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How Biosimilars are Affecting the Pharmaceutical Industry

Honey Nut Cheerios™ or Honey Nut Tasteeos®? Glad® Trash Bags or Walmart's Great Value™ brand? Aleve® or CVS Health Ibuprofen™? Most of us are familiar with knock-off brands or so-called generics in our day-to-day shopping, but we also see them in the drug industry. When we get a prescription from our doctor, many have the option to get a lower cost alternative of the same drug. Once a drug comes off patent, the pharmaceutical industry has the ability to manufacture and sell a replicate of the innovator drug. For small molecule drugs, that process is streamlined due to the ability to make identical copies of the active pharmaceutical ingredient (API). However, it isn't as easy with biosimilars.

A biosimilar (also known as follow-on biologic or subsequent entry biologic) is a biologic medical product that is almost an identical copy of an original product that is manufactured by a different company. Unfortunately, with large molecule drugs it is impossible to make an identical copy of the innovator drug. This poses a challenge for companies to get their biosimilar product approved as quickly as a small molecule.

Following the footsteps of the Hatch-Waxman Act and introduced in 2009 by the Obama administration, the Biologics Price Competition and Innovation Act (Biosimilars Act or BPCI Act) initiated a faster FDA approval process for biosimilars that show interchangeability.

Biosimilars are a hot topic in the pharmaceutical world with many companies investing significant resources into producing the next iteration of a drug.

For biosimilars to get approved,the company must demonstrate comparability, or similarity, to the innovator biologic. This requirement includes structural analyses, functional assays, animal data, and clinical studies. At the core of these investigations is an intensive structural characterization of the new biologic. The characterization analyses includes identification of primary structures, higher order structures, enzymatic post translational modifications, other potential variations, and intentional chemical modifications. The reason such a large emphasis is placed on characterization is because of the downstream implications in safety, efficacy, and immunogenicity.

Recently, my colleagues and I collaborated on an article for Chromatography Today that explains the importance of chromatographic analysis on higher order structure of biosimilars using ion exchange chromatography and size exclusion chromatography.

These particular methods are critical for identifying charge variants and aggregation, respectively. Although it is just two pieces of the complex characterization requirements, they are arguably the most important when assessing the recombinant generation and formulation of biosimilar products. At the end of the day, the conclusion of the comparability studies should indicate that the biosimilar has the same effecton a human, just as expected for small molecule generics.

Find our full article on these studies here:

https://www.chromatographytoday.com/article/bioanalytical/40/phenomenex-bv/the-higher-order-structure-analysis-of-biosimilars-using-iex-and-sec/2467

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Summary

Article Name

Biosimilars, Generic Drugs, and the Pharmaceutical Industry

Description

Chad Eichman, PhD, takes a look into the world of generic drugs and how they are working with biosimilars in correlation with the FDA and generic drugs.

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