MARSQA MONITOR

Newsletter of the Mid-Atlantic Region Society of Quality Assurance

Volume 16, Issue 1, Spring 2012

Welcome to 2012!

Welcome MARSQA Members to 2012!
I would like to first thank you all for the opportunity to be your 2012 MARSQA President. I had no idea when I joined MARSQA many years ago, that I would find myself leading the entire organization someday. But that is why MARSQA is so different than any other professional organization I have been involved in. It's the people you get to meet and work with!

My wonderful and talented predecessors and other skilled board members made getting involved not only so easy, but so personally and professionally rewarding, that I just couldn't help myself. In a very short time, I found myself volunteering to help make a call to friend to speak at one of the meetings and then when that fell through, I found myself volunteering to actually do the presentation. Soon, I found myself nominated to a Board position and then evolved into being elected as 2011 Vice President and now 2012 President. Not bad for someone that just wanted to just make a few phone calls, lay low and have something to note on my CV or LinkedIn profile.

My goal as your 2012 President is simple. I want to create an environment that helps all of you learn and grow professionally. I want to create an environment that facilitates good conversation and long lasting relationships that help you advance in your career and be a part of your personal and professional development. There are so many things that I want to do and know that I have only a short time to do it. My reign is short and by the time you read this, 1Q will already be in the books. I have planned for a very aggressive year with even more Membership Meetings at our favorite spot in Lahaska's C*ck-n-Bull Restaurant. For those that have never attended, you don't know what you are missing! Those that have come know exactly what I'm talking about and why so many return time and time again. We are looking to provide more 1 or 2 day Training Sessions as well. When appropriate, we are also going to provide Webinars, to offer our sessions to those that cannot attend in person, but still want to enjoy the many benefits of being a MARSQA member.

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In this issue...

This year, we are also in the process of making some much needed improvements to our website, which will transform it into a more interactive and engaging site, in keeping with the theme of ensuring that you feel that your membership is providing you with real value. We know that times are tough and more often than not, the first things that get cut are sometimes the luxuries of being a part of a professional organization or participating in professional development programs, such as this. We know you have to choose between us and others and thank you for allowing us to be a part of your career and professional development.

I'm looking forward in being your President in 2012! I take this position and role very seriously and I'm committed to making this year, a year filled with great possibilities!

Please feel free to contact me anytime at ranee.henry@marsqa.org

Sincerely,

Ranee Henry
President of MARSQA 2012

MARSQA
Mid-Atlantic Region Society of Quality Assurance

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MISSION STATEMENT

Our Mission is to provide current regulatory information, education and networking opportunities for the Quality Assurance Professional. Through meetings, workshops, our Newsletter and our Chapter Website, we look to advance quality concepts and methods to members and provide a forum to interact with other professionals having the same common interest.

Applying the GLPs to In Vitro and Alternative Studies

Tanja Vaneman, RQAP-GLP
MARSQA Member, Newsletter Committee Member

In vitro (literally meaning "in glass") and alternative studies have evolved to include experiments in which the test system ranges from biochemical assays or cells, to ex-vivo tissue culture of animal organs. Typically, these test systems are treated with test article (pharmaceutical, cosmetic, or industrial chemicals) to determine potential toxicity, thus minimizing the use of animals in GLP studies. Between 1985 and 1995, several in vitro and alternative methods were validated as a replacement for the Draize rabbit eye irritation study, including the Chorioallantoic Membrane Vascular Assay (CAMVA) and Hen's Egg Test Chorioallantoic Membrane (HETCAM), which utilize eggs as the test system and the Bovine Corneal Opacity and Permeability Test (BCOP), which utilizes excised bovine corneas, obtained as animal byproducts. In 1996, the OECD issued the Application of GLP Final Report for the Harmonization of Validation and Acceptance Criteria for Alternative Toxicological Tests Methods, to define requirements for planning, conducting, recording, and reporting these types of studies. Today validated and accepted in vitro studies include the Murine Local Lymph Node Assay (LLNA), which tests the allergic contact dermatitis potential of a test substance, using mouse lymph nodes; 3T3 Neutral Red Uptake Assay, which detects the phototoxicity potential of a test article and solar-simulated light, using a mouse fibroblast cell line; and 3d ocular and skin tissue equivalent viability assays.

