

# Effective Clinical Data Acceptance Testing

**Location:** Your Computer **Offering #** 0903-701 **Priority Code:** 520

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## WHO SHOULD ATTEND

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This course is intended for anyone directly or indirectly responsible for the creation, content or validation of summary data sets, tables, and data lists 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.

- SAS Statistical Programmers
- Medical Writers
- Clinical Data Managers
- Health Care Professionals
- Quality Assurance Specialists
- Statisticians
- Directors of Statistical Programming
- Research University Professionals
- SAS Statistical Managers
- Regulatory Affairs Associates
- CRO's

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## LEARNING OBJECTIVES

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

- Identify and prevent unexpected data issues
- Apply proven strategies for effective communication and documentation of results
- Use methods to monitor improvements in data quality

In addition, you will be able to run SAS macros to display data values for clinical data and protocol issues.

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## COURSE DESCRIPTION

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This **intense** 90-minute accredited online course focuses on isolating and cleaning data issues to assure that correct, consistent and reliable analysis data sets 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 accepting and locking the clinical study data base in a timely manner. Selected edit check macros and acceptance testing guide are included in the course.

### **Module 1: Analysis of Clinical Data Issues:**

- Identifying and quantifying the impact of bad clinical data
- Establishing protocol criteria for clinical data acceptance testing
- Checking for data compliance at all three levels: general, CDISC domain, and study protocol specific

### **Module 2: Effective Methods and SAS Macros to Identify Data Issues:**

- Developing and testing edit check macros
- Applying standard edit check macro parameters

### **Module 3: Communicating and Monitoring Improvements in Clinical Data Issues :**

- Timely and effective communication of results with Clinical Data Management
- Managing metrics on clinical data acceptance testing for quicker data base lock

**Question and Answer**

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## TUITION AND REGISTRATION

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**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 #0903-701** 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.

For more information see reverse side ➡



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## COURSE DIRECTOR

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

Sunil Gupta has been an Independent Consultant since July 1994. He became a SAS Institute Quality Partner the following year. In 2000, he became a SAS Certified Professional V6 and in 2003 he passed the SAS Base Programmer Certification exam. During his 14 years experience in the Biomedical, Pharmaceutical, Biotech and Sales & Marketing Industries, Mr. Gupta has been in management and project lead positions. He understands how business functions and how to work together as a team member to achieve results.

Mr. Gupta has developed and taught many topics related to SAS skills and has done numerous presentations and workshops at SUGI, Regional and Local SAS User Groups meetings. Most recently, Sunil was honored to be one of the top 100 notable people in the Medical Device Industry for 2008. In 2006, he released his third SAS book titled "Data Management and Reporting Made Easy with SAS Learning Edition 2.0".

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## ACCREDITATIONS

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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.

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## WHO WE ARE

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The Center for Professional Advancement (CFPA) is the largest accredited technical training organization in the world with a curriculum of approximately three hundred and fifty 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

For more information visit our website at [www.cfpa.com](http://www.cfpa.com)

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## COURSES OF INTEREST

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- **21 CFR Part 11: Strategies for Cost Effective Compliance Using a Risk-based Approach–An Online Course**  
course id# 2225
- **Best Practices in SAS Statistical Programming for Regulatory Submission–An Intense 2-Day Course**  
course id# 2234
- **Best Practices in SAS Statistical Programming for Regulatory Submission: Creating Publication-Quality Summary Tables (SECOND in a Two-Part Series)–An Online Course**  
course id# 2214
- **Best Practices in SAS Statistical Programming for Regulatory Submission: Understanding and Applying the QC Plan to Validate Summary Tables (FIRST in a Two-Part Series) –An Online Course**  
course id# 2213
- **Clinical Testing Process–An Online Course**  
course id# 2271
- **Clinical Testing Submissions–An Online Course**  
course id# 2272
- **Computerized Systems Used in Clinical Investigations: The New FDA Guidance–An Online Course**  
course id# 2184
- **Good Clinical Practices (GCP)**  
course id# 107
- **INDs/NDAs/CTDs**  
course id# 448

### 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.

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## TERMS AND CONDITIONS

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**\*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.