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True or False?

The FDA regulates the introduction of new drugs and enforces U.S. drug laws. - Answer-True

True or False?

Pharma companies must submit extensive data to the FDA demonstrating the safety and effectiveness of new drugs before receiving approval for sale. - Answer-True

What is the average review time for a new drug? - Answer-18 months

Sales Team (pg 7) - Answer-Pg 7

What is considered the "engine of innovation," focused on discovering or inventing promising new product? - Answer-Research & Development (R&D)

What includes the supply chain, manufacturing, trade, and distribution functions of the business? - Answer-Manufacturing & Operations

True or False?

In 2012, FDA regulators approved 39 new drugs for use in the U.S. - Answer-True

True or False?

3,070 new meds are in development for cancer. - Answer-True

Define "Off-label" - Answer-Usage of a medication for purposes other than the specific ones appearing on the label

Define "Toxicity" - Answer-The extent, quality, or degree to which a substance is poisonous or harmful to the body

What is the Institutional review Board (IRB)? - Answer-A committee of physicians, statisticians, community advocates, and others which ensure that a clinical trial is ethical and that the rights of the study participants are protected. "All clinical trials must be approved by an IRB before they begin".

Napsr Exam Study Guide

Anthony S. Fauci



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