GRC Online Training Hub
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Webinar on

4 Essential Webinars On FDA's Project Management And Documentation

Webinar Description

This bundle of webinars will address approaches to regulatory affairs project management, marketing authorization applications and ongoing management of regulatory obligations. The webinars will also cover batch record review and product release documentation and Breakthrough Therapy Designation, SAE reporting requirements for OTC Drugs, Cosmetics and Dietary Supplements and labeling and recordkeeping regulations.

The webinar format is 1-1.5 hours of audio-visual presentation, including a brief Q&A session.

This webinar bundle includes below 4 recorded webinars:

Adverse Event Reporting Rules for Drugs, Dietary Supplements & Cosmetics

How Successfully Apply for a Breakthrough Therapy Designation

Batch Record Review and Product Release

Regulatory Affairs Project Management

Adverse Event Reporting Rules for Drugs, Dietary Supplements & Cosmetics

Presented by Norma Skolnik

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.

How Successfully Apply for a Breakthrough Therapy Designation

Presented by Carolyn Troiano

The Breakthrough Therapy Designation (BTD) is perhaps one of the most impactful incentives from the FDA as it helps get the product to market much faster than any other expedited approval pathway. Once a drug is successful in getting the BTD, the non-clinical and clinical requirements for market approval are significantly reduced. The applicants can request special meetings with FDA to discuss the development steps and become eligible for priority review. However, getting a BTD is not easy; there is about 70% rejection rate for applicants of BTD; the success of BTD award depends a lot on the disease targeted and the product being developed, and BTD request requires significant resources from the applicant.

Batch Record Review and Product Release

Presented by Danielle DeLucy, MS,

Most Regulatory Agencies require firms to have written procedures in place to document production and process controls, better known as batch records. Additionally, there must be written procedures for a batch record review process that demonstrate compliance. A strong batch record review system is essential in order to properly document all critical processing parameters that go along with the production and manufacture of pharmaceuticals, biologics, medical devices, etc.

Regulatory Affairs Project Management

Presented by Peggy J. Berry, MBA, RAC

This program will address approaches to regulatory affairs project management for clinical trial applications, marketing authorization applications, and ongoing management of regulatory obligations. The information obtained will enable effective management and tracking of time and resources to complete the project objectives and ensure regulatory compliance.

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