

ASSESSING THE IMPACT OF SINGLE USE SYSTEMS ON PATIENT SAFETY

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Single use process technology is routinely used in the manufacture of pharmaceuticals and biopharmaceuticals. The potential for extractables and leachables from single use systems and their impact on patient safety are an important focus of drug manufacturers and regulators. While current regulatory guidelines and industry standards provide general direction on compound-specific safety assessments, they do not offer a comprehensive approach to safety evaluations of extractables and leachables. Smaller, emerging companies might not even be aware of the extent of the extractables and leachables data expected by regulatory authorities and that the FDA has issued warning letters in cases where the appropriate extractables and leachables studies were missing for a drug product. The authors will describe a comprehensive approach to determine the impact single use process technology has on patient safety.