eurofins | EAG Laboratories



MEDICAL DEVICES AND DIAGNOSTICS

Drive productivity while keeping pace with evolving regulations

When you have questions about your material's chemistry, EAG Laboratories provides comprehensive data for FDA submissions, innovation and product improvement.

From polymers to alloys to ceramics, we understand how these materials impact safety and effectiveness. EAG offers the most diverse and comprehensive suite of testing which includes:

- Polymer reverse engineering
- Polymer characterization and degradation studies
- Particulate size and characterization
- Morphological and topographical characterization to meet standards
- Cleaning validations for chemical manufacturing (not finished devices)
- Raw materials characterization
- Biocompatibility studies requiring material characterization (e.g. particulate ID, morphology, etc.)
- Chemical characterization per ISO 10993-18
- Failure analysis
- Alloy identification
- Oxide thickness determination
- Surface chemistry
- Crystallinity and phase ID

WWW.EAG.COM
+1 877-709-3393

eurofins | EAG Laboratories

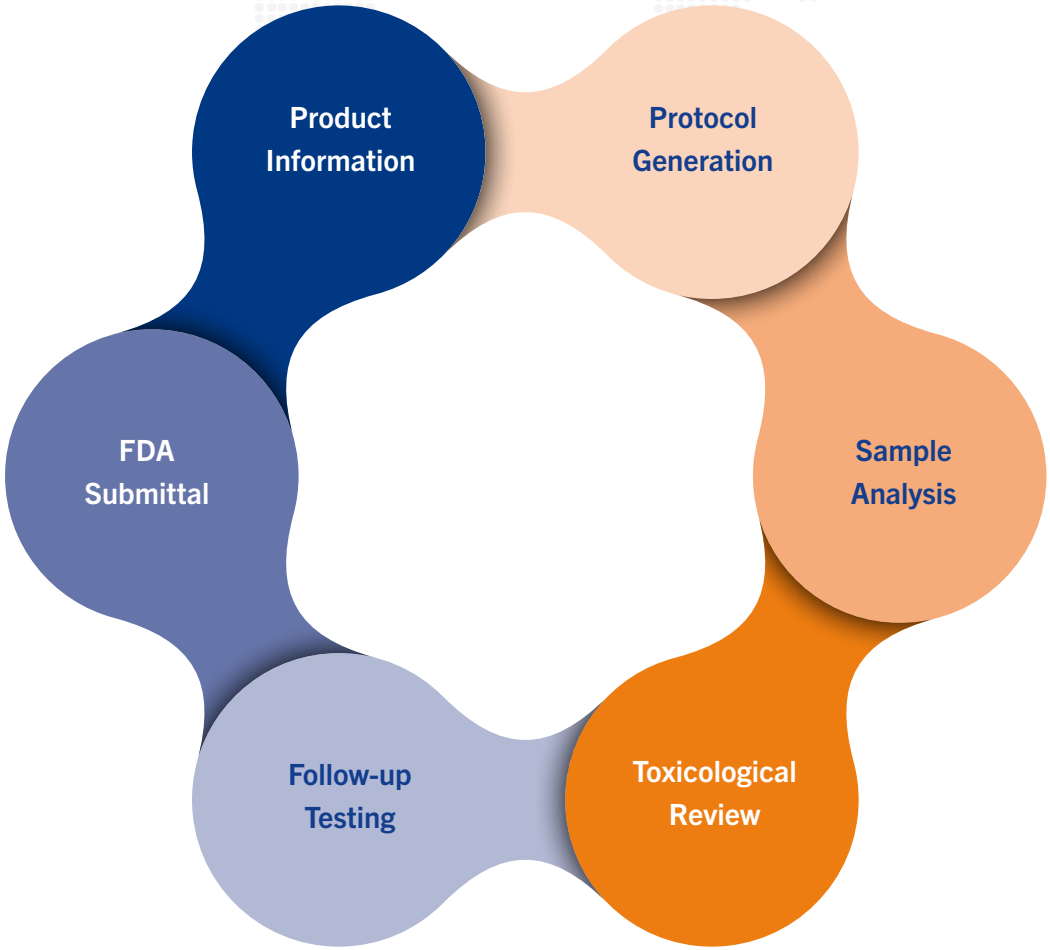


MEDICAL DEVICES AND DIAGNOSTICS

Get support for Biocompatibility and ISO 10993-18

EAG Laboratories applies vast experience with the materials that go into medical devices to assist our clients in performing the necessary chemical characterization studies per ISO 10993-18. Our scientists can provide robust data for toxicological evaluations.

- ISO 10993-18 testing details chemical characterization of medical device materials
  - Ensure product safety
  - Judging equivalence to clinically established material
- Extraction per ISO 10993-12 guidelines
- Extract analyzed by the following techniques
  - FTIR and gravimetric analysis of residue
  - Volatiles and Semi-Volatiles by GC/MS
  - Non-Volatiles by LC/MS
  - Metals by ICP/MS
  - Other methods if client specified
- Testing nickel leach and corrosion for metallic implants



Eurofins | EAG Laboratories is a global scientific services company serving clients across a vast array of technology-related industries. Through multidisciplinary expertise in materials and engineering sciences, EAG helps companies innovate and improve products, ensure quality and safety, strengthen supply chains, protect intellectual property and comply with evolving global regulations.

WWW.EAG.COM
+1 877-709-3393