



# Equipment Qualification in a Nutshell

Location: Your Computer

Offering # 0710-715

Priority Code: 520

## WHO SHOULD ATTEND

This online training will benefit professionals in the following industries:

Medical Device, Pharmaceutical, Human Tissue, Biotechnology

In departments such as:

QA/QC/RA, Manufacturing/Operation, Research and Development, 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 of this course will learn key concepts essential for the qualification of equipment used during the manufacture of medical devices and pharmaceutical, biotechnology or human tissue products. Specifically, they will be able to explain:

- "Why" equipment must be formally qualified
- "When" equipment must be formally qualified
- "What" equipment qualification is and how to plan and prepare for it
- "How" to write and execute qualification protocols
- "How" to document and deal with deviations
- "How" to document and deal with deviations
- "How" to write qualification reports
- "How" to maintain the "qualified state"

## COURSE DESCRIPTION

Equipment Qualification has come under intense scrutiny by the FDA in recent years. This course will examine the current industry/FDA environment and will give you tools for survival; it will provide a step-by-step guide to planning and preparing for equipment qualification and includes a discussion of how to write qualification protocols, handle deviations, report qualification reports and "maintain the qualified state". Further, this course provides "content understanding" so important for auditing qualification activities as required in today's FDA regulated industry environment.

### Module 1:

- Background-Regulatory Requirements
- Why do I need to qualify equipment?
- What is equipment qualification?

### Module 2:

- Qualification Basics
- Protocol Basics

### Module 3:

- Handling Deviations
- Qualification Reports
- When do I need to do all this?
- How do I "maintain the qualified state" and what does that mean, anyway?

## 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.

## REGISTRATION

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

Register at [www.cfpa.com](http://www.cfpa.com). Enter **Course Offering #0710-715** 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 [olinetraining@cfpa.com](mailto:olinetraining@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.