



CfPA

The Center for Professional Advancement
Accredited Technical Training Worldwide
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ON-DEMAND Online Training Course

The cGTP in a Nutshell

Location: Your Computer
Priority Code: 520

Offering # 0711-718

WHO SHOULD ATTEND

This online training will benefit professionals in the following industries: Human Tissue Processors, and Medical Device manufacturers where human tissue is used as a component.

In departments such as: QA/QC/RA, Manufacturing/Operations, Research and Development, Distribution, Legal

With job functions: Department managers and supervisors, QA/QC/RA specialists and engineers, Manufacturing and R&D engineers, chemists, scientists, formulators, documentation specialists, auditors, technicians

LEARNING OBJECTIVES

Participants will gain an understanding of the requirements of the cGTPs and will learn key concepts essential for the deployment and smooth continuous operation of a cGTP compliant Quality Program. Specifically, they will be able to answer the following:

- "What" is a Quality Program?
- "What" are the Core Requirements of a Quality Program?
- "What" general controls do I need to implement to fulfill the Core Requirements?
- "What" is "aseptic processing"?
- "How" do I determine what specific controls are right for my organization?
- "How" do I implement these controls?
- "How" do I control the processing environment?
- "How" do I control Suppliers? Processing partners? Labeling, Storage? Distribution?
- "When" do I need to validate processes? Software? Cleaning?
- "When" do I need to qualify equipment?

COURSE DESCRIPTION

The release of the Current Tissue Practice Regulation in 2005 represented a watershed change for the Human Tissue Industry and for other FDA regulated industries where human tissue is used as a component. This course is intended to provide training in the nuts and bolts of this landmark regulation.

Module 1:

- Introduction: The Big Picture: 21 CFR Part 1271, Subparts A through E
- Subpart D, the sixteen subsections of the cGTPs
- The Core Requirements
- Comparison with the cGMPs (pharma) and the QSRs (medical devices)

Module 2:

- What is a Quality Assurance Program? What does it do?
- What are the Personnel requirements? Procedure requirements?
- What about my Facility? Environmental Controls?
- Equipment: what are my requirements?
- Processing and Processing Controls
- Controls for Supplies and Reagents
- Recovery Controls

Module 3:

- Processing and Processing Controls. What about Process Changes?
- Labeling Controls
- Storage Controls
- Receipt, Pre-distribution Shipment and Distribution requirements
- Control of Records
- Tracking requirements
- Complaint File

COURSE DIRECTOR

Michael Patrick Barile, founder and Managing Partner of the consulting firm, Barile & Associates

ACCREDITATIONS



The Center for Professional Advancement has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, 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. As a result of their Authorized Provider membership status, The Center for Professional Advancement is authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards.

Other Accreditations: ACPE, AATB, ASQ (See website for details)

REGISTRATION

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

Register at www.cfpa.com. Enter **Course Offering #0711-718** into **Quick Jump**. To register use **Priority Code: 520**.

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.

ABOUT ON-DEMAND:

Our pre-recorded on-line training courses are available for viewing at your convenience at your computer. Register for a CfPA 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 olinettraining@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 CfPA'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. CfPA is not responsible for any outside related costs incurred by registrant's cancellation.