zurko
bioresearch

MEDICAL DEVICES

SCIENTIFIC TESTING & SERVICES

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WHO ARE WE?

ZURKO RESEARCH is a company of clinical trials, in vitro testing and regulatory services, focused on providing an integral service to medical devices, manufacturers, importers, distributors, etc. We are also certified to work with cosmetics, cosmeceuticals and biocides.

We have over 15 years of experience; we conduct over 6000 projects a year and work with almost 300 partners.

QUALITY MANAGMENT SYSTEM & CERTIFICATIONS

Zurko Research fully complies with the ISO 9001 Quality Management System. We also have the ISO 17025 certification, Crédit d'Impôt Recherche (CIR) accreditation and we are registered as a Clinical Research Organization with the FDA in the US.

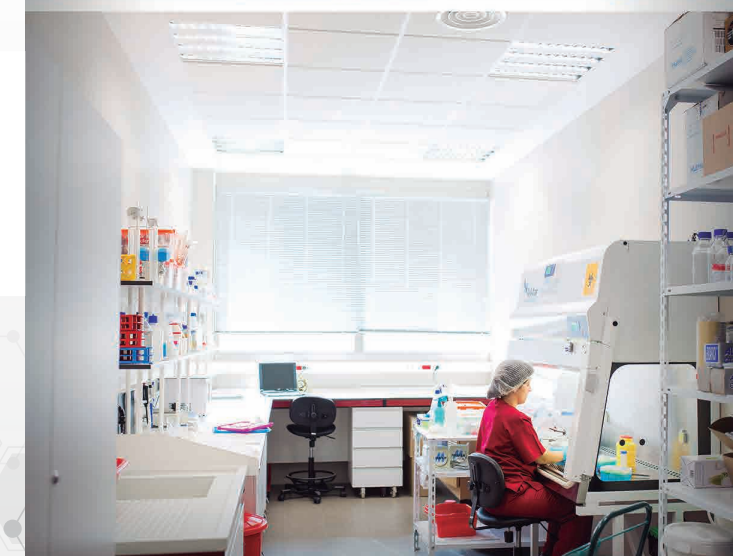
FDA REGISTERED

Crédit impôt Recherche Agréé CIR

SYSTEM CERTIFICATION ISO 13485:2016 MEDICAL DEVICES

SYSTEM CERTIFICATION ISO 9001 SGS

SYSTEM CERTIFICATION ISO 17025



WHY ZURKO?

We design the best strategy in time and price, from the beginning of the project. Innovating constantly.

Over 15 years of experience in borderline products (cosmetics, cosmeceuticals and medical devices).

Ad-hoc service for each product until obtaining the CE marking. Tailor-made to your needs.

We offer 360 degrees advice, both in the regulatory phase as preclinical and clinical trials and even for manufacturing your MD.

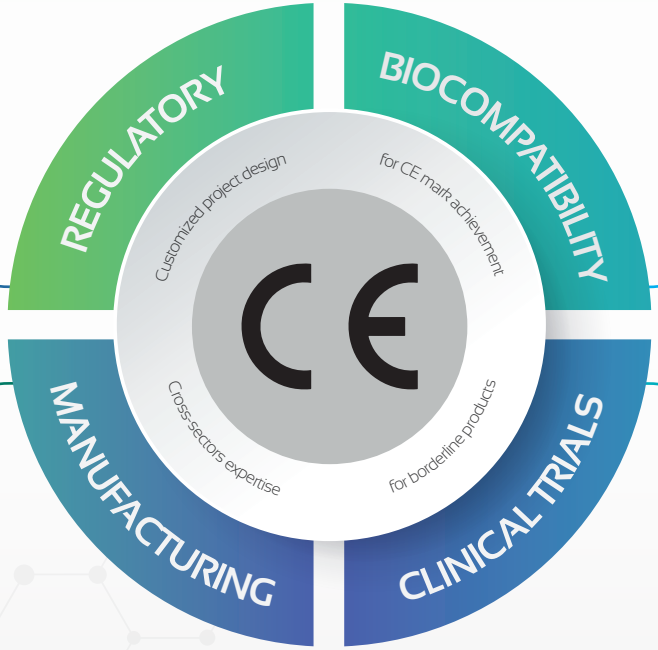
WHAT KIND OF SERVICES DO WE OFFER?

Please click on one of the following areas:

Navigate through our interactive menu

All Medical Devices have to get a CE Mark in order to be commercialized. Knowledge and long-standing experience in regulation and normative are vital for the achievement of this purpose.

Biocompatibility testing is essential to evaluate any potential biological risk arising from the use of Medical Devices. The aim is to protect patients or users from adverse or harmful effects.



The manufacturing of a Medical Device requires the accomplishment of the highest quality production standards. Product design, sterilization requirements, quality controls, packaging and shipment have to be organized and supervised according to the specifically related regulation.

Clinical trials with Medical Devices are regulated with a series of provisions which establish the objectives, the ethical and methodological principles they have to follow, the administrative authorizations needed and the documentation the promotor is required to provide.

