Pre/Post-Conference Seminars for PharmaSUG 2008

There are 12 exciting seminars scheduled for 2008 covering a wide variety of topics and taught by some leading experts! Any of these seminars are sure to enhance your conference experience! Plan now to arrive in Atlanta early or stay on after PharmaSUG at the conference hotel's special room rate. There will be five seminars offered on Saturday, five on Sunday, and two on Wednesday afternoon. A box lunch will be provided to the Wednesday afternoon seminar attendees at no cost, and snack breaks will be provided during all seminars. All seminars this year are half-day and cost $99 each, same as last year! Seminar fees are in addition to the conference registration fee and you must register for the conference in order to enroll in seminars.

Space is limited, so sign up early online when you register for the conference!

Please read carefully the seminar descriptions below before you register AND keep a copy of your conference registration form for your records!!

SEMINAR REGISTRATION, ATTENDANCE AND CANCELLATION POLICY

1. You must register for the conference in order to attend a seminar.
2. You must register for a seminar via the PharmaSUG 2008 conference registration form either by postal mail, fax, or online (preferred).
3. You may cancel a seminar prior to May 1, 2008 and receive a full refund minus a $25 administration fee per cancelled seminar.
4. Prior to May 1, 2008, you may swap one seminar for another; however, this is considered a change in conference registration and will incur a $25 administration fee.
5. Beginning May 1, 2008, you **MAY NOT SWAP** seminars; however, a new seminar may be added depending on space and availability.
6. **There will be NO REFUNDS on or after May 1, 2008**. However, if you are unable to attend, the seminar material will be provided to you (either by postal mail or email) without additional charge.
7. Should a seminar be cancelled at any time for any reason, the sole liability of PharmaSUG and the instructor is a refund of the seminar fee, and they are NOT liable for any special or consequential damages arising from the cancellation of the seminar.
8. On-site registration will be permitted based on space and availability, and payable by cash (No personal checks) or major credit card (MC, VISA, Discover, AMEX). However, seminar materials may not be available on-site but will be provided later to paid attendees.

For questions about the above seminar policy and availability, please contact Diana Williams at dianasunset@earthlink.net or phone (919) 929-5015 (weekdays) and/or Mary Anne Hope at mdepesquo@cox.net or phone (602) 745-6312 (weekdays).

Seminar Schedule for PharmaSUG 2008

SATURDAY – May 31, 2008		
7:30 – 8:00am	#	Morning Seminar Registration only
8:00am – Noon	1	*Testing and Validating SAS Programs in an FDA Regulated Environment (Neil Howard)*
	2	*XML for SAS Programmers (Frederick Pratter)*
Noon – 1:00pm		Lunch is on your own
12:30 – 1:00pm		Afternoon Seminar Registration only
1:00 – 5:00pm	3	*Best Practices in SAS Statistical Programming for Regulatory Submission (Sunil Gupta)*
	4	*Understanding Why Your Macros Don't Work (SAS Personnel)*
	5	*Advanced ODS (Chris Olinger)*
SUNDAY – June 1, 2008		
7:30 – 8:00am	#	Morning Seminar Registration only
8:00am – Noon	6	*An Animated Guide: The logic of some basic statistical procedures (Russ Lavery)*
	7	*A Health Outcomes Case Study: Data Management, Summary, and Analysis (Richard Read Allen)*
Noon – 1:00pm		Lunch is on your own
12:30 – 1:00pm		Afternoon Seminar Registration only
1:00 – 5:00pm	8	*Modernizing Your SAS Code, or How to Avoid Becoming a SAS Dinosaur (SAS Personnel)*
	9	*SAS® Macro Tools: Building Reusable Macros (Kirk Paul Lafler)*
	10	*CDISC Logic: A hands on experience (Russ Lavery)*
WEDNESDAY – June 4, 2008		
12:45 – 1:30pm	#	Seminar Registration / Box Lunch provided
1:30 – 5:30pm	11	*Advanced SAS® Programming Techniques (Kirk Paul Lafler)*
	12	*Manipulating Data Using Functions and Arrays (Ben Cochren)*

PharmaSUG 2008 Seminar Descriptions

1. Testing and Validating SAS Programs in an FDA Regulated Environment by Neil Howard

Intended audience/Pre-requisite: Managers, programmers, analysts, validation programmers, statisticians who program or oversee programmers, database programmers, QC or QA staff/Basic knowledge of SAS.
Course material: Binder with copies of slides and worksheets
Seminar Description: This half-day seminar will focus on testing and validating SAS programs, particularly in the context of an FDA regulated environment, with special emphasis on SAS tips and techniques to facilitate the process.

