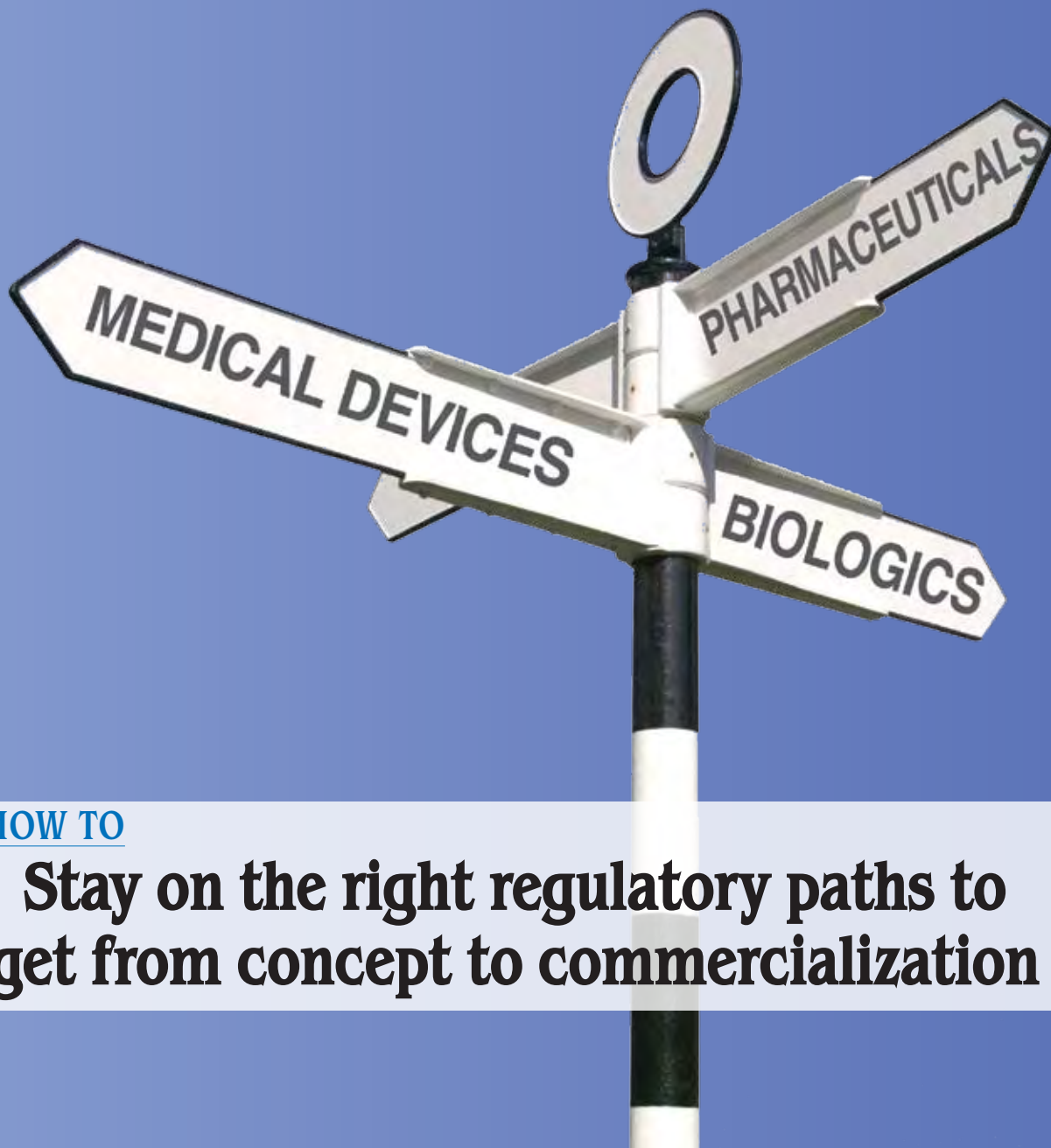


# Combination Product Services



## HOW TO

**Stay on the right regulatory paths to get from concept to commercialization**



The Leader in Combination Product Services



# Services for Combination Products

*Expert guidance to help you choose the right testing path for regulatory approval*

**W**uXi AppTec is the global leader in combination product services (CPS) – unmatched in our ability to offer clients an alignment of expertise that comes from 20 years of superior testing and manufacturing services for medical devices, tissue products, biologics and pharmaceuticals.

