

CHECKLIST

2D & 3D Custom-Designed Bioprocessing Solutions



PRODUCT CONSIDERATIONS

Within biopharmaceutical development and production, thin film 2D and 3D bioprocessing bags are often utilized in single-use systems. These highly custom bags come in multiple sizes and configurations, depending on the system type and desired volume. Designed to hold cell culture media, biologics, and cell and gene therapies, bioprocessing bags are produced from multi-layer medical grade plastic films that feature high-quality welded seams, carefully balanced MVTR, flexibility and overall strength.

Before a bag can be successfully validated and implemented within a system, a number of elements must be taken into consideration. Leveraging knowledge and experience of an outsourced manufacturing partner with 2D and 3D bioprocessing bag expertise is one way medical OEMs can better navigate the essential elements and considerations of product design, production and quality.

WHEN PROTECTING YOUR HIGH-VALUE CELL CULTURE MEDIA MATTERS MOST:



Process & Components

- What materials have been specified and why? Are there permeability requirements?
- Are there any regulatory requirements? Or requirements to keep formulations safe?
- Does the bag need an exact cut edge or a soft cut edge? A soft edge, for example, will save on process steps and cost.
- Are there connectors, tubing or supports that should be considered? Are there extra components for filtration and/or filling? What does the overall system structure look like?
- Does the bag have clarity, color or printing requirements?



Quality

- How long will the bag be in use?
- Will there be skin contact?
- What is in the fluid that the bag will contain?
- How long will the media and/or fluid be contained in the bag?
- What is the estimated hang weight and anticipated maximum psi?



Real World Applications

- What are the potential environmental risks, e.g. abrasion or puncture risk?
- Will the bag be frozen at any point?
- What are the storage, transportation and fluid transfer protocols?
- Are specific testing requirements defined?
- Will the bag require sterilization? If so, what method is specified? Have the base materials been tested for reactivity?