- WHY: examination of FDA regulations and guidance; exploration of reviewers' expectations (processes and accountability); implications of audits; and discussion of client requirements and specifications
- WHAT: interpretation of guidances; definition of the terms testing, debugging, verification and validation; test plans; and discussion validation items
- WHO: accountability in pharmaceutical companies and CROs
- WHEN: planning and timing of testing and validation
- WHERE: documentation specifics and tips
- HOW: SAS and programming tips and techniques [for programmers and statisticians] for debugging, testing, and validation of production and ad hoc code for tables, listings, figures, and derived data sets; syntax, logic, requirements checks; and error handling

The SAS system is easy to use and the learning curve to productivity is relatively short. However, SAS is easy to abuse. Indisputable facts remain in that data is seldom clean, logic is too often faulty, and fingers walk clumsily over the keyboards. Condition codes and a 'clean log' are not always accurate indicators of successful programs.

Since as much as 80% of a programmer's time is invested in testing and validation, it is important to focus on tools that facilitate correction of different types of errors in SAS programs. This seminar focuses on a variety of SAS features, tips, techniques, tricks, and system tools that can become part of your routine testing methodology consistent with 21 CFR Part 11 and other FDA guidances.

2. XML for SAS Programmers by Frederick Pratter

Pre-requisite: A basic understanding of SAS DATA and PROC steps and a burning interest in XML; Intended Audience: SAS users with an interest in XML, in particular the background for the FDA XML Data Format Requirements Specification.
Course material provided: Binder with handouts with code examples
Course description: This seminar is an expanded version of the famous SUGI 27 paper "Beyond HTML: Using the SAS System® Version 8.2 with HTML and XML". In particular, the following topics will be covered:

- What is XML?
- What is the difference between XML and HTML?
- What does XML do?
- What SAS tools are available for XML processing?
- What do they do, and why would you want to use them?
- In addition, new topics will include using examples of using XMLMap to parse arbitrary XML documents, using templates to create XML and XHTML, and the use of DTDs (Document Type Definitions) for validating XML data documents.

3. Best Practices in SAS Statistical Programming for Regulatory Submission by Sunil Gupta

Pre-requisite: Students are expected to have some knowledge of clinical trials and experience in clinical or statistical programming.
Intended Audience: Anyone 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, and Clinical Data Managers.
Course material provided: Course notes, e-mail Enterprise Guide project, SAS programs and macros.
Course description: This intense course provides a comprehensive overview to develop a clinical reporting system for producing publication-quality summary tables and shows how to validate throughout the process. Get your SAS clinical programming and validation questions answered and learn efficient tips for producing a quality regulatory submission in a timely manner.

4. Understanding Why Your Macros Don’t Work by SAS Personnel

Pre-requisite: Some basic macro knowledge is recommended.
Course description: This brain-teasing seminar will discuss the behind the scenes workings of the macro facility and explain why macro variables you thought would resolve don't, why you need an extra period or four after a macro variable reference, why you care about the difference between %LET and CALL SYMPUT, and what all those extra ampersands are for.

5. Advanced ODS by Chris Olinger

Intended audience/Pre-requisite: Report writers and SAS programmers/Basic ODS knowledge; Course material: Handouts and CD of examples
Seminar Description: This half-day advanced ODS seminar will cover topics relating to getting the most out of ODS Styles, reporting techniques using the Base SAS reporting procedures, ODS Tagsets, and using SAS to interface with alternative reporting environments. It will also touch on some of the newer technology coming in SAS version 9.2 such as Statistical Graphics and ODS enhancements to make life just a little easier.

6. An Animated Guide: The logic of some basic statistical procedures by Russ Lavery

Pre-requisite: Algebra
Intended Audience: Those who would like to review hypothesis testing, ANOVA, regression and power.
Course material provided: Book of selected slides which are hand annotated to reduce the need for note taking.
Course description: This graphically oriented talk is for people who want a review of the logic behind basic statistical techniques. This talk uses common place examples (romantic problems and losing a playground game in first grade) to show that we always knew the basics of statistical reasoning. This talk is low on math and high on "Oh! That's what that really means". Covers Hypothesis Testing, p-values, one-way ANOVA, Two-way ANOVA, interactions, regression, and statistical power.

