



CfPA

The Center for Professional Advancement
Accredited Technical Training Worldwide
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On Demand Online Training Course – FIRST in a Two-Part Series

Best Practices in SAS Statistical Programming for Regulatory Submission: Understanding and Applying the QC Plan to Validate Summary Tables

Maximize learning and minimize expense: Register for both parts and save \$100 OR take either as a stand-alone course.

Location: Your Computer

Offering # 0805-704

Priority Code: 520

WHO SHOULD ATTEND

This course is intended for anyone directly or indirectly responsible for the creation, content or validation of summary tables, data lists and graphs used to support research, drug or medical device efficacy and safety in a regulatory submission. Professionals in the pharmaceutical, biotechnology and medical device industries who want to be 21 CFR Part 11 compliant with effective and practical solutions to address real-world issues will benefit from this unique course.

- SAS Statistical Programmers
- Critical Path personnel
- SAS Statistical Managers
- Statisticians
- Clinical Data Managers
- Quality Assurance Specialists
- Medical Writers
- Regulatory Affairs Associates
- Director, Statistical Programming

LEARNING OBJECTIVES

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

- Help prevent unexpected setbacks
- Apply proven strategies for effective validation
- Use SAS utility macros to validate summary tables

COURSE DESCRIPTION

This **intense** 90-minute online course focuses on the validation process to assure that correct, consistent and reliable summary tables are reproducible. Discussions will focus on proven techniques to address real-world issues. Get your SAS technical and validation questions answered and learn efficient tips for producing a quality regulatory submission in a timely manner.

Module 1:

Analysis of potential setbacks

- Identify potential delays and setbacks when creating and validating summary tables
- Develop plans to address these potential problems

Module 2:

Developing a strategy in the QC Plan

- Understand the three levels of checks performed: Self, QC, & External QA
- Develop a game plan for risk-management validation

Module 3:

Effective methods and SAS macros to validate summary tables

- Understand the advantages of selected SAS procedures for validating tables
- Apply SAS macros to standardize the validation process

COURSE DIRECTOR

Sunil Gupta, Associate Director, Statistical Programming, Quintiles Inc., International SAS Expert, Speaker, Trainer and Author

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****
(Attend both parts and SAVE \$100! Tuition for entire series– Single Rate: U.S. \$490.00 Group Rate: U.S. \$390.00)

Register at www.cfpa.com. Enter **Course Offering #0805-704** 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.

OTHER PARTS IN THIS SERIES:

Part 2: Best Practices in SAS Statistical Programming for Regulatory Submission: Creating Publication-Quality Summary Tables (Offering # 0805-406)

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 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.