

The Compass

POINTING THE WAY TO COMPLIANCE AND PROFESSIONAL GROWTH

Quarterly Newsletter of the Southern Regional Chapter SQA • Volume I • Number 2 • Winter 2007

Message from the President

The Southern Regional Chapter of the Society of Quality Assurance has been established now for several months and we continue to move forward. It is still an honor for me to lead this new chapter and to work with such a great group of individuals who so generously serve as SRCSQA Officers. None of this would be possible without them. I'd also like to thank the SQA Board of Directors, officers and administrative personnel for continued support.

At this time, I would like to introduce the newest SRCSQA Officers. **Joe Mike Fowler** is the Senior Quality Assurance Auditor for Biotechnical Services, Inc. and will be serving as our Chair of the Membership Committee. **Pat Carver** is the Director of Quality Assurance for Biotechnical Services, Inc. and will be serving as our Chair of the Teller Committee. Both have jumped right into their leadership roles and have already proven to be valuable assets to our organization in just a short period of time. Thanks, Gentlemen!

SRCSQA

The Southern Regional Chapter of SQA serves the following geographic areas: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Oklahoma, Puerto Rico, South Carolina, Tennessee.

Webpage

www.southernSQA.org

I also want to welcome our new members who have recently joined the SRCSQA. We're glad that you chose our organization to share your Quality experiences with.

The Southern Regional Chapter has tentatively scheduled our first meeting/training for February 2008. Although it will be a smaller meeting, we will be providing a tremendous educational opportunity, as well as allowing us to meet and network face-to-face. So please stay tuned for upcoming information regarding this event.

Since the last newsletter was issued, several things have been accomplished. We have approved our logos for use with all things SRCSQA. Our website is up and running containing the membership application, a schedule of upcoming events, and links to some informative and useful Quality websites.

Our bank account was established and is now operational. The Officers have brain-stormed training ideas and potential speakers for the upcoming regional meeting. With the upcoming meetings, we are preparing to mount a massive membership drive. We want to get the SRCSQA name out into the mainstream Quality world for all to see. We have come so far in such a short amount of time and have so much to offer our region – and this is only the beginning. Many good things are yet to come.

In closing, please don't forget

that we are here to serve our members. It is our mission to provide you with the best training, meeting and networking opportunities available in the Quality industry. Whether this is done through meetings, conference calls, online trainings, or newsletters, we hope to benefit our members with years of Quality experience from leaders in various industries.

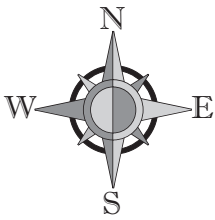
As members, we hope that you find everything in the SRCSQA that you are looking for in a professional organization. As always, we welcome all suggestions and recommendations, so please contact me or one of our Officers by phone or by visiting our website.

On behalf of the SRCSQA Officers, I would like to wish everyone Happy Holidays and a great start to 2008. We look forward to meeting each and every one of you at the upcoming meetings.

Joey Kellum,
President of SRC-SQA

INSIDE THIS ISSUE

- Note from the President
- Chapter Officers
- Committee Member Roster
- Regulatory Updates
- Book Reviews
- In the News
- Issues to Consider
- Quality & Compliance
- Specialty Section
- Activities Calendar



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Chapter News

The Society of Quality Assurance (SQA) is an international professional membership organization dedicated to promoting and advancing the principles and knowledge of quality assurance essential to human, animal and environmental health.

The current membership of the Society exceeds 2,300 Active and Affiliate members in over 31 countries working in industry, government, academia and consulting.

The Society includes general membership, special interest groups, administrative committees and specialty sections.

Chapters are conveniently organized by regions; for example: RMRCSSQA is the Rocky Mountain Regional Chapter of SQA and includes Arizona, Colorado, Montana,

Nebraska, New Mexico, North and South Dakota, Texas, Utah and Wyoming.

PRCSQA is the Pacific Regional Chapter, which serves California, Washington, Oregon, Idaho, Nevada, Hawaii and Alaska.