When applying the GLPs to short-term in vitro and alternative studies, interpretation may be problematic, since early versions of the GLPs were directed toward long-term animal based studies. Some areas of focus include: the use of controls, the identification of the test system, facility concerns, and decontamination, suitability of reagents, and quality monitoring. For specific tests, guidelines may require the use of positive, negative, and vehicle controls, which must then be evaluated to determine the validity of the assay. Test systems such as cells and tissues should be assessed for functional and morphological integrity, as well as for potential contamination. Work with cell and tissue culture requires differentiation of workspace, specialized equipment, and careful decontamination procedures. Reagents used should be assessed for suitability, verified for compatibility with the test system, and evaluated for contamination. Quality monitoring of in vitro and alternative studies encompasses all aspects of the GLPs, including defining critical phases of the study and inspection frequencies. Special attention should be paid to manipulation of cell and tissue cultures and reconstitution of cells, cleaning and decontamination of the facility and equipment, assessing status and integrity of the test system, and training for in vitro procedures.

As institutions of higher learning and industry work together to implement the three Rs (Refinement, Replacement and Reduction) of animal welfare in their testing strategies, the outcome will be a successful effort to decrease the use of animals while ensuring safety. These in vitro and alternative GLP assays will continue to shift from novel scientific advancements to a routine and vital element of the testing strategies which are pivotal in providing a complete safety profile for new compounds. As the use of these assays increases, the results will only maintain their validity if they are conducted in a laboratory that uses careful scientific evaluation and strategic interpretation of the GLPs therefore yielding results with the highest integrity. It is these ethical principles of science and compliance which will catapult the scientific advancements of in vitro and alternative safety testing from with "in the glass" of skepticism and scrutiny to the equal footing and status they have earned.

MARSQA Member Profile

Nancy Gravino
Director, MARSQA Board of Directors

Q. If you could meet any famous person today, who would it be? Why?
A. I admire Evangelist Billy Graham. His life work has been serving God and helping others. He has probably preached to more individuals than anyone else, and yet someone who is shy like me has trouble speaking in front of a small room full of people.

Q. What advice would you give to someone starting out as a GXP (GLP, GCP and/or GMP) compliance professional?
A. Get involved with organizations like MARSQA and SQA and try to learn as much as you can about each of the functional disciplines (GLP, GMP, and GCP). You will get to know a lot of good people and you will become more marketable in case your company downsizes or outsources work.

Q. What is your favorite leisure time activity?
A. I have a few favorite leisure time activities; floating on a raft in our pool, sitting in a beach chair at the Jersey Shore doing my puzzle books, or cruisin' down the highway with my husband in one of his classic cars and not having a care in the world.

Q. What aspect of your job gives you the most personal satisfaction?
A. I am proud that the work I do every day helps to extend and enhance human life.

Q. What is your opinion of reality TV? Do you have a favorite or a not-so-favorite show?
A. I am not a fan of reality TV; I would rather watch repeats of the show 'The Wonder Years'. But if you were to ask my husband, he would probably say that he finds me watching the TV show 'Hoarders' and then he wonders why I would want to watch that show. I am a bit of a pack rat and if I watch 'Hoarders', I don't feel as bad about my own boxes and tubs full of 'stuff'.

Q. How do you deal with the stress of everyday life?
A. It helps to have a husband who keeps you laughing every day. But, I am pretty good at multi tasking and if you ask my friends and coworkers, I write lists on post it notes of things that need to get done and then I make sure it gets done.

Q. Where would you like to reside when you retire? Why?
A. I would like to retire somewhere without snow in the winter and without crowds in the summer. But really, anywhere close by all of my family.

