COMPARATIVE BIOSCIENCES, INC.

A TRANSLATIONAL APPROACH TO PRECLINICAL RESEARCH

Technical Bulletin:
BIOCOMPATIBILITY AND DEVICES

Biocompatibility And Devices Research

Biocompatibility is the ability of an implant material to function in vivo without eliciting detrimental local or systemic responses in the body. Prior to their use in human fracture fixation, biomaterials undergo tissue and animal testing to determine their safety and efficacy.

Here at Comparative Biosciences, Inc.
We offer a range of safety evaluation and biocompatibility services for medical devices.

Toxicology, Pathology and Related Services

CBI's Biocompatibility Testing Services For Medical Devices

• We take pride in the technical depth, experience and breadth of services we offer, while maintaining our focus on putting our clients' needs first. CBI has the team you can trust to get the job done, regardless of your specific needs, including:

• Bringing a new product through research and development, including interacting with the Regulators as part of pre-IND meetings and pre-approval inspections.

Comparative Biosciences Inc.
A TRANSLATIONAL APPROACH TO BIOMEDICAL SERVICES

GD3 GENESIS™
DRUG DISCOVERY & DEVELOPMENT

Comparative Biosciences, Inc and GD3 have joined together to providing expert scientific resources and high quality contract research services to all sectors within the biomedical and pharmaceutical community.

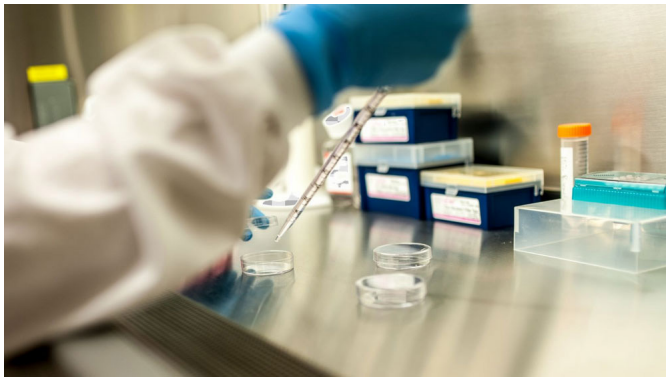
Medical Devices Biocompatibility Testing
A Risk-Based Framework for Biocompatibility Assessment

What exactly is a "risk-based approach?"

ISO 14971 defines the term "risk" as "the combination of the probability of occurrence of harm and the severity of that harm." The standard defines harm primarily as physical injuries and damage to health, but it also includes harm to goods and to the environment.

ISO 14971 is the key to effective risk management for medical devices.

ISO 14971 is the risk management standard for medical devices. This includes software as a medical device and in vitro diagnostic medical devices. It contains a structured approach for effective risk management. The risk-based approach adds the harm resulting from regulatory non-compliance and bureaucracy. It is about weighing the likelihood and the consequence of the identified risks and adapting the expenditure of resources accordingly.



A consistent and comprehensive approach to risk management.

To achieve successful and timely product launches, CBI avoids quality risks, which add costs and cause delays. Automated risk management enables us to quickly identify and mitigate risks in every phase of a product's life cycle.

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GENESIS™
DRUG DISCOVERY & DEVELOPMENT

IN VIVO ASSAYS INCLUDE:

- Acute, systemic, subacute, chronic and carcinogenicity toxicity studies
- Beuhler, Draize and Magnussen-Kligman maximization testing
- Biocompatibility
- Bone, joint, and orthopedic
- Contact lens testing, ISO-9394
- Device-drug combinations
- Device-stem cell combinations
- Dermal, ocular, mucosal irritation testing
- Bone, joint, and orthopedic
- Long-term surgical implantation studies
- Muscle, bone, subcutaneous and intradermal implantation
- Topical, intracutaneous, ocular and primary skin irritation testing
- Pyrogenicity testing

CBI has conducted numerous studies related to dural, amnionic, pericardial and other patches, coated films, sutures, matrices, osteoinduction materials, cartilage regeneration, morselized bone, spinal fusion, bone regeneration and tendon repair. These studies are often customized or unique experiments.

How is Biocompatibilities used in preclinical research?

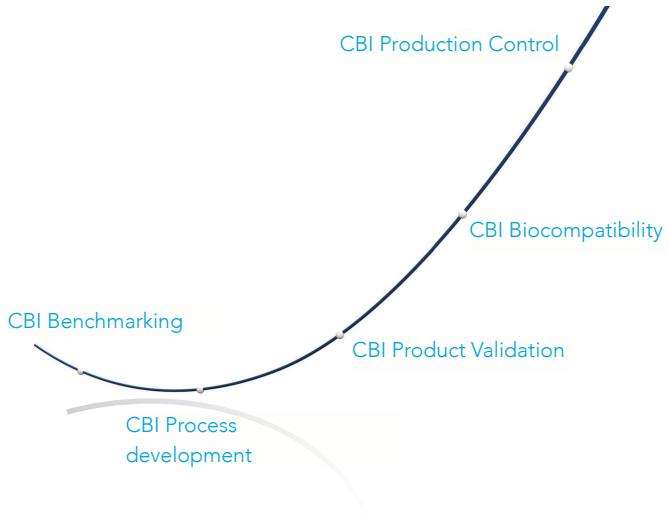
BIOCOMPATIBILITY TEST PLANNING

The primary goal of a biocompatibility screening program is the protection of humans. However, since animal testing is necessary for many biocompatibility tests, a secondary goal is to eliminate unnecessary testing and minimize the number and exposure of test animals.