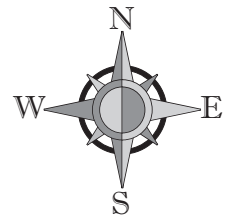
The Southern Regional Chapter Society of Quality Assurance (SRCSQA) serves Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Oklahoma, South Carolina, Tennessee, and Puerto Rico.

Our goal is to encourage interaction and promote best practices among quality assurance professionals. It's easy to join, just complete the application form in this newsletter and mail it with your payment to: SRCSQA
2365 Hunters Way,
Charlottesville, VA 22911.
Tel: (434) 297-4772.

Trouble Finding an HHS Contact?

If you are unable to find a U.S. Department of Health and Human Services employee, try the Directory at <http://directory.psc.gov/employee.htm>.

The directory includes ACF, AHRQ, AOA, ATSDR, CDC, CMS, FDA, HRSA, HIS, MIH, OIG, OK, PSC and SAMHSA Agencies.



Regulatory Update

On October 1, 2007 the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) launched its web-based medical device registration and listing system. The new program allows device manufacturers, contract sterilizers, contract manufacturers, single-use device reproprocessors and specification developers to list and register products electronically.

The new system, which will be part of the FDA Unified Registration and Listing System (FURLS), will replace forms FDA 2891, Registration of Device Establishment; FDA 2891a, Annual Registration of Device Establishment; and FDA 2892, Device Listing.

The new process was first considered in October 2002, with the amendment to Section 207 of the Medical Device User Fee and Modernization (Pub. L., 107-250) or MDUFMA 1. The amendment added a requirement for electronic submission of registration information. In September 2007, Congress enacted the Medical Device User Fee Amendments of 2007 (MDUFMA II) which further amended the device registration and listing provisions found in section 510 of the Act and also added user fees in connection with initial or annual registration. The Act now requires all device establishments to submit their device registration and listing information by electronic means unless FDA grants a request for a waiver.

For more information contact devicereg@fda.hhs.gov or call 240-276-0111.

IN THE News

This past summer the House and Senate passed legislation to enhance post market drug safety. An article in the August 9th issue of the *New England Journal of Medicine* referred to the legislation as “the most important drug legislation in a century”. The authors concluded the legislation (HR2900 and S.1082) would aide in resolving the crisis of confidence in our nation’s drug supply.

Looking at HR2900, the bill expanded FDA’s authority to conduct or require post-

market safety studies and to require changes to drug labeling. Restrictions on direct to consumer advertising of new drugs and increased post-market safety review were the key elements of the legislation. The bills would provide FDA the authority to review drug advertisements before they are released. If known or potential serious risk related to a drug are suspected, the Secretary may require manufacturer to conduct post approval studies.

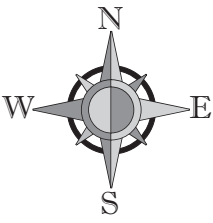
Senate Bill S.1082 would require experts serving on FDA advisory panels to disclose any potential conflict of interest. Waivers may be granted depending upon the type, nature and magnitude of

the financial interest.

Although there are differences between the bills overall, they are similar and simply need to resolve issues of how drug safety is addressed.

One point of agreement: both bills expand the NIH clinical trial registry of trials that are conducted to test safety or effectiveness of a drug or device, irrespective of whether the trial is federally or privately funded.

The registry would include trials conducted outside the U.S. The House bill requires clinical trial results to be included in the registry and made publicly available through the registry website.



2007-2008 Committee Chairpersons

EDUCATION COMMITTEE

Open

POSTER

Open

MEMBERSHIP

"Joe" Mike Fowler

PUBLICATIONS/ NEWSLETTER

Margaret F. Fay

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Debbie Kerr

Dkerr52@earthlink.net

WEB PAGE/WEBMASTER

April Robb

robb@sri.org

TELLER CHAIRPERSON

Patrick "Pat" H. Carver

ANNUAL DUES

Annual Chapter dues are \$25. New members will receive a SRCSQA membership card. Please encourage your QA staff to join and actively participate as committee members.

SRCSQA Mission Statement

To sponsor education programs in quality assurance.

