical and functional analysis is required. Results from this approach should be reflective of a molecules critical quality attributes and should hopefully minimize the extent of any clinical studies required for verification of biosimilarity, safety and efficacy. A large challenge for biosimilars understands the structural function association as it relates to the activity of the antibody. Characterization of IgG1 glycosylation has been shown to be of utmost importance, as it can impact the mode of action. We present a case study which exemplifies how identification of critical quality attributes linked to the known mode of action could have mitigated risk to a bio-similar development program at the CMC characterization stage. A CMC strategy has been employed to link quantification of glycosylation with the mode of action.

Biography

Samantha Little is a Lead Scientist within the Bio-Pharmaceutical CMC Solutions Division at Covance, a global drug development company, where she has worked since 2009. She has experience in CMC methodologies to support drug development of Biologics including ADCs and Biosimilars and has been a Member of the Global Bio-analysis Consortium Harmonization Team for Large Molecule Run Acceptance. Prior to Covance, she worked as a Senior Scientist for a bio-defense company and was a Post-Doctoral Fellow at the Hull York Medical School researching proteomics and angiogenesis. She has a PhD in analytical chemistry.

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