Call for Participation

Computerized Systems in Clinical Research: Current Quality and Data Integrity Concepts

A Continuation of the Red Apple II Conference

Our objective is simple: To develop a practical and useful reference for technical, clinical research, clinical laboratory and management personnel who design, develop, test, use, support and manage computerized systems used in clinical research.

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Overview

In response to numerous requests from individuals and organizations aligned within the international clinical research community, DIA continues the Red Apple initiative, this time addressing clinical research. This effort aims to examine and advance the current role of science and technology in establishing best practices. The areas covered include – the design, validation and practical application and understanding of computerized systems used in the clinical research environment. This will ensure quality, integrity and verifiability of clinical research data. This effort will be global in scope, addressing computer-related issues observed in all complexities of clinical research within our respective regulated environments.

Our objective is simple: To develop a practical and useful reference text for technical, clinical research, clinical laboratory and management personnel who design, develop, test, use, support and manage computerized systems used in clinical research. Only relevant topics, principles, and practices regarding GCP-regulated computerized systems and projects will be discussed.

As with the initial Red Apple models, an editorial board of established experts and thought leaders will be selected to lead the conference effort, compile and complete the final manual.

A limited number of selected international participants from industry, government, industry associations and academia will be chosen to contribute in this conference. They will be selected based on experience from a cross-section of clinical research and regulatory professionals. All individuals wishing to participate will do so by completing the survey form available at http://www.zoomerang.com/survey.zgi?p=WEB2273JL7CLMR. This form will capture all individuals wishing to participate will do so by completing the survey form available at http://www.zoomerang.com/survey.zgi?p=WEB2273JL7CLMR. This form will capture

Please note that there will be an attendee selection process to ensure balanced representation at the conference. The deadline for completion of the questionnaire is January 15, 2008. Notification of acceptance into this conference will begin in January, 2008.

No registrations can be considered confirmed until a written confirmation letter is received from DIA. Please make your hotel and travel reservations ONLY UPON RECEIPT OF THIS CONFIRMATION.

If you are interested in participating, please click on the link below to go to the Call for Participants.


By completing the questionnaire, selected applicants commit to complete assigned tasks onsite, pay the $995.00 registration fee, and follow up tasks through to production of the benchmark manual.

See page 2 for additional information.
information related to an applicant’s qualifications, training and experience. Based on this information, the screening and selection teams will have a complete basis for recommendations. Each applicant must obtain their company approval for participation.

Additional specialists will be selected to represent the required mixture of skills and a cross section of pertinent organizational affiliations.

All those involved in this book will be recognized as contributors. The reference manual is projected to publish in 2009.

**HISTORY**

**Red Apple, Red Apple II and Peach**

The initial *Red Apple* conference had its genesis in 1987, when a global team gathered to write a book on the quality assurance of computerized systems used in nonclinical safety assessment. Held at the Red Apple Conference Center in Heber Springs, Arkansas, the “Red Apple Conference,” as it became known, was a milestone in establishing best practices in the design and testing of computerized systems in nonclinical laboratories. The outcome of the conference was a reference published in 1988 by DIA entitled *Computerized Data Systems for Nonclinical Safety Assessment: Current Concepts and Quality Assurance*.

Recognizing that by 2006 the science and technology of computerized systems had changed significantly, a second conference – *Red Apple II* – was held in Horsham, PA on March 22-24, 2006. This conference reviewed the original reference and updated the material to address the current environment and new challenges confronting nonclinical laboratories. The result is an updated reference that will be published by DIA in fall 2007, *Red Apple II – the Update: Computerized Data Systems for Nonclinical Safety Assessment: Current Concepts and Quality Assurance*.

As we identified and subsequently organized the clinical effort, a theme emerged; this new initiative would use some information applicable from the Red Apple II project and had a working title of ‘Peach’ – reflecting an especially attractive, well liked, and enjoyed effort to finally tackle a crucial focused clinical information need. While the name ‘Peach’ was officially removed from the title, the basic qualities associated remained; appeal to many as a reference manual, usage which will be global in scope, addressing clinical issues observed in all complexities, within our respective regulated environments.

Future Red Apple style Conferences envisioned may tackle Pharmacovigilance, Medical Devices and Manufacturing.

**MEETING GOALS**

To create an up-to-date benchmark manual for “Computerized Systems in Clinical Research: Current Quality and Data Integrity Concepts,” as we develop a ‘Best Practices’ reference text and document current technologies, new issues and exchange information on global regulatory and industry best practices.

**WHO SHOULD ATTEND**

Those with experience in Clinical Research involving human subjects such as;

- Sponsors
- Contract research organizations
- Academic and government institutions involved in clinical research
- Clinical investigators
- IRBs
- “Third party” vendors (e.g., data storage companies; program development companies)
- Laboratories – clinical and analytical
- Private medical practices
- Regulatory bodies
- Standard organizations

Others who should attend are those with “Computerized System” experience in developing and preparing specifications, using instrumentation in clinical research, involved in SOP preparation, managing and reporting of regulatory statements.

This program will benefit professionals who work in the area of:

- Medical Research
- Principal Investigators/Site Staff
- Monitoring/CRAs
- Statistical Analysis
- Data Management
- Project Management
- Regulatory
- Quality Assurance
- Information Technology
- Diagnostic Software Developers

**CONTACT INFORMATION**

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