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Surface Preparation for Medical Device Manufacturers

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American Medical Device Summit 2016

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Introduction

Surface preparation is a critical manufacturing process that enables sealing, bonding, painting, coating, printing and cleaning. By utilizing appropriate surface preparation processes medical device manufacturers can speed production, ensure product safety, and decrease the likelihood of recalls.

Despite the critical nature of this process the majority of manufacturers are still relying upon outdated surface evaluation methods such as dyne and water break. These current methods lack precision, allow for subjective interpretation, and are often destructive.

We sat down with BTG Labs to find out more about the challenges of surface preparation and how manufacturers can overcome them.

What are the biggest challenges that medical device manufacturers face when properly preparing surfaces?

The biggest challenges that MD & M face when properly preparing surfaces is verification.

How does the OEM know if the product has been treated?
What contaminants can interfere with successful treatment?
What is the best treatment method?
What is too much treatment?
What is too little treatment?

There are many treatment technologies available that are best suited to specific applications; but without the proper processing parameters and verification, there is very little guarantee for success.

What surface preparation processes are medical manufacturers currently using?

Currently, the medical device industry uses vacuum plasma, atmospheric pressure plasma, and corona treatments for polymer bonding.

For sterilization and more complex surface chemistries most manufacturers utilize a combination of ultrasonic baths and vacuum plasma chambers. There are also UV curable adhesives and inks that are commonly used in the industry for the processing of electronic components. All of these processes suffer from a lack of verification and understanding of Process. The Surface Analyst™ provides this verification for the first time in the industry.

What are some of the issues manufacturers face when using these processes?

The largest issues really stem from lack of process optimization and no true verification on the factory floor. These material systems are fairly sensitive to contaminants as well. If a supplier changes something, or handling is introduced, many times the processing method cannot deal with these changes. This can result in poor bonding, cleaning, or sealing. A process which at one point worked well is suddenly unreliable. If the processing method is not optimized, and then not maintained (due to lack of available tools in the past) pre and post treatment, how can the manufacturer design, manufacture, and guarantee success?

How can manufacturers improve the efficiency of their surface preparation processes?

The Surface Analyst allows manufacturers to understand, quantify, and control their surface critical process, whether bonding, coating, sealing, printing, or cleaning. Manufacturers can use this instrument to bring greater visibility to what their surface is, what it requires for processing, and how to maintain that process day after day, shift after shift. This is accomplished through a well-documented process design DOE.

What benefits will manufacturers attain by updating their surface preparation processes to the hand held surface analyst?

Manufacturers will be able to measure their surface at an unprecedented sensitivity level on the factory floor. This allows them to prevent failures, recalls, and rework. This also allows medical manufacturers to have a full audit trail for quality control, FDA compliance, and liability purposes. Now surfaces are verifiable with the Surface Analyst.

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The Surface Analyst™

Your factory floor handheld solution for reducing waste, rework, and recalls. In two seconds, measure any surface and determine if it is properly prepared. No more unacceptable failure rates, or lost productivity and materials.

- Verify stainless, aluminum, titanium, or polymer surfaces

- Verify and audit concerns with the shelf-life and uniformity of an antimicrobial coating

- Verify catheters for antimicrobial and lubricious coating uniformity

- Identify the presence of silicone in a bonding step

Find out more at:

www.btglabs.com

Join BTG Labs at the

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