When, How and Why to File a Drug Master File (DMF)

Location: Your Computer  Offering #  1410-707  Priority Code: 520

WHO SHOULD ATTEND

This online training will be of great benefit to regulatory compliance professionals working on DMF, NDA, IND or ANDAs. Regulatory affairs professionals, attorneys, project managers, and management professionals in small and mid-size manufacture operations are also encouraged to attend.

LEARNING OBJECTIVES

Upon completion of this training, you will be able to:

• Determine when and why a DMF can or should be filed
• Explain the basic elements of a DMF
• List the user fees and describe the impact of compliance issues

COURSE DESCRIPTION

This 90-minute accredited training is designed to provide a complete understanding of the purpose of a Drug Master File and how it is used by FDA. Included will be a discussion of the user fees, why to file, the elements that need to be included in the DMF, and how to update or change that information. There will also be a discussion of when and how a DMF is reviewed and how that review can impact an NDA or ANDA that has a reference letter.

Review of Learning Objectives
Module 1:
• What is a DMF
• FDA Expectations and Guide to Inspections
• Types of DMFs

Module 2:
• Types of DMFs (continued)
• Fees
• Needed Elements
• Duplicate Filings

Module 3:
• Approved/Disapproved?
• Authorizing Reference
• Updating
• Guidelines
  – DMF for Industry
  – DMF for Bulk Antibiotic Drug Substances

Question and Answer Session

TUITION AND REGISTRATION

TUITION* – Single Rate: U.S.$295.00 per person  Group Rate: U.S.$245.00 per person**


For Questions and Information call Customer Service at 732-613-4500.

Please Note: Multiple participants are not authorized to share access provided to a single registrant; a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

System Requirements: PC-based attendees: Windows® 7, Vista, XP or 2003 Server/Macintosh®-based attendees: Mac OS® X 10.4.11 (Tiger®) or newer

For more information see reverse side
COURSE DIRECTOR

Gary L. Yingling, Esq., Senior Counsel, Morgan, Lewis & Bockius

Gary Yingling is Senior Counsel in the Washington, DC office of Morgan, Lewis & Bockius. His practice focuses on regulatory and legal issues concerning food, drugs, medical devices and cosmetics working with the FDA, USDA Food Safety Inspection service and various states. His work has ranged from ingredient safety questions, preparing INDs, to product labeling with particular interest in clinical research/contract research organization/sponsor matters.

Former president of the Food and Drug Law Institute and Director of the Over-the-Counter (OTC) Drug Review, Mr. Yingling received FDA’s Award of Merit, the agency’s highest award, for his legal and administrative work on the OTC Review. He is a registered pharmacist in Maryland and the District of Columbia.

Mr. Yingling earned a B.S. degree in Pharmacy from the University of North Carolina, a M.S. degree from Purdue University, and his J.D. from Emory University. His court admissions are to the US District Court for the District of Columbia and the US Supreme Court. He is co-author of the Guide to Good Clinical Practice.

ACCREDITATIONS

The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500 McLean, VA 22102. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. The Center for Professional Advancement is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEU will be awarded for participation in The Center for Professional Advancement’s courses at the rate of .1 CEU per contact hour. CEU will be awarded only upon successful completion of the entire course and 70% accuracy in the required Learner’s Assessment.

WHO WE ARE

The Center for Professional Advancement (CIPA) is the largest accredited technical training organization in the world with a curriculum of approximately four hundred and fifty short courses in 15 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. CIPA courses are offered in a variety of formats – Public offering, Client Site and Online – to fit you or your company’s training needs.

For more information visit our website at www.cfpa.com

COURSES OF INTEREST

• Building the eCTD for FDA Submission course ID# 2466
• CMC Writing and Submission Strategies: A Global Regulatory Approach course ID# 1989
• FDA Drug Approval, Regulation and Compliance course ID# 587

• Generic Drug Approvals course ID# 1462
• INDs/NDAs/CTDs course ID# 448
• Pharmaceutical Process Development course ID# 1358

ABOUT ON-DEMAND:

Our pre-recorded on-line training courses are available for viewing at your convenience at your computer. Register for a CIPA on-demand course, your registration will be processed within two (2) business days, after payment and registration are complete you will receive an email from onlinetraining@cfpa.com with your password to access the on-demand course. You will have two (2) business days to view the course. You MUST complete all polls and the course evaluation to receive your accreditation certificate for this course.

TERMS AND CONDITIONS

*Payment: Tuition payable in US funds net of all charges. Payment is due at time of registration in the form of a credit card. Please contact CIPA’s Customer Service for other payment options.

**Group Rate: The Group Rate is for two or more enrollments, up to five registering from the same company at the same time. For groups of six or more, please contact Customer Service for group pricing.

Cancellations/No Show: “Live” - Registrants may cancel up to two working days prior to the course start date and will receive a letter of credit to be used towards a future course up to one year from date of issuance. No credit will be issued for no-shows and/or cancellations less than two working days prior to the course. “On-Demand” - No refund or credit will be issued for no-shows and/or cancellations of on-demand training courses. CIPA is not responsible for any outside related costs incurred by registrant’s cancellation.