TEST METHOD DEVELOPMENT FOR NEXT-GENERATION SINGLE-USE BIOPROCESSING APPLICATIONS

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Key Words: Mechanical Testing, Chemical Compatibility, ADC

As single use disposable (SUD) bioprocessing systems become more commonplace, the range of applications and workflow steps served by single use continues to grow. Nearly all of the process steps and techniques currently used in bioprocessing were developed on stainless steel or glass vessels which exhibit thermal, chemical and mechanical properties which differ greatly from the polymer films used in SUD. While in many cases (e.g., cell culture) these differences have negligible effects on performance, as the industry pushes the limits of intensification and increases in the breadth of SUD applications (antibody-drug conjugation – ADC, microbial culture, etc.) single-use materials and systems face new challenges. This highlights the need for testing capabilities to qualify and develop new SUD materials, components and systems to ensure integrity, cleanliness and performance.

In this presentation, we will comment on the current state-of-the-art in standardized testing as well as highlighting several small-scale test methods developed internally, specifically for testing materials for SUD bioprocessing. In order to assess film and component (e.g., port, tubing) capabilities for the full range of current and foreseeable process steps, we have developed/adapted/adopted test methodologies to model environments experienced both in conventional use (abrasion, flexure, pressurization), as well as challenging new use cases including high and low temperature extremes (freezing, pasteurization) and aggressive, non-aqueous environments used in bioconjugate chemistry (e.g., ADC, conjugate vaccines), chemical viral inactivation and non-traditional cell culture (e.g., microbial).

For each of these applications, our methods were developed based on generating an understanding of the environment in which the chosen SUD system is to be used, identifying the primary failure modes that are (or could be) encountered in use and reducing these risks to their fundamental physics to generate small-scale tests that can be performed rapidly on small samples of material. These test methods allow for rapid screening of film and component materials to reduce risks in new applications prior to prototype development and assess product and process quality in the long term