SIX IMPORTANT CONSIDERATIONS WHEN EVALUATING MEDICAL DEVICE FLEXIBLE PACKAGING.

The time to begin thinking about medical device packaging is when clinical trials or other tests have shown the device to be safe and effective, and an application for FDA approval is being prepared for submission. Since package development takes time and is required for FDA approval, considering packaging late in development will only further delay introduction to market.

1. What is your product?

Does it need to be kept wet or dry? Where will it be opened? What is the end use and who is the end user? Answering these basic questions will help define the parameters of your package development efforts.

2. From what does the product need to be protected?

Is it abrasion, environmental damage (heat, cold, humidity, etc.) or atmospheric damage (light, oxygen, water vapor, etc.)? Answering these questions will help determine packaging materials, which may include foil or a coex to produce the required barrier properties (oxygen, moisture vapor, etc.).

3. Does the package need protection from the product?

Could sharp edges or protrusions puncture the film? Could the film stretch or tear when subjected to the weight of the product? Answering these questions will help refine the focus on the specific required protective attributes resulting in the most cost-effective package.

4. How long is protection required?

While the preceding addresses the protection of your product, you also need to consider the length of time that protection needs to be at its optimal level. This is when the shelf-life discussion occurs. Shelf life is a bit of a misnomer because the key consideration is to make your best conservative estimate of the sum of time the packaged product spends in various stages of its life cycle. The shelf-life clock starts ticking when the product is packaged in the manufacturing facility. You then need to add estimated time spent in inventory, time in transit, time at the distributors as well as time and turnover frequency with the end users. Note on the last item - don't think about averages, think about when the last package will be opened in its customary end user's location.

5. What other features may be required?

While containment is the primary goal, there are numerous other features that may be desirable, required or used to distinguish your product from a marketing or regulatory perspective. Examples include:

- Reclosability
- Tamper resistance construction
- Tamper evident design
- Package shape
- Information – color, graphics, print, legal requirements, marketing, information/instructions
- Utility – convenience, optimizes unit use/control, quality, choice of product forms, waste prevention

6. What attributes should you look for in a package supplier?

Accreditation by a recognized independent organization is a good place to start. A supplier should not only have a wide range of packaging options but also the knowledge and experience to help you decide exactly which option is best suited to your unique product and packaging requirements. You should also review a list of the potential supplier's current customers. If a number of companies with packaging requirements similar to yours have chosen a particular manufacturer, it is usually with good reason.

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About LPS Industries

LPS Industries was founded in 1959 by John M. Robinson as a converter of military specification barrier materials. Today, under the direction of Madeleine D. Robinson, CEO, LPS Industries is a diversified manufacturer and leader in the flexible packaging industry, providing packaging solutions for a diverse range of markets, including medical, food, transportation, electronics and agricultural. LPS Industries is an ISO 9001:2008 registered company and a woman owned and operated enterprise. For more information on the company's products and services, please visit www.lpsind.com.