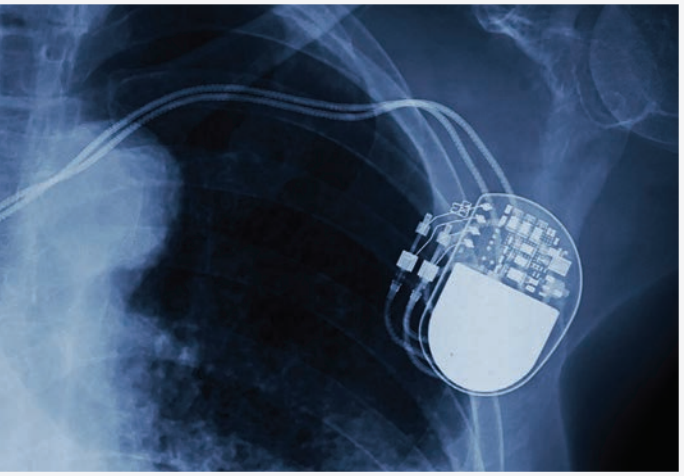
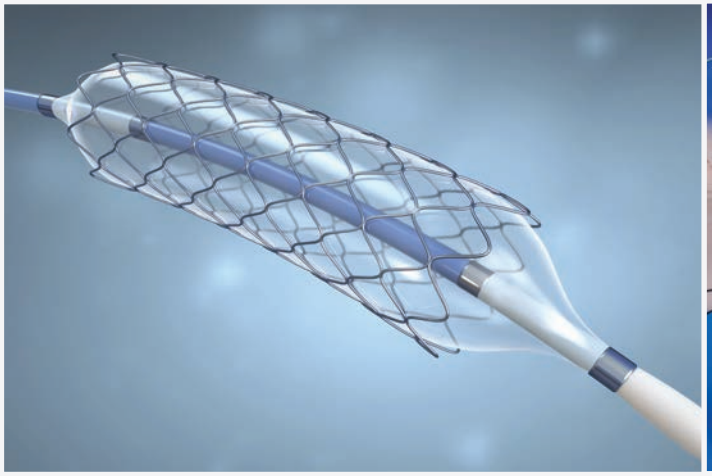
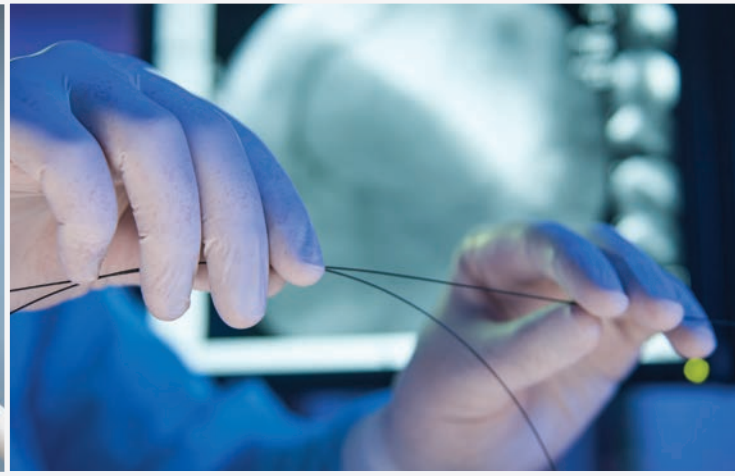

