ORTHOBIOLOGIC SERVICES

Bio-activity Studies

WuXi AppTec

Bio / Pharma | Combo Products | Medical Devices

Demonstrating efficacy through bio-activity is a critical aspect of product evaluation. WuXi AppTec provides a broad spectrum of both *in vitro* and *in vivo* orthobiologic testing programs.

As many orthopedic devices incorporate tissue, we can also help you navigate the requirements for bacterial and viral inactivation assays. WuXi AppTec is an international leader in these types of studies with more than twenty years' experience.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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Osteoinductivity (*In Vitro*)

BMP

BMPs (bone morphogenic proteins) have been associated with the induction of new bone growth. BMP-2 is considered to be the most relevant protein in orthobiologic products, though BMP-4 and BMP-7 can also play important roles in new bone growth. Direct measurement of BMP in a product can be indicative of their osteoinductive ability. Products are extracted in collagenase or guanidine extraction buffers to isolate the BMP protein. Extracts are then evaluated in an ELISA based assay for the amount of BMP present.

Alkaline Phosphatase

BMPs, as well as demineralized bone products, can act *in vitro* to activate a differentiation pathway in an immortalized mouse cell line. C2C12 cells stimulated by these compounds produce increased levels of alkaline phosphatase. This assay has been designed to detect the presence of these stimulatory compounds in bone products by their ability to induce alkaline phosphatase activity in C2C12 cell culture.

Osteoinductivity / Osteoconductivity (*In Vivo*)

In vivo assays are used to determine a material's bone-forming potential in an ectopic site. Frequently, these assays are required by regulatory authorities as definitive proof that a product is efficacious. In general, an *in vivo* assay is performed by implanting the material intra-muscularly in nude mice or rats. Implant location can vary, depending on clinical application. Histopathological evaluation using a pre-determined scoring method is then used to evaluate the amount of new bone formed. Testing of IO and OC articles using the *in vivo* models can be used for a variety of endpoints ranging from research to regulatory submission.

Bacterial and Viral Inactivation Studies

Customized studies are designed to validate removal, inactivation or other treatments for a variety of bacteria, viruses, yeast and filamentous fungi.

Studies are performed on human and animal tissue, including:

- Bone
- Skin
- Ligaments
- Collagen
- Cartilage
- Synovial Fluids

In these studies, the product is inoculated with the chosen organisms. Each step of the client's inactivation / removal process is reproduced in the laboratory so the effectiveness of each step can be analyzed by determining the log reduction of the inoculated organism.

Other Custom Services

WuXi AppTec offers additional customized studies that complement a processed-tissue testing program, including biocompatibility testing and cell-based potency assays.

For more information on WuXi AppTec's services please contact:

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The Leader in Combination Product Services

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