Q. What is your dream job (other than being a compliance professional, of course)?
A. When I was growing up, I wanted to become a Veterinarian because of my love of all animals. I worked part time as a veterinary assistant for a few years, so I did get to fulfill a portion of my childhood dream.

MARSQA Member Profile

Kim Baratelli
Treasurer, MARSQA Board of Directors

Q. If you could meet any famous person today, who would it be? Why?
A. Patrick Henry because he is a great figure in Virginia and American history

Q. What advice would you give to someone starting out as a GXP (GLP, GCP and/or GMP) compliance professional?
A. Take lots of notes.

Q. What is your favorite leisure time activity?
A. Playing with my dogs and wine tasting.

Q. What aspect of your job gives you the most personal satisfaction?
A. Knowing that I'm ensuring quality and integrity of report data

Q. What is your opinion of reality TV? Do you have a favorite or a not-so-favorite show?
A. I dislike reality TV because I feel it is contrived and trite. My not-so-favorite show is the Real Housewives of "***". It doesn't matter which one, they are all bad.

Q. How do you deal with the stress of everyday life?
A. Listen to classical music or various types of instrumental ensemble.

Q. Where would you like to reside when you retire? Why?
A. I would love to retire in Virginia because I enjoy history and the atmosphere. What better place to visit than Williamsburg.

Q. What is your dream job (other than being a compliance professional, of course)?
A. Become a pastry chef because I love to bake.

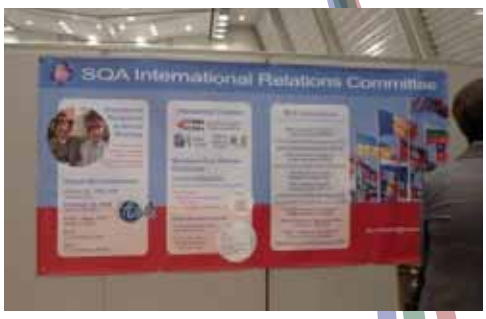
Report from Kyoto

Leslie Kvasnicka, RQAP-GLP
Barbara Foy, RQAP-GLP
SQA International Relations Committee

The 3rd Global QA Conference opened on a beautiful fall day at the impressive Kyoto Conference Center, site of the Kyoto Protocol agreement in 1997. Over 900 attendees from 23 countries packed the main hall and donned their headsets to tune into Japanese or English translation as needed. After a welcome from JSQA President **Akira Takanaka**, Shoji champion **Yoshiharu Habu** gave the first keynote address. He shared the decision-making method that has helped him rise to the top of the chess-like strategy game and can also be applied in other professions. He described how he balances intuition with analysis, how he focuses on the forest rather than the trees, and how he makes decisions quickly without having complete knowledge.

Dr. Andrew Waddell, former Chairman of BARQA, was the second keynote speaker. He described the personal and technical attributes that are most valuable to successful quality assurance professionals. He emphasized the need for auditing skill, experience and also for emotional intelligence to motivate others to view quality improvement as valuable and integral to achieving business results.

During the global conference, members of the SQA International Relations Committee had a brief, joint meeting with members of the JSQA International Affairs Committee. SQA IRC members included **Barbara Foy, RQAP-GLP** (outgoing IRC Liaison to JSQA), **Leslie Kvasnicka, RQAP-GLP,** (incoming IRC Liaison to JSQA) and **Elliott Graham, RQAP-GLP**, SQA's Executive Director. We joined JSQA International Affairs Committee members, **Toshiro Asahina** (committee chair), **Shigero Makizaki** (former committee chair), **Toshiaki Tamura, Teiki Iwaoka, Rika Ohnishi, Migawa Hirosake, Fujun Chen** and **Naemi Fukuda**.



