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# Characterizing changes in protein quality attributes to assess leachable risks from single-use bioprocess containers

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## CHARACTERIZING CHANGES IN PROTEIN QUALITY ATTRIBUTES TO ASSESS LEACHABLE RISKS FROM SINGLE-USE BIOPROCESS CONTAINERS

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Leachables from bioprocess containers (BPCs) are a source of process-related impurities that have the potential to alter product quality and impact patient health. The leachables often exist at low concentrations that are difficult to detect and assess their impact on quality attributes (QA) of biotherapeutics stored in the BPCs. This study examines two monoclonal antibodies in a small-scale stressed model to detect and assess the presence of relevant BPC leachables by monitoring protein QA. The results from this study demonstrate that the stress model can inform a risk assessment of leachables on protein QA during routine manufacturing and assist in making informed decisions on process parameters and process technical transfers. As part of the assessment, high molecular weight species (HMWS) formed after storage in BPCs under stress conditions were characterized by size-exclusion chromatography (SEC), capillary electrophoresis sodium dodecyl sulfate (CE-SDS), and sub-visible particle analysis. In addition, strategies to prevent the detrimental effects of BPC leachables on protein stability for a successful BPC implementation in the manufacturing process of antibody therapeutics will be discussed.