

Services Overview

Gateway Analytical is a multi-analytical testing laboratory specializing in foreign particle source determination for the medical device industry. We characterize particulates for identification, counting, sizing and morphology according to ASTM F1877 methods for wear debris. As a cGMP compliant, ISO/IEC 17025 and ISO 9001 certified, 21 CFR Parts 820/210/211 compliant, and FDA registered and inspected lab, we ensure that all testing is performed to provide results efficiently and effectively, while maintaining the highest quality standards. Gateway Analytical is committed to supporting the medical device industry through support in product development, wear debris testing and product life cycle sustainability. Our multi-analytical approach is essential for providing you with the vital information you require to see your product from the development stages through medical application. Also, as the industry leader in turnaround times, Gateway Analytical provides results faster than any competition.

Laboratory Accreditations

- FDA Registered and Inspected
- ISO 17025
- ISO 9001
- 21 CFR Parts 820/210/211
- Compliant ICH Q7 Compliant
- cGMP Compliant

Services Offered for Each Phase of Product Life Cycle

PHASE 1 – R&D, Data Collection and Analysis

- Independent R&D consultation
- Investigation and analysis of materials for the manufacturing process

PHASE 2 – Product Verification, Validation, and Manufacture

- Raw materials specification, selection, validation, and analysis
- Quality control testing
- Foreign particulate matter identification and source determination
- Wear debris studies
- Technical support for FDA submittals and regulatory compliance

PHASE 3 – Customer Feedback and Market Acceptance

- Root cause investigations into product failure and end-user complaints
- Litigation support and consultation services

Medical Device Support Examples

- Wear Testing of Implants
 - Spinal
 - Knee
 - Shoulder
 - Hip
- Bone Cement
- Dental Cement/Implants
- Stents/Balloons
- Catheters/Guidewires
- Pacemakers/ICDs/CRTs
- Peripheral Dilation
- Detachable Coils

Medical Device Services

Gateway Analytical provides a variety of analytical testing services to support medical device development, manufacturing and testing. Our medical device services include:

- Wear Debris Analysis
- Failure Analysis
- Particulate Contamination Identification
- Raman Chemical Imaging of Stent API/Polymer Substrate Distribution
- ASTM F1877
- High Resolution SEM of Medical Device Surfaces
- Automated Scanning Electron Microscopy/ Energy Dispersive Spectroscopy
- Automated Raman/LIBS

Wear Debris Analysis Testing Services

Gateway Analytical provides wear debris testing services for medical devices utilizing automated scanning electron microscopy to determine the size, morphology, chemistry and a variety of statistical evaluations of the inorganic wear debris product generated during product lifetime testing.

Rinses are collected following lifecycle testing and submitted to our laboratory for analysis. The samples are filtered in an ISO certified Class 5 sample preparation environment and analyzed by automated SEM/EDS. The analysis provides information utilized by medical device manufacturers to demonstrate the identification of wear debris products and their relative abundance and concentration in support of FDA product filings. On average, thousands of particles can be characterized in hours, providing substantial information for the wear characteristics of a particular product.

In addition, our capabilities have expanded into the characterization of organic wear particles (e.g. polymers, plastics, API, etc.). The automated Raman spectroscopy technique utilizes the Single Particle Explorer (SPE™) manufactured by rap.ID. This technique allows us to characterize overall populations of organic particles that are generated during particle wear studies.

Failure Analysis

Gateway Analytical provides failure analysis of medical devices using standard analytical testing methods such as optical microscopy, SEM/EDS, FTIR, and Raman spectroscopy. We are experienced in the analysis of polymers (degradation, oxidation), adhesives, metals and coatings.

Contamination Analysis

Contamination analysis is a critical aspect of the process of medical device development. Our forensic scientists have over 20 years of experience investigating the source of particulate contamination and its direct effect on product quality and device development.

Chemical Imaging

Gateway Analytical offers Raman Chemical Imaging services for the analysis of medical devices to determine the distribution of API in the polymers, directly relating to the design and product testing of stents. This unique technology combines imaging technology with Raman spectroscopy to produce information not only of the API and polymer substrates, but demonstrates spatial information of the drug as it is dispersed in the system. This critical evaluation method allow developers and manufactures better understand the distribution of drug product within the stent device with clear and concise visual representation of the materials. In addition, Raman Chemical Imaging methods have been utilized to evaluate layer thickness uniformity in stent products.