To encourage interaction and promote best practices among quality assurance professionals in government, industry and academia.

To serve as a focal point for quality assurance practitioners and their professional interest.

Issues to Consider

As if the profession did not have enough acronyms in its armamentarium, we can now add FTC to our list of alphabet soup items to watch.

The Federal Trade Commission (FTC), the Department of Justice (DOJ) and the Office of Inspector General (OIG) are taking a closer look at medical device advertising and related claims in light of the False Claims Act (FCA). The FTC has broad authority to prohibit unfair or deceptive acts or practices and/or the dissemination of misleading claims for food, drugs, cosmetics and devices.

Companies must have a reasonable basis for claims made (preferably emanating from well-controlled clinical studies but at a minimum, the company must have data from clinical investigations before claims are disseminated). In general, it is not the quantity of studies from which claims are drawn, but rather the quality of the data that is of ultimate importance.

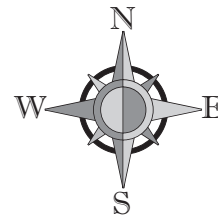
Where no specific levels of substantiation is claimed, the basis for a claim will be determined by analysis of the following factors:

- The type of product sold and its classification
- The type of claim
- Benefits if the claim is true
- Consequences if the claim is false
- The ease and cost of developing support documentation for the claim
- The level of assurance experts in the field agree is reasonable to support a claim.

Any claim that is misleading, contains misrepresentations, or omissions is likely to raise eyebrows and possibly trigger enforcement actions. It may expose a company to liability under the federal False Claims Act, the anti-kickback statute or both.

The FCA prohibits knowingly making or using a false record or statement to get a false or fraudulent claim paid or approved by the federal government or its agents. For QA managers it is important to insure colleagues know the elements of an FCA violation. These include knowledge, materiality and causation. Violations are punishable by statutory civil penalties of \$5,000 to \$11,000 per false claim and treble damages.

Because each sale can be considered a separate "claim", a company's potential liability could be substantial. A company must not only ensure promotional campaigns comply with applicable FDA regulations, but also meet the letter and intent of all laws.



QUALITY & COMPLIANCE

A new guidance, recently issued, is to be used in conjunction with Compliance Program Guidance Manual for Inspection of Medical Device Manufacturers (CP 7382.845).

In any firm, executive management is ultimately responsible for establishing, implementing and maintaining a quality system. Specific responsibilities include formulating the quality policy, defining organizational structure, assigning authorities and responsibilities, appointing management representatives, periodically reviewing the quality system and making available resources and personnel necessary to maintain the system.

The QA system creates a framework for defining the control of materials, process and verification of activities, thus providing confidence in the design, manufacture and servicing of products in a well-defined and controlled environment.

The Quality Systems Model is based on four key elements: Management Responsibilities, Resources, Manufacturing and Evaluation Activities. Among these four elements are an additional 19 individual sections, including items such as contract review, design control, document and data control, purchasing controls, product identification and traceability, process control, inspection and testing, training, servicing and so forth.

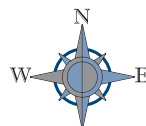
One section also addresses "outsourcing operations". Outsourcing is a growing practice that delegates operations to a second party under a contract to perform operational processes that are part of manufacturers' inherent responsibilities.

Governing standards and regulations offer clear evidence of the growing importance of quality oversight for outsourcing in terms of vendor selection, vendor validation and risk reduction. Standards such as ISO 13485:2003 and ISO 14971:2000 have codified a risk-based approach for every aspect of a company's operations that touch on the quality system. With growing economic pressure to improve the bottom line, many companies have outsourced design, manufacture, packaging, labeling and/or other assembly responsibilities. Regardless of who performs that service it must be remembered that the overall responsibility and accountability for the end product remains with the natural or legal person/organization of record and the activities are accounted for in the organizations' quality management system.

As Quality Assurance Managers respond to corporate plans, they should be encouraged to look for suppliers that are 13845 certified. Why? With increasing focus on safety and risk reduction, QA managers are facing tighter regulatory scrutiny by domestic and international regulatory agencies.