WHY IS BIOCOMPATIBILITY TESTING IMPORTANT?

Even if a material that makes up the medical device has been tested for biocompatibility, processes such as manufacturing, packaging, aging, and sterilization may have adverse effects on the material's composition and how it reacts in different environments. Because of these potential changes, biocompatibility is an important test protocol that must be completed for every medical device end product prior to receiving global regulatory approvals.

A global overview in medical devices



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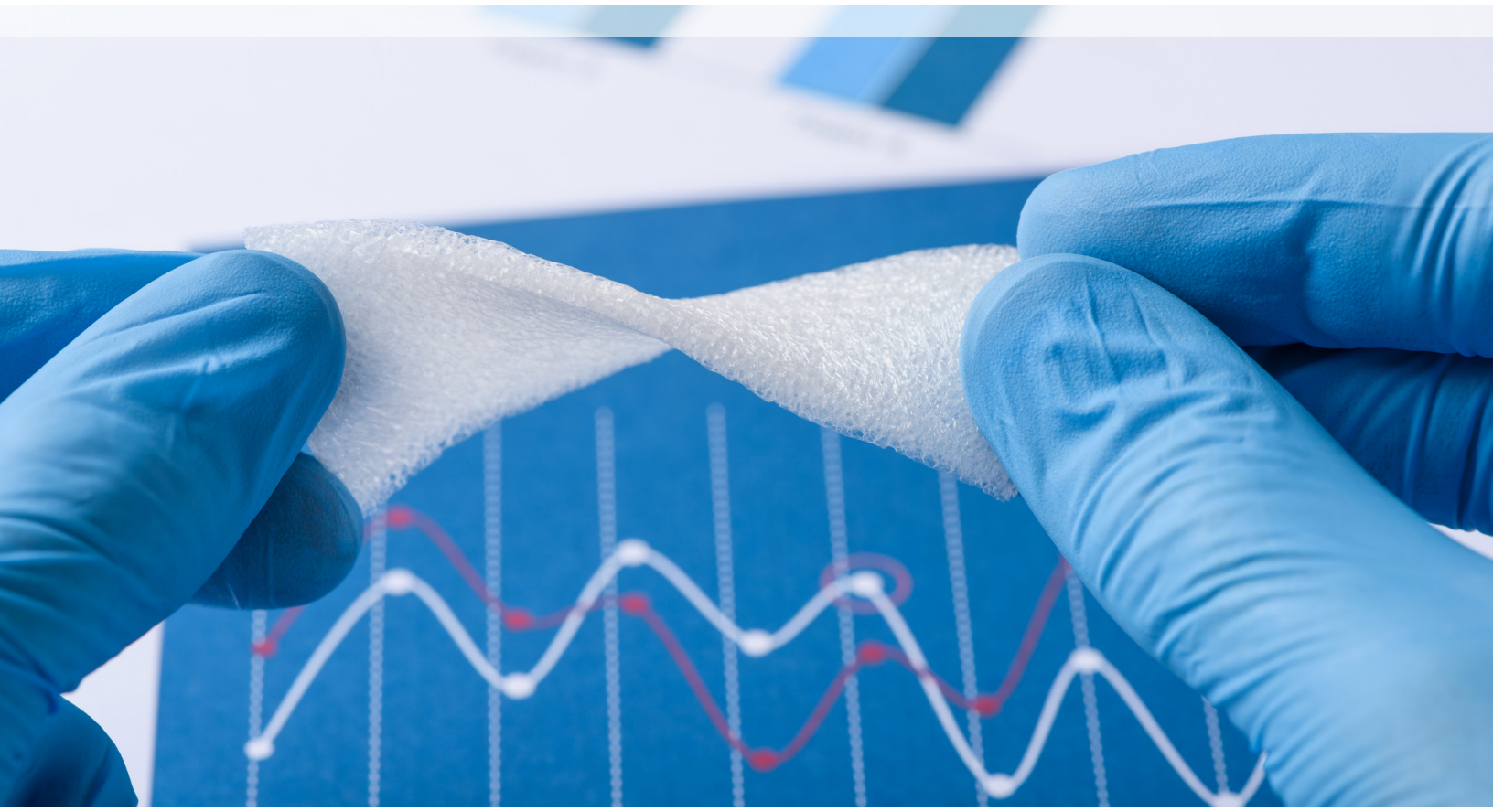

Scientist show new research of foam lightweight flexible material in laboratory. The development of therapeutics for orthopedic clinical indications exploiting minimally invasive surgical techniques has substantial benefits, especially for treatment of fragility fractures in the distal radius of osteoporotics and vertebral compression fractures.

HOW DOES CBI TEST BIOCOMPATIBILITY OF A MATERIAL?

Implant studies are often the most direct evaluation of device biocompatibility. The test material is placed in direct contact with living tissue. After an appropriate period, the implant site is recovered and examined microscopically for tissue reaction.

"We are looking forward to meeting you and helping you be successful."

- Carol Meschter, DVM, PhD, DACVP, CEO

WHAT THE FDA ASSESSES OR EVALUATES

"Medical devices that come into direct or indirect contact with the body" are evaluated "for the potential for an unacceptable adverse biological response resulting from contact of the component materials of the device with the body."

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
FDA

We have state of the art equipment and high quality detailed reports to support your research activities and FDA regulatory submissions.

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