MARSQA MONITOR

Serving the Mid-Atlantic Region Society of Quality Assurance

President's Message

Greetings members!

If all goes well, by the time you read this, all of the holiday gifts will have been opened, the lights and decorations will already have been taken down and stored for another year, and Punxsutawney Phil will be getting ready to decide our fate on whether Spring will come early in 2004. Our new chapter President, Cynthia Gronostajski will be at the helm, and I wish her nothing but success in charting the future course of this great organization.

I wanted to take this opportunity to extend my sincere thanks to the many volunteers who helped make 2003 a very productive and successful year. Our financial situation is strong and, as demonstrated by the offering of free registration for our members to our Membership Meetings throughout the past year, we are exploiting every opportunity to return value to the membership. And speaking of membership, we now have more than 325 names on the membership roster!

We continue to be the model for other chapters to emulate regarding our outstanding workshop offerings. We trained more than 200 members and non-members alike in basic QA principles through workshops such as, *Analytical Chemistry for Auditors*, *Basic Computer Systems Validation*, and *GLP Fundamentals*. In addition, we were able to offer a new workshop to our community, *Advanced Computer System Validation*, which was a resounding success and will continue to be offered in the years to come. We have also established a business partnership with a professional firm to handle our administrative and bookkeeping needs. This should help streamline some of the registration processes and Membership Directory issues we have encountered in the past.   I am pleased to be able to tell you that we are currently negotiating with them to develop and distribute a high quality, hard cover membership directory that our members can be proud of.

It has been both an honor and a pleasure honor to serve as your chapter president, and I look forward to being an active participant in this first rate quality community for years to come.

Frank

Frank Bosley
MARSQA President, 2003

INSIDE THIS ISSUE

MARSQA MISSION STATEMENT

It is the mission of MARSQA to

- Continually strive to advance the research quality assurance professions by providing the resources, programs, and training necessary for the professional development and recognition of its membership.

- Serve as a forum for the open discussion of the theoretical, practical, and ethical applications of the quality assurance profession.

- Foster a partnership between the quality assurance profession and the regulatory agencies that results in the attainment of mutually beneficial compliance.

- Support and advance the goals and mission of the Society of Quality Assurance.

Corporate Sponsors

MARSQA would like to thank our corporate sponsors for their generous support to our continuing mission:

Fort Dodge Animal Health

MARSQA Board of Directors – 2004

Past President: Frank Bosley
President: Cynthia Gronostajski
Vice-President: Jane Nelson
Treasurer: Janet Emeigh
Secretary: Kimberly Garnett
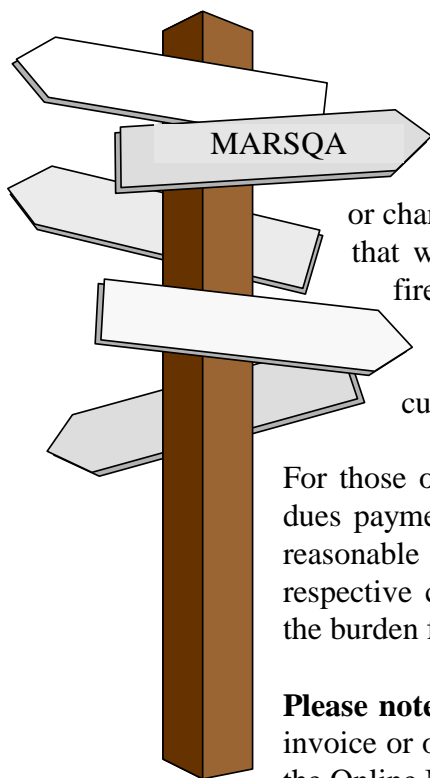
Directors:
Tony Jones
Steve Junker
Mariarose Maria
Lynda Olsen

Membership Committee Update
By: Jane Nelson

It's that time again! The membership drive for 2004 is on. The goal is to make this as painless as possible for all involved. A renewal notice will be mailed in and around the first week of January. We ask that **all** registrations or changes in personal information be done via the web site. We have a great website that we want to utilize to its fullest potential. Now don't get excited if you have firewall problems regarding payment! Payment can still be done offline. As always, individual situations can be accommodated. With all the pertinent information entered in one location by the individual, this should drastically cut down input, and editing time.