ENSURE **MEDICAL DEVICES** ARE SAFE, COMPLIANT AND EFFECTIVE

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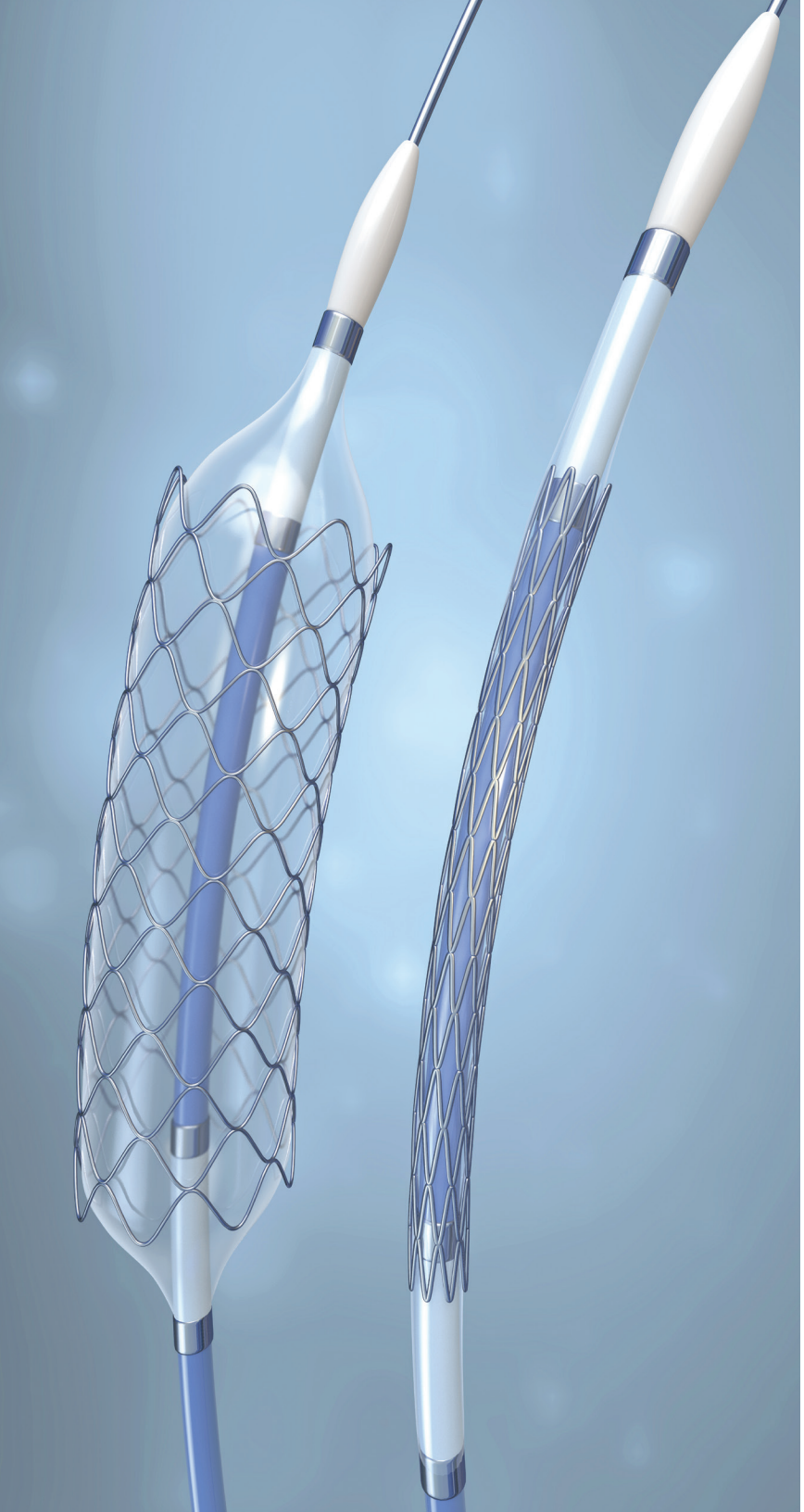

Why Choose Eurofins EAG for Medical Device Testing?

For medical device manufacturers, Eurofins EAG Laboratories offers unmatched capabilities and analytical expertise, a unique range of in-house techniques and instruments, and fast, flexible problem solving.

Experience and Scientific Excellence

- EAG has over 40 years experience in medical device testing. From a single analytical support partner, clients gain expertise in chemical characterization, surface analysis, and materials chemistry.
- EAG offers scientific excellence with a large number of Ph.D.s on staff. Our clients have direct access to our expertise in project design and technique selection. Through a consultative approach, these projects utilize the most appropriate techniques and clients get the right answers the first time.

Reliable Support and Shortest Industry Turnaround

- With a strong focus on communication and responsiveness, EAG provides the shortest industry turnaround timelines. Clients also gain efficiency from our equipment redundancy and consultative approach.

Ensuring Regulatory Compliance

- We help clients maintain strict adherence to the latest regulations from Notified Bodies including the FDA and those designated under the EU MDR.

