

Program Preview

Overview of the FDA

Responsibilities of the FDA and its impact on the drug approval and marketing process

Drug Development Process

Preclinical and phase 1-3 clinical studies

NDA's & BLA's

New Drug & Biological License Applications; Priority Review versus Standard Review

Patents & Generic Drugs

Patent life of a new drug; how generic drugs are approved; the Orange Book and its common usage

Review & Access Programs

Accelerated Approval, Fast Track, Parallel Track and Treatment INDs

Phase 4 Studies

Phase 4 post-marketing surveillance

Post-Marketing Surveillance

PMS system, its purpose and functions; MedWatch, its purpose and functions

DDMAC

Purpose and functions of the Division of Drug Marketing, Advertising & Communications

Direct-to-Consumer (DTC) Advertising

Over-the-Counter Products

FDA's role in regulating these products

Orders:

Please contact the Illuminate order line

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FDA Fundamentals

The Food and Drug Administration (FDA) is responsible for approving and monitoring all drugs, biologics and medical devices in the United States. Understanding the unique language and role of the FDA is critical to your sales representatives' success:

- The FDA's decisions, programs, and processes greatly affect sales representatives' everyday marketing and sales efforts.
- Appreciating how the FDA works enables sales representatives to understand their business and communicate more confidently with customers, other health professionals and colleagues.

The **FDA Fundamentals** learning program is designed to meet these specific training and information needs of your sales professionals.

Description	Subjects	Goals	Next Steps
expanded controlled clinical studies	several hundred to several thousand patients	<ul style="list-style-type: none"> acquire effectiveness and safety data evaluate overall benefit-risk relationship provide basis for generalizing study results 	<ul style="list-style-type: none"> positive results NDA is submitted to FDA

Why This is Important to You!

- Phase 1 clinical studies provide information that is found in the Pharmacokinetics section of a Package Insert (PI) They also provide some information about adverse effects that may be found in the PI.
- You may be given phase 2 studies that have been FDA-approved for use in detailing Phase 2 studies often deal with dosing and adverse effects.
- Phase 3 studies may be documented in the clinical studies section of your product's PI, as well as in other areas of the PI.
- Your company will probably have some of the phase 3 clinical studies approved for use in detailing. These clinical studies have a large number of patients and typically show statistically or clinically significant results.
- Remember, you can only use studies your company has given you in your calls; these have been approved for use in detailing by the FDA.

The Why This is Important to You! feature helps representatives understand how the information in each lesson relates directly to them.

Both new and experienced sales representatives can benefit from this program. It is designed to deliver maximum learning in the minimum amount of time and it can be completed in under an hour.

A 25-question **Challenge** is provided to assess each representative's understanding of the program's learning objectives. Results can be sent to management for tracking, or the Challenge content can be incorporated into your company's learning management system (LMS) for online testing and management.

The **FDA Fundamentals** program can be integrated immediately into your sales training efforts, or can be tailored to address specific company or product training needs.