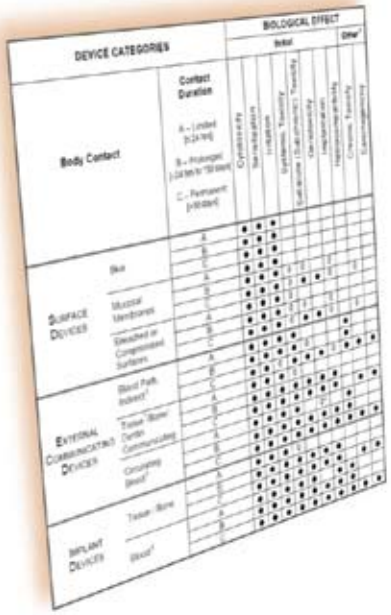
ORTHOBIOLOGIC SERVICES

Biosafety/Biocompatibility Testing

WuXi AppTec

Bio / Pharma | Combo Products | Medical Devices



Among the most important challenges you confront as you develop your orthobiolgic product is to provide significant and appropriate biosafety and biocompatibility data to meet complex and evolving regulatory requirements.

With our unique blend of medical device, tissue, biologic and pharmaceutical experience and capabilities, WuXi AppTec can offer expert guidance to help you develop a customized program of coordinated studies that integrates safety, development, regulatory and lot release testing.

Our expertise and comprehensive biosafety testing services allow a consolidation of efficacy and safety studies that helps you control costs and provides you with access to the rich data you need.

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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Representative Case Studies: Combination Product Testing

While each combination product offers its own unique set of challenges, following are representative "case studies" that demonstrate how WuXi AppTec has developed and performed successful biosafety programs in support of regulatory submissions.

EXAMPLE 1

Aseptically packaged kit with device and biologic components (orthobio putty kit)

Development/Screening Phase
- Spine Fusion
- Bioreactivity – BMP-2
- Small bone drill defect

Regulatory Preparation Phase
- Endotoxin
- Biocompatibility
  - Cytotoxicity
  - Acute systemic toxicity
  - Intracutaneous Irritation
  - Maximization Sensitization
  - Subacute/Subchronic toxicity
  - Intramuscular implant
  - Genotoxicity
  - Pyrogenicity

Lot Release
- Bioreactivity – BMP-2
- Endotoxin
- Rat Osteoinduction Assay

EXAMPLE 2

Terminally sterilized drug-coated device (antimicrobial-coated bone anchor)

Development/Screening Phase
- Pin Placement
- AME
- Bioreactivity – Alkaline Phosphatase

Regulatory Preparation Phase
- Endotoxin
- Biocompatibility
  - Cytotoxicity
  - Acute systemic toxicity
  - Intracutaneous Irritation
  - Maximization Sensitization
  - Subacute/Subchronic toxicity
  - Intramuscular implant
  - Genotoxicity
  - Pyrogenicity

Lot Release
- Bioreactivity – Alkaline Phosphatase
- Endotoxin

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

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The Leader in Combination Product Services

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