

Risk Management of Combination Products

WCC PDA September 2011



Drug + Device = Combination Product

Biologic + Device = Combination Product

Drug + Biologic = Combination Product

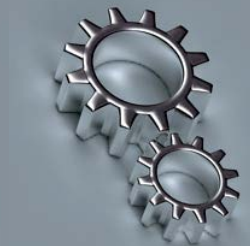
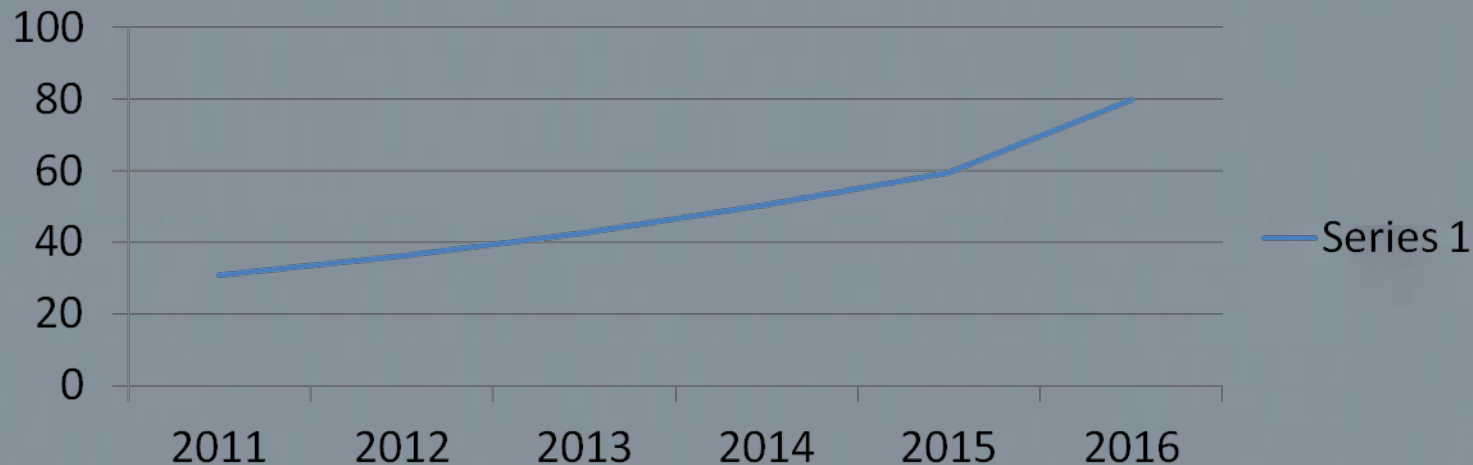
Drug + Diagnostic = Combination Product

This presentation does not represent the views and opinions of Novartis Vaccines and Diagnostics, Inc. This presentation represents my own views and opinions.



Opportunities in Combination Products

- The number of combination drug delivery systems has increased significantly in the past decade with more growth expected to come.



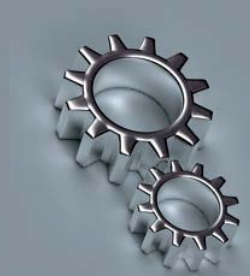
Benefits of Combination Products

- Targeted delivery
- Patient comfort/compliance
- Portfolio development
- Reduced product development risk



Case Study

- Lidocaine
 - Well characterized
 - Used by medical professionals all over the world daily.
 - Lidocaine creams are available OTC
- Then marry it with a needle-free injector or transdermal patch and what do you have?
- Is it truly a product with reduced risk?



- In 2008, a local firm initiated a recall for their needle-free delivery system as the product may not deliver the full dose as indicated.
- In 2009, the FDA issued a public health advisory regarding the use of certain transdermal patches which contain metallic backings which could overheat during an MRI scan and cause skin burns.

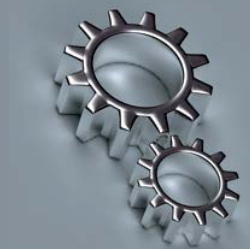


Risk Analysis is not a snapshot in time



Extension of Risk Management Program

- Change Management
- Investigations
- Post-market Review



What is required for success?

- Depth and breadth of product knowledge
- Leverage strength of individual contributors
- Fully implemented Risk Management program

