

## **MANAGING RISK AND CONSISTENCY IN THE RAW MATERIAL SUPPLY CHAIN FOR SINGLE USE SYSTEMS**

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As the bioprocessing industry moves increasingly towards single use systems (SUS), security of supply at the raw material level becomes imperative to quality. Long term supply of consistent, high quality materials desired for single use film is directly attributed to the stability, continuity and quality of raw material supply from the film manufacturer. This presentation will focus on the strategic selection of raw materials for a single use platform film in the bioprocessing industry to minimize risk associated with change notifications. Utilizing a quality by design approach, a single use film was formulated with no added Irgafos 168, enhanced abuse resistance and a low extractables and leachables profile. There are several factors that are critically important to understanding quality and risk of supply in raw material sourcing. This presentation will outline the raw material selection process established to ensure supply continuity and high quality desired for use in bioprocessing films. A comprehensive study was conducted on raw materials prior to film validation and quality controls were established to ensure consistency prior to processing into single use films.