Instrument Diversity and Risk Mitigation

- EAG has the most diverse instrument group with location redundancy to mitigate risk. We have multiple versions of key instruments used for medical device testing and are committed to consistently growing capacity through capital investment.
- EAG reduces risk for device companies needing compliance support or facing safety challenges. All medical device testing is performed at ISO 17025 certified laboratories. By utilizing EAG expertise in the composition of a device, clients confidently assess their product's safety and performance. For clients managing different supply chains, EAG reduces risk by providing redundancy of equipment and analytical services from multiple global locations.

Expert Support for Every Stage of Your Medical Device Product

Concept and Research

- Deformulation
- Raw Material
- Trace Elemental Analysis
- Microscopic Structure (AFM, TEM, SEM)
- Metallurgical Analysis
- Polymer Chemistry
- API Crystal Form (Combo Devices)
- Proof-of-Concept & Preliminary Performance

Prototype Design Development

- Materials Selection
- Surface Morphology
- Microscopic Structure (AFM, TEM, SEM)
- Analytical Method Development & Validation
- Corrosion Resistance
- Particulate Investigation

Design Verification and Validation

- Supplier Qualification & Selection
- Materials Characterization
- Extractables & Leachables Testing
- Analytical Method Development & Validation
- Surface Chemistry (XPS, Auger, etc.)
- Stability & QC Release
- Reliability (RGA, etc.)
- Assistance with Biological Safety Evaluation Plan (BSEP) preparation

Regulatory Submission

- Extractables & Leachables Testing
- Evaluate Safety, Qualify Suppliers & Demonstrate Control of Manufacturing (ISO 10993-18)
- Tailored Strategies for EU MDR Compliance
- Consultation for Regulatory Submission

Post Market Surveillance

- Lot Release Testing
- Impurity ID & Characterization
- Particulate Investigation
- Contaminant Identification
- Failure Analysis
- Surface Chemistry (XPS, Auger, etc.)
- Stability & QC Release
- Material & Vendor Change (incl. ISO 10993-19)

Extractables & Leachables

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 and the EU MDR. We are able to identify bioavailable chemicals released from a product through simulated use, exaggerated, or exhaustive conditions.

- Internally developed Part 18 testing program
  - Validated methods for use across a wide variety of materials/extractables
  - Driven by a protocol unique to each device
  - Performed using extractions based upon 10993-12 and using the Analytical Evaluation Threshold (AET) as a sensitivity target
- Extracts are analyzed by the following techniques
  - NVR with FTIR characterization
  - Volatiles and semi-volatiles by Headspace GC-MS and GC-MS
  - Metals by ICP-MS
  - Non-volatiles by LC-MS
  - Other techniques as required by our clients (IC, GPC, Raman, HPLC-ELSD/CAD, Pyro-GC-MS, Thermal Desorption, etc.)
- Our state-of-the-art Q-Exactive and Orbitrap LC-MS systems facilitate improved sensitivity and mass accuracy, which support achieving lower AETs and improved unknown ID
- We use a combination of internal and external mass spectral databases as well as a robust and rigorous science-based review to evaluate data and identify the compounds present. This process ensures that the assignments make sense and provide our clients with the best data so they can make informed decisions about their devices.

In Vitro Biocompatibility

EAG is the premier scientific services company with expertise in biomedical products, chemistries and materials, regulatory insight, and a proper sense of urgency to deliver meaningful results with an impact.

- Cytotoxicity: MEM Elution, Direct Contact
- Skin irritation: EpiDerm™ RhE model
- Skin sensitization
  - Direct Peptide Reactivity Assay (DPRA)
  - KeratinoSens™
  - Human Cell Line Activation Test (h-CLAT)
- Genotoxicity
  - Micronucleus Assay (OECD 487)
  - Ames Bacterial Reverse Mutation Assay (OECD 471)
- Custom Assays

Particulate & Particle Analysis

EAG has developed expertise in identifying and characterizing particles of an unknown origin with individual and combined compositional analysis techniques in conjunction with expert data interpretation. We have developed a library of FTIR, LC-MS and GC-MS spectra to speed particle identification investigations.

