



MARSQA Monitor

NEWSLETTER OF THE MID-ATLANTIC REGION SOCIETY OF QUALITY ASSURANCE

Volume 15, Issue 3

MARSQA'S EXCITING YEAR-END EVENTS



I have exciting news to share with all of you! Our September 7th meeting was such a success. For the first time we were able to offer our members the opportunity to attend our Membership meeting via Webinar. We were able to offer this meeting to the other SQA regional chapters as well. The feedback was so positive that we hope to bring this dual format to future meetings. I am so glad that this was well received.

During the planning of the last meeting, I realized how truly lucky I am to be a part of MARSQA. We are lucky to have such a large membership and readily available resources, be it through our members or through our contacts, which enable us to hold the type of events we do. When looking for presenters, people to man the registration desk, or help setup the room, volunteers were there. And as always our Board of Directors has always been ready to step up to fill in wherever and whenever needed. I personally want to thank all of these people ...past, present, and future... for all their hard work and dedication to our society. Without these volunteers, we wouldn't have a chapter.

As 2011 starts to wind down, as always the work only increases. We are planning now to hold an Intro to GLP 2-day training course November 29-30th, and on December 9th, we are planning to do another round-table session for our Membership meeting. We

are excited to bring these two events to you and the planning around making them happen is in full swing. But the work doesn't stop there. In my past letters to the membership, I had expressed how getting involved with MARSQA can make a difference. Hopefully this has inspired some of you to want to get involved more. We are currently also looking for candidates for our 2012 Board of Directors. We are looking for Vice President, Secretary, and Director candidates. Let me assure you, that it isn't that difficult being on the Board of Directors. If you worry that you don't know enough or need to be a long time member to be on the board, don't. The rest of the board is there to help. Even for the position of Vice President...you have the President and Past President to help you. There is definitely a support team there to help, so if this is the reason that has led to hesitation in the past, don't let it immobilize you now. We always have veteran board members available both on and off the board to provide guidance and support. If you have any questions, please feel free to reach out to me or any of our board members to ask about these positions or how to get involved. I hope that some of you consider running for these positions. It is a great opportunity to meet new people while still helping to make a difference.

Alyssa Colon
President

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I have no idea what this meeting is about, I just know he's wrong!



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MARSQA MISSION STATEMENT

- 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.



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A LOOK AT THE MARSQA MEMBERSHIP MEETING

Jane Goeke

MARSQA Newsletter Committee Chair



Speakers from the Sept 7, 2011 MARSQA Membership meeting in Lahaska, PA. Pictured from left to right:

Courtney Rodriguez who presented on *Challenges of Validating and Implementing Global Technologies*

Nancy Gongliewski who presented on *Changes in Skill Sets Required for GLP Professionals in the Past 15 Years*

Leila Scott who presented on *Digital Imaging-Validation Challenges in a Regulated Environment*



A few members of the MARSQA Board of Directors. Pictured from left to right:

Nancy Gravino, Secretary

Kim Baratelli, Treasurer

Tony Borisow, Past President

Alyssa Colon, President

Ranee Henry, Vice-President

Mike Franks

MARSQA Member



Working as an independent research quality assurance professional or “consultant” has changed in the last 15 years or so, much the same as being employed by another company may have changed, but there are some additional considerations when you are self-employed. For example, as a consultant, depending on how independent you

are, some understanding of business management is necessary such as bookkeeping, purchasing, IT and marketing, as well as personal financial planning and healthcare.

Understanding the market for our skills and the supply of individuals available that possess those skills (supply and demand) is crucial to the decision to pursue a career path as an independent consultant or to decide in which areas you want to develop yourself professionally.

The business climate in the mid 1990’s – characterized by a bustling economy, flourishing startups, outsourcing strategies, and advances in personal computing – created a much more positive climate than today for one to voluntarily pursue a career path as an independent QA consultant. However, although fewer people are choosing to do so, more people are finding themselves self-employed as a result of involuntary separations from their companies. Regardless of how one arrives at being a consultant, doing so successfully is dependent upon maintaining a marketable skills set and applying them at a high level of proficiency. After gaining considerable experience applying GLPs to various FDA and EPA regulated studies, and applying FDA GCP guidelines to animal drug efficacy studies, I had the confidence

to choose to become an independent consultant. For the first five years or so the preponderance of my work as a consultant was for major drug and agricultural chemical companies. At that time consultants were commonly used to mitigate audit backlogs in Quality Assurance Units. These backlogs were often coupled with tighter and tighter deadlines for completion. By the year 2000 computerization was widely used in preclinical research; new FDA rules were promulgated (21 CFR Part 11); the need to audit paper documents was diminishing; and auditing electronic data required specific training and skills in the use of the computerized systems used to capture and store the data. Maintaining an understanding of current good computerization practices became another must for consultants.

