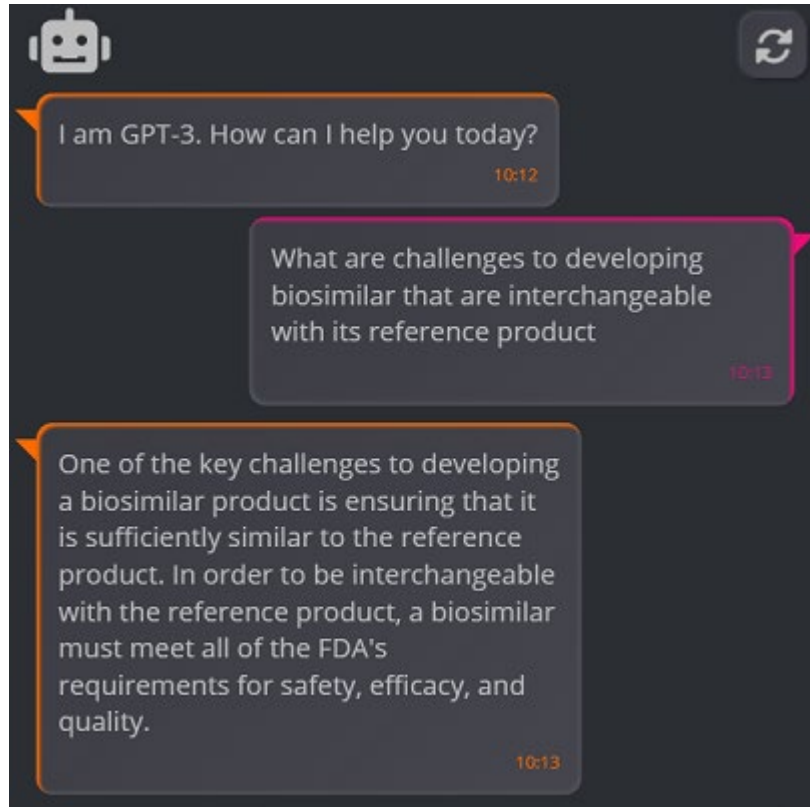


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What are the FDA requirements for safety and efficacy

10:13

The FDA requires biosimilar products to demonstrate safety and efficacy in order to be approved for marketing. In order to demonstrate safety, a biosimilar must show that it is unlikely to cause any unexpected or dangerous side effects. To demonstrate efficacy, a biosimilar must show that it is as effective as the reference product in treating the intended condition.

10:13

This is English poppy talk-explain in FDA terms

10:14

The FDA requires that all drugs be shown to be safe and effective before they can be marketed.

10:14

What does FDA expect for quality

10:14

The FDA has specific expectations for the quality of biosimilar products. In order to be approved for marketing, a biosimilar must meet all of the FDA's quality requirements.

10:14

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