VALIDATION CHECKLIST

Wound Care

PRODUCT CONSIDERATIONS

A delicate process by nature, wound healing requires optimal conditions for the body to respond correctly, such as a correct balance of blood supply and oxygen. At the core of wound care devices such as negative pressure wound therapy, the ultimate purpose is to promote effective wound healing by drawing the edges of the wound together, promoting granulation, allowing for drainage and reducing the risk of infection.

For medical device OEMs, that equals a great deal of science, research and innovation behind their wound care product lines. OEMs know that patients and healthcare providers are depending on their products to provide for positive health outcomes and lessen the risk of wound reoccurrences. Often lives depend on it.

Before a negative wound therapy device 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?
- What are the defined dimensions and tolerances?
- Are there any regulatory requirements? For example, do the components need to be PVC or DEHP free?
- Does it need to be clean room manufactured?
- Do you need an exact cut edge or a soft cut edge? A soft edge, for example, will save on process steps and cost.

QUALITY

- What is the intended duration of use? Ten minutes? A few days?
- Will there be direct skin contact?
- During normal use what is the anticipated amount of negative pressure the device must endure?
- Are there specific testing requirements defined?

REAL WORLD APPLICATIONS

- What are the potential environmental risks, e.g. abrasion or puncture risk.
- 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?
- What is the level of skin adhesion needed?

Vonco Products LLC is an ISO 13485 certified contract manufacturer providing radio frequency (RF) welding and heat sealing applications of plastic products and flexible packaging solutions for various industries. Visit vonco.com