- ISO 7 clean room with an ISO 5 zone
- Sample filtration and particle isolation
- Particulate matter testing per AAMI TIR42
- Digital microscope
  - Magnification up to 5000x
  - Particulate analysis per USP<788> and USP<789>
  - Stitched images to capture high resolution in larger field of view
  - Particle counting, sizing, and morphology
- FTIR microscope
  - Characterization of particles and bulk materials
- Scanning electron microscope
  - Elemental profiles of particles and bulk materials
  - EDS mapping to observe spatial orientation of elements
- Raman microscope
  - Stitched images to analyze a larger depth of field
  - Characterization of particles and bulk materials
  - Determine approximate size of APIs or excipients within a tablet
  - Count thousands of particles and collect Raman spectra for each particle on a filter

Deformulation

In some circumstances, detailed information about the materials of construction for a device may be required. In these situations, our experienced chemists can perform a full deformulation on one or many components of a device.

Impurity Investigations

- Isolation and characterization of visible contaminants: Optical microscopy, FTIR, SEM-EDS
- Organic materials: GC-MS, HPLC, UPLC
- Inorganic materials: ICP-OES, ICP-MS

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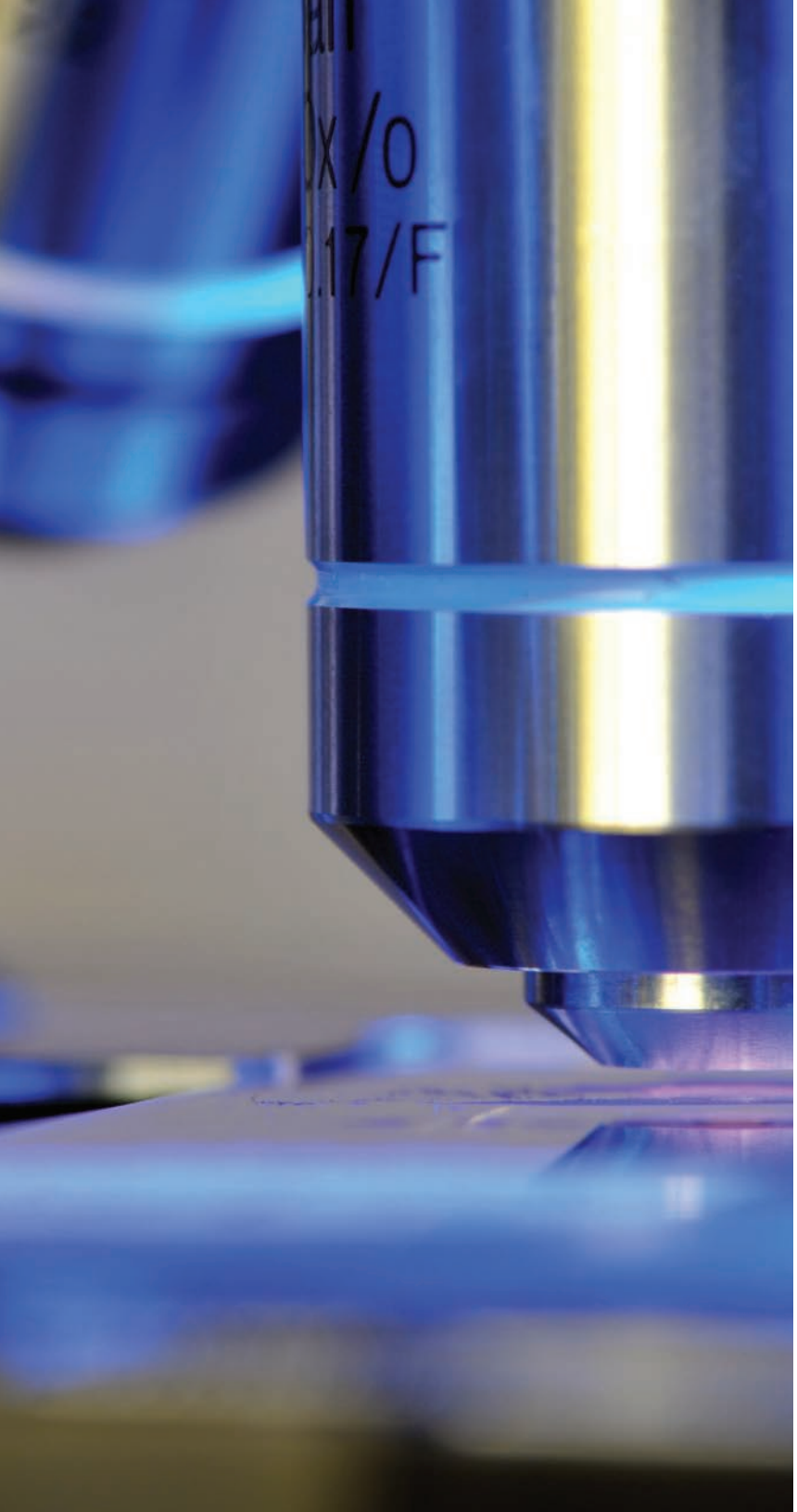

