



MARSQA Monitor

NEWSLETTER OF THE MID-ATLANTIC REGION SOCIETY OF QUALITY ASSURANCE

Volume 13, Issue 1

NEW MARSQA PRESIDENT JUMP STARTS 2009



Welcome to the New Year of 2009, as well as, to the more recent New Year of the Ox.

By the time you receive this edition of the MARSQA newsletter the Board of Directors will have met face-to-face for the first time in 2009. This initial

meeting was planned to ease transition of the outgoing and the newly elected board members. Our new Board members include Anthony Borisow serving as new Vice-President; Michael Franks serving as the new Treasurer; and two new Directors, Raymond Borysewicz and Melissa Elliott, RQAP-GLP. Some of these members are familiar faces and some are brand new to the Board. In either case I am looking forward to working with all the members to provide a prosperous New Year for all of MARSQA.

My main goal as President in 2009 is to maintain and enhance the basic services that Janet Emeigh has worked on re-establishing for the MARSQA membership in 2008. Services like the re-established newsletter, the membership directory and the revitalized Computer Validation committee. In addition to these services I would also like to fine-tune or further enhance some of the behind the scenes services related to the Treasurer's responsibilities and

the website, as well as to provide meaningful training opportunities for all our members.

One of these training opportunities will be available via a MARSQA sponsored scholarship to attend SQA's annual meeting in San Diego. This award is to cover cost of registration, travel, hotel and meal expenses for the recipient associated with attending this meeting.* To date we have had more applications submitted than we have seen in previous years. The Board of Directors will decide upon and announce to whom the scholarship will be awarded by February 20, 2009.

In closing I would be remiss if I did not ask the MARSQA membership to consider getting involved to support the activities of this organization and to help enhance and improve any of the services we provide. As it is always echoed in any volunteer organization, MARSQA can always use a few more volunteers. There are many ways you can help this organization that don't take a lot of time or effort and there are new friendships and increased networking opportunities MARSQA can provide you in return for any effort invested.

Lynda

Lynda Olsen
2009 MARSQA President

* Please note that the recipient will receive a form 1099 for the full value of the award.

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Winter is upon us and hopefully everyone had a very restful and enjoyable Holiday season and a wonderful New Year!

It's that time of year again when the MARSQA Board says good-bye to some who have served us well over the past years. We would

like to thank Alex Trantalis and Meredith Russo for their dedication as Directors on the Board. Alex also served as the Board liaison to the CVC and Meredith was our liaison with the Communications Committee as well as with our webmaster. Thanks also to Melissa Elliott for hanging in there as Treasurer during some very rough times, maintaining some of our financial records while SQA maintained others and then trying to "marry" the two sets come tax time (no mean feat). We are in the process of trying to turn the maintenance of all of our financial records over to SQA, so hopefully our new Treasurer won't have such a difficult time. While she is stepping down as Treasurer, Melissa will continue to serve the MARSQA Board for two more years as a Director. Finally, to our outgoing Past President, Nicki Iacono, RQAP-GLP, thanks for your help and support of me this year as well as the many years you have served the MARSQA Board as a Director, Vice President and President.

My main goal as President in 2008 was to bring back the basic services that MARSQA has provided over the years, when in the past several years seem to have slipped through the cracks. One of those goals was bringing back the newsletter on a regular basis. You are reading this today thanks to hard work of Jane Goeke and her Communications Committee who have also dedicated themselves to bringing this service back on a regular basis. The first edition back was so much more than I expected and I believe there are only better things to come from this group. I know I will be eagerly awaiting each new issue to see what they will do next.

Another item was the Membership Directory. We managed to get one out in early December 2008 and

while it may not have been perfect, we did finally get it out. My goal as chair of the Membership Committee is to get a directory out to the Membership by early June. Once we get our website issues ironed out, we would like to also be able to maintain an interactive directory on our Member's Only section, which will allow you to make updates to your information as things change. We'll keep you posted on those developments.

