TECNALIA · **HEALTH AND AGEING**

ASSESSMENT OF BIOMATERIALS

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MEMBER OF BASQUE RESEARCH & TECHNOLOGY ALLIANCE

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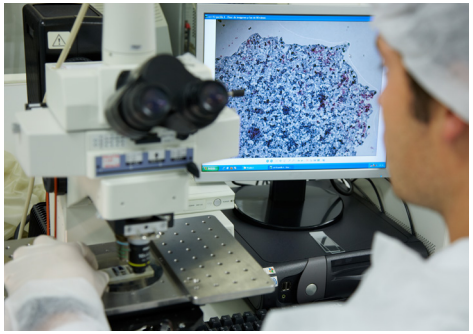
ASSESSMENT OF BIOMATERIALS



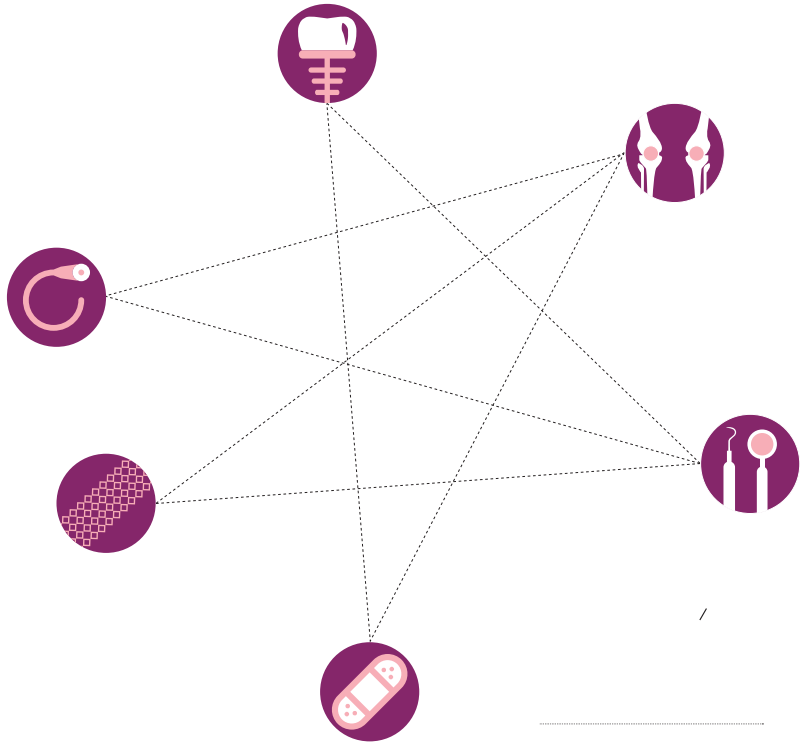
CHARACTERIZATION OF BIOMATERIALS AND BIOCOMPATIBILITY

MICROBIOLOGICAL TESTS

CELL-BASED ASSAYS

TOXICOLOGY (*IN VIVO* AND *IN VITRO*)

WE PERFORM THE NECESSARY TESTS SO THAT COMPANIES CAN CERTIFY THEIR **MEDICAL DEVICES** THROUGH THE CE MARKING.



CHARACTERIZATION OF BIOMATERIALS AND **BIOCOMPATIBILITY**

We have the necessary resources to carry out the biocompatibility tests required in the **ISO-10993** for *in vivo* and *in vitro* CE marking.

→ BIOLOGICAL TESTS (*IN VIVO* AND *IN VITRO*)

Cell-based cytotoxicity (ISO 10993-5).

Irritation (ISO 10993-10).

Intracutaneous Reactivity (ISO 10993-10).

Sensitization (ISO 10993-10).

Systemic Toxicity (ISO 10993-11).

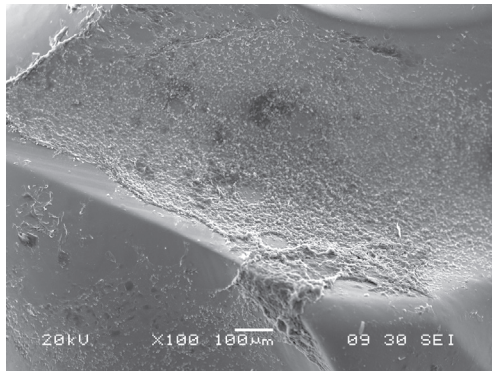
Genotoxicity: bacterial mutagenicity (Ames Test) and cell mutagenicity (Mouse Lymphoma Assay) (ISO 10993-4).