Surface Characterization and Morphology

EAG Laboratories uses over 30 different surface characterization methods to provide answers to our customers. As ISO 10993-19 (physico-chemical, morphological and topographical characterization of materials) continues to evolve, we have pioneered the utilization of several relevant techniques to meet industry-expected needs. EAG materials characterization services are relevant at multiple stages in the medical device life cycle.

- Research and development: the testing of new concepts and materials
- Process development: to investigate and characterize new processes, designs, tools, prototypes and products
- Production: to qualify incoming materials; vendor assessment; process monitoring; quality control; verification of identity
- Process improvement: to monitor process changes and subsequent process performance
- Failure analysis: to investigate problems; contamination/defect analysis; to identify contaminant sources; good/bad, old/new comparisons

Example Techniques and Uses	
X-Ray Photoelectron Spectroscopy (XPS) Auger Electron Spectroscopy (AES) Time-of-Flight Secondary Ion Mass-Spectrometry (TOF-SIMS)	• Materials identification • Characterization of particles, stains, discolorations and contaminants • Compositional analysis of powders, residues and thin films • Evaluation of cleaning processes • Determination of oxidation state and oxide thickness of alloys • Analysis of carbon (et al.) functionality of polymers and low k dielectrics • Depth profile analysis of thin films for matrix level constituents • Sub-monolayer analysis • Surface characterization of organic, inorganic and metallic materials • Mapping distributions of surface species
Atomic Force Microscopy (AFM) Optical Profilometry (OP) Nanoindentation (NI)	• Surface roughness, morphology, topography • Dimensional measurements • Physical and mechanical properties (eg hardness, modulus)
X-Ray Diffraction (XRD)	• Qualitative and quantitative phase identification • Crystallinity, average crystallite size • Fiber texture orientation (transverse and longitudinal) • Residual stress
X-Ray Fluorescence (XRF)	• Alloy identification • Elemental composition
NanoIR	• Materials identification, vibrational spectroscopy and imaging from sub-mm features

Cleaning Validations

Cleaning validation verifies that a process will consistently result in devices that meet a predetermined level of cleanliness. Our analysis focuses on the residue remaining on the devices including, chemicals or substances the cleaning step intended to remove, residue from the cleaning process (detergents, solvents, etc.), and other potential contamination residue. The test method may include target specific techniques (i.e. LC-MS, GC-MS and ICP-MS) and non-target specific techniques (i.e. UV-Vis, Conductivity, TOC).

Corrosion Testing

Corrosion testing provides critical insights throughout the medical device product lifecycle, from materials selection early in the design process to quality control and failure analysis. EAG is equipped to evaluate the composition, microstructure, surface features and corrosion performance. Corrosion potential, corrosion rate and pitting susceptibility are also measurable. The standard approach of ASTM F2129 applies cyclic potentiodynamic polarization to small medical implant devices (vascular stents, ureteral stents, filters, endovascular grafts, cardiac occluders, etc.) in the final form and finish.

Electronics Testing

Our engineering support services for medical devices include failure analysis and electronic troubleshooting, fault localization and root cause determination. Electrostatic discharge (ESD) testing ensures that medical device chips will withstand events that may occur during handling and assembly.

Microscopic Structure (AFM, TEM, SEM)

EAG Laboratories scientists are experts in medical device surface analysis, including the factors that affect biocompatibility, corrosion-resistance, crack-resistance, adhesion and bonding ability. Our laboratories investigate and understand the issues associated with surface modifications, including how surfaces may change and degrade with use and time.