When it comes to QA, don't cut corners. Review the newly released guidance documents update your SOP's and seek out vendors with 13455 certification. Set precise definitions internally and insure your internal documents adequately define and document your requirements before you outsource a project. ISO certification may save you in an audit!

Margaret F. Fay



SRC -SQA

**Southern Regional Chapter
Society of Quality Assurance**

www.southernsq.org

Name of Member _____

2007

MEMBERSHIP CARDS

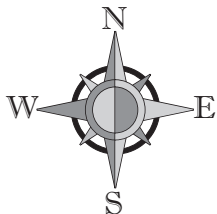
The SRCSCQA now issues a professional membership card as a proof of professional participation. The card is issued each year upon payment of dues. Renewal notices will be sent to members by SQA headquarters.

2008 MEETING

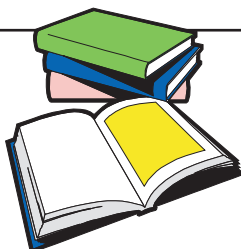
Keep your calendar open for February 2008! SRCSCQA will hold its first annual spring meeting on the Emory University Campus, Atlanta, Georgia. Look for national speakers and a stimulating agenda.

NEXT ISSUE DEADLINE

The deadline for submitting news, articles or events for the Spring 2008 Issue of the SRCSCQA Compass is March 1, 2008. Please send your submissions to Peggy Fay at kiafay@yahoo.com.



BOOK REVIEWS



Project Quality Management: Why, What, and How.

Kenneth H. Rose, PMP

Quality is a much mentioned but little employed component of project success. There are many quality books, tools, and training courses on the market, oriented toward the manufacturing domain, yet they provide little information of relevance to project managers who work with intellectual processes more than the action details of production. So where does a project manager go for guidance on integrating the quality demanded in project implementation?

Project Quality Management by Kenneth Rose offers project managers a specific, succinct, step-by-step project quality management process not found anywhere else. It gives you immediate hands-on capability to improve project implementation and customer satisfaction in any project domain, and will help maintain cost and schedule constraints to ensure a quality project.

Experimenting with Humans and Animals: From Galen to Animal Rights.

By Anita Guerrini, 2003. Johns Hopkins University Press. \$18.95.

In the course of drug and device development, scientists have employed animals in physiological, psychological and social experiments for years. Today, scientists have expanded the use of animals in the search for safer products. This book provides insight into the history of animal experimentation, with reference to human experimentation. The book carries the reader through historical evolution and experimentation and the philosophical debate over animal trials.

Traditionally, researchers held the belief that animals felt no pain and did not have the capacity to communicate or respond to kindness. The reader will come away with a new perspective on animal experimentation and may gain insight into human subject protections as well.

The 165 page book includes eight chapters. The conclusion: Human rights, animals rights and the conduct of Science is a must for anyone involved in Animal Experimentation.

Have you considered joining a Specialty Section?

The Society offers tremendous networking and educational opportunities for members. Whether you are involved in Compliance, Animal Health, Computer Validation, GLCP, GMP or Scientific Archiving, the Organization has a section to fit your needs.

The sections' goals are to broaden perspectives for initiating, enhancing and maintaining QA process that support compliance. For more information on your area, contact sectional chairs at:

Animal Health Specialty Section

Chair: Mary Puetz
mpuetz@hematech.com

Compliance Section

Chair: Dirk Hoogenboom, RQAP-GLP
hoogenbd@bsci.com

BioAnalytical Specialty Section

Chair: Peggy Beamer
margaret.beamer@nmsslabs.com

Biotechnology Specialty Section

Chair: Kathryn Hackett-Fields, RQAP-GLP
kahfields@aesop.rutgers.edu

Clinical Specialty Section

Chair: Eric Humes, RQAP-GLP
ehumes@bioanalytical.com

Computer Validation

Chair: Michael Regehr
michael.regehr@basf.com

Good Laboratory Practices Specialty Section

Chair: Nancy Gongliewski
nancy.j.gongliewski@gsk.com

Good Manufacturing Practices Specialty Section

Chair: Nikolas Burlew
nburlew@reguluspharma.com

Medical Device Specialty Section

Chair: LaDonna Camrud, RQAP-GLP
lcamrud@apsemail.com

Scientific Archiving Specialty Section

Chair: Marsha West
m.west@lilly.com

University Specialty Section

Chair: Raymond C. Anderson
rcanderson@uams.edu

Commercial/ Business
Insurance

Personal
Insurance

Surety
Bonds

Employee
Benefits

Luck favors the prepared.

