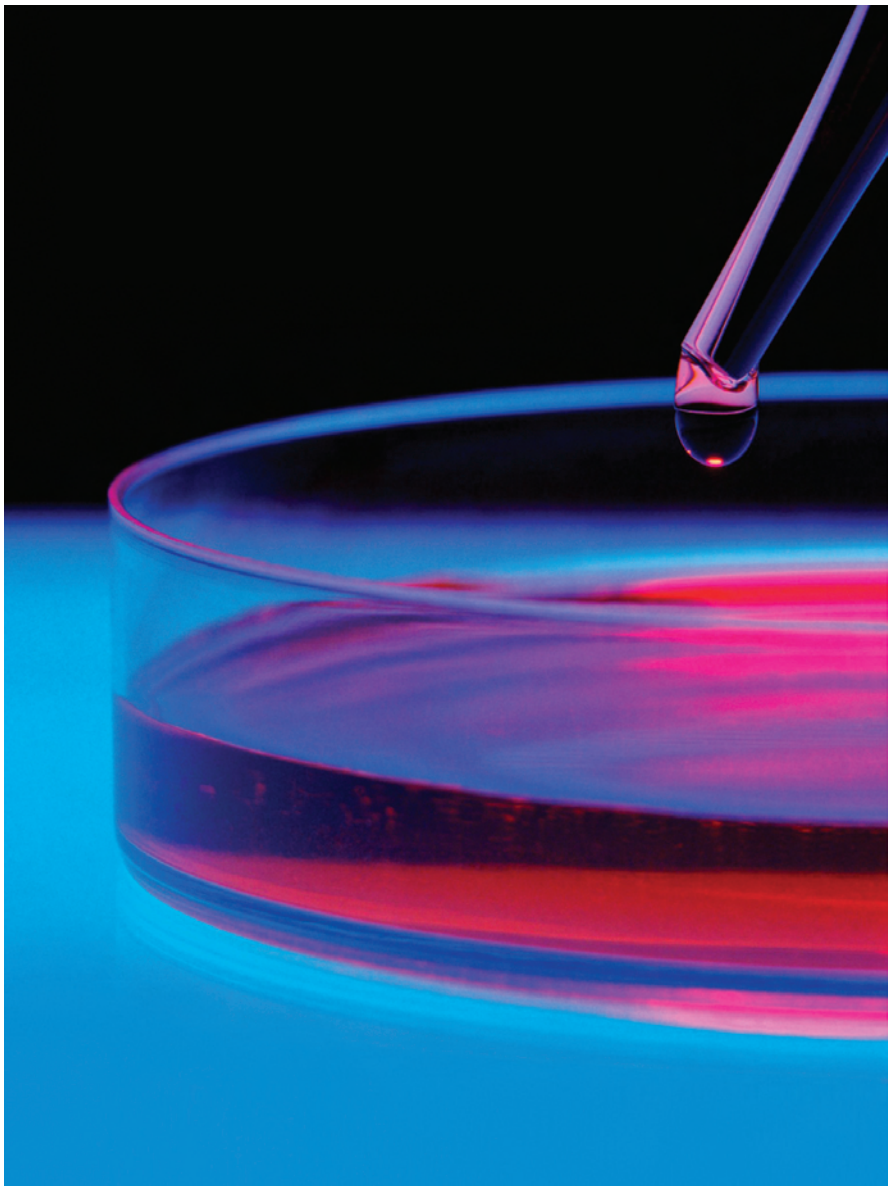
# Services for Medical Devices



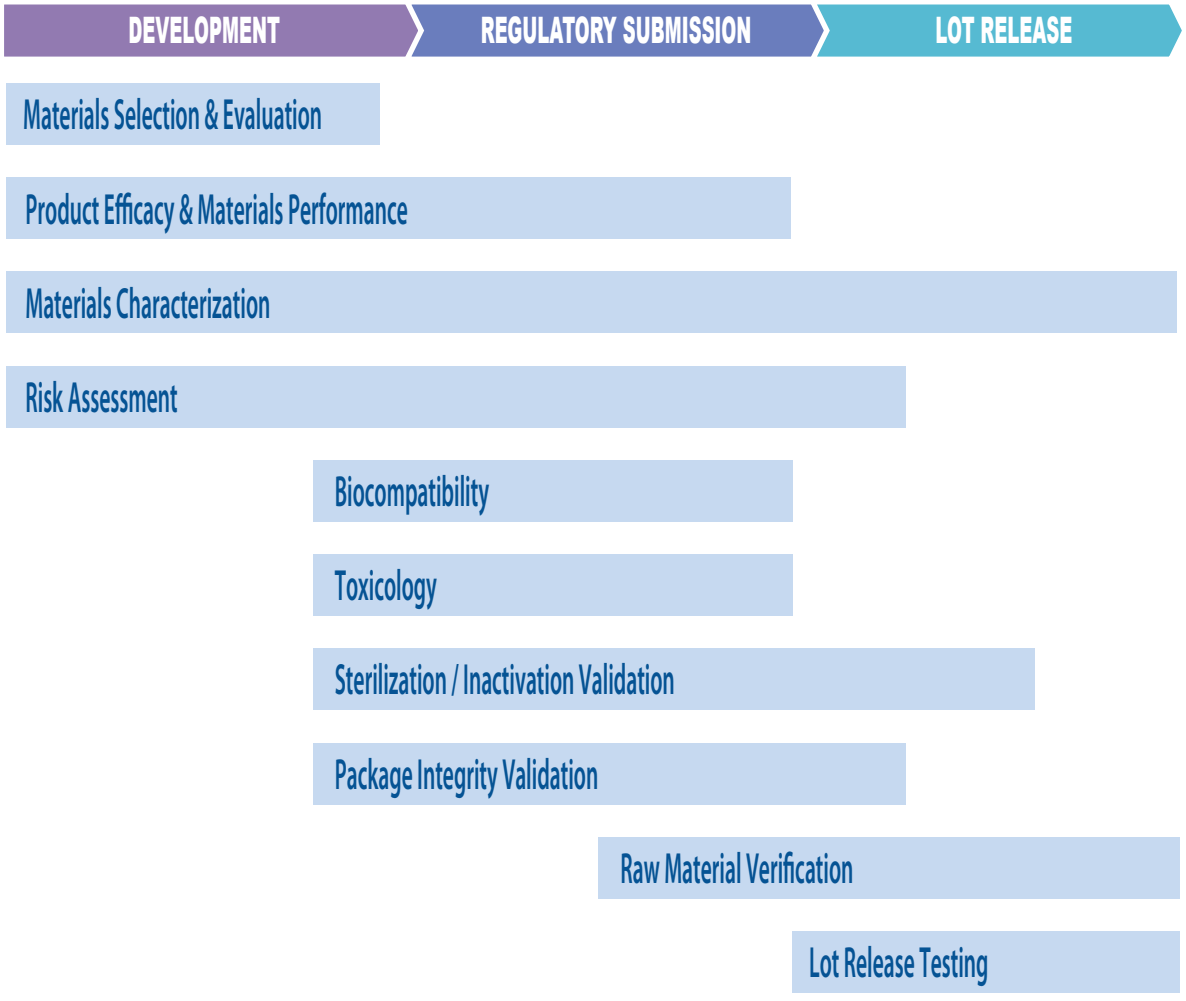
Testing and expertise from concept to commercialization

药明康德
WuXi AppTec

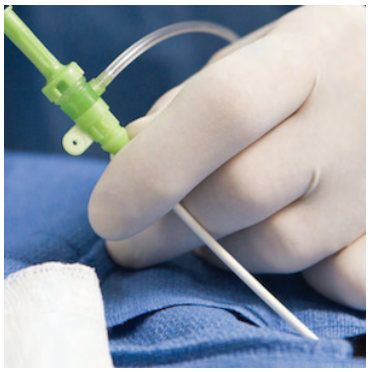
Expert Solutions for Product Development

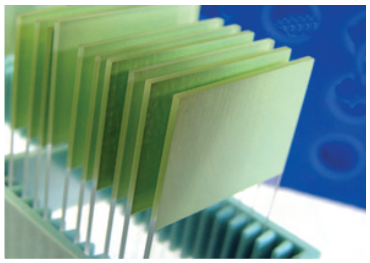
WuXi AppTec's comprehensive testing programs and expert guidance help speed devices and combination products to market. Our industry-recognized experts offer manufacturers the support they need to make smart development and regulatory testing decisions – from product concept through commercial release. And our wide menu of R&D, GLP- and GMP-compliant testing programs can be tailored to suit particular needs at every stage of product development.

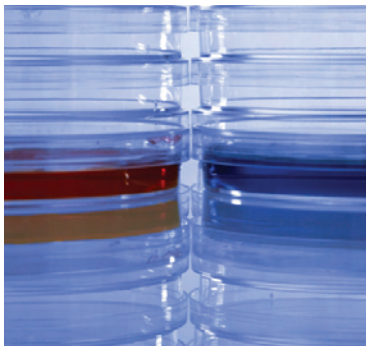
# expert guidance and comprehensive testing



# R&D, GLP- and GMP-compliant testing programs







## MATERIALS SELECTION & EVALUATION

WuXi AppTec provides screening assays – from basic chemical analysis to in-vitro models – to provide preliminary data estimating the safety and efficacy of your product.

