VALIDATION CHECKLIST

Fluid Bags

PRODUCT CONSIDERATIONS

Healthcare systems utilize fluid bags designed to protect staff and patients alike from exposure to waste or therapeutic liquids. Hundreds of thousands of individuals living with serious diseases rely on collection bags and fluid pouches as a part of their everyday lives. For OEMs, meeting the increasing need for reliable fluid collection devices means greater opportunity to develop bags that are durable and safe, yet provide for ease of use.

Before a product can be successfully validated and brought to market, a number of elements must be taken into consideration. Leveraging the knowledge and experience of an outsourced manufacturing partner is one way medical OEMs can better navigate all the essential elements related to product design, production and quality.

PROCESS & COMPONENTS

- What materials have been specified and why?
- Are there any regulatory requirements? For example, does the bag need to be PVC or DEHP free?
- Do you need an exact cut edge or a soft cut edge? A soft edge, for example, will save on process steps and cost.
- Is tubing required? Is there a preference for how it's attached?
- Does the fluid bag have clarity, color or printing requirements?

QUALITY

- Is the bag intended for single use or multi-use?
- Will there be skin contact?
- What is the fluid the bag will contain?
- What is the estimated hang weight?
- How long will fluid be contained in the bag?
- During normal use what is the anticipated maximum psi?

REAL WORLD APPLICATIONS

- What are the potential environmental risks, e.g. abrasion or puncture risk.
- Are there specific testing requirements defined?
- Will it require sterilization? If so, what sterilization method is specified?
- If materials have been defined and sterilization is required, have the base materials been tested for reactiveness?

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