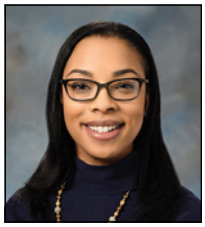
INSIDE STORY

Advances in manufacturing technologies are fostering an age of unprecedented innovation in the development of reusable medical devices and instruments. As designers develop smaller, more-complex, and increasingly intricate devices, however, manufacturers must not overlook the importance of ensuring that such products can be effectively cleaned and disinfected before being reused. In fact, appropriate cleaning processes must be validated by the manufacturer before a reusable product can be released into the marketplace. To find out more about the expertise required to establish safe processes for cleaning and disinfecting reusable medical devices, *MDB* recently spoke with Elizabeth Sydnor, Director of Microbiology Medical Device Testing for Eurofins Medical Device Testing (Lancaster, PA).



Elizabeth Sydnor
Director of Microbiology Medical Device Testing
Eurofins Medical Device Testing

***MDB*: What characteristics define a reusable medical device?**

Elizabeth Sydnor: The term encompasses any device that is intended to be used more than once. Most attention, however, is paid to the products that must be cleaned, disinfected, or sterilized between uses. Common examples include a wide range of surgical instruments, from stainless steel retractors and forceps to endoscopes and drill guides for orthopedic implants.

***MDB*: Are such instruments typically cleaned by hospital staff between surgeries?**

Sydnor: After use, devices that will be reused for another surgery are sent to the hospital's central sterile supply department, where they are cleaned, disinfected, and sterilized. This is one of the most important steps to ensure patient safety and reducing the potential risk of cross contamination between patients.

***MDB*: Is it the responsibility of the hospital to validate these processes?**

Sydnor: No. It is the responsibility of the device manufacturer to provide a validated cleaning, disinfection, and or sterilization method. Once the manufacturer has an FDA approved method, the product's instructions for use (IFU) is provided to the hospital to execute the cleaning instructions between each use. It's the hospital's responsibility to ensure that they are precisely following the instructions provided by the manufacturer. This is a critical step because each validated cleaning method is unique to the specific medical device.

***MDB*: What FDA regulations should be followed to validate reusable medical devices?**

Sydnor: The FDA's guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," is a good source of information to gain insight into the validation of reprocessing methods for reusable devices. However, a new standard, ANSI/AAMI/FDS ST98, "Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices," will be the overarching standard that will shape cleaning validations moving forward. This standard is anticipated to release sometime in 2022.

***MDB*: How does a company go about validating a method for reprocessing its instruments?**

Sydnor: The process involves inoculating a device with an artificial contaminant known as a *soil* and then testing the device for cleanliness after it has undergone a well-defined cleaning method. The choice of a particular soil is based on the application of the device, and is a synthetic formulation of proteins, acids, and lipids meant to simulate the environment where the device will be used, which may be blood-filled, mucosal, or gastric. Validation should be conducted under worst-case conditions, including inoculation of the device at a site identified as the most challenging location for cleaning.

***MDB*: Instruments used in orthopedic procedures can involve nearly a dozen different trays, each filled with a dozen or more instruments or trial implants. Does the manufacturer need to validate its reprocessing protocol for each part, or for the entire instrument set?**

Sydnor: In instances where a surgical tray is categorized as a medical device, cleaning validation is required on the tray and instruments. However, regulators will accept the bundling of products if a sufficient justification can be provided for treating items as a single family of products. In such a case, data for a worst-case example, or perhaps for a bracketed set of trays and devices, can then be applied to an entire set of trays devices. A typical example might be a set of trial implants, or a set of reamers that vary only in diameter or length.

***MDB*: How can you establish equivalence between different detergents for cleaning? Should the selected detergent be recommended in instructions for use (IFU), or is it only required to describe the type of detergent?**

Sydnor: Overall equivalence can be established through the detergent type. (e.g., enzymatic). The type of detergent should be included in the IFU document. The brand used can be referenced also, but this is not required. Process residuals should be detected by the device manufacturer. The product and material could vary, which would prohibit detergent manufacturers from establishing acceptable process residuals data.

To find out more about Eurofins Medical Device Testing, visit ***www.eurofins.com****.*