For those of you paying by company check, it is imperative that the individuals for the dues payment be specified with the check.   If the individuals cannot be identified in a reasonable amount of time (and effort!), it will be necessary to return the check to the respective company. MARSQA has identified an administrative company that will ease the burden for volunteers during the next membership renewal.

Please note: Please review and submit any changes to your personal information on the invoice or on the Members-Only section of the website. All members will be included on the Online Membership Directory.

STUDENTS TAKE NOTE!!! There is a reduced membership rate of $25 for full-time students who furnish proof of their full time status and a copy of their student ID.

WHAT'S NEW IN 2004…The Members-Only section of the MARSQA website continues to get better! Members have access to the Online Membership Directory, the latest edition of the MARSQA Monitor and the ability to update personal information. The bulletin board is being tested and is just about ready to go!

If you are a member and have not received a user name and password, please contact the Webmaster on the MARSQA homepage.   Coming soon… regulatory information updates, Committee updates, and presentations. Stay tuned….

Education Committee Update

MARSQA is offering a number of workshops to its membership. MARSQA takes pride in offering quality training workshops at very reasonable prices. Please check the MARSQA website www.marsqa.org for updates on courses and dates for 2004.

If you have any questions or if you are interested in becoming a presenter/facilitator at one of MARSQA's workshops, please contact: Joanne R. Jackson (908) 218-6660 or Lynda Olsen (908) 298-4478

Program Committee Update
By: Jane Pasquito

Hope you all had a wonderful holiday season! Moreover, I am sure each of us is grateful to be back at work. The MARSQA Program Committee is busy planning the March 2004 membership meeting. Dr. C. T. Viswanathan will be speaking at our first membership meeting of the year, which will be held at the Ramada in Delaware. He will provide us with an update on the trends in the FDA GLP industry. We are also hoping to have additional regulators representing the industry speak at this meetings. So be sure to visit www.marsqa.org for the details!

The Computer Validation Committee put together a great line-up of speakers at the November 4, 2003 membership meeting. This meeting was held at the Jamesburg, NJ Holiday Inn. Gary Secrest of Johnson & Johnson presented *"Public Key Technology: Application of Public Key to Meet Security Challenges of Transactions in an e-world"*, Colleen Turner of Bristol-Myers Squibb presented *"Audit Trails for Electronic Records: A Common Sense Approach"*, and Kevin Martin of CimQuest, Inc. concluded the meeting with his presentation of **"Automated System Security".** A big thanks goes out to the Computer Validation Committee for providing us with another very informative meeting!

I hope that those of you who attended the SQA annual meeting in October were able to attend the Opening Reception, which was co-hosted by MARSQA and NCARSQA. Although there were mixed reviews on the Oom Pah band it seems that the beer tasting was greatly appreciated. MARSQA also participated by setting up a booth and providing a game at the SQA Society Faire. Thanks to Jane Nelson, Steve Junker, Lynda Olsen and Kim Garnett for the work they did to make the Opening Reception and the MARSQA Booth at the Society Faire a success.

Treasurer's Report
Janet Emeigh

MARSQA continues to be financially strong. Our membership numbers continue to grow, the Education Committee continues to provide excellent training programs that draw participants (both members and non-members) and the MARSQA Board continues to take it's fiscal responsibilities very seriously. All of the above have enabled MARSQA to maintain a healthy balance while we continue to offer services to the membership such as free membership meetings (there were 2 last year), no additional charges for those who prefer to pay for their membership dues and meeting registration fees by credit card and one of the best regional chapter websites (if not the best).

We are also working towards consolidation of our assets to Commerce Bank. While we may be losing some interest in terms of the CDs that we have at Citadel Federal Credit Union, we will be gaining the convenience of having all of our financial information on one statement and the ability to bank at hundreds of branches throughout the MARSQA region, thus making the transition between officers when the time comes more convenient.

That being said, below are the MARSQA assets as of December 31, 2003 along with a comparison to the figures from 2002:

12-31-2003	12-31-2002	BALANCE SHEET
$57,977.06	$56,483.32	Credit Union-CDs, Money Market
2,004.49	3,803.51	Willow Grove Bank-Checking
Closed	215.97	Willow Grove Bank-Savings
30,891.35	18,473.75	Commerce Bank-Small Business Checking
$90,872.90	$78,976.55	Total Liabilities and Equity

MARSQA Computer Validation Committee
Summary of 04 Nov 2003 Meeting
Held at Holiday Inn, Jamesburg, NJ (prior to the MARSQA meeting)

The November 4th MARSQA membership meeting was hosted by the CVC, the speakers and topics are listed below:
Gary Secrest (J&J) -- Topic: Application of Public Key to Meet Security Challenges of Transactions in an e-World
Colleen Turner (BMS) -- Topic: Audit Trails for Electronic Records: A Common Sense Approach
Kevin Martin (Cimquest) – Automated System Security

Anyone interested in joining the CVC is welcome to attend the next committee meeting scheduled for February 20 (contact a committee member via the MARSQA website for more information).

