

# **Biologics and Biosimilars**

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# Objectives



# Biologics – a definition

**Biological medicines are derived or** manufactured from a living biological system. They include hormones (e.g. insulin), enzymes (to speedup chemical reactions), blood factors (to regulate clotting), antibodies (to support the immune system), vaccines and advanced therapies (such as cell, gene and tissue therapy products).



### What is a Biological Product?

- · Biological products, or biologics, are medical products.
- Biological products could be made of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues.
- · Like drugs, biological products are used to either:
  - treat or cure diseases and medical conditions,
  - prevent diseases, or
  - diagnose diseases
- Biological products are made from a variety of natural sources.



U.S. Food and Drug Administration Protecting and Promoting Public Health www.fda.gov



Mammalian cell-culture



Bacteria



Insect cell-culture



Source Materials





Avian cell-culture





Transgenics



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# **Biologic manufacturing**



# **Biologic manufacturing**





#### Red Velvet Cake Recipe

1/2 c. Crisce 2 eggs 11sp. conta 11/2 c. sugar 11sp. salt 11sp. salt 21/4 c. flour 1350, boking sada 1350, vitreger 1360 the red food colar 14, butternillk

#### Directions:

In a large mixing bowl mix together the Crisco, eggs, corna, sugar, and solt. Add varnina and internulls. Them add the flour and red food coloring. In a separatic howl, mix together the baking solda and vinegar. Add this mixture to the rest of the mixed ingredients and mix together. Once everything is combined, separate the baking redients and nixe together. Once everything is combined a separate the batter into two round cake pans and bake for 30 mimute at 350 degrees. Let the cakes coel completely, then add frosting to the top of one. Add the second cake on top of the iced bottom cake and add frosting to the whole cake. Refrigerate and enjoy!



### From research to approval







### Other agents are available......









# Biosimilar – a definition

 A biosimilar is a biological medicine that is developed to be similar to an approved biological medicine (the'originator' biological medicine) and can only be marketed after the patent and data exclusivity period has expired.

# Biosimilars

 Manufacturers of biosimilars are required to demonstrate that there are no clinically meaningful differences between the biosimilar and originator biological medicine in terms of safety, quality and efficacy.

# Biosimilar

 As its name suggests, a biosimilar is not an exact copy of its originator biological medicine due to its complex molecular structure and unique manufacturing process.

### WHAT ARE BIOSIMILARS?



## **Biosimilar manufacturing**





Originator manufacturing process changes are the basis for biosimilarity goal posts.





### Biosimilar

### No clinical trials process



### Questions raised by biosimilars







# **Biosimilar debate**

# Q. How is the safety of biological medicines, including biosimilars, monitored?

**A.** As with all medicines once biological medicines, including biosimilars, are approved, safety is closely monitored through a process called 'pharmacovigilance'.

All biological medicines, including biosimilars, are monitored according to the EU Pharmacovigilance legislation. In addition, national competent authorities have to ensure that for the purpose of reporting suspected adverse reactions, biological medicines, including biosimilars, that are prescribed, dispensed or sold in theirterritory can be clearly identified.

Given the complexity of biological medicines and the fact that products from different manufacturers are similar but not identical; product-level traceability (i.e. collection of brand name and batch number) is especially important for suspected adverse reaction reporting.

#### WHY ARE BIOSIMILARS IMPORTANT?

Biologics can treat patients with cancer, chronic kidney disease and autoimmune diseases, such as rheumatoid arthritis and inflammatory bowel disease



The availability of biosimilars is expected to lower the costs of these critical biologic medicines.

# Conclusion -The great debate









# Thank you for listening

Any questions ?

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