As convergence of these products accelerates, WuXi AppTec is uniquely positioned, with specialized programs and our years of experience, to provide the services – and guidance – manufacturers require.



## COMPREHENSIVE SERVICES

WuXi AppTec's broad range of testing services covers safety, claims and efficacy testing and includes the following:

### Safety Testing Capabilities

- ▶ Biocompatibility
- ▶ Toxicology
- ▶ Materials Evaluation
- ▶ Stability Storage & Analytical Testing
- ▶ Sterilization Validation
- ▶ Microbial Contamination
- ▶ Packaging Integrity
- ▶ Pathologic Tissue Analysis
- ▶ Identification & Quantitation of Agent Distribution

### Efficacy Testing Capabilities

- ▶ Model Development
- ▶ Device / Drug Infection Models
- ▶ Device-Delivered Drug Response
- ▶ Device-Delivered Nanoparticle
- ▶ Collagen Bioabsorption
- ▶ Efficacy of a Device-Delivered Drug (Insulin, Antibacterial)
- ▶ Bone Defect
- ▶ Spinal Fusion
- ▶ Chronic Inflammation Reaction
- ▶ Biodistribution



Navigating through complex testing options can be daunting for many manufacturers as combination products may require the knowledgeable application of guidances for devices, biologics/tissue and/or pharmaceuticals. Knowing which choices to make and what the regulatory bodies expect can mean the difference between staying on course for product development and having to re-route and re-do testing.

WuXi AppTec, with our exceptional expertise, can work with your design team to provide guidance in determining the most appropriate microbiology, safety and efficacy programs to bring your product from research to proof-of-concept to commercial launch.

## TESTING CONSIDERATIONS

	COMBINATION PRODUCTS		
	PHARMACEUTICALS	DEVICES	BIOLOGICS & TISSUE
	REGULATORY PATHS <i>Including: IDE • NDA • IND • 510K • PMA • BLA • CE Mark</i>		
<b>Product Characterization / Chemistry</b>	Analytical	Extractable / Leachable	Bioanalytical
<b>Efficacy / Performance</b>	Clinical & Non Clinical - <i>In vitro</i> - <i>In vivo</i>	Clinical & Non Clinical - <i>In vitro</i> - <i>In vivo</i>	Clinical & Non Clinical - <i>In vitro</i> - <i>In vivo</i>
<b>Safety</b>	Toxicology	Biocompatibility	Biosafety
<b>Microbial Contamination</b>	Microbial limits/enumeration Microbial IDs Endotoxin	Bioburden Microbial IDs Endotoxin	Microbial enumeration/bioburden Microbial IDs Endotoxin Mycoplasma Bacterial clearance/inactivation
<b>Sterility</b>	USP sterility Sterile fill process validation	Sterilization process validation Product/BI sterility	Aseptic processing validation 21 CFR 610.12 sterility
<b>Viral Contamination</b>	<i>Not Applicable</i>	<i>Not Applicable</i>	Virus screening Viral clearance/inactivation
<b>Package Characterization / Validation</b>	Packaging material selection, microbial barrier, interaction	Packaging material selection, microbial barrier, interaction	Packaging material selection, microbial barrier, interaction
<b>Package Integrity</b>	Package integrity validation – shelf life / expiration / closure integrity / simulated distribution	Package integrity validation – accelerated aging / simulated distribution / seal integrity	Package integrity validation – shelf life / expiration / closure integrity / simulated distribution
<b>Stability</b>	Molecular stability	Aging / Expiration	Shelf life Forced degradation
<b>Clinical</b>	Scope / Design Study Management		
<b>Compliance</b>	Gap Analysis Risk Assessment Regulatory Submission		

NOTE: This chart is not an all-encompassing list of testing options and is not designed to serve as the outline for a specific testing program.

# Combination Product Services (CPS)

## EXPERTISE

WuXi AppTec's many years of experience in applying testing schemes to complex products has made us a leader in the field. In recognition of our expertise, WuXi AppTec scientists actively participate in and advise regulatory groups responsible for the testing guidances.

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 combination products. Our extensive experience includes providing comprehensive services in these selected product areas:

Implants	Vaccines
Stents	Human cells
Orthopedics	Cellular products
Wound care	Monoclonals
Catheters / Leads	Natural products
Uterine devices	Analgesics
Suture material	Anti-infectives
Drug delivery	Anti-inflammatories
Gene therapy products	



The Leader in Combination Product Services



Contact WuXi AppTec to discuss your combination product:

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