MARSQA continues to be a strong organization thanks to the many people who have stepped up to volunteer. The Computer Validation Committee has been revitalized, thanks to the efforts of Ranee Henry and the rest of the committee. As you will read elsewhere in this newsletter, they once again hosted and provided the speakers for our Fall meeting in early December 2008 in Lahaska. It was very well attended and both speakers provided excellent information on auditing technology vendors and computer validation projects. MARSQA can always use a few more volunteers. Without them, our organization would not continue to exist. There are many ways you can help the organization that don't take a lot of time or effort and, as I've stated before, the friendships and networking opportunities you get in return are more than worth the effort invested!

I want to thank all the returning MARSQA members for sticking with us through the difficult times. I also thank our new members who have decided to join us and hope that you decide to remain with us.

Finally, I want to thank all of the Board members (past and present) with whom I have served. Thanks for all of your support and encouragement. Without you, I could not have done it.

I now pass the baton to Lynda Olsen and the rest of the MARSQA Board (old and new). I know I leave this organization in good hands and I'm excited to see where they will take it in the years to come!

Janet

Janet Emeigh, MS
2008 MARSQA President

NEW MEMBERS OF THE MARSQA BOARD IN 2009 INCLUDE:

Vice President - Anthony Borisow

Treasurer - Michael Franks

Director - Raymond Borysewicz

Director - Alyssa Colon, RQAP-GLP

Director - Melissa Elliott, RQAP-GLP

MARSQA would like to thank those members who ran for office this time but were not elected. Your willingness to serve is much appreciated and we hope that you will consider running again when election time rolls around again this fall.

Also, thanks to MARSQA's outgoing Board members who include Alex Trantalis (Director) and Nicky Iacono, RQAP-GLP (Past President). Their service to MARSQA as a whole has been appreciated. Anthony Borisow served on the Board previously as a Director and has taken on a new role as Vice President; Melissa Elliott, RQAP-GLP served on the Board previously as Treasurer and has taken on a new role as Director.

Tony had one year remaining in his term as Director. As per MARSQA bylaws, the Board discussed and voted for Alyssa Colon to fulfill his remaining term at their first meeting of 2009, held February 12, 2009.

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.

2009 MARSQA OFFICERS

PRESIDENT

Lynda Olsen
lynda.olsen@spcorp.com

VICE PRESIDENT

Anthony Borisow
aborisow@prdus.jnj.com

PAST PRESIDENT

Janet Emeigh, MS
jemeigh@medarex.com

TREASURER

Michael Franks
michael.franks@qaresources.net

SECRETARY

Nancy Beck, RQAP-GLP
nancybeck@bms.com

DIRECTORS

Raymond Borysewicz
rborysew@prdus.jnj.com

Alyssa Colon, RQAP-GLP
alyssa.colon@roche.com

Melissa Elliott, RQAP-GLP
elliottm@princeton.huntingdon.com

Judy Goble, RQAP-GLP
jgoble@prdus.jnj.com

Meredith Russo
meredith.russo@spcorp.com

THE RQAP-GCP REGISTRATION PROGRAM

Courtney Glass

MARSQA Member

The GCP Registration Program for Regulatory Quality Assurance Professionals is relatively new. In order to make sure that MARSQA members had the most up-to-date information on this registration, I spoke with Cheryl Bissey-Black, RQAP-GCP, Chair of the SQA Council on Professional Registration (CPR), and Danna Carver, RN, RQAP-GCP, of the CPR's RQAP-GCP Examination Committee. They provided me with the following information.

