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Webinar on

Drug Product Performance, In Vivo: Bioavailability And Bioequivalence

Learning Objectives

- *To introduce the basic concepts of bioavailability and bioequivalence*
- *To show how bioavailability and bioequivalence can be related to drug product performance, in vivo*
- *To discuss how bioavailability and bioequivalence principles may be used in drug product development*

This webinar will be of interest to scientists and managers in the pharmaceutical industry, regulators and other pharmaceutical scientists

PRESENTED BY:

Leon Shargel, Ph.D., R.Ph., is Manager and Founder of Applied Biopharmaceutics LLC, a pharmaceutical consulting company and holds academic appointments as Affiliate Professor, School of Pharmacy, Virginia Commonwealth University. Prior to forming his own company, Dr. Shargel was Vice President, Biopharmaceutics, Sandoz (formerly, Eon Labs).

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

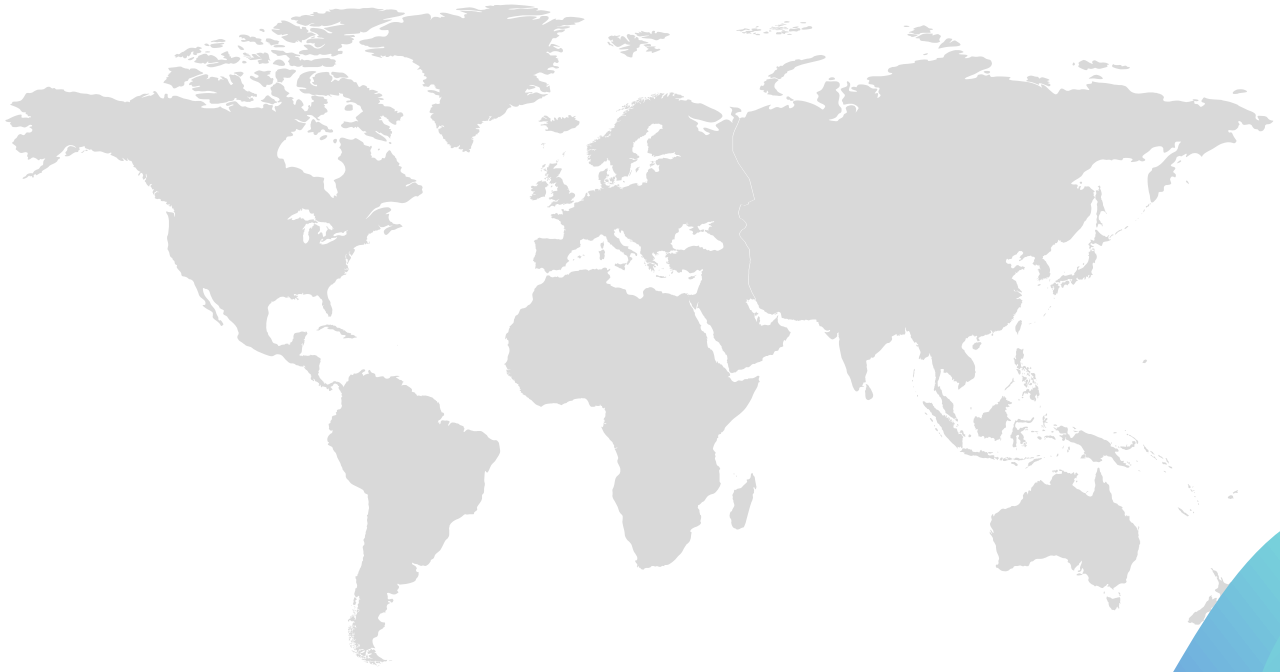
Webinar Description

Drug product performance, in vivo, is defined as the release of the drug substance from the drug product leading to the bioavailability of the drug. The evaluation of drug product performance relates bioavailability to the therapeutic response and adverse events. Bioavailability and bioequivalence studies are measurements of drug product performance and can be used to evaluate new drug formulations, changes in drug formulations and development of generic drug products.

Who Should Attend ?

This webinar will be of interest to scientists and managers in the pharmaceutical industry, regulators and other pharmaceutical scientists who want to learn more about the pharmacokinetics of systemic drug absorption and its applications to the development of oral dosage forms.

Pharma (brand) and generic drug companies, faculty and students in the department of pharmaceutical sciences, at various colleges of pharmacy.



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Topic Background

Drug product performance and drug product quality, Absolute and relative bioavailability

Bioavailability and bioequivalence as measures of in vivo drug product performance

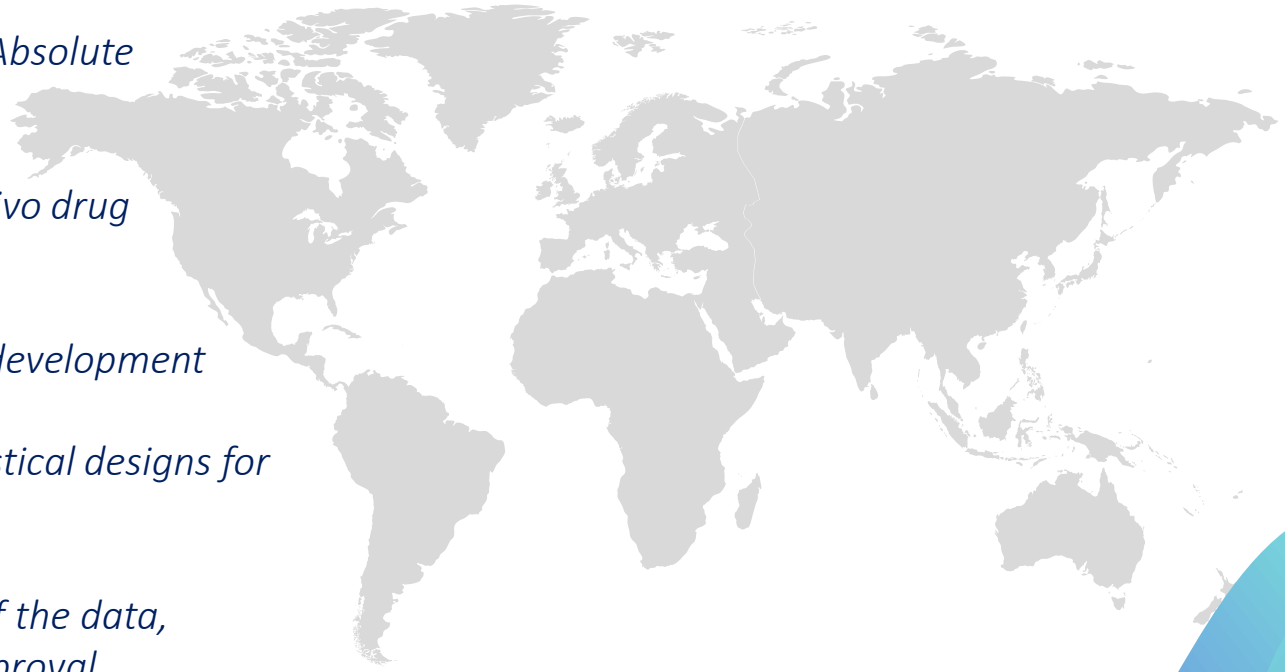
Bioequivalence studies in new drug and generic drug development

Methods for the measurement of bioavailability, Statistical designs for bioequivalence studies

Statistical criteria for bioequivalence and evaluation of the data, Therapeutic equivalence and generic drug product approval

Biowaivers and rationale for not to performing bioequivalence studies, Scale up and post-approval studies (SUPAC)

Issues in demonstrating bioequivalence for specialized drug substances and drug products



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