## PRODUCT EFFICACY & MATERIALS PERFORMANCE

Advanced surgical skills are used in innovative testing programs, as well as established antimicrobial and orthobiologic efficacy and wound healing studies.

## MATERIALS CHARACTERIZATION

Quantitative analytical methods can be tailored to determine the extractable and leachable compounds present in your product, supporting R&D and submission efforts.

## RISK ASSESSMENT

Highly experienced staff toxicologists will help you interpret and link your *in-vitro* and *in-vivo* biocompatibility assays and chemistry testing to ensure the clearest interpretation of risk assessment.

## BIOCOMPATIBILITY

A comprehensive menu of *in-vivo*, *in-vitro* and genotoxicology testing services includes all the tests related to the ISO/FDA test modalities frequently used to study the biological safety and biocompatibility of devices and combination products, as well as tests that may be required for Japanese (JMHLW) submissions and other regulatory submissions worldwide.

## TOXICOLOGY

Our toxicology programs are specially developed to accurately assess the toxicological questions presented by medical devices and combination products. Specialized dose regimens are available, including surgical implantation in a variety of species.

## STERILIZATION / INACTIVATION VALIDATION

Our scientists can develop and perform sterilization validations to prove the efficacy of your sterilization methods. A selection of methods is available, with service levels ranging from standalone testing services to total management of your validation.

## PACKAGE INTEGRITY VALIDATION

Quantitative analytical methods can be tailored to determine the extractable and leachable compounds present in your product, supporting R&D and submission efforts.

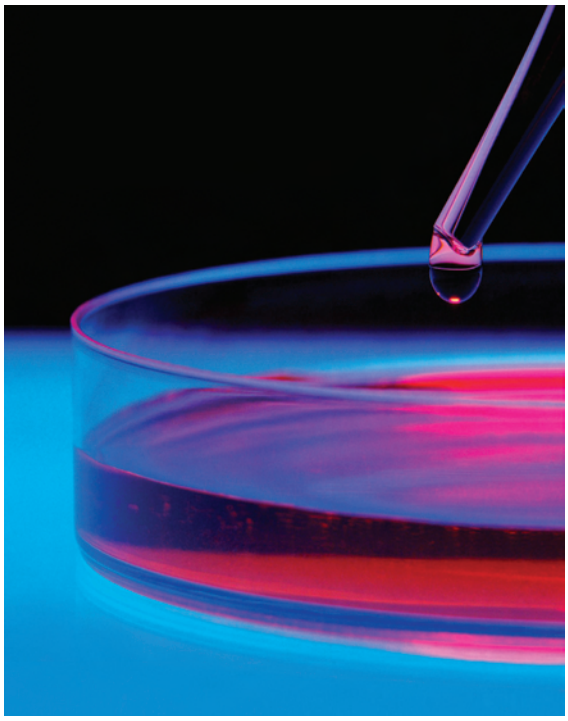
## RAW MATERIAL VERIFICATION

Analytical methods – including elemental analysis through ICP, FTIR fingerprinting, and liquid or gas chromatography – can be used to screen the materials coming into your processes, as well as provide critical characterization data for your regulatory submissions.

## LOT RELEASE TESTING

A full range of lot release testing services – from bacteriostasis/fungistasis to sterility and endotoxin testing – is available to provide reassurance and proof that your processes are reliable and sound.

# Services for Medical Devices



*Expert guidance and a wide range of testing solutions help you navigate your product development requirements – from concept to commercialization and beyond.*

## EXPERTISE

WuXi AppTec's many years of experience in developing and excuting testing programs for medical devices – including innovative and complex products – has made us a leader in the field.

We understand fully how important it is to select the right testing scheme – from the very beginning of product development – and we work with your design team to help ensure successful regulatory submission.

## EXPERIENCE

Specialized programs are offered for all types of devices and combination products. Our extensive experience includes providing comprehensive services in numerous product areas, including:

- Implants
- Stents
- Orthopedics
- Wound care
- Uterine devices
- Suture material
- Drug delivery
- Human cells
- Cellular products
- Tissue-based devices
- Re-usable devices
- Single-use devices
- Endoscopic devices
- Cardiovascular devices
- Natural products
- Anti-infectives

LEARN MORE

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