The first six to eight years of the new millennium saw biotechnology companies, many of them virtual, flourishing and outsourcing much if not all of their preclinical and clinical research. This provided an increasing market for test facility audits, as well as implementing and monitoring GLP, and providing training at new GLP test sites. As a QA consultant continual training was required to understand new areas to apply GLP, such as bioanalysis and large molecule assay methods.

In the last five or so years we have seen developments such as the move toward globalization of business; increasing use of novel medical devices and related safety concerns; development of new models for testing the safety of drugs and medical devices; and use of biomarker studies and digital imaging such as PET, CT and MRI to predict safety. These and many other developments will shape our jobs in the future. Whether working as an employee of a company or as a consultant, for our work to remain employable we will have to be adaptive, diversify our experience and skills set, and keep pace with the changes in the science, technology and regulations affecting our field.

MARSQA MONITOR SURVEY RESULTS

At the last MARSQA membership meeting, attendees were surveyed for their views on MARSQA's newsletter, the Monitor. There were also a few additional survey responses provided by e-mail. The survey was conducted because the Newsletter Committee is interested in the Monitor's success and wants to keep it as responsive to the society's needs as possible. There were a number of great suggestions and the committee will be considering them.

25 individuals responded to the survey. 22 of these individuals were MARSQA members and 19 indicated that they read the newsletter. 3 of the member responders indicated that they did not receive the newsletter. These individuals should contact the committee chair (Jane Goeke) to correct this situation.

The majority of responders liked the appearance and content of the newsletter although some felt that a change in appearance would improve presentation. Almost all responders liked the delivery and frequency of the newsletter very much.

There were numerous suggestions for topics to be covered in the newsletter. Some of these are:

- Quality by Design
- Managing CAPAs in a GLP Environment
- GCP Topics
- Cloud Computing
- Focus of FDA Part 11 Inspections
- Immunoassay Validation Requirements
- Practical QA information with pointers to tools, resources, etc.
- Real Life Stories-problems and challenges encountered by individuals in the process of doing their jobs.

MARSQA Members should note that you don't have to be a member of the Newsletter Committee to contribute to the newsletter. Articles, updates, reports from meetings, jokes, cartoons and all other kinds of information that would interest our membership are welcome. For more information on the newsletter, contact jane.goeke@gsk.com.





Q In your opinion what is the key to happiness?

A Friends and family. At the end of the day, it's the people in your life that make it good. Good health, life balance, and a passion for what you do (professionally and personally) are also key.

Q What is your all-time favorite movie? Why?

A I'd still have to say its 'Gladiator' with Russell Crowe. Yes, it's a quintessential "guy movie" but I really enjoy Crowe's character of Maximus Desimus Meridius. Throughout the movie, regardless of his place in life, Maximus led by example, and led from the front with "strength and honor". This won him the loyalty, admiration and respect of his subordinates, peers, masters, politicians, Emperors and enemies throughout the movie. What a managerial concept!

I'm also a big fan of Office Space because of the "it's funny because it's true" factor.

Q What do you like most about your current role in QA?

A I'd say there are three parts that I really enjoy as a GCP auditor. The first of which is how every time you go out on audit, you're reminded that these are real people you're there to help. Secondly is the opportunity to travel. In the past 18 months I've been to Costa Rica, Peru, Brazil, Russia, South Africa, and Kenya as well as multiple destinations in the US, Canada and Puerto Rico. Admittedly business travel is not glamorous, and without fail I always have travel anxiety leading up to my trips, but these are experiences of a lifetime. Lastly, I do enjoy the flexible work options that my company allows for. I'm currently a work-from-home employee, and it's a huge bonus in helping to achieve a good work-life balance.

Q What are your views on the outlook for quality assurance professional in the future? Do you see the field as having a shortage, an over-saturation, or the right number of QA professionals?

A Quality and compliance is always in a state of flux and evolution, and I believe there will always be a growing need for the QA professional. The hard question is staying ahead of the curve and placing yourself in a position to be where the future stress areas will be. I think the best thing a QA professional can do is to diversify their professional portfolio and take advantage of educational opportunities early and often.

Q What aspect of your job gives you the most personal satisfaction?

A Typically the clinical protocols that I audit are blinded. But when I review patient files and see general indications that a patient's regimen is making that person's life better. Just knowing that I play a small part in helping make that happen is a great feeling!

Q How important do you think it is to have a work-family life balance?

A I don't remember where I heard the quote, but no one lies on their death bed wishing they would have worked more instead of spending time enjoying life. Don't get me wrong - our careers are a big part of our lives, and everyone wants to be successful at what they do. But there's a time and place for everything. When I was fresh out of college working in the labs, I would actually compete with my colleagues to see who could get the most overtime in a year. Financially and professionally I did benefit. Socially I suffered for it. It's a tight rope to be walked for sure. Nowadays that time with my family and friends has become much more important. So when my manager tells me to stay off the computer and take a day or two off after spending two weeks on the road... I follow instructions happily (for the most part anyway).