In 2004, the Clinical Specialty Section (CSS) of SQA decided to explore the need for a registration examination in Quality Assurance for professionals focused on GCP. Many SQA members working in the GCP area have contributed to the development of the examination by participating in surveys and serving on various committees. A team of volunteer content experts (SQA *ad hoc* Registered Quality Assurance Professional (RQAP) GCP Examination Committee), and CPR partnered with Applied Measurement Professionals, Inc. (AMP) to analyze the tasks that the GCP QA professional performs. The analysis was reviewed by a broad cross-section of GCP Quality Assurance professionals for accuracy and relevance. From this analysis, an examination was developed.

The RQAP-GCP registration program is an examination-based program intended for GCP auditors. Individuals passing the examination will be credentialed as Registered Quality Assurance Professionals in GCPs (RQAP-GCP). The examination covers all international regulations and has a broad content base to cover. The Professional Registry Examination consists of 165 multiple-choice questions. Candidates are allowed three and one half (3.5) hours to complete the examination. Costs to take the exam are \$350 for SQA Members and \$460 for non-members.

In order to qualify to take the exam, applicants must have the equivalent of four years of full-time experience working as a quality assurance professional

in GCP prior to the examination date OR have a baccalaureate degree AND the equivalent of two years of full-time experience working as a quality assurance professional in GCP prior to the examination date.

To date, several full certification exams have been successfully completed. At last count, there were approximately 90 RQAP-GCP designated professionals. However, with the addition of a computer based testing approach to administer the exam, this number is constantly growing.

Additional information, including a comprehensive list of references for exam readiness, a detailed content outline, and an exam application is provided in a recently updated handbook found on the RQAP-GCP exam web page: <http://www.sqa.org/newsite/cpr/rqap-exam-gcp.asp>.



HERE'S A CHANCE TO GET YOUR MESSAGE ACROSS

MARSQA's Program Committee organizes three excellent and well attended membership meetings per year.

Would you like to be part of this effort? Are you interested in giving a presentation? Do you have an idea that would provide a theme or topic for an entire meeting? Would you like to volunteer to help organize and manage a meeting?

If the answer to any of these questions is yes, just e-mail Jane Pasquito, Program Committee Chair at jane.pasquito@sp.intervet.com.

DECEMBER 2 MEMBERSHIP MEETING: A GREAT SUCCESS!



MARSQA's CSV Committee organized a general membership meeting in December which focused on computer auditing approaches. There were approximately 100 attendees at the Lahaska, PA event (Peddler's Village) who enjoyed a great lunch at the Cock'n Bull restaurant prior to the presentations.

Nancy Tucker of Validation Associates, Inc. gave the initial presentation on "Auditing Technology Vendors." Nancy focused on the best way to assess vendors who supply products (software/hardware) as well as those who supply services. Nancy based her approach on business as well as regulatory requirements and used actual events to make her points. She advised auditors to focus on the development process as well as the final product.



Harry Huss of Charles River spoke about "Auditing Computer System Validation Projects." Harry offered practical advice to auditors who play a "consultant" role in computer validation projects. He reminded everyone that the GxP professional is often the most experienced and knowledgeable person on a validation project. Harry elaborated on the overwhelming importance of the System Requirements Specification (SRS) and gave a condensed version of current expectations for electronic records, audit trails and signatures.

Jane Goeke

Chair, MARSQA Communications Committee

In September 2008, I attended PhRMA's Bioresearch Monitoring Committee's Annual Workshop. This two-day event focused on such issues as regulatory modernization, new audit methodologies, risk based quality management systems and mutual recognition in both GLP and GCP environment. I attended the GLP track.

