2020 Guide to Medical Devices Quality Control and Testing

Simplifying Progress

SARTORIUS

Introduction

To remain competitive in the medical device market, you need to be able to reduce costs while improving quality.

It's time to start trusting your manufacturing processes again; you need better quality control.

Sartorius offers a variety of solutions for your medical device manufacturing and quality control processes—options that can improve your productivity and help you meet rigorous compliance standards.

Some of our solutions include:

- Microbiological Testing Solutions
- Premier Performance Back-weighing Solutions for Stents
- HPLC Sample Preparation Solutions
- Endotoxin Testing Solutions
- Moisture analysis solutions for medical-grade plastics

Partner with Sartorius to streamline your time-consuming, labor-intensive, and potentially error-prone manufacturing processes and ensure product quality.

Chapter 1:
How to Accurately Measure the Moisture Content of Plastic Resin?

Moisture content is an important variable that must be monitored for and controlled during the production of plastic medical device parts. ASTM standard D6869 is the benchmark for measuring the moisture content of plastic resin, and stipulates the use of Karl Fischer titration as the applicable standard method. Herein, we show that the Sartorius Mark 3 High Performance Moisture Analyzer correlates well with Karl Fischer titration standards for a number of plastic resins commonly used in medical device manufacture.

Download the App Note

Chapter 2:
Are You GLP/GMP Compliant When It Comes to Pipetting?

Are you following methods for current Good Laboratory Practice (cGLP) or current Good Manufacturing Practice (cGMP)?

Our new application note introduces tools and principles that can help you with these demanding requirements, especially when it comes to your pipetting practices. A pipette is a precision measuring apparatus that has a significant influence on your lab results, but it can also be your companion in ensuring compliance.

Download the App Note

Chapter 3:
Continuous Microbial Air Monitoring in Clean Room Environments

Download our application note to learn what you need to know to be prepared for Annex 1 regulations. Learn how you benefit from implementing continuous microbial air monitoring to your entire manufacturing and quality control processes of medical devices.

Download the App Note

Chapter 4:
Do You Know How NASA Detects Airborne Microbes in Their Space Station?

You have to continuously monitor airborne microbes in your Medical Device manufacturing Clean Room facilities—just as they do in the NASA Space Station. Learn how NASA uses Sartorius's MD8 Airscan® technology for cataloging and characterizing potential disease-causing microorganisms aboard the International Space Station (ISS).

Learn More

Chapter 5:
Advanced Weighing Compliance for Use in Regulated Medical Devices Industry

Sartorius's Cubis® II balance is designed to follow US FDA data integrity principles for accurate, legible, contemporaneous, original, and attributable (ALCOA) data. The Cubis® II balance, with pharma package, contains all the technical controls to support compliance with common regulations. Achieve full compliance with additional procedural controls and systems for long-term data storage.

Download White Paper

Chapter 6:
How to Achieve Accurate Weighing Results for Medical Stents

Download our handbook to discover four steps to highly accurate and reproducible weighing results with the Cubis®II balance -the perfect choice for stent manufacturers in the Medical Devices industry. Ensure high-throughput and boost your productivity via fast stabilization times, regardless of the stent size or weighing conditions in your facility.

Download Handbook

Chapter 7:
Improved Sample Preparation for HPLC Analysis

Improving your HPLC Sample Preparation is easier than ever with the Sartorius's Cubis® MSA Dosing System. The Cubis MSA individual system with Q-App software eliminates the need to reach a precise target weight by automatically calculating the solvent volume to the appropriate value; the software uses the weight of the compound(s) and the volume of the solvents to calculate the verified concentration(s) of your standard solution.

Interested in learning more? Our application note demonstrates how the automated capabilities of the Cubis MSA system with gravimetric monitoring can simplify your HPLC workflow.

Download the App Note

Chapter 8:
Ultrapure Laboratory Water for HPLC Analysis in Medical Devices

The presence of trace contaminants in your solvent during gradient elution can result in "ghost or phantom peaks," so the quality of your solvent is often decisive in the reliability of your HPLC analytical run. However, deionized or distilled water still contains quantities of organic substances, which can cause ghost peaks. Water of the quality required for HPLC can be either purchased from a manufacturer or produced on site with a water purification system. Our application note evaluates a water purification system as an alternative to commercially sold ultrapure water for the preparation of high-purity eluents for HPLC analysis.

Download the App Note

Chapter 9:
How to Avoid Endotoxin Contamination in Pipetting When Testing Medical Devices

Preventing contamination during pipetting is paramount to achieving reliable results in medical device testing. Aseptic pipetting requires knowledge of the potential contamination mechanisms so they can be addressed. Our app. note discusses the three contamination types that originate from pipetting: Pipette-to-sample contamination, sample-to-pipette contamination, and sample-to-sample contamination.

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Chapter 10:
Did You Know That Endotoxin Contamination of Lab Consumables Can Influence Your Assay Results in Medical Device Testing?

Pipetting is an integral part of the endotoxin testing workflow for medical devices. To minimize potential sources of endotoxin contamination, use endotoxin-free consumables, such as pipette tips, within the testing workflow. Additionally, pipetting errors are a common source of variance in testing procedures. For example, variance in endotoxin testing standard curves can have a deleterious effect on the reliability of test results.

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