Q What's your favorite vacation spot?

A North Carolina's Cape Fear Coast is my favorite destination and almost a second home. St. James, Southport and Oak Island form a triangle of small towns at the mouth of the Cape Fear River and the Atlantic. My wife and I visit the area often, and in 2009 we were married in the area which has been described as some as 'New England gone south'. Friendly folks, great memories, and ironically, a couple of fellow MARSQA members also have properties in the area as well. We'll often muse over starting-up our "Cape Fear Consulting" business.... Perhaps the vacation destination will someday become home!

Q What's your favorite hobby?

A I enjoy sports and fitness. Whether it's taking my mountain bike on the Columbia trail in NJ or diving into the sand while playing beach volleyball. I'm also an avid motorcyclist. A ride on twisty country back roads will clear the mind and calm the soul.

UPCOMING EVENTS

November 29-30

Two Day Training Course-Introduction to GLP
Lahaska, PA

December 9

Membership Meeting-Roundtable Discussion Sessions
Lahaska, PA

OECD UPDATE

Eva Haszcz

MARSQA Member

ARGENTINA JOINED THE OECD AGREEMENT ON MUTUAL ACCEPTANCE OF SAFETY DATA

On September 12, 2011, Argentina joined the OECD system for the Mutual Acceptance of Data (MAD) in the assessment of chemicals. Through MAD Argentina's non-clinical safety data related to the protection of human health and the environment must be accepted by OECD and other adhering countries. Initially, the scope of Argentina's compliance monitoring program will be limited to non-clinical environment and health safety data developed in Argentina on pesticides, biocides and industrial chemicals, with the possibility of future addition of other products.

2010 MARSQA AMBASSADOR AWARD

On behalf of the MARSQA Board of Directors, it is an honor to announce that Ms. Jane Pasquito is the recipient of the 2010 MARSQA Ambassador Award in recognition of her years of dedicated



and selfless service in shaping the society. As chair of the Program Committee for many years and in her many leadership roles on the Board, we cannot put into words how much her efforts for the chapter are appreciated. Jane is the epitome of what this award symbolizes; she has been a true Ambassador of MARSQA in all her efforts to help make the chapter what it is today. Thank you Jane for all you have done and continue to do to support MARSQA.

COMMITTEE CORNER: FIND YOUR WAY TO JOIN IN!

Links to all MARSQA Action Committees and the dates of their Meetings and TCs are now posted on the MARSQA Website at <http://www.marsqa.org/>. It's easier than ever to volunteer!

COMMITTEES

MARSQA has eight committees.

They are listed below along with the Chair(s) for each.

CSV	Paula Eggert	Paula_Eggert@merck.com
Education	Dwight N Crawford	Dwight.n.crawford@gmail.com
	Stephen Simpson	Simpson.stephenr@kendle.com
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	Carinne Park	carinnepaige@gmail.com

MARSQA's committees are very active and play a huge role in supporting the society. Please consider volunteering for one of them. Their activities are described below.

COMPUTER SYSTEM VALIDATION COMMITTEE

The MARSQA Computer System Validation Committee is designed to assist individuals working in this highly complex environment, by networking with other individuals in the industry, discussing current and relevant CSV material, and offering members valuable insight from keynote speakers. The MARSQA CSV committee meets regularly and the goal is to give participants hands-on experience in applying practical techniques and solutions to solve computer systems validation challenges. Participants are encouraged to discuss and analyze unique situations, apply newly acquired knowledge to their work environments, and have the opportunity to discuss their own real-life validation challenges with other participants and expert trainers. Participants are encouraged to come prepared to work in groups to devise workable and creative solutions to realistic problems, facilitated by the MARSQA CSV Committee Chairperson.

EDUCATION COMMITTEE

MARSQA's Education Committee consists of 2 chairpersons and a core group of volunteers from MARSQA's membership. The committee has presented a popular and successful Basic GLP Training Workshop for over 10 years. This program has been presented at least once, and as many as three times a year, for over ten years, and it is always filled to capacity. Each time the workshop is presented, members who would like to participate and volunteer their time are encouraged to act as facilitators or presenters. After participating as facilitators, volunteers are then able to present a section or sections of the next workshop, adding from their own experience to a presentation provided by MARSQA. The presentation has evolved over the years, incorporating changes in the regulations themselves as well as regulatory trends. Due to its reputation for being a quality, yet economical course, this workshop frequently has attendees from beyond the Mid-Atlantic Region giving the presenters and attendees the opportunity to interact with representatives from other areas of the country. In addition to the development and presentation of the basic GLP workshop, the Education Committee offers assistance

COMMITTEE CORNER CONTINUED

to MARSQA's other committees in developing and scheduling specialized training programs. Currently, an Introduction to GCP training workshop is being planned in response to member feedback. Participation in MARSQA's Education Committee gives members an opportunity to network with other QA professionals, to develop presentation/training skills, and provide necessary GXP training to personnel from our members' companies. It is a great way to be actively involved in MARSQA.