Here are a few interesting points:

- FDA has begun to add permanent staff in India and China. The current focus is on GMP compliance but this will change.
- FDA conducted some remote audits in 2008 and is evaluating whether this is an effective approach to compliance monitoring.
- FDA hopes to make GLP requirements/expectations consistent across all FDA centers. This is being studied as part of the modernization effort.
- There is an FDA expectation that all facilities will have a program for incurred sample analysis. This should include an SOP and appropriate documentation in data and reports.
- FDA has encountered some instances where foreign labs have been certified as GLP compliant by local authorities; when inspected by FDA, these labs were found to be non compliant with their national GLPs. FDA advice is to verify compliance yourself in these cases.
- There were presentations and a great deal of discussion around the conduct of GLP studies in India and China. Some of the points made about India are:
 1. There is no centralized agency like the FDA yet to monitor pharmaceutical/biotechnology products;
 2. Indian GLPs are based on the OECD model; and
 3. India is a provisional member of the OECD.
 Some interesting aspects of the Chinese GLPs are:
 1. Test facility management must review and approve final reports and must have a Bachelor's degree or higher;
 2. QAU staffing is required to be directly proportional to the size of the facility; and
 3. Technical staff must have a government certification.
- Pathology Imaging Systems have been accepted by the FDA. However, it is not clear what the requirements for such systems will be in a GLP environment. For example:
 1. What is the raw data, the slide or the image from which the diagnosis is made;
 2. What should be retained;
 3. How does one ensure the quality, consistency and longevity of the images;
 4. What part does 21CFR Part 11 play; and
 5. What role does cost play?

Overall, the meeting was very energizing. Every topic presented and discussed was relevant and timely.

SUPPORT/ADVERTISE IN THE MARSQA MONITOR!

The Communications Committee writes, collects and assembles the copy for the MARSQA Monitor. We are always happy to hear your ideas, suggestions and *especially* to publish your contributions in the newsletter. Just contact Jane Goeke, RQAP-GLP, Communications Committee Chair at jane.goeke-1@gsk.com. Other members of the committee are: Kim Evans, Courtney Glass, Kimberly Lytle, Rachel McGowan, Ana-Maria Rodriguez-Rojas and Denise White, RQAP-GLP.

Please also remember that you can advertise in the Monitor. For example, the discounted fee for members is only \$75 for a full page add for three editions. The MARSQA monitor is published in the Fall, Winter and Spring. Contact Jane Goeke, RQAP-GLP for more information on advertising.

Announcements

UPCOMING MEMBERSHIP MEETINGS

MARCH 26, 2009- Cock'n Bull in Lahaska, PA. The planned speakers for this meeting include Doreen McGirl, Senior Manager at Schering Plough, who will speak on "Auditing in a Monitored World"; Jane Goeke, RQAP-GLP, Director of North American Preclinical Compliance at GlaxoSmithKline who will speak on "Managing, Classifying and Justifying QAU Observations/Findings"; and Nicki Iacono, RQAP-GLP, Vice President of Quality and Data Management at Huntingdon Life Sciences, who will provide an update from the SQA Board.

MARSQA will be sending e-announcements regarding this meeting in February as details are finalized.

There will be a second membership meeting in June. The third and last MARSQA Membership Meeting of 2009 will be unusual in that it will be held in conjunction with SQA's Quarterly Meetings in a New Jersey or Pennsylvania location. The event will likely occur in October or November.

MARSQA has seven committees. They are listed below along with the Chair for each.

Communications	Jane Goeke	jane.goeke-1@gsk.com
CSV	Ranee Henry	ranee.henry@crl.com
Education	Joanne Ramundo	joanne.ramundo@sanofi-aventis.com
Historical	Fran Jannone	jannonef@princeton.huntingdon.com
Membership	Janet Emeigh	jemeigh@medarex.com
Nominating	Fran Jannone	jannonef@princeton.huntingdon.com
Program/Planning	Jane Pasquito	jane.pasquito@spcorp.com

MARSQA activities and projects are driven to a great extent by its committees. And, most of the members of these committees are volunteers. For this edition of the MARSQA Monitor, roving reporter Denise White asked a member of the Education Committee and a Member of the Program Committee to tell us about their experiences as committee volunteers. These are their stories.

Mike Franks: Education Committee

If you have an instinct to teach, or you want to hone your presentation skills, or diversify your professional experience, then contributing to the MARSQA Education Committee may be your next opportunity. I have found presenting at MARSQA training courses to be both enjoyable and rewarding.

