Gupta Programming
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New!

Best Practices in SAS® Statistical Programming for Regulatory Submission

COURSE DESCRIPTION and INFORMATION

Purpose: This two-day hands-on course provides a good overview to meet the regulatory submission deadlines, to develop a clinical reporting system for producing publication-quality summary tables, data lists, and graphs, and to show how to validate throughout the process. Get your SAS technical and validation questions answered and learn efficient tips for producing a quality regulatory submission in a timely manner.

Audience: 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 will benefit from this course. This course is ideal for SAS Statistical Programmers and Managers, Statisticians, Clinical Data Managers, Quality Assurance Specialists, Medical Writers, and Regulatory Affairs associates.

Course Prerequisite: This course requires knowledge of SAS/BASE, SAS MACRO, PROC SQL, PROC REPORT and ODS. In addition, students are expected to have at least six months experience in developing and validating summary tables and data lists in the pharmaceutical industry. They should also have a good understanding of the clinical trials process and the regulatory environment.

Instructor: Sunil Gupta is a well known author, speaker and consultant in the pharmaceutical industry. He has project management and hands-on experience of over eight successful FDA submissions and has written three books on SAS.

TWO DAY OUTLINE

Day 1 – Understanding the environment and setting the stage

- Chapter 1: Regulatory Environment: Requirements, Standards and Clinical Data
  - Section 1: US Code of Federal Regulations (CFR) Title 21 Part 11 requirements
  - Section 2: Creating the required documentations for effective impact
  - Section 3: FDA expectations and QA Audits
  - Section 4: Clinical data flow and structure

- Chapter 2: Overview of Regulatory Processes and SAS Techniques
  - Section 1: About this Course

- Section 2: Process for creating and validating output
- Section 3: Various techniques to address requirements
- Section 4: Sample Clinical Study – Summary Table, Data Lists, Graph
- Section 5: Analysis of potential set backs

- Chapter 3: Understanding and Applying the QC Plan
  - Section 1: Differences between Quality Control and Reviewer/Quality Assurance
  - Section 2: Applying methods to validate programs from QC Plan
  - Section 3: Completing tasks with Validation Documentation

Day 2 - Producing Summary Tables, Data Lists and Graphs

- Chapter 4: Programming standards, conventions and training for improved productivity
  - Section 1: Program Index and Directory Structure for better organization
  - Section 2: Software Development Life Cycle (SDLC) for accurate, reliable, and validated results
  - Section 3: Information in the Program Header
  - Section 4: Anatomy of a SAS Application Program

- Chapter 5: Creating Summary Tables, Data Lists, and Graphs
  - Section 1: Developing Summary Tables
  - Section 2: Developing Data Lists
  - Section 3: Developing Graphs
  - Section 4: Clinical Trials Reporting Templates

- Chapter 6. Identifying data-related issues using edit checks and validation macros
  - Section 1: Focus on generating output instead of writing SAS code
  - Section 2: Easier to read SAS code that would traditionally be lengthy
  - Section 3: Power and flexibility of Proc SQL for queries and validation
  - Section 4: Data integrity with edit checks as PDF file
  - Section 5: Automate communication of updated data sets and output files

Appendix – Self Study

- A. Handling Errors and Debugging Programs
  - Section 1: Recognizing and correcting syntax and non-syntax errors
  - Section 2: Examining and resolving data errors
  - Section 3: Program debugging techniques
- B. Enterprise Guide Basics
- C. Style Definitions and Table Templates using Proc Template

Course Length: 2-Day Course	Ask for special college student rate