

Wound Healing Assessments



HOW TO

**Steer your product to market
ahead of the competition**

 WuXi AppTec

The Leader in Combination Product Services

Bio /
Pharma

Combo
Products

Medical
Devices

Why do wound healing studies?

Demonstrating efficacy can set your product apart from the field.

The development of improved products to treat wounds is essential to meet today's clinical demand. In particular, the growing incidence of obesity and diabetes – as well as the emergence of challenging microorganisms – has meant an increase in wounds that are difficult to treat. For manufacturers, well-designed studies modeling clinical scenarios can help not only improve and speed their product development cycle, but also smooth the regulatory review process.



Why do your studies with WuXi AppTec?

We have years of experience managing critical care in vivo cases.

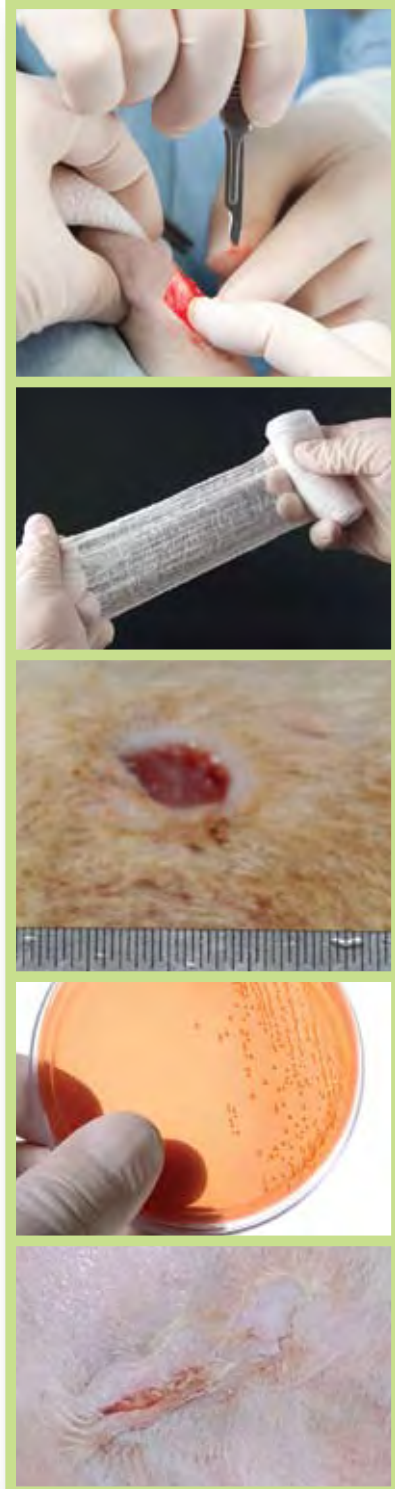
- EXPERIENCE**
Nearly 20 years of conducting sophisticated *in vivo* studies, including wound care models; highly successful in maintaining disease-state animals under GLP conditions.
- EXPERTISE**
Exceptional proficiency in innovative and customized studies, complex surgical techniques, and advanced microbiology; ability to provide personalized guidance in an uncertain regulatory environment.
- INTEGRATED SERVICES**
Ability to combine multiple disciplines from a broad spectrum of available services, including safety/toxicology, surgery, advanced animal care, microbiology and disease-state induction.
- OPERATIONAL EXCELLENCE**
Established metrics to measure and control key processes, allowing WuXi AppTec to deliver high quality results while adapting studies to address your specific product development needs.

Differentiate your product with clinically relevant data.

WuXi AppTec's established and robust methodologies provide clinically relevant data to support your R&D, regulatory and marketing needs.

To help you meet increasing regulatory demands for product approval and claims, WuXi AppTec offers several wound healing models designed to target the most critical clinical needs. Models include acute wounds, diabetic wounds, and wound infection models.

Through the use of an assay designed specifically to challenge the effectiveness of your product, data can be generated to prove the improved efficacy of your product to manage tough clinical problems like wound infections or diabetic wounds. Strong supporting data can ease the regulatory process and provide the marketing edge to put your product ahead.



ACUTE WOUND STUDIES

- **Incisional Wounds**
Wounds created by a single clean cut with a sharp instrument.
- **Excisional Wounds**
Wounds created by surgically excising an area of the skin to create an open wound.
- **Partial Thickness Wounds**
Wounds involving the top layer of skin but not throughout the full subcutaneous layer (i.e., through the epidermis but not fully through the dermis).
- **Full Thickness Wounds**
Wounds through the full layers of skin (i.e., epidermis and dermis) or through the underlying subcutaneous tissue.

WOUND INFECTION

Full thickness wounds surgically created on rats or pigs, followed by the addition of bacteria.

DIABETIC (TYPE II) MODELS

Full thickness wounds surgically created on genetically diabetic rats or mice.

CUSTOM STUDIES

WuXi AppTec can also design a wide range of other wound healing studies such as growth factor evaluations, adhesion models and ischemic wounds.

Wound Healing Assessments

WuXi AppTec's established, clinically relevant testing models are designed to demonstrate efficacy that can help speed your product to market and set it apart from the competition.

CAPABILITIES

- Expertise to create full service programs that combine wound healing studies with toxicology and safety testing.
- Depth of experience in study execution, including surgical techniques and critical animal care.
- Over 30 years experience in microbiological techniques, including development of stock and clinical isolates through BSL-2.
- Established methods to evaluate antimicrobial efficacy in vivo, including isolation and quantitation of bacteria from wounds and tissues.
- Long history of services for pharmaceuticals, biologics, devices, and combination products.
- Ability to provide personalized guidance and clarity in an uncertain regulatory environment.

PROGRAM FEATURES

- Testing custom designed with sponsor for each test article.
- Wound models developed to target specific product applications.
- Regulatory and consulting services available to support sponsors.
- BSL-2 animal suite and state-of-the-art surgical suite.
- In-house histology; on-staff veterinary pathologists.



The Leader in Combination Product Services



Contact WuXi AppTec for your wound healing assessments:

(1) 651-675-2000 / 888-794-0077 • www.wuxiapptec.com • www.comboproducts.com