



LifeScience Alley™

# Welcome to the 6<sup>th</sup> Annual LifeScience Alley Conference and Expo!

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## What are “combination” products?

A product comprised of two or more regulated components,

i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic,

that are physically, chemically, or otherwise combined or mixed and produced as a single entity



## Examples of recently approved Combination Products

- Absorbable Collagen Sponge With Genetically Engineered Human Protein
- Dermal Collagen Implants For Aesthetic Use
- Exubera, inhaled powder form of insulin (rDNA)
- FluMist™ Influenza Virus Vaccine, Live, Intranasal
- Glucose Monitor / Insulin Pump
- Paclitaxel-Eluting Coronary Stent System
- Peginterferon Alfa-2a in combination with Ribavirin
- Spinal Fusion Putty
- Surgical Mesh With Antibiotic Coating

- Approximately 30% of new products under development are “combo products”
  - Medical devices embedded with pharmaceutical or biologics components.
  - The convergence of drugs/biologics and devices also brings a host of regulatory challenges to manufacturers

- The combination products market is estimated at \$5.9B in 2004, and will continue to grow at a compound annual rate of 10% through 2009.
- By 2009, the market is expected to reach approximately \$9.5B worldwide
  - Primarily drug-eluting stents and steroid-eluting electrodes



## ***AppTec Platform***

*Unique, integrated single source provider of  
development, manufacturing and testing services  
for biopharmaceutical and medical device  
companies worldwide*

# The Strategy

## Development

Process Development / Scale up

Custom Assay Development

Custom Lot Release Assay Design

Animal Model Development

Biologic Cell Line Construction

Medical Device Performance and Evaluation

## Testing

Biocompatibility

Toxicology

Histopathology

Custom Lot Release

Cell Line Characterization

Viral Clearance Validation

Sterilization Validation

Chemistry / Microbiology

Stability / Package

## Manufacturing

Monoclonal Antibodies

Therapeutic Proteins

Cellular Therapeutics

Tissue based Medical Devices

Vaccines



# Markets



Medical Devices

Tissue Based Medical Devices

Cellular Therapeutics

Gene Therapy Products

Recombinant Proteins

Monoclonal Antibodies

Vaccines