

STANDARDIZED EXTRACTION PROTOCOLS FOR SINGLE USE COMPONENTS: INSIGHTS AND LESSONS LEARNED FROM IMPLEMENTATION OF USP, BPOG, AND HISTORICAL PROTOCOLS

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A primary concern limiting the rapid adoption and implementation of single use technology has centered on standardizing single use component data packages to be used for end user risk assessments. Without a standardized industry approach, end users will continue to be challenged with compiling cohesive overall impurities risk assessments of their entire process stream, which often contain multiple supplier components with uniquely different extractables datasets. It is critical to ensure that the analytical methods are optimized for materials of construction of the various components in the single use portfolio prior to using standardized extraction protocols proposed by USP, the Biophorum Operations Group (BPOG), as well as historical methods. Herein we show lessons learned from the laboratory implementation as well as scientific insights gained from the extraction profile when comparing the solvents, time points, and surface area to volume parameters proposed by each method, including data for biocontainers, fittings, aseptic connectors, and multiple sterilizing grade filters.