Vaughan Insurance Group, LLC is a full service independent insurance agency, offering insurance coverage to commercial, personal, and professional association insurance customers. We are licensed to do business in all 50 states and have a large existing national customer base. Prompt, superior customer service and 100% customer satisfaction are our standards. Combined, our staff has over 100 years of insurance experience. All of which provides “a personal approach to all your insurance needs.”

David Vaughan, Principal
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1515 S. Utica Ave.
Suite 300,
Tulsa, OK 74104
918-779-7881 Direct
918-633-2040 Cell

Professional Association Insurance.

Coverage Highlights

- Coverage is written on an occurrence form for both general liability and professional liability
- Defense cost limits do not subtract from policy limits regardless of cost
- Coverage includes bodily injury, property damages, personal injury and professional liability along with other coverage’s automatically built into the policy
- Prior Acts coverage is available for a 2-year period if you have had previous coverage on a claim form
- Increased limits of liability are available, up to \$5 million
- Worldwide coverage as long as claim is brought within the United States
- Easy to complete and submit online application

Premium Determination

The basic policy coverage form provides you with a \$1 million occurrence with a \$2 million aggregate limit of liability. You have the option to purchase higher limits as well as prior acts coverage. For detailed pricing information specific to your association, please see the online applications.

Online Forms

RAPS • CRPC • CRSM • NESHTA • SWS • IECA • CPESC • SME

Activities - SQA Calendar of Events

22-24 January 2008
SQA Quarterly Meetings
Baltimore, MD, USA

24-25 January 2008
Strategies for Prelaunch Success

Las Vegas, NV, USA
This course is an intensive two-day workshop for experienced regulatory affairs professionals. Participants use case studies and practical applications to help discover strategies and tactics to challenging real-life regulatory situations.
Level III, IV - 12 RAC points

SQA ALERT!!

February 9, 2008
SRCSQA - QA Strategies and Applications

Emory Conference Center.
Atlanta, GA, USA
10:00 am - 2:00 pm, Fee: \$15
For more information contact
dmpoucher@charter.net

10-11 March 2008
Principles & Practices of EU and US Medical Devices
Munich, Germany
19 April 2008

RQAP -GCP and RQAP-GLP Exams

Baltimore, MD; Las Vegas, NV; Memphis, TN; and Montreal, Canada. Application deadline: 1 March 2008

20-25 April 2008
24th SQA Annual Meeting Pre Conference and Post Conference Training
Memphis, TN, USA

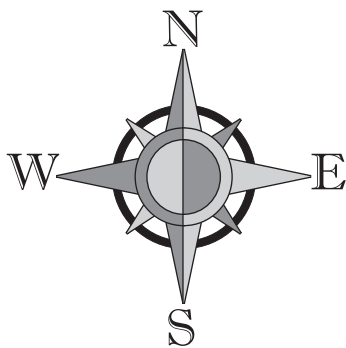
July 2008
Midwest Society of Quality Assurance Summer Meeting
Madison, WI, USA

22-26 September 2008
SQA Fall Training
Philadelphia, PA, USA

28 October, 2007
RQAP-GCP and RQAP-GLP Examinations
Edinburgh, United Kingdom
Application postmark deadline: 6 September 2008

26-28 March 2008
RAPS 2008 Horizons Conference
Fairmont Hotel
San Francisco, CA, USA
Raps@raps.org

Start planning for the 24th Annual Meeting!
20th-25th April 2008
The Memphis Cook Convention Center, Memphis, Tennessee
Registration will be available December 2007. Visit www.sqa.org for more information.



The Compass