



IN VIVO BIOCOMPATIBILITY TESTING FOR MEDICAL DEVICES AND OTHER PRODUCTS

DESCRIPTION

DFVM BIOEVAL research laboratory has expertise in biological studies performed in accordance with ISO 10993 standard series, the main source of guidance on the general principles governing the biological evaluation of medical devices. Two most common in vivo biocompatibility testing services are offered:

- Irritation test - determines the likelihood of a material, device, or their extract to cause irritation. BIOEVAL only performs the in vivo primary skin irritation test that is less aggressive.
- Sensitization test - explores the potential of a material to cause a sensitizing effect or allergenic reaction over an extended period of exposure. Sensitization is characterized by the fact that reactions are delayed, not localized, and independent of dose. BIOEVAL uses the Guinea Pig Maximization Test (GPMT) - the most sensitive method for skin sensitizing potential - to evaluate the sensitizing capacity of the test material in animals. If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

POTENTIAL CUSTOMERS OR COMMERCIAL APPLICATIONS

Medical device manufacturers and suppliers
Designers/ manufacturers of biomaterials and related consumer products that will be in direct contact with the body and/or physiological fluids

KEYWORDS

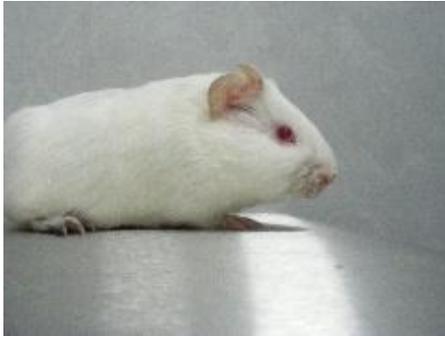
biocompatibility, irritation, sensitization, in vivo studies

APPLICATION DOMAINS

Safety evaluation studies on medical materials and devices, biomaterials and related consumer products.

MAIN ADVANTAGES

By maintaining an approved animal facility and specialize in small laboratory animals (mice, rats, guinea pigs and rabbits), BIOEVAL can perform both in vitro and in vivo biocompatibility testing according to ISO 10993. It can also support the biocompatibility testing through additional research activities pertaining to toxicological studies.



CONTACT

Tel: (021) 404 61 34

Dr. Maria Adriana Acasandrei

e-mail: macasan@nipne.ro

Dr. Cosmin Mustaciosu

e-mail: cosmin472000@yahoo.com