Technical Discussion
1. A Review of the SQA meeting held in October 2003 – some meeting highlights were discussed.
   - Part 11 – current validation practices session
   - Karen Raskasky's presentation on the new guidance
   - Risk assessment ISO guidance

2. How much verification is required/recommended for a commercial off the shelf (COTS) statistics program
   - SAS white paper recommended as a reference
   - Need to assess the risk – show due diligence
   - Vendor assessment is also recommended
   - The GCP guide for computerized systems is still available as a reference

3. Discussion of GAMP 4 (Guide for Validation of Automated Systems):
   - This guide can be a great tool when deciding how much validation/verification is needed
   - Waiting for a GAMP for R&D that focuses less on product and release
   - Used to help develop SDLC methodology for the company
   - Helps with risk assessment categorization

4. How is training being tracked, how are training materials being version controlled and updated?
   - Some automated systems for training data collection were discussed
   - Mainly paper records are used for tracking

Hit the Jackpot with SQA!

20TH ANNIVERSARY
SQA ANNUAL MEETING
RENO, NEVADA

25 - 29 APRIL 2004

The Annual Meeting and Preconference Training will be held at the Reno Hilton in downtown Reno.

Online and printable registration forms are available at **www.sqa.org**!

Reserve your hotel room by 26 March 2004 to take advantage of special SQA rates!

Encourage non-member colleagues to join SQA and receive up to $385 in savings on their registration fees!

ATTENTION ADVERTISERS:

The Mid-Atlantic Region Society of Quality Assurance is pleased to announce that advertisements will be available both in the Monitor, as well as on our website, www.marsqa.org. The fee structure has been discounted to better serve the advertisers, including consultants and corporate sponsor companies.

The fee structure will be as follows for the entire year (3 newsletters, website):

- Full page ad: members: $75, non-members: $150
- ½ page ad: members: $50, non-members: $100
- ¼ page ad: members: $25, non-members: $50

The fee structure for placing an advertisement on the website only will be $25 per ad per year. You will have the ability to change you advertisement as necessary throughout the year for both the newsletter and the website. All fees for these new advertising plans will be billed at the beginning of the year.

The fee structure will remain unchanged for placing an advertisement in a single issue of the Monitor only:

- ½ page ad: members: $25, non-members: $50
- ¼ page ad: members: $15, non-members: $25
- 2" x 3 ½" ad: members: free, non-members: $15

If you are interested in more information or would like to place an advertisement in the next issue of the newsletter or on the website or both, please contact Ms. Debra Sedor at 215-628-5474 or by e-mail at: dsedor@prius.jnj.com.

THE DEADLINE FOR SUBMISSION OF ARTICLES AND ADVERTISEMENTS FOR PUBLICATION IN THE MAY 2004 NEWSLETTER IS
April 15, 2004.

Validation Associates, Inc.

305 E. Pennsylvania Blvd. ◆ Feasterville, PA 19053-7846

Computer System Validation Specialists

2004 Seminar Schedule

❖ Achieving & Maintaining 21 CFR Part 11 Compliance ❖

Feb 2 Baltimore, MD   Mar 29 New Orleans, LA   Jun 22 Toronto, ON, Canada
Sep 27 Albuquerque, NM   Nov 30 Princeton, NJ

❖ Computer System Validation in FDA-Regulated Industries ❖

Feb 03-04 Baltimore, MD Mar 30-31 New Orleans, LA   Jun 23-24 Toronto, ON, Canada

❖ Auditing Computer System Providers ❖

Feb 5 Baltimore, MD   Apr 01 New Orleans, LA   Jun 25 Toronto, ON, Canada
Sep 30 Albuquerque, NM   Dec 03 Princeton, NJ

For additional information, contact us at:

Tel: 215.354.1720   Fax: 215.354.1725   E-mail: info@validassoc.com   Web: www.validassoc.com

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