HISTORICAL COMMITTEE

The Historical Committee maintains MARSQA's historical records as provided by the Board or various committees. These records include committee reports, meeting minutes (monthly teleconferenced and/or membership meetings), photograph albums, ballot package and financial records some of which are required to be maintained indefinitely.

MEMBERSHIP COMMITTEE

SQA Headquarters is responsible for the maintenance of the MARSQA membership list and for the production of the MARSQA directory. If you would like to serve MARSQA in the role of Membership Liaison with SQA to ensure our list is current and that we publish a directory annually, please contact the MARSQA President, Alyssa Colon at alyssa.colon@roche.com. It is a way to give back to the MARSQA organization and should involve minimal effort and time commitment.

NEWSLETTER COMMITTEE

This committee produces the society's newsletter. This is called the MARSQA Monitor and is published 3 times annually (winter, summer and fall) in electronic format. The committee meets approximately once monthly by TC and also keeps the MARSQA Board up to date on its activities. The Newsletter Committee aims to provide the membership with up to date information about society activities and members, articles on professional and current topics and QA humor.

NOMINATING COMMITTEE

The Nominating Committee presents a slate of candidates for Officer and Director Positions open for election. The committee prepares a solicitation appeal to the membership sent via e-mail by the Society of Quality Assurance (SQA). The committee will contact all nominees to determine their ability and interest. Once a nominee has agreed to run for office, the committee will obtain the appropriate biographical information for the ballot using a MARSQA format. Once the MARSQA Board approves the slate of nominees, SQA will send the ballot, biographies and instructions for voting via e-mail to the membership. The Board President will communicate the results of the voting to the membership shortly afterwards.

PROGRAM/PLANNING COMMITTEE

The Program/Planning Committee plans three membership meetings a year. The meetings are at various locations in the Mid-Atlantic area. MARSQA has recently expanded to using Webinars to benefit those individuals unable to attend in person. Meetings are affordable at only \$20.00 for members and \$40.00 for non-members. A meeting typically begins with a buffet lunch and plenty of time to network and meet with colleagues. The President opens the meeting with a "MARSQA Business" update and a brief overview of current SQA topics. The core of the meeting is really an information exchange either via speakers or roundtable discussions covering multiple topics.

COMMITTEE CORNER CONTINUED

Examples of some recent topics include:

“Challenges of Validating and Implementing Global Technologies”

“Digital Imaging-Validation Challenges in a Regulated Environment”

“Changes in Skill Sets Required for GLP Professionals in the Past 15 Years”

“Audit is Done, Now What”

Panel Discussion: “Recreating Yourself to Succeed in a Challenging Job Market”

Details for upcoming programs can be found on the MARSQA website.

TECHNOLOGY COMMITTEE

MARSQA's Technology Committee's primary goal is to effectively provide the membership with electronic resources and communication tools. The committee maintains a current website with reference materials and details to inform the membership of MARSQA's activities. The committee also monitors online forums and identifies changes in technology capabilities that may enhance communication across the membership. We aim to create the opportunity for discussions and participation from the entire membership no matter how near, far or the time zone. As sometimes topics of discussion arise at atypical hours, we aim to have continuous availability for members to present their questions or concerns and to have a forum of resources and other members at their fingertips to offer perspective and suggestions.

Why Join MARSQA?

Simply put, it's a good deal!

Here's what you get for your annual dues of \$50:

- Low cost half day membership meetings which include lunch and professional presentations relevant to your job. (\$20 for members; \$40 for non-members) It is now possible to attend these meetings by webinar.
- Low cost professional training classes (e.g., GLP Fundamentals, Principles of Computer Validation, Analytical Chemistry for the QA Professional). These classes last from one half day to several days, have a limited number of students and allow for a great deal of interaction with the trainers.
- Website and contents (e.g., presentations, career center, past newsletters)
- Electronic Newsletter 3x annually with useful industry information
- Membership Directory
- Low cost advertising rates
- Scholarships to defray the cost of attending the annual SQA meeting
- Opportunities to network, form communities of interest and keep up with the latest industry trends

So, if you're not a MARSQA member and think you'd benefit from all these offerings contact our website at www.marsqa.org and hit the “join” tab on the upper right of the page. Welcome to our community.