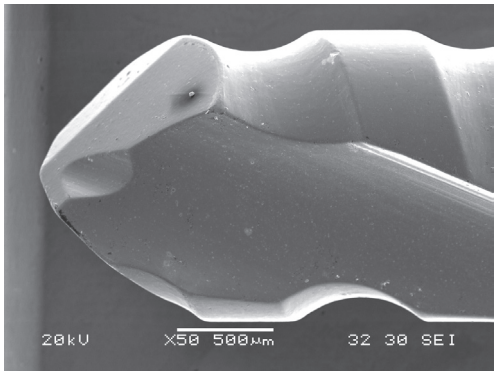
Haemocompatibility: haemolysis, coagulation time, platelet adhesion (ISO 10993-4).

Implantation Effects (ISO 10993-6).

TECNALIA acts as Testing Laboratory of Notified Body 0318 - Spanish Agency for Medicines and Healthcare Products - to conduct Biocompatibility Testing; ISO 10993; Fatigue Tests; in Total Knee-Joint Prostheses ISO 14879-1; Partial and Total Hip Joint Prostheses ISO 7206, parts 4, 8, 10; Joint Replacement Implants UNE-EN-ISO 21534; Endosseous Dental Implants UNE-EN-ISO 14801.

→ BIOMATERIAL CHARACTERISATION





Degradation products from polymeric devices ISO 10993-13.

Degradation products from ceramics ISO 10993-14.

Degradation products from metals ISO 10993-15.

Chemical characterisation of materials ISO 10993-18.

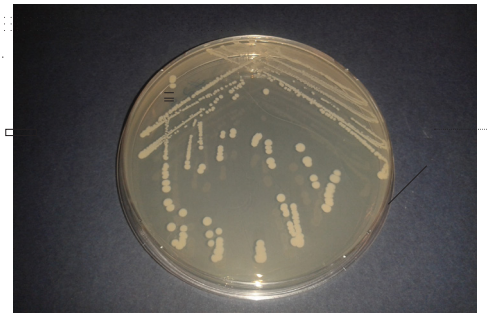
Surface Characterisation (SEM).

Fatigue Tests.

We have extensive experience in the characterisation of antimicrobial efficacy against common micro-organisms in infections produced in medical devices. *S. aureus; S. epidermidis; MRSA; P. aeruginosa, E. coli...*

MICROBIOLOGICAL TESTS

- Assessment of **Bioburden and Sterility** (ISO 11737): Characterisation, validation and routine control.
- Determination of **endotoxins**.
- Tests with **Biocides** (disinfectants, antiseptics): efficacy of preservatives, surface resistance to bacteria and fungi, minimum inhibitory concentration, etc.).
- **Antimicrobial activity** of surfaces (metal, polymeric, textiles, ceramic), liquids, powder, nano-particles, etc.:
  - ISO 22196 (or JIS Z2801): Measurement of antibacterial activity on plastics and other non-porous surfaces.
  - ASTM E2149: Antimicrobial Activity under dynamic contact conditions.
  - AATCC Test Method Antibacterial Activity Assessment of Textile Materials.
- Tests on the **Adhesion** and **Biofilm** formation on surfaces.
- **Microbiological** Tests. Diffusion in agar-Antibiogram (liquid and solid samples).
- General count of aerobic and anaerobic bacteria and fungi.

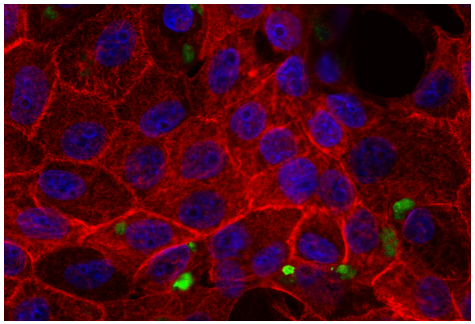


CELL-BASED ASSAYS

- **Cytotoxicity** tests in different cell lines depending on the application of the product to be tested (lung fibroblasts, osteoblasts, mesenchymal cells, human hepatoma cells...).
- Cell **Adhesion, Proliferation and Differentiation** tests on different surfaces of materials (discs, scaffolds, etc.).
- Nanoparticle uptake tests.
- Inflammation, Apoptosis and Cell Necrosis Tests.
- **Molecular** Tests: extraction and quantification of DNA, RNA and proteins, expression of molecular markers via PCR, qRT-PCR and ELISA.