Scenes from 3rd GQAC
photos by Barbara Foy, RQAP-GLP

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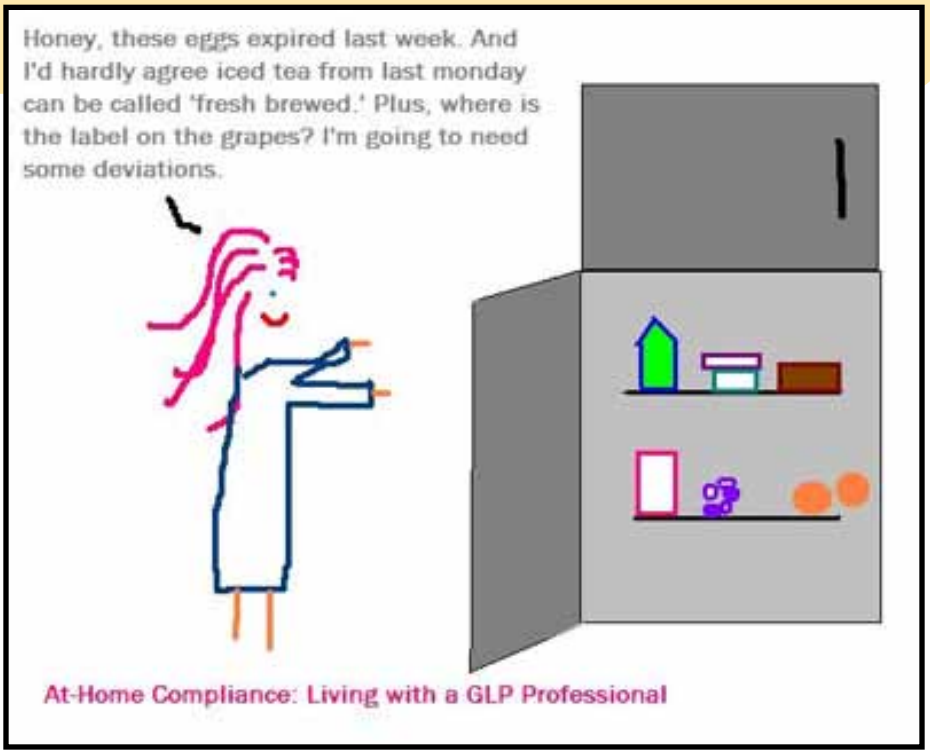
Report from Kyoto - continued

Together we were able to have a valuable exchange of information. To begin, each side gave an overview and listed the main activities of each of our international committees. Discussion continued on how to best further our system of communication on topics of interest to both memberships. We also briefly discussed the status of the FDA Part 11 regulations, perspectives on the progress towards GLP global harmonization, and an update on the computer-based examination process for the RQAP-GLP registration. We agreed to continue to keep the information stream open between our two committees via email, and we will plan on having a similar meeting at the 2012 SQA conference in Miami.

In the evening our JSQA hosts pulled out all the stops and transformed the convention hall into “Japan Night” with a buffet of delicious dishes, sushi and tempura chef stations, sake tasting experience, origami lessons, and plenty of socializing for all of their guests.

Our friends at JSQA have set a high bar for the next GQAC, to be held in Las Vegas in 2014. The IRC will play a prominent role in that conference. If you have an interest in broadening your QA experience beyond the USA borders, please contact us via the SQA website.

cartoon submitted by
Carinne Park, Chair of the
Technology Committee



UPCOMING MARSQA TRAINING SESSION-COMPUTER VALIDATION

MARSQA will offer a two day training course in Computer Validation Basic Training. This will be held at the Cock and Bull Restaurant at Lahaska (Peddlars’ Village) near New Hope, PA. The session will be interactive. An announcement with more information will be sent out in April, 2012. Reserve these dates!!

MARSQA 2012 Committee Chairs

MARSQA has eight committees which are listed below along with the Chair(s) for each. Please consider volunteering for one of these groups.