7. A Health Outcomes Case Study: Data Management, Summary and Analysis by Richard Read Allen

Pre-requisite: Good Base SAS background and basic statistical understanding.
Intended Audience: Intermediate; Course material provided: Course Notes
Course description: This seminar will present the summary and analysis of a health outcomes study, beginning with reviewing the requested analysis plan from the investigator, to setting up analysis datasets from various sources, to producing summary tables/figures and finishing up with testing some basic hypotheses on the data. Some programming techniques to perform these tasks for these types of studies will be presented, including the basic use of hashes and DOW loops to obtain the desired datasets, tables, figures and analyses. A study of *Impact of Benefit Designs on Medicare Part B Plans* will be used as an example, but the techniques can be applied to similar research studies. They also can be applied in Phase IV studies.

8. Modernizing Your SAS Code, or How to Avoid Becoming a SAS Dinosaur by SAS Personnel

Course description: This seminar can be considered a historical "What's New in SAS" discussion with task-based examples that allow experienced SAS programmers to identify and implement techniques that were added since those programmers first learned to use SAS software and permit less experienced users to understand code that was composed prior to their initiation as SAS programmers. The content compares older and newer techniques for completing specific SAS programming tasks such as: concatenating two SAS data sets using a DATA step SET statement versus using the APPEND procedure; importing a Microsoft Excel worksheet versus using the corresponding SAS/ACCESS LIBNAME engine; and creating a combination bar chart-line graph using the SAS/GRAPH Annotate facility versus running the GBARLINE procedure.

9. SAS® Macro Tools: Building Reusable Macros by Kirk Paul Lafler
Pre-requisite: Minimum 6-months Base-SAS programming experience.
Intended Audience: SAS Users
Course material provided: Seminar notes are provided.
Course description: The SAS® Macro Language is a powerful feature for extending the capabilities of the SAS System. This seminar presents a collection of techniques for constructing reusable and effective macros tools. Attendees learn how to build functional macros that process statements containing SAS code; create macros containing positional parameters; build a library of macro utilities; interface the macro language with the DATA step and SQL procedure; and develop efficient and portable macro language code.

10. CDISC Logic: A hands on experience by Russ Lavery
Pre-requisite: Algebra
Intended Audience: Those who would like exposure to CDISC by working through examples.
Course material provided: Book of selected slides which are hand annotated to reduce the need for note taking.
Course description: This seminar is a mixture of presentation and group exercises. The presentation part will discuss CDISC domain structures and rules for relating entering data. While the basic task in this class will be a hands on transferring data from Case Report Forms to paper versions of "CDISC data sets", this seminar concentrates on relationships among CDISC variables and data sets, not on filling in individual values in cells in a data set. It uses PowerPoint presentations to explain rules and then uses the task of recording of data to: reinforce lessons learned, spark discussion, and expose areas needing review.

11. Advanced SAS® Programming Techniques by Kirk Paul Lafler
Pre-requisite: Minimum 1-year Base-SAS programming experience.
Intended Audience: SAS Users
Course material provided: Seminar notes are provided.
Course description: SAS users who have acquired basic skills presented in a SAS Software Basics course and want to expand their knowledge with the DATA step programming language will want to attend the Advanced SAS Programming Techniques seminar. Attendees learn complex programming techniques in data access, data manipulation, data management, and data presentation. Topics include programming techniques including reading a variety of file formats; using column and line pointers; specifying system and language options; coding loops, ranges, and arrays; using operators and modifiers; reshaping columns of data; techniques on managing data; custom report writing techniques; and integrating ODS for improved output.

12. Manipulating Data with SAS Functions by Ben Cochran
Intended audience/ Pre-requisite: SAS Users from Novice to Intermediate/None
Course material: Textbook consisting of over 150 pages
Seminar Description: This half-day seminar explores the area of data manipulation and shows attendees how to accomplish this through using the myriad of functions provided by the SAS® System. Examples range from simple to complex so that students will learn a lot about SAS Functions regardless of their background. The presentation and textbook have been updated to include SAS9 functions.

