

Webinar on

Adverse Event Reporting Rules For Drugs, Dietary Supplements & Cosmetics

Learning Objectives

Background to FDA Serious Adverse Event reporting regulations

Understand how to define a Serious Adverse Event

Learn what products are covered and what changes are coming

Understand specific SAE reporting and recordkeeping requirements and information

Changes that are coming for Cosmetics with the Personal Care Products Safety Act

It will also cover what to expect regarding reporting changes for Cosmetics when the Personal Care Products Safety Act is passed.

PRESENTED BY:

Norma Skolnik has over 35 years of regulatory experience working with the pharmaceutical and dietary supplement industries. She served as Director of Regulatory Affairs for the Americas for Cadbury Adams. Prior to that, she was Director of Regulatory Affairs for the Adams Division of Pfizer and Associate Director of Regulatory Affairs for the Warner-Lambert company.

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

Webinar Description

This event will cover everything you need to know about how to Define a Serious Adverse Event and FDA's Serious Adverse Event (SAE) reporting requirements for OTC Drugs, Cosmetics and Dietary Supplements. It will also cover what to expect regarding reporting changes for Cosmetics when the Personal Care Products Safety Act is passed.

All OTC drugs and Dietary Supplements are required to report Serious Adverse Events to FDA. When the Personal Care Products Safety Act becomes law, Cosmetics will also have to report Adverse Events to FDA. It's essential that companies understand how to define and report a Serious Adverse event and what labeling and recordkeeping regulations are required under the Dietary Supplement & OTC Drug Consumer Protection Act.



Who Should Attend ?

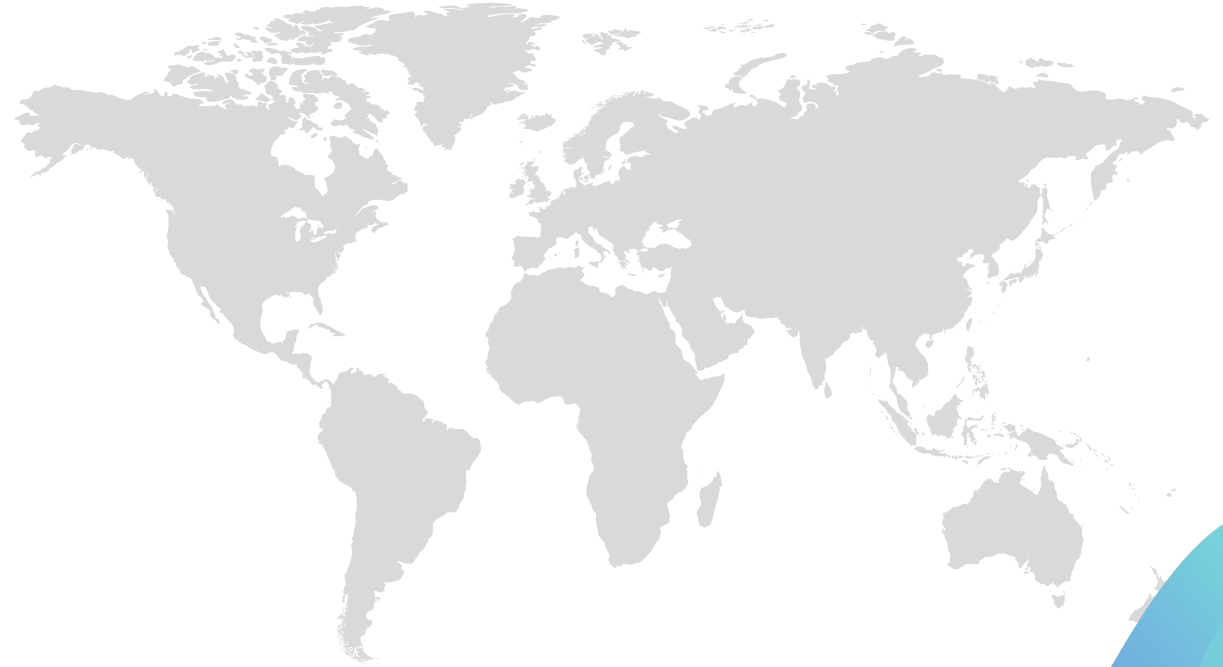
Regulatory Affairs managers and associates at drug, Supplement or Cosmetic firms

Quality Assurance managers at drug, Supplement or Cosmetic firms

Consumer Affairs managers & representatives

Marketing managers in Drug, Supplement or Cosmetic industries

Safety managers



To register please visit:

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