confarma

Medical Devices

Biological Analysis, Validation and Method Development

Our experience and expertise support your product development and quality control, from raw material to finished products, according to GMP, CGMP (FDA), GLP, pharmacopeia and ISO guidelines (ISO 17025, ISO 9001).

Confarma provides scientific services for medical devices, biomaterials and biological materials. We offer high calibre microbiology, chemistry, toxicology and biocompatibility services according to the highest quality standards.

FINISHED PRODUCTS

- Orthopedic and spine
- Ophthalmic
- Intra-articular
- Dental
- Cardiovascular
- Packaging

RAW MATERIALS

- Polymers (NaHA, PCL, UHMWPE, PLA, PEEK)
- Metals (Titanium, Stainless steel)
- Ceramics (HAp, Al2O3, ZrO2, β TCP)
- Combination products (with drug and/or biological)
- Liquids (buffer, glycerol, water)

ANALYTICAL SERVICES

- Physico-chemistry
- Biology/Microbiology
- Molecular Biology
- Toxicology
- Virology

RESEARCH & DEVELOPMENT

- Biological Evaluation According ISO 10993* (Biocompatibility)
- Biological indicators (D-Value determination)
- Cell based assays
- Cleaning validation
- Container Closure Integrity Testing
- Extractables and leachables
- ***In vitro*** Pyrogen Test (MAT)[1]
- Method development and validation
- Qualification of water system*
- Site qualification mapping (Clean Room)
- Stability studies

QUALITY CONTROL

- Analysis according to Pharmacopoeia's and ISO guidelines
- Bioburden*
- Identification of microorganisms
- Sterility Test (Standard* & Rapid in 5 days)
- Endotoxins (LAL)*
- Cytotoxicity*
- Particulate contamination
- Determination of Particle size
- Total organic carbon (TOC)
- Total hydrocarbons (THC)

WHY CONFARMA?

- Respect the high quality standards
- Flexible and reactive to your needs with expert interpretation
- Long-standing experience in biological method development
- Independent partner

[1] The rule of "3R" TO REFINE, TO REDUCE, TO REPLACE from Russel and Burch (1959) recommends the reduction and the substitution of animal testing by ***in vitro*** procedures.

* Accreditation ISO 17025 (COFRAC) number 1-2383. Scope available on www.cofrac.fr

Confarma France SAS
ZI, rue du Canal d'Alsace, F-68490 Hombourg
info@confarma.fr