Seminar topics will include:

- Introduction to Data Manipulation
- The Structure of SAS Data Sets
- Processing Data with the SAS System
- Introduction to Functions
- Manipulating Numeric Data
- Manipulating Character Data
- Data Conversion
- Other Very Useful Functions

Seminar Instructor Biographies:

Richard Read Allen has been using SAS since 1981 while in graduate school at Montana State University. After leaving school, he continued his SAS career as a statistician/programmer at the FDA's National Center for Toxicological Research in Jefferson, Arkansas. In 1994 he moved to Evergreen, Colorado and started Peak Statistical Services, an affiliate member of the SAS Alliance. He has presented at SUGI, NESUG, WUSS and PharmaSUG conferences in the past and has been co-chair of the PharmaSUG conference in 2004 and 2007.

Ben Cochran started his own consulting and SAS Training business in the fall of 1996 – The Bedford Group, after more than 11 years with SAS Institute in the Professional Services (as an Instructor) and Marketing Departments (as Marketing Manager for the SAS/EIS product). As an affiliate member of SAS Institute's Alliance Partner Program, Ben has been involved in many teaching and consulting projects over the past 10 years. Since 1988, Ben has authored and presented papers at SUGI and regional user groups on a variety of topics.

Sunil Gupta is Associate Director of Statistical Programming at Quintiles. He has been using SAS® for over 14 years and was the program chair for the Western Users of SAS conference in 1998. He has been an invited speaker at numerous SAS User Group International and regional conferences. He has over 47 publications, and is the co-author of *Sharpening Your SAS Skills*, the book to help users have a better understanding of SAS. He is also the author of *Quick Results with the Output Delivery System*. Recently, Sunil released his third book titled *Data Management and Reporting Made Easy with SAS Learning Edition 2.0.*

Neil Howard is Director of Biostatistical Programming for Clinical Development at Amgen Inc.; she is therapeutic area head of Inflammation and General Medicine. She has been a SAS user and trainer for more than twenty years; and has a background as manager of statistical programmers in both CRO and big pharma environments. Neil has been an invited speaker and trainer since 1983 on such topics as: efficiency techniques, DATA step processing and internals, advanced DATA step techniques, testing and validation, graphics, effective presentations, and interviewing/hiring SAS programmers. She was a contract instructor for SAS Institute for seven years teaching fundamentals, programming, macro, report writing, graphics and the annotate facility. Neil has been a member of the SAS Global Users Group Executive Board since 1993 and was proud to chair SUGI 20 in Orlando, FL.

Kirk Paul Lafler is consultant and founder of Software Intelligence Corporation and has been programming in SAS since 1979. Kirk provides IT consulting services and training to SAS users around the world and is the author of four books including *PROC SQL: Beyond the Basics Using SAS* (SAS Institute. 2004). He has written more than two hundred peer-reviewed papers and has been an Invited speaker and trainer at more than two hundred SAS user group conferences. His "Kirk's Korner of Quick and Simple Tips" and fun-filled SASword Puzzles appears regularly in several SAS User Group newsletters and at sasCommunity.org.

Russ Lavery started learning SAS in 1985 and has never stopped. He is a frequent, and award winning, presented at SAS User Groups and is the creator of the "An Animated Guide" series of talks on SAS and statistical topics.

Chris Olinger, President of d-Wise Technologies, has been developing enterprise software for over 17 years. While employed at SAS Institute he was the manager of the Base SAS reporting group and lead developer of ODS as well as being involved in the design and development of the SAS Drug Development platform. More recently, Chris has been involved in the development of SAS and web based applications within the framework of his software company.

Frederick Pratter teaches in the Computer Science Program at Eastern Oregon University in La Grande, OR. He is the author of Introduction to Web Development Using SAS AppDev Studio™, 2nd. Ed. SAS Press (August 2006). Dr. Pratter also works as an independent SAS consultant, primarily in the financial services area. His presentation "Access to Relational Databases Using SAS®" was honored as Best Paper in the PharmaSUG 2002 Tutorials section. He has been a SAS user since 1975, and has previously presented a papers and workshops at PharmaSUG, SUGI, WUSS, NESUG, SESUG, and PNWSUG, and local user groups in Boston and New York City.