

Outsourcing Outlook on Packaging and Sterilization | Qmed

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Maintaining quality systems, ensuring traceability, and providing packaging and sterilization validations are key factors that medical device OEMs should consider when evaluating prospective packaging contractors. Highlighting these and other issues is Charlie Ricci, vice president of sales and marketing at Life Science Outsourcing Inc. (Brea, CA).

MPMN: What capabilities should medical device OEMs demand of packaging service providers?



Ricci: First and foremost, the contractor should have a bulletproof quality system. Proper documentation, a comprehensive standard operating procedure package, and traceability procedures are of primary importance. The OEM should ask the provider how often it has been audited and whether it has been issued FDA Form 483 nonconformance reports. An appropriate partner should have a clean audit trail. From a technology standpoint, the OEM should confirm that the service provider has a seasoned engineering group that is well versed in component and packaging materials and understands the effects of sterilization methodologies on materials. The OEM should also ensure that a contractor conducts all packaging and shelf-life validations according to ISO 11607-1:2006 standards.

MPMN: What packaging and sterilization trends should concern medical device OEMs?

Ricci: Both packaging and sterilization methodologies continue to evolve. Thus, the OEM should select a contractor that can master the use of new materials, modern processes, and the long-term impact of packaging and sterilization methods. Good packaging design should address the need for the package to arrive at its destination with its sterile barrier intact and the need for the secondary packaging to transport the medical device safely so that it is fully functional and ready for use upon arrival.

MPMN: What equipment should a qualified packaging service provider have in-house?

Ricci: The OEM should expect a prospective partner to have both band and bar pouch sealers in-house, as well as a tray sealer. The former permits the operator to continuously seal pouches by running them through a heated 'opposing-wheel' sealing fixture, while the latter can be used to seal pouches containing heavier devices one at a time. In all cases, heat-seal validation must be performed on all pouches and trays in accordance with ISO 11607-2:2006 packaging standards. The medical device OEM should also select a contracting partner that can validate sterilization techniques to ensure that the device and the packaging material are compatible with the sterilization method chosen. For OEMs, a contract manufacturer that offers turnkey sterilization services is another advantage. Such suppliers can develop protocols, run the necessary cycles, conduct biological testing, and generate final reports for regulatory submission. In addition, the supplier should be able to perform accelerated aging and distribution simulations to establish a device's shelf life.



Sterile and nonsterile medical device packaging

Offering both sterile and nonsterile packaging services to the medical device manufacturing industry, Barger Packaging Inc. performs a range of related operations, including design, prototyping, die-cutting, RF welding, and narrow web flexo printing. The company also manufactures thermoforms, protective packaging, lid stock, and microflute cartons. Produced in ISO-certified Class 100,000 cleanrooms, the company's products range from thermoformed trays, blister packaging, and clamshells to protective packaging and plain and printed lids made from Tyvek, foil, and paper. [Barger Packaging Inc.](#) Elkhart, IN



Sterilization-ready packaging services

Tegra Medical offers bulk and individual-unit nonsterile packaging and sterilization-ready packaging services to medical device manufacturers. Providing medical device packaging services in a Class 100,000 controlled-manufacturing environment, the company has capabilities in instructions for use, product labeling, variable-content printing, bar coding, pouch and tray sealing, and bulk packaging. In addition to providing packaging services, the contract manufacturer works with approved, local contract sterilizers to provide customers with turnkey gamma and EtO sterilization services. The company can also coordinate test results and documentation to complete sterilization validation.

[Tegra Medical](#)
Franklin, MA

Minimally invasive and implantable device packaging

A provider of packaging, labeling, and design and development services for a variety of applications offers Tyvek packs, blister packaging, and vacuum-formed trays. Specializing in the packaging of minimally invasive surgical devices, implantable devices, and accessory kits, Cirtec Medical Systems supports customers' packaging requirements by providing sterile package designs, including tray and pouch specifications. It also offers packaging procurement, tray and pouch sealing validation, package integrity testing, package conditioning, validation for EtO and gamma sterilization methods, management support, protocols, and release reports.

[Cirtec Medical Systems](#)
East Longmeadow, MA



Custom medical packaging

Specializing in cleanroom packaging and assembly services, Quality Tech Services delivers package design assistance, process development, material sourcing, and complete project management—from engineering validations and sterilization to routine processing. Operating Class 7 cleanrooms, the company analyzes the device design for package ability; reviews the anticipated use environment; designs secondary and tertiary box packaging; designs sealing, distribution, and aging protocols to support the quality plan; assists with copy translation, instructions for use, and label design; and conducts risk analysis and failure mode and effects analysis to promote package design.

[Quality Tech Services](#)
Bloomington, MN

Class II and Class III medical device packaging and sterilization

Full-service medical device contract manufacturer Life Science Outsourcing Inc. specializes in the development of both primary and secondary packaging for Class II and Class III medical devices. The FDA-registered and ISO 13485-certified company assesses customers' packaging preferences and recommends a configuration that will withstand accelerated aging studies and ISTA distribution testing. A certified ISTA medical package testing division, the service provider maintains several aging chambers and conducts humidity and freezing-temperature studies. Operating an 18-cu-ft steam sterilizer and a 75-cu-ft sterilizer, the company's sterilization validation division can write protocols and manage the entire validation process. In addition, it performs EtO, gamma, and E-beam sterilization processes.

[Life Science Outsourcing Inc.](#)
Brea, CA

