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SINGLE-USE BAG EXTRACTABLE CASE STUDY: LESSONS LEARNED

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A supplier's ability to furnish extractable data from single-use components and systems to end users is of extreme importance. The data allows an end user to effectively assess the risk these extractables have on process fluids and final drug products. The protocols followed to produce such data are currently a point of discussion between suppliers and end users. In this case study, single-use bags were subjected to a portion of the BioPhorum Operations Group (BPOG) extractable protocol. This poster documents the testing process and lessons learned when executing such an evaluation, along with suggestions to improve the uniformity of the process.