

Registration Form

Course Offering # **1109-501**

Best Practices in SAS Statistical Programming for Regulatory Submission

September 26–27, 2011 • Burlingame, CA

Priority Code: **520**
(Please use this code when registering)

Dr. Mr. Ms. _____
First Name Last Name

Job Title _____

Company/Institution _____

Company Address _____

City _____ State _____ Zip _____

Tel _____ Fax _____

E-mail Address _____

(Required in order to send confirmation material. CfPA does not rent or sell e-mail addresses)

Note: Please complete separate form for each registrant.

Tuition and Payment Methods

Early Registration (Save \$200)
(Must register and pay by August 1, 2011)

U.S. \$ **1450** / \$ **1380**
Single Rate Group Rate*

Regular Registration

U.S. \$ **1650** / \$ **1580**
Single Rate Group Rate*

Tuition payable in US funds net of all charges includes continental breakfast, luncheon, breaks and course notes.

*Group Rate is per person, for two or more enrollments registering at the same time, from the same company, for the same course.

Note: Payment is due before course start date.

Send Invoice/Bill Me Purchase Order # (If Required) _____

Check (payable in U.S. funds to The Center for Professional Advancement)

Credit Card Visa MasterCard American Express Discover

Card # _____ Exp. Date _____

Cardholder Name _____
(As appears on card)

Signature _____ Security code _____
(3 or 4 digit code)

Credit card billing address (if different than above address)

3 Ways To Register

- Internet: www.cfpa.com
- Fax registration form to: **732.238.9113**
- Mail registration form to:

The Center for Professional Advancement (CfPA)
P.O. Box 7077
East Brunswick, NJ 08816-7077

General Information

Payment: Tuition payable in US funds net of all charges. Payment is due BEFORE course start date. If payment has not been received two weeks before the course, a credit card will be required to guarantee registration.

Discounts/Rates: To receive the Early Registration Discount, payment is required at time of registration and/or BEFORE early registration discount expires or the regular tuition rate will apply. If choosing invoice/check/wire transfer, payment must be received prior to expiration of early registration discount or the regular tuition rate will apply. All tuition prices are a per person rate. To qualify for the Group Rate tuition, registration must be for two or more enrollments registering at the same time, from the same company, for the same course. Multiple discounts not applicable.

Cancellations/Substitutions/FEES: ALL cancellations, refunds and credits are subject to a \$150.00 processing fee. Applicants may cancel up to four (4) weeks prior to the course start date for a refund. Applicants that cancel less than four (4) weeks prior to the course will be issued a credit that can be used towards a future course up to one year from the date of issuance. No refunds or credit will be issued for those who cancel less than ten (10) working days before the course start date and/or do not attend the scheduled course. Substitutions are permitted at any time. If for any reason, CfPA decides to cancel this course, we are not responsible for airfare, hotel or other costs incurred by the registrant. Program content, schedule and instructors are subject to change without notice.

Confirmation Letters: Before each course begins, all registrants will receive written confirmation including detailed information regarding course location – VIA EMAIL. If confirmation is not received two weeks prior to the course please contact Customer Service.

For questions/more information contact Customer Service at 732-613-4500 or info@cfpa.com

Our full terms and conditions can be found on our website at www.cfpa.com

Courses of Interest

- **Early Stage Clinical Studies for Drugs and Devices**
course id# 2118
- **Laboratory Analysis in Clinical Trials**
course id# 2137
- **INDs/NDAs/CTDs**
course id# 448
- **CMC Submissions in CTD Format**
course id# 1989
- **Analytical Methods Validation for FDA Compliance**
course id# 1887
- **Preparation, Packaging and Labeling of Clinical Trial Materials**
course id# 858

Who We Are

The **Center for Professional Advancement (CfPA)** is the largest accredited technical training organization in the world with a curriculum of approximately 350 short courses in 18 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. CfPA courses are offered in a variety of formats – Public offering, Client Site and Online – to fit you or your company's training needs.

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. CEUs will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal training and a minimum score of 70% on the assessment.

SAVE \$200-Register & Pay by Aug 1

September 26–27, 2011
Burlingame, CA

Best Practices in SAS Statistical Programming for Regulatory Submission

Course Topics Include:

- Validation of Summary Tables
- Analysis of Potential Setbacks
- Anatomy of SAS Macros, Proc Report, ODS and RTF Control Words
- Programming Standards and Conventions for Improved Productivity
- Edit Check and Exception Reporting Macros

Directed by:

Sunil Gupta

Senior SAS Consultant
Gupta Programming



CfPA

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Accredited Technical Training Worldwide

The Center for Professional Advancement

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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 in relation to the SAS programming environment will benefit from this unique course. Effective technical and practical solutions to address real-world issues will be provided.

This course is recommended for:

- SAS Statistical Programmers
- SAS Statistical Managers
- Director, Statistical Programming
- Statisticians
- Clinical Data Managers
- Quality Assurance Specialists
- Medical Writers
- Regulatory Affairs Associates
- CRO Professionals
- Health Care Professionals
- Research Universities

Learning Objectives

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

- Identify SAS programming areas to enforce 21 CFR Part 11 requirements
- Help prevent unexpected setbacks from incorrect SAS programming or from data issues
- Apply proven strategies for effective SAS validation, programming, and documenting of summary tables
- Use SAS utility macros to validate and produce publication-quality summary tables

Course Description

This **intense** two-day course focuses on the validation process to assure that correct, consistent and reliable summary tables are reproducible. In addition, a variety of effective methods for producing standard and custom summary tables will be provided. SAS data sets used in the course are CDISC ready. 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. Students will receive a CD containing all tools and SAS macros reviewed in the course.

