



CfPA

The Center for Professional Advancement
Accredited Technical Training Worldwide
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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.

Day: Tuesday, April 22, 2008 Time: 11:00 a.m. - 12:30 p.m. (EST–New York time)

Location: Your Computer Offering # 0804-407 • Priority Code: 520 (Available On-Demand starting 05/06/08)

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- US \$395.00* Attend both parts and SAVE \$100!** Tuition for entire series- US \$690.00

Register at www.cfpa.com. Enter **Course Offering #0804-407** into **Quick Jump**.

Begin registration by entering **Priority Code: 520**. For Questions and Information call Customer Service at 732-613-4500.

OTHER PARTS IN THIS SERIES:

Part 2: Best Practices in SAS Statistical Programming for Regulatory Submission:

Creating Publication-Quality Summary Tables (Offering # 0805-406) Live 5/20/08; available On-Demand starting 6/3/08

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.

**To qualify for the \$100 savings you must register for both parts at the same time. Note: Only one discount per course is permitted. Savings/discounts may not be combined.

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.