

## **CASE STUDY: SUBJECTING A WELL-CHARACTERIZED BIOCONTAINER FILM TO THE STANDARDIZED BPOG EXTRACTABLES PROTOCOL**

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Both the supplier and end-user communities require access to extractables data that is technically adequate for initial assessment of risk during material selection, component assessment and qualification, and subsequent process evaluation of single-use assemblies. Standardized extractables data for single-use components promises efficiencies in the adoption and application of single-use technologies, as well as functional equivalency substitutions. This is especially valid when combined with the concept of well-characterized materials that has taken centerstage in recent USP publications. The opportunity to achieve a comprehensive extractables data set reminiscent of a polymeric material's processing signature augmented with forensic analysis and toxicology evaluation can expand our knowledge of polymeric materials and form factors that are suitable for bioprocessing. SME's in materials science tasked with enhancing the understanding of the materials of construction go beyond the basic resin formulations to include discerning the impact of a material's processing signature on standardized extractables profiles, and ultimately to understanding associated process variability and/or potential impacts to patient safety. This presentation will provide a comprehensive case study of the standardized BPOG extractables protocol applied to a well characterized biocontainer film, forensic analysis of radiolytic degradation chemical compounds, and lessons learned.