

# CLEANLINESS AND CONTAMINATION CONTROL VALIDATION OF MEDICAL DEVICES AND CLEANING SYSTEMS

## CSMA

### INTRODUCTION

Regulatory approval, prior to product launch, is becoming increasingly important in the healthcare industry worldwide. In the medical device sector, the surfaces of implant devices are of critical importance as they control many clinical properties including the immediate response from the biological host. Surfaces are becoming more complex both in terms of chemistry and geometric form. For example, new-generation cardiovascular stents need to accept drug-loaded polymer coatings and orthopaedic implants, for knee and hip replacement, have complex shapes with beaded or porous surfaces which are coated with hydroxy-apatite to aid tissue adhesion. This makes cleanliness critical in order to optimise coating performance e.g. wettability and to minimise toxicological effects in the body.

Over the last 15 years CSMA Ltd. has built up its own unique level of expertise in the application of surface analysis to medical device technology.

#### If your company requires .....

- Characterisation of product surface cleanliness
- Validation of new or existing cleaning equipment
- Provision of a validated turnkey installation or continued process monitoring, ...**CSMA is uniquely equipped to provide your needs.**



### TYPICAL CLEANLINESS VALIDATION PROJECT.

The medical device manufacturing process may include milling, turning, polishing, lapping, de-burring with intermediate cleaning stages or more delicate operations such as laser treatment, printing or surface modification. The former processes will almost certainly introduce contamination onto the surface.

Surface analysis techniques such as XPS or SIMS are valuable tools in understanding which of these manufacturing agents remain after cleaning and how easily they are removed. With the correct and appropriate sample preparation, e.g. controlled laser cutting, even the most difficult geometries can be accessed.

A TYPICAL CLEANING VALIDATION PROJECT WOULD INCLUDE THE FOLLOWING :-

- **Chemical characterisation of contaminants**
- **Effects of each manufacturing process stage on surface condition**
- **Production of finalised cleaning specification**
- **Characterisation of detergents to be used**
- **Assess Cleaning Stages and Final validation**
- **Continued System Monitoring**



