BIOSIMILARS
— A Podcast Series —

The New Era of Management in Gastroenterology and Rheumatology

Development of Biosimilars

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Learning Objective	Podcast Discussion Summary
Distill the Immense Amount of R&D That Occurs to Develop Biosimilars	After target identification, the molecule is synthesized. It undergoes rigorous analytical testing to establish a comprehensive understanding of the similarity of the biosimilar to the reference product. Preclinical studies are then conducted in various laboratory and animal models to assess safety, toxicity, pharmacokinetics (think absorption, distribution, metabolism, and excretion) and pharmacodynamics (which boil down to the effects on the body). After that, clinical studies take place in human subjects. These studies include PK & PD evaluations to demonstrate that the proposed biosimilar moves through the body in the same way and provides the same effect.
Articulate the Biosimilar Manufacturing Process	The first step is cell line development, which involves selecting a suitable cell line capable of producing the target biosimilar protein. Once the cell line is established, it is cultured and expanded in bioreactors under controlled conditions. This allows the cells to multiply and produce the desired protein through the process of fermentation. After the fermentation period, the cell culture is harvested. The harvested cell culture undergoes a series of purification steps to isolate and purify the biosimilar protein. Once the biosimilar protein has been purified and characterized, it is formulated to optimize stability and compatibility for its intended use.
Explain How Biosimilars Are Named	The structure consists of a prefix, substem A, substem B, and mab at the end. The prefix is chosen randomly to help us be able to pronounce the word. Substem A specifies the target of the antibody, such as an interleukin or tumor, while substem B specifies the sequence from which the monoclonal antibody was derived, like a mouse or human. A mab is placed at the end to signify the molecule is a monoclonal antibody. Like the biosimilar core name, there actually is a framework for the suffix or letters you see attached at the end. The reason these suffixes are needed is because unlike generic copies of non-biologic, small-molecule drugs, biosimilars are not exactly the same as the original or reference product. Because the process by which a biologic is produced is proprietary and the molecules are complex, biosimilars are expected to have minor differences when compared with the reference product, despite being highly similar with no clinically meaningful differences.

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