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COURSE OUTLINE

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First Day

8:00 a.m.: Registration/Continental Breakfast

Review of Learning Objectives
Understanding and Applying the QC Plan to Validate Summary Tables

8:30–10:15 a.m.:

Overview of Regulatory Submission Processes and SAS Techniques:

- US Code of Federal Regulations (CFR) Title 21 Part 11 requirements and terms
- Review of Required Standard Operating Procedures (SOPs)
- Meeting FDA Submission Expectations
- FDA Submission Process Flow
- Ten General Categories of Submission Issues

10:30–12:00 noon:

Analysis of Potential Setbacks

- Sample Clinical Study – SAS Data sets, Summary Table
- Identifying potential delays and setbacks when creating and validating summary tables
- Developing plans to address these potential problems

1:00–2:00 p.m.:

Developing a Strategy in the QC Plan

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

2:00–3:00 p.m.:

Creating the Required Documentations for Effective Impact

- Completing validation excel file for summary table SAS program
- Completing validation excel file for STDM analysis data set

3:15–4:00 p.m.:

Effective Methods and SAS Macros to Validate Summary Tables

- Classifying the advantages of selected SAS procedures for validating tables
- Applying SAS macros to standardize the validation process
- Using SAS Enterprise Guide tasks to validate summary tables

4:00–4:30 p.m.:

Tips and Techniques for SAS Validation

- Tips for validating Lists and Graphs
- Tips for SAS Macro Testing

4:30–4:45 p.m.:

Programming Standards and Conventions for Improved Productivity

- Software Development Life Cycle (SDLC) for accurate, reliable, and validated results
- Directory Path Structure for better file organization
- Important information in the Program Header of all SAS programs
- Anatomy of a SAS Application Program

Second Day

Creating Publication–Quality Summary Tables

8:30–10:15 am:

Overview

- Using the Program Index (PI) excel file to manage summary tables
- From PI, extract metadata information for summary tables
- Six-Sigma techniques, KPIs and Metrics for maximum performance

10:30–12:00 noon:

Process Flow for Developing Summary Tables

- Preparing the data structure and variables

- Extracting descriptive statistics using SAS's Output Delivery System
- Assembling and summarizing reporting SAS data set

1:00–2:00 p.m.:

Effective Methods and SAS Macros to Create Summary Tables

- Summarizing the benefits of effective methods for creating tables
- Effective techniques for creating standard macros
- Applying CDISC compatible SAS macros
- Planning for other useful techniques: zero-fill, break text, and blank-table

2:00–3:00 p.m.:

Anatomy of Proc Report, ODS and RTF Control Words

- Customization and flexibility with Proc Report and ODS
- Standardization with SAS's Style Definitions
- Inserting RTF Control Words in SAS programs and Table Templates

3:15–4:00 p.m.:

Edit Check and Exception Reporting Macros

- Three levels of standards for Clinical Data Quality and Compliance Checks: General, CDISC standard domain, and protocol compliance
- Compare and Conquer SAS: Proc Compare, Proc Means, and Proc Transpose
- Power and flexibility of Proc SQL and Proc Tabulate for queries and validation
- Data integrity with edit checks as PDF file
- Easier to read SAS code that would traditionally be lengthy

Assessment Opportunity

www.cfpa.com

Client Site

Training at your site and at your convenience. For further information, please contact **Client Site** Programs: Direct Dial (USA) +1/732.238.1600, ext. 4547; or fax +1/732.238.9113; or **E-mail** clientsite@cfpa.com.

Online Training Now Available

A convenient and cost-effective way to experience our accredited training, easily access the knowledge you need through the Internet. For a list of upcoming courses visit www.cfpa.com/online-training.

Course Director

Sunil Gupta, Senior Consultant, Gupta Programming, is a well known author, international SAS expert, speaker and consultant in the pharmaceutical industry for over 18 years. He has project management and hands-on programming experience of over eight successful FDA submissions with major pharmaceutical companies including Amgen, Pfizer and Isis Pharmaceuticals. Mr. Gupta has written the following popular books on SAS: *Quick Results with SAS e-Guides*, *Quick Results with the Output Delivery System*, *Sharpening Your SAS Skills*, and *Data Management and Reporting Made Easy with SAS Learning Edition 2.0*. In 2008, Mr. Gupta was selected as one of the top 100 Notable People in the Medical Device Industry. Mr. Gupta has over 50 SAS technical and industry-related publications.

Recommended Reading

The Course Director recommends the following texts: *Sharpening Your SAS Skills* by Sunil Gupta and Curt Edmonds, Chapman & Hall 2005.

Quick Results with the Output Delivery System by Sunil Gupta, SAS Publishing 2006.

SAS Programming in the Pharmaceutical Industry by Jack Shostak, SAS Publishing 2005.

Five Quick Results with SAS e-Guides - Quick Results with Proc SQL, Quick Results with Proc Report, Quick Results with Proc Tabulate, Compare and Conquer SAS Programming Techniques, and Anatomy of SAS Macros (a \$75 value included with class registration)

Course Location

This course will be held at the **Hilton SF Airport Hotel** in **Burlingame, California**. Participants must make their own reservations; the cost of hotel accommodation is not included in the course fee. Hotel information will be included with your acceptance. For reservations call 650.340.8500.

"The class will help me implement new standards immediately and will aid in creating a programming environment where planning and validation are integral in developing submission tables and listings sufficient for regulatory review and audits. Sunil's course was a pleasure to take."

- C.W., Biostatistic Supervisor, Tolmar Inc.