The Education Committee's most popular course offering is the mainstay Basic GLP Training Course provided once or twice a year, usually with sell-out attendance at Peddler's Village in Lahaska, PA. Attendees for this course typically include a nice mix of QA and study personnel from FDA and EPA regulated sponsors and contract research organizations.

It's very gratifying to be able to answer some of the burning questions of those less experienced in the GLPs. And I have found that presenting to and interacting with attendees and co-presenters in this course keeps me well grounded in "the basics". This is a valuable tool for me as a consultant and it reinforces the need to consider the adaptability of GLP to a broad range of research and development environments. I've found no better way to bring GLP into new areas than starting with the basics, and I often find that at some of the more experienced organizations, reinforcing the basics can be just as important.

In 2008 the Education Committee also offered courses entitled "Personal Development and Effectiveness for QA Professionals" and "Bioanalytical Chemistry for QA Professionals" – two more excellent courses at very reasonable cost to MARSQA members. Whether you are still in training and looking for a good course to attend, or you would like to share your knowledge with the less experienced, I hope to see you soon at one of the Education Committee's courses.

John Cihiy: Program Committee

I have participated on the MARSQA Program Committee for over five years. I would like to describe my experiences and the value of the Program Committee.

Jane Pasquito is the chairperson of the Program Committee. She organizes three excellent meetings a year. She is the "heart" of the Program. However, a healthy heart needs fresh blood to function. The fresh blood of the committee consists of the volunteers. The volunteer duties include registration, preparation of certificates of attendance, surveys, receipts, name tags, handouts, providing survey and speaker gifts, and taking pictures.

My experiences on the committee have been primarily with registration. Through the Program Committee, I have had the opportunity to meet new people. I believe that the Committee has provided professional enrichment. I highly encourage MARSQA members to volunteer for the Program Committee.

THANK YOU COMMITTEE MEMBERS!

Communications

Jane Goeke, RQAP-GLP – *Chair*
Kim Evans
Courtney Glass
Kim Lytle
Rachel McGowen
Ana Maria Rodriguez-Rojas
Cary Sutherland
Denise White, RQAP-GLP

Computer System Validation

Ranee Henry – *Chair*
Rachel Adler
Chander Badwal
Sourav Baneerjee
Nancy Beck, RQAP-GLP
Mary Ann Berthrong
Frank Bosley
Daniel Boss
Denise Botto
Tim Bream
Brian Burns, MS, RQAP-GLP
Tamara Cadora, RQAP-GLP
Irinia Colligan
Charles Collins
Grace Crawford
Paula Eggert
Melissa Elliott, RQAP-GLP
Karen Evans
Lisa Fluharty
Nancy Gongliewski
Jennifer Kennedy
Kathy Loewen
Darlene Looney
Kiet Luong
Ruth Michener
Donna Morelli
Art Pezzica
Joanne Ramundo
Neelima Raval
Felecia Renz
Robert Rhea, RQAP-GLP
Courtney Rodriguez
Maria Rose

Computer System Validation *continued*

Lynda Sands
Peter Sheehan
Regina Shive
Craig Singwald
Alex Trantalis
Nancy Tucker
Lisa Weiss
Patti Zychowka

Education

Joanne Ramundo – *Chair*
Melissa Elliott, RQAP-GLP
Janet Emeigh MS
Mike Franks
Jane Nelson
Lynda Olsen
Jane Pasquito
Jen Safford

Historical

Fran Jannone, RQAP-GLP – *Chair*

Membership

Janet Emeigh, MS – *Chair*

Nominating

Fran Jannone, RQAP-GLP – *Chair*

Program/Planning

Jane Pasquito – *Chair*
John Cihiy
Patrick Dalton
Chirine Fiouzi
Wanda Franklin Hunter
Sonya Gray
Linda Morgan
Jane Nelson
Helene Rosenthal
Meredith Russo
Denise Wilson
Barb Simms, RQAP-GLP
Cynthia Kelsch, RQAP-GLP

MARSQA would
like to extend a big

*Thank
You*

to all the members
who volunteer for
our Committees.