TOXICOLOGY
(*IN VIVO* AND *IN VITRO*)

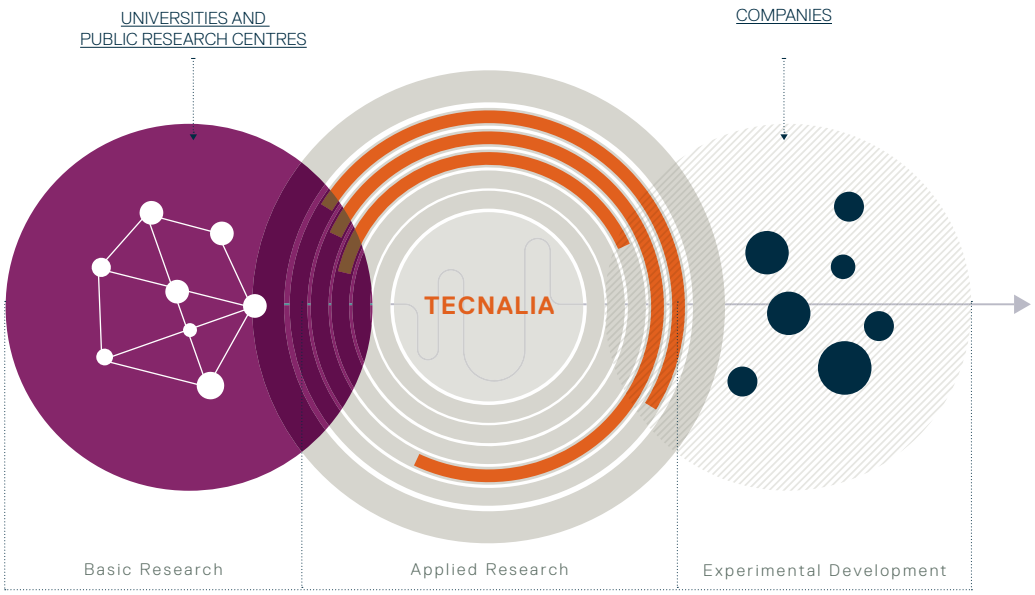
- In vitro skin irritation (OECD 439).
- In vitro skin corrosion (OECD 404).
- Mutagenicity (Ames Test) (OECD 471).
- Mouse Lymphoma Cell Mutagenicity Assay (OECD 476).
- Acute oral toxicity (OECD 423).
- Acute dermal toxicity (OECD 402).



- **NANOTOXICOLOGY**
  - Development/adaptation of toxicological test methods.
  - Toxicological evaluation of nanomaterials.
  - Tests for cell uptake of nanoparticles.
  - Evaluation of the biocidal activity of nanomaterials.
  - Biocompatibility evaluation.

Adaptation of *in vitro* and *in vivo* toxicological testing methods to nanomaterials. Tests on nanoparticle uptake by cells.

TECNALIA
IS AN APPLIED RESEARCH AND TECHNOLOGICAL DEVELOPMENT CENTRE



FROM SCIENCE

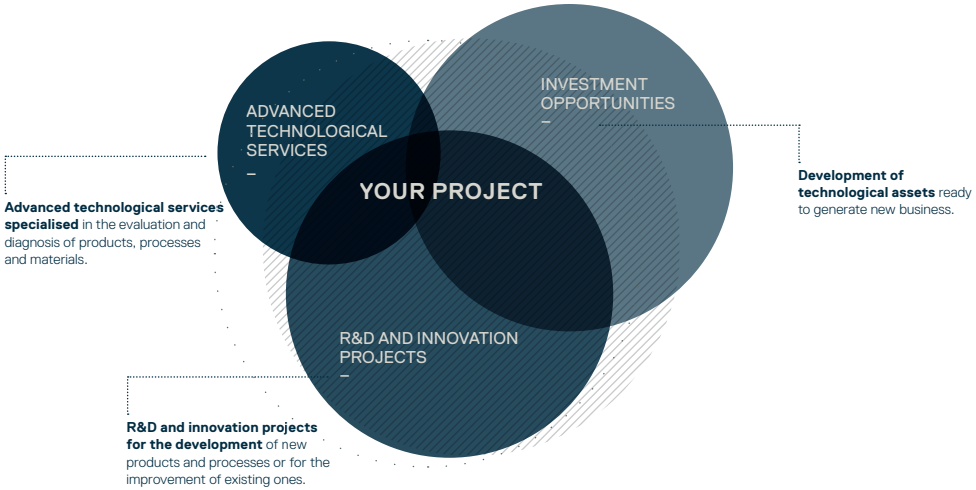
TO MARKET

MISSION

We transform technology into **GDP**

We transform technology into wealth to obtain beneficial visible results for companies, society, our environment and in short, for people.

SERVICE **OFFER**



Advanced technological services specialised in the evaluation and diagnosis of products, processes and materials.

Development of technological assets ready to generate new business.

R&D and innovation projects for the development of new products and processes or for the improvement of existing ones.

WE CAN DO SO MUCH **TOGETHER**

Our work is not understood without yours; we want to work together so your company can compete better. Because together, we can develop technologies that transform the present.

The future is technological, let's share it!

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