Intellectual Property and Product Liability Support

Our scientists and engineers provide expertise, technical consulting, data interpretation, analytical support, and expert testimony in product liability, intellectual property, and other cases. Our experts have played key roles in cases involving surgical instruments, guidewires, hip and spinal implants, and other medical devices.

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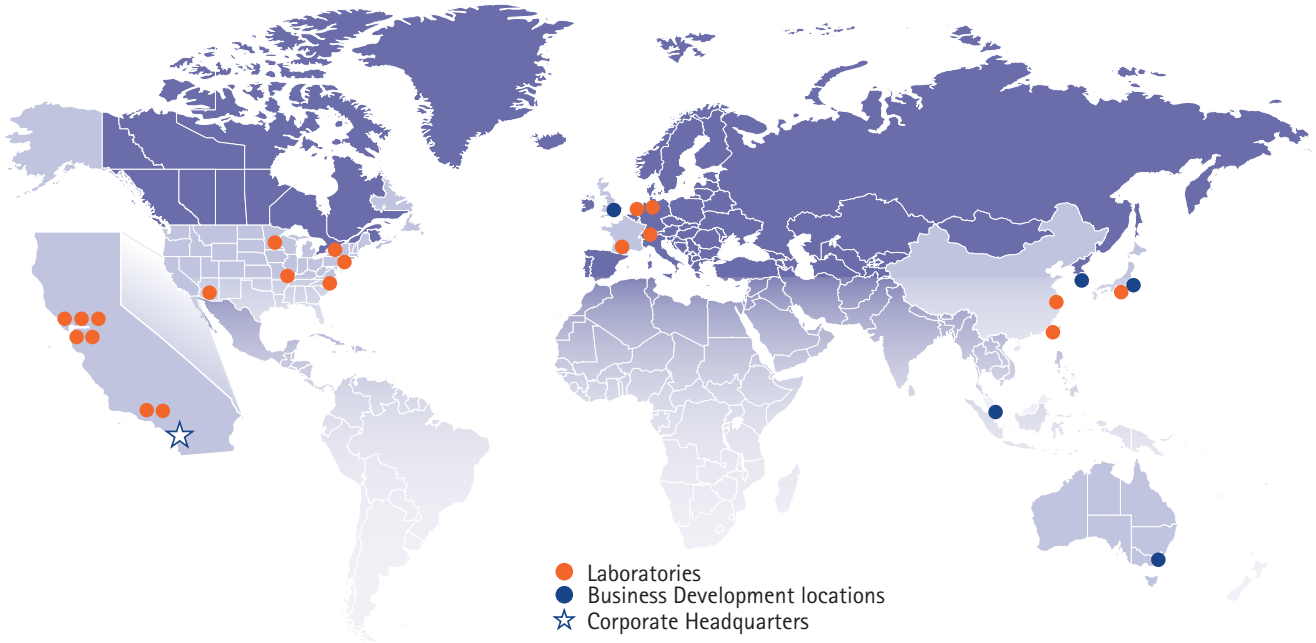

About Eurofins EAG Laboratories

When it comes to understanding the physical structure, performance, chemical properties and composition of materials, no other scientific services company offers the breadth of experience, diversity of analytical techniques or technical ingenuity of Eurofins EAG Laboratories. We don't just perform testing, we drive commercial success—through thoughtfully designed investigations, technically superior analyses, and expert interpretation of data.

We deliver multi-disciplinary, problem-solving expertise to help our customers accelerate innovation, ensure quality and safety, and protect intellectual property. Whether you are seeking to reduce time-to-market, solve manufacturing problems or ensure regulatory compliance, turn to Eurofins EAG. We know how to bring the power of science to every phase of your product lifecycle.

- 20+ facilities located in the US, Europe, and Asia
- 2,500+ instruments
- 1,000+ highly-educated employees
- Serving more than 5,000 clients worldwide
- Revenue sourced from more than 50 countries

Complete Lifecycle of Services

- PRODUCT INNOVATION & IMPROVEMENT
- INVESTIGATION & TROUBLESHOOTING
- QUALITY ASSURANCE
- MANUFACTURING SUPPORT
- FAILURE ANALYSIS
- REGULATORY COMPLIANCE
- MANUFACTURING & SUPPLY CHAIN SUPPORT
- CONSULTING & LITIGATION

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