Jane Goeke

Chair, MARSQA Communications Committee

Those who work in the areas of regulatory compliance easily meet the current definition of “Knowledge Workers”. These are workers who are hired for what they know and who are educated and have experience. They require knowledge to function and they create new knowledge as they function. They learn continuously.

Knowledge Management has been part of the human condition (and one of its blessings) for a long, long time. However, it is now coming into its own. The first significant meeting held for Knowledge Management professionals was the 1995 Knowledge Imperative Symposium. It was sponsored by Arthur Anderson and the American Productivity and Quality Center and was attended by 500 people. There are now employees in some companies who bear the title Director of Knowledge Management or Knowledge Architect, to name but two.

Knowledge Management is a really, really big and encompassing concept. First, consider what knowledge is. Of course, it includes information and data. But it also includes experience and context. A distinction is usually made between implicit knowledge, the kind that is written down, and tacit

knowledge, the kind that is in your head. When you consider how to manage knowledge, many verbs come to mind such as: collect, generate, organize, communicate, utilize, etc., etc., etc. The possibilities are endless.

Why would you want to manage knowledge? Well, there are numerous reasons. First and foremost, you don’t want to live in or work for a company that is a knowledge junkyard with lots of knowledge that no one can find or use. In today’s competitive environment you also want to manage knowledge so that you can leverage it, so that you can work more easily and efficiently and make a bigger profit. You want the knowledge you have to clear the road to success rather than to make it impossible to find.

