

IMPLEMENTATION OF SINGLE-USE TECHNOLOGIES FOR ANTIBODY CONJUGATION PROCESSES

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Implementation of single use technologies offers significant advantages for antibody-drug conjugate (ADC) processes, including removal of cleaning validation requirements, reducing the volume of cleaning solutions which must be handled as hazardous waste, and eliminating the risk of product carryover. While these advantages afford numerous cost, resource, and timeline savings, there are several challenges that must also be addressed to support implementation of single use equipment for ADC processes. During conjugation process development, additional effort is required to understand the potential process/product quality impact, Material-of-Construction (MOC) compatibility, and potential leachables risk. A key focus area is to understand whether the MOC has any interaction with the reagents and/or process reactions that may influence the product quality attributes including the average drug-to-antibody ratio (DAR) and product aggregation. Additionally, the solvent background in ADC processes requires a detailed, risk assessment of the MOC compatibility and leachables risk prior to GMP implementation of single use technologies. Finally, increased at-scale process evaluation may be required prior to GMP implementation to ensure that the process performs as expected and delivers consistent product quality in the single use equipment upon scale-up.

This presentation will provide current strategies that have been utilized during development and GMP implementation of ADC processes to assess single use technologies. Case studies from multiple programs will be shared describing how these various challenges can be addressed to ensure successful implementation of robust processes in GMP.