

Registration Form

Offering # **0910-405**

Best Practices in SAS Statistical Programming for Regulatory Submission

19–20 October 2009 • Hoofddorp, The Netherlands

Priority Code:
(Please use this code when registering)

Dr./Mr./Ms. _____
Surname Given Name

Job Title _____

Company/Organization _____

Department/Mail Code _____

Mailing Address _____

Postal Code _____ City _____ Country _____

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 24 August 2009)

U.S. \$ **1640** / \$ **1560**

Regular Registration

U.S. \$ **1840** / \$ **1760**

Tuition payable in US funds net of all charges includes 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

Purchase Order # _____
(If Required)

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

Bank Transfer (Pay by Bank Transfer to Account No. 62.62.46.628 (US\$) at ABN-AMRO Bank N.V., Postbus 2078, 1000 CB Amsterdam, The Netherlands. The course Offering # (above) and participant's name must be included on bank transfer.)

Credit Card

Visa MasterCard American Express Discover

Card # _____ Exp. Date _____

Cardholder Name _____

Signature _____

3 Ways To Register

- Internet: www.cfpa.com
- Fax registration form to: +31.20.620.21.36
- Mail registration form to:

The Center for Professional Advancement (CfPA)
Oudezijds Voorburgwal 316A
1012 GM Amsterdam, The Netherlands

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 are subject to a \$150.00 processing fee. Applicants may cancel up to two weeks prior to the course start date for a refund. If less than two weeks, a credit will be issued 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 do not attend the scheduled course and/or cancel less than two working days before the start date. 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 those requiring visas, confirmation letters will not be sent until payment is received.

Please note: **English** will be used in all lectures and course notes.

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/NDA/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)**, 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.

SAVE \$200-Register & Pay by 24 Aug

19–20 October 2009
Hoofddorp, The Netherlands



Best Practices in SAS Statistical Programming for Regulatory Submission

Course Topics Include:

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

Directed by:

Sunil Gupta

Director, Statistical Programming
Quintiles Inc.

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 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's
- 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

08.00: Registration

Understanding and Applying the QC Plan to Validate Summary Tables

08.30–10.15: 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: 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

13.00-14.00: Developing a Strategy in the QC Plan

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

14.00-15.00: 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

15.15-16.00: 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

16.00-16.30: Tips and Techniques for SAS Validation

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

Second Day

Creating Publication–Quality Summary Tables

08.30–10.15: Overview

- Using the Program Index (PI) excel file to manage summary tables
- From PI, extract metadata information for summary tables

10.30-12.00: 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

13.00-14.00: 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

14.00-15.00: 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

15.15-16.00: Edit Check and Exception Reporting Macros

- Three levels of standards for Clinical Data Quality and Compliance Checks: General, CDISC standard domain, and protocol compliance
- Data integrity with edit checks as PDF file
- Focus on generating output instead of writing SAS code
- Easier to read SAS code that would traditionally be lengthy
- Power and flexibility of Proc SQL for queries and validation
- Conditional execution based on existing data set, variable and records

16.00-16.30: 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

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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. 4549; or fax +1/732.238.9113; or **E-mail** clientsite@cfpa.com.

Online Training Now Available

A NEW 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, Director, Statistical Programming, Quintiles Inc. Quintiles is one of the world's largest contract research organizations. Most recently, he was selected as a Subject Matter Expert for the new Edit Check Design Principles chapter in the Good Clinical Data Management Practices document. In addition, Mr. Gupta is also one of the top 100 Notable People in the Medical Device Industry in 2008. Mr. Gupta is also a well known author, international SAS expert, speaker and consultant in the pharmaceutical industry for over 15 years. He has project management and hands-on experience of over eight successful FDA submissions and has written the following three books on SAS: *Quick Results with the Output Delivery System*, *Sharpening Your SAS Skills*, and *Data Management and Reporting Made Easy with SAS Learning Edition 2.0*. 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.

Data Management and Reporting Made Easy with SAS Learning Edition 2.0 by Sunil Gupta, SAS Publishing 2006.

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

Validating Clinical Trial Data Reporting with SAS by Carol Matthews and Brian Shilling, SAS Publishing 2008.

Course Location

This course will be held at the **Courtyard by Marriott–Amsterdam Airport**. The hotel is holding a limited block of rooms at a reduced rate for course participants. To obtain the preferred rate, you must inform the hotel that you are registering for this course. To ensure accommodations, reservations must be made at least four weeks prior to the course.

Courtyard by Marriott–Amsterdam Airport

Bosweg 15
2131 LX Hoofddorp, NL
Phone: +31/23/556.9000 • Fax: +31/23/556.9009

Past Participants Have Said...

"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.*