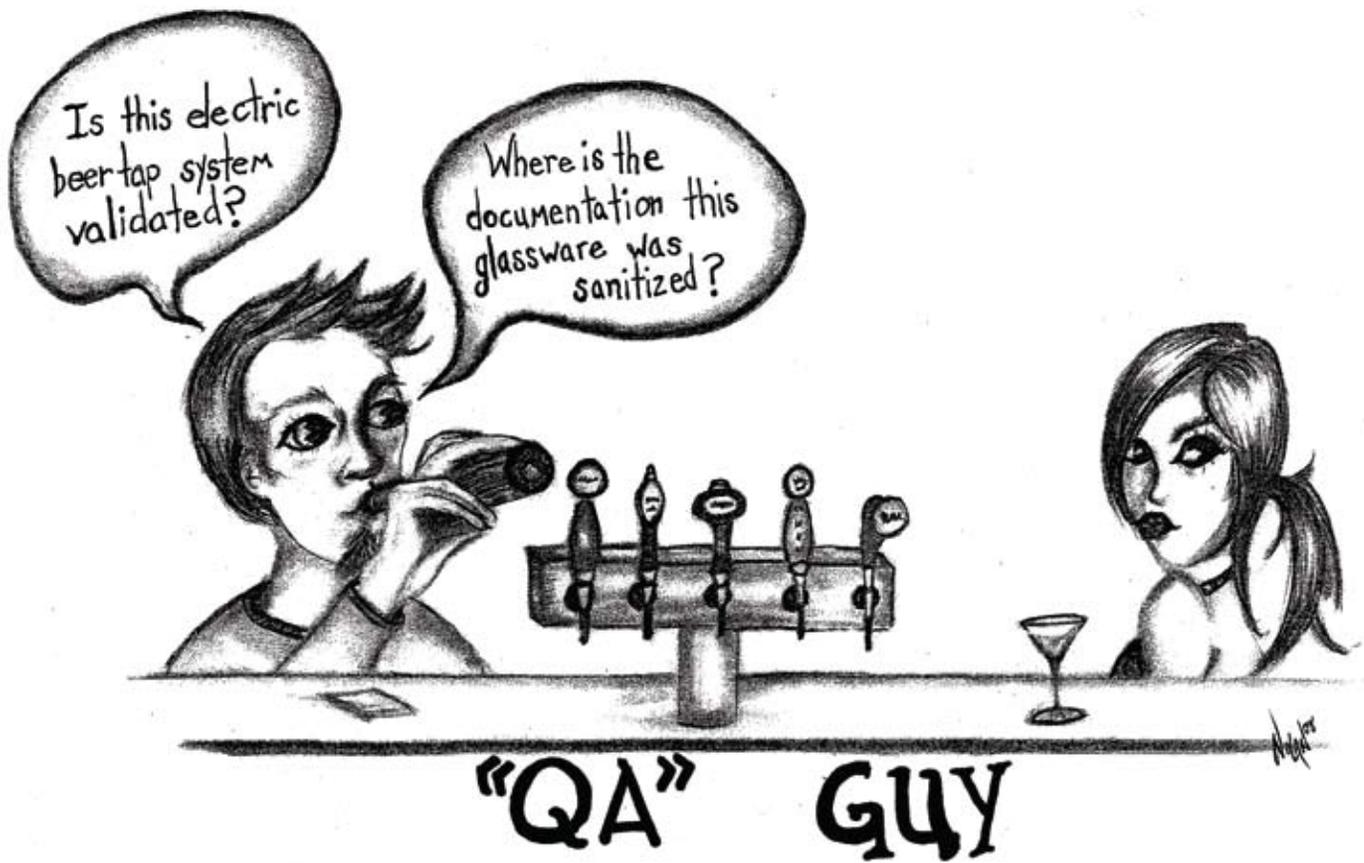
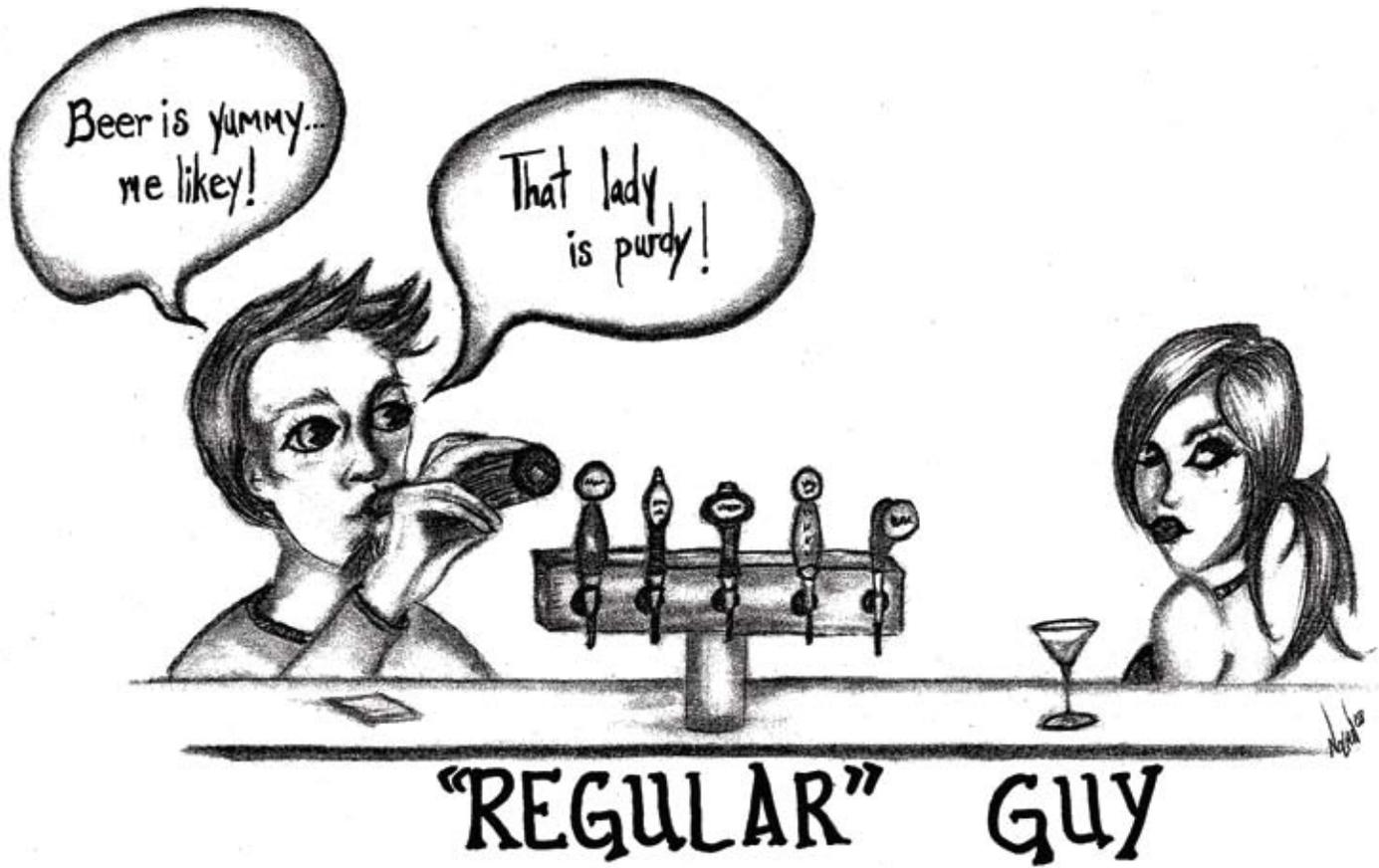
MARSQA would like to know if you or your company has experimented with or actively practice Knowledge Management. Is someone on your staff responsible for this function? Do you have “Communities of Practice”? Do you collect and disseminate best practices? Do you have post action briefings? Do you use automated tools to manage your knowledge? Did you apply Knowledge Management principles to a successful project?

