Article Citation:
Ralph J. Basile, Alpa Patel, and Kaumudi Kulkarni (*2016*) Characterizing Simulated-Use Test Soils Used in Reprocessing Validations. Biomedical Instrumentation & Technology: Challenges and Solutions for Medical Devices, Vol. 50, No. s3, pp. 11-18.

doi: http://dx.doi.org/10.2345/0899-8205-50.s3.11

INDUSTRIAL STERILIZATION

Characterizing Simulated-Use Test Soils Used in Reprocessing Validations

Ralph J. Basile, Alpa Patel, and Kaumudi Kulkarni

About the Authors

Ralph J. Basile is vice president of marketing and regulatory affairs of Healthmark Industries Company, Inc. in Fraser, MI. Email: ralphjb@usa.net

Alpa Patel is senior scientist of Nelson Labs in Salt Lake City, UT. Email: apatel@nelsonlabs.com

Kaumudi Kulkarni is manager of research and development of Healthmark Industries Company, Inc. in Fraser, MI. Email: kkulkarni@hmark.com

First Page Preview:

Characterizing Simulated-Use Test Soils Used in Reprocessing Validations

Ralph J. Basile, Alpa Patel, and Kaumudi Kulkarni

As part of their submission to the Food and Drug Administration (FDA) and submissions to regulatory bodies around the globe, manufacturers of reusable medical devices must validate that the reprocessing instructions provided to healthcare facilities will produce a device that is safe, capable of being cleaned, and ready to use on the next patient. Since the testing often must be done in an independent laboratory setting, and not with devices used for clinical procedures on patients, the medical device needs to be inoculated with test soil(s) that closely simulate soiling that would occur during clinical use. The medical device manufacturer needs to scientifically demonstrate that the formulation of simulated-use soil(s) is clinically relevant and closely approximates the challenge to reprocessing that actual soiling presents. Test soils are often characterized based upon various properties including biomarkers (e.g., protein, hemoglobin, total organic carbon [TOC]) and physical properties (such as viscosity and adhesion). These properties give the test soils their "product dimensions" and can be used to compare one soil to another. This article will discuss the means and methods for physically characterizing simulated-use test soils as well as clinically occurring soiling. This information will be useful to medical device manufacturers, independent testing labs, academicians, regulators, and standards-writing groups.

Biomarkers and the State of the Practice

The composition of the test soil plays an important role in soil selection. Most ingredients used to prepare test soils for validations closely simulate components found in the bodily fluids medical devices are contaminated with during clinical use.

The recently published FDA guidance on this subject directs medical device manufacturers (MDMs) to use at least two biomarkers when validating the effectiveness of their cleaning instructions for reprocessing their medical device.[1] Protein is often selected with another biomarker, such as TOC, hemoglobin, or some other measure. While the test methods are not completely standardized, they are, for the most part, well studied and documented in the literature. For example, there are several means to detect and measure protein; ortho-phthalaldehyde (OPA) and micro bicinchoninic acid (Micro BCA) are two common methods. They may provide somewhat different results, but their limitations and advantages are well documented in peer-reviewed studies.[2]

In a laboratory setting, the starting composition of the soil contamination can be defined, so the use of any detection/quantification method after cleaning can be compared to the starting point to demonstrate a level of cleaning effectiveness. As outlined by the FDA guidance, the positive control can be determined by inoculating a defined volume of test soil on the

About the Authors

Ralph J. Basile is vice president of marketing and regulatory affairs of Healthmark Industries Company, Inc. in Fraser, MI.
Email: ralphjb@usa.net

Alpa Patel is senior scientist of Nelson Labs in Salt Lake City, UT.
Email: apatel@nelsonlabs.com

Kaumudi Kulkarni is manager of research and development of Healthmark Industries Company, Inc. in Fraser, MI.
Email: kkulkarni@hmark.com

top