DESIGN & REGULATORY

CUSTOMIZED DESIGN & REGULATORY
We advise our clients with the best strategy adapted to their specific needs, guaranteeing that organizations are meeting all the applicable regulations.

PROJECT PLANNING
We adapt to our clients needs designing & developing complete project/product viability studies for CE mark achievement.

LICENCES
We elaborate and manage all type of documentation and procedure for Medical Device activity license obtainment.

ISO 13485
We support our client in the establishment and review of the quality management system required for Medical Devices.

TECHNICAL DOCUMENTATION
We elaborate the complete technical file, design dossier and QMS documentation.

WORLDWIDE REGULATORY EXPERTISE
(USA-FDA, Latam, Japan & Australia)

ALL RISK CLASSES

At Zurko Research we offer our clients all necessary support for their medical devices, from all risk classes (I, IIa, IIb, III)

I | II a/b | III

Large experience with **Class III injectables**

BIOCOMPATIBILITY

BIOCOMPABILITY

- Cytotoxicity
- Sensitization
- Irritation (skin, eyes, mucose)
- Intracutaneous reactivity
- Acute systemic toxicity (subacute, subchronic and chronic toxicity)
- Genetic toxicology (in-vitro and in vivo)
- Implantation
- Implantation in combination with systemic toxicity
- Hemocompatibility
- Pyrogenicity

COMPLEMENTARY

At Zurko Research, we provide complementary pre-clinical trials:

- Stability studies (accelerated, shelf life, in use, etc.)
- Final product CoA specifications.
- Antimicrobial efficacy studies of preservative system.
- Efficacy studies for medical devices disinfectants.
- Efficacy studies with cell culture.
- Bacterial/bacteriostatic activity of surfaces, substances and formulations
- Microbiological control of the product (bioburden, sterility, LAL test)
- Microbiological control of processing environment.
- Processing water control.
- Control of ethylene oxide residues.
- Control of chemical parameters (HPLC, GC-MS, ICP-MS)
- Heavy metals

CLINICAL TRIALS

CLINICAL TRIALS

At Zurko Research, we guide manufacturers of Medical Devices through the entire clinical trials process:

- Application to the national competent authority
- Application to the clinical research Ethics Committee (EC)
- Internal facilities or identification of the research centre (public or private)
- Coordination of multicentric research
- Designing of trial protocol and essential related documents (CRF, ICF)
- Presentation and defense of the project before the EC
- Support with the selection of patients panel
- Trial supervision
- Statistical analysis
- Elaboration of Final Report

MANUFACTURING

MANUFACTURING

Medical Devices class III injectable

Mesoceuticals

COMPLETE PROJECT

At Zurko Research, we follow up through all stages of the project:

- Design support & development
- Testing
- Process validation
- Reception & analysis of raw materials
- Product manufacturing
- Product sterilization and Packaging
- Quality control and batch release
- Traceability
- Shipment

FORMATS

- Liquid
- Powder
- Extemporaneous products (Powder + liquids)
- Lyophilized
- Emulsions & microemulsions

LICENSES

- Manufacturing cosmetic license
- Manufacturing medical devices Class III Injectable license
- ISO 13485 license
- Good manufacturing practices (BPL/GMP)
- Standards & QC according to ISOs & Pharmacopeia

PRODUCTION PLATFORM

- Clean rooms & B Pharma grade
- Cosmetic Lab
- Project monitoring
- Technical & document support

WHERE ARE WE BASED?

Our Headquarters is based in Madrid (Spain), where we conduct all the clinical testing and other in vivo services in our modern 500 m2 facilities.

We are also based in Albacete, where our in-vitro laboratory develops biocompatibility testing and preclinical trials for medical devices.

Subcontracting of manufacturing processes, if needed, also take place in Albacete in ISO 13485 certified manufacturing plant.

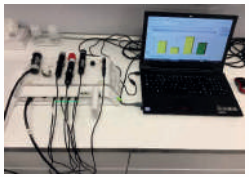
OUR EXPERIENCE IN EUROPE

We have worked with European companies for 5 years ago, all our services are carried out following international standards (ISO 14155, ISO 10993, etc.) and support full compliance with European Regulation 2017/745 of Medical Devices.

FACILITIES

Madrid: Clinical laboratory



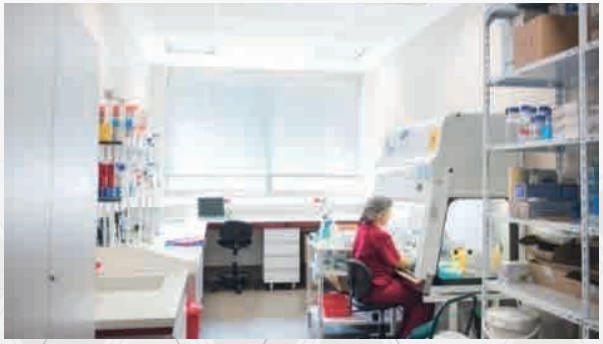




Albacete: In vitro Laboratory

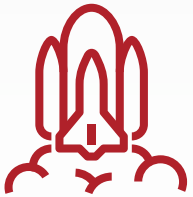












TEST ● SUCCEED ● GROW

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