CSV
Paula Eggert — paula.eggert@merck.com
Courtney Rodriguez — courtney.rodriguez@crl.com

Education
Dwight N Crawford — dwight.n.crawford@gmail.com
Stephen Simpson — stephen.simpson@boehringer-ingelheim.com

Nominating/Historical
Fran Jannone — jannonef@princeton.huntingdon.com
Nancy Gravino — nancy.gravino@bms.com

Membership
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Newsletter
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Program/Planning
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Technology
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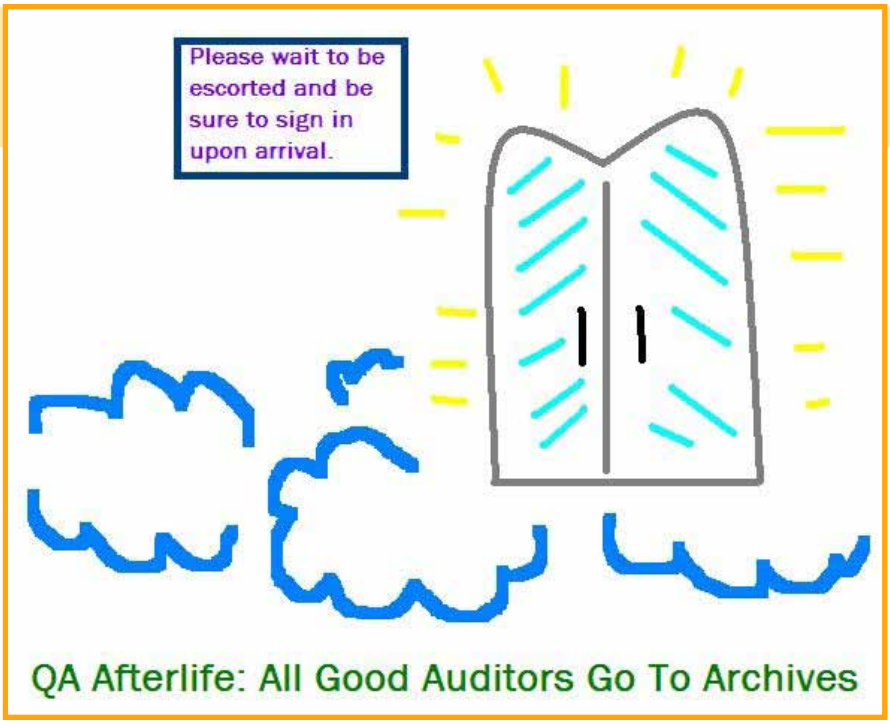
Marlena Maier — oriziba77@yahoo.com

cartoon submitted by Carinne Park, Chair of the Technology Committee



AMERICAN COLLEGE OF TOXICOLOGY

The American College of Toxicology was incorporated in 1979. The mission of the A.C.T. is to educate, lead and serve professionals in toxicology and related disciplines by promoting the exchange of information and perspectives on applied toxicology and safety assessment.

This year we will be offering the following courses:

TOXICOLOGY FOR INDUSTRIAL & REGULATORY SCIENTISTS
APRIL 23 - 27, 2012
Noblis, Inc.
3150 Fairview Park Drive
Falls Church, VA 22042

ACT Member Registration	$1,295.00
Non-Member Registration	$1,595.00
Government Registration	$1,295.00

PATHOLOGY FOR NON-PATHOLOGISTS
"Hepatobilliary, Urinary, Reproductive, Cardiovascular and Respiratory Systems"
MAY 14 - 16, 2012
Noblis, Inc.
3150 Fairview Park Drive
Falls Church, VA 22042

ACT Member Registration	$1,195.00
Government	$1,195.00
Non-Member Registration	$1,395.00

AMERICAN COLLEGE OF TOXICOLOGY 33rd ANNUAL MEETING
NOVEMBER 4 – 7, 2012
Omni Orlando Resort
Championsgate, Florida

For more information and registration forms on these programs, please go to our website www.actox.org.

www.validassoc.com

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