We would really like to hear from you so we can continue sharing information with one another in this relatively new arena.

THE ART OF MANAGING AND COMMUNICATING QA FINDINGS/OBSERVATIONS

At our upcoming Membership Meeting in March, there will be a presentation on Managing, Classifying and Justifying QA Findings and Observations. You might want to give this topic some advance thinking and also consider how this is handled in your company. Here are some questions you may want to consider.

1. Is there a difference between classifying and trending your findings/observations?
2. What is an ideal classification/trending scheme for a GXP environment?
3. Is it better NOT to classify/trend your findings/observations?
4. What is the value of classifying/trending your findings/observations? What would you do with the information?
5. What is the best way to report findings/observations? Should this be done face to face?
6. How do you get management to pay attention to your findings/observations?
7. How can you assure that management does not use your QA findings/observations as the basis for staff performance evaluations?
8. What do you do when your findings/observations are met with hostility?
9. What do you do when your findings/observations are not responded to?
10. How do you assure that your QA reports remain confidential?
11. Should you add advisory comments to your QA reports that are not findings/observations but which might result in better practices?
12. What is the basis for your findings (GLP violations, bad science, other)?



An original cartoon drawn by Dan Nolan with the wording by Rachel McGowan.

CALENDAR OF EVENTS

26 March 2009

MARSQA Membership Meeting
Cock'n Bull Restaurant, Lahaska, PA

19 - 24 April 2009

25th SQA Annual Meeting and Training
Town and Country Resort & Convention Center, San Diego, CA
See www.sqa.org/am2009 for details!

21 - 25 September 2009

SQA Fall Training
Minneapolis, MN



Mid Atlantic Region Chapter
Society of Quality Assurance
154 Hansen Rd, Suite 201
Charlottesville, VA 22911

WE MOVED!

Please update your files.