



MARSQA Monitor

NEWSLETTER OF THE MID-ATLANTIC REGION SOCIETY OF QUALITY ASSURANCE

Volume 13, Issue 2

NEXT HALF OF 2009 BRINGS CONTINUED TRAINING OPPORTUNITIES



Hello and Happy Summer!

This spring has sped by as we have hosted our March meeting, attended the April SQA Annual meeting, and presented the GLP Basic training in May. We are finalizing plans for our next membership meeting in

mid-July in Lahaska, PA. We are tentatively planning another training session for September depending on the interest we receive.

Besides the above mentioned projects most of our energies are currently focused on the preparations required for a shared SQA and MARSQA meeting scheduled during the week of 26 - 30 October in Philadelphia, PA.

MARSQA will be presenting a training session at this meeting entitled, "Navigating the Global Regulated Environment: Advanced GLP Training for Managing Multi-Site Studies". This one day training will be offered on October 28, 2009, following the 2-day SQA Symposium: Global Regulatory Compliance Challenges. The MARSQA training is designed to assist in identifying and developing solutions to global compliance issues including a review of the roles and responsibilities outlined in the OECD

Principles for GLP, how to apply the OECD Principles to multi-site studies, challenges in study conduct and communication and utilizing non-OECD member facilities.

You may also be interested in attending the SQA symposium entitled, "Global Regulatory Compliance Challenges," which will explore global compliance issues encountered by regulators and the regulated community, with a focus on interactions with countries that are not members of the OECD, e.g., China, India and Brazil. In addition, a speaker will describe compliance issues in Africa. Speakers for the symposium are coming from around the globe, including Africa, Brazil, China, France, Germany, India, Japan, Korea and the US, featuring government regulators from Africa, China and the US.

Information for the October meeting can be found on the MARSQA and SQA websites for anyone interested in attending.

Lynda

Lynda Olsen
2009 MARSQA President

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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.



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.

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When knowledge workers think about contacting someone for help on a distinct issue, do they email, walk down the hallway, twitter or phone? Do they post their question on the community website, text message, search on a wiki page or check their FAQs and training documents?

Most of these workers have access to top-notch company repositories of best practices, methodologies and tools, case study examples, expertise databases, discussion forums and reusable work products. Regardless of such a wealth of tools, instead they choose to take the issue to a colleague because it is one of the best ways to stimulate new thinking and ideas.

Knowledge workers choose to communicate (by whichever preferred method) because they have discovered that conversations really matter. It matters especially when this conversation naturally produces a valid exchange of knowledge. And change is the end product of deep and insightful conversations. Peter Block, a consultant on empowerment, stewardship and accountability, has written books on ways to create workplaces and communities that work for all. In his 2008 book “Community: The Structure of Belonging” Mr. Block says: “To change the organization, change the conversation”¹. His work recommends bringing change into the world through consent and connectedness rather than through mandate and force. Thus, the role of conversation is crucial in knowledge management practices within an organization when dialogue is used to connect working networks in an effective manner. These quality conversations adapt and diversify our thinking about how we relate to each other, how we understand the notion of belonging and how we encourage the bringing of our collective gifts into our working communities.

Generally, knowledge management is a social phenomenon operating within an expertise management environment. It enables people in

organizations to find each other and efficiently work together on the basis of their specialization. It should encourage people to establish formal and informal communities where they can know each other, get to know each other and freely and openly share their views, opinions, knowledge and experiences on what works well and what doesn't. These knowledge communities could drive innovation and creativity, potentially resulting in a shorter time to market. Hence, as a positive side effect, people might become enthusiastic and motivated to continue improving their own working environment for themselves and for others. Likewise, any knowledge worker should aim to help develop an evolving “learning organization” by becoming skilled at creating, capturing, defining, sharing and applying knowledge, and consequently, by modifying behaviors to reflect new knowledge and quality insights.

Traditionally, the preferred one-to-one conversations have been the norm. Nonetheless, organizations need to move more towards changing the conditions of the conversation to an open group dialogue where the thinking and sense-making message is exchanged. A mutually engaged discussion generating multiple valuable answers has the greatest benefit from a knowledge management perspective. It results in a compliant organizational culture continuously improving performance from dialogue and lessons learned.

The proper characterization of a quality lesson is essential to add value to the knowledge management system. These lessons learned should be specific recommendations and actionable. The lessons must be something that is useful, that can be picked up, applied, and help improve their own performances and results.

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The initial stage of a knowledge management enterprise starts with the sharing of what is commonly known in the industry as good or best practices, alternatively. Best practices are practical techniques gained from experience that organizations may use to improve internal processes. A best practice is a bit like engineering where principles, processes and methodologies from different disciplines are applied towards a practical end. That being said, a best practice represents the recommended and most effective approach used to achieve a particular objective in a project. Many organizations are already doing that including two essential components: explicit knowledge such as a good/best practices database (connecting people with information), and procedures for sharing tacit knowledge like communities of practice (CoP), connecting people with people. Best practices are one of the key factors in knowledge management but similarly in quality management. Best practices consolidate benchmarks and serve in great measure as a time saver. Likewise, a best practice addresses the value of someone else's work.

The immediate benefits from identifying and sharing best practices include: learning from each other and re-using knowledge. An effective identification and sharing of best practices can serve companies to:

- Identify and replace poor practices
- Avoid reinventing the wheel
- Minimize re-work caused by use of poor practices
- Save costs through better productivity and efficiency
- Improve services to clients, vendors, suppliers or patients

David Skyrme, a consultant specializing in the practical application of knowledge in organizations, recommends a 6-step approach to identifying and sharing good practices.² His overall approach targets:

- documenting the essential characteristics of a good practice,
- sharing advice with relevant experts in that practice,

- deducing general guidelines,
- sharing basic knowledge,
- and managing subject matter experts to utilize and accommodate the practices in a new context.

Dr. Skyme's six steps are as follows:

1. Identify user's requirements
2. Discover good practices
3. Document good practices
4. Validate good practices
5. Disseminate and apply
6. Develop a supporting infrastructure

Besides the procedures described above, any knowledge management has to include and accommodate the human factor. Critical points of consideration include personal motivation and an organization's culture. For example, within a resistant-to-change company, these types of initiatives will be slow to emerge and spread. If employees are not convinced of the management approach or perceive it as cumbersome, only a fraction of the organization's knowledge will be captured and shared.

Now, some controversy surrounds the term "best practice." While surprisingly some knowledge workers are not aware of best practices, others deny their existence. At the same time, another group refers to them as standard practice or common sense practice, not best practice. Some think that the term "best practices" could be harmful to knowledge management out of fear that it might stifle improvement. The argument is that if something has been labeled as a "best practice", consequently rigid work communities will be reluctant to change it: "We can't improve this! It is Best Practice!" So the way to look at this is to think of "best practice" as a recommended practice for a specific operation or process, not as an unchangeable reality. There should always be room for improvement beyond the "current best recommended practice" and every project should be dissected to look for improvements. Best practice case stories or database entries could be used to describe a project, including a description of the situation before, the specific changes introduced, the situation afterwards, and any collaborative working.

COMPARATIVE WORK ENVIRONMENTS

THE PROS AND CONS OF CONSULTING

Debra McDougall

MARSQA Member

The economic downturn has resulted in the unemployment of many American workers including Quality Assurance professionals. Qualified individuals may be considering “hanging out their shingle” and giving consulting a try. Qualifications include but are not limited to years spent in QA, diversity in types of audits conducted, certifications and/or positions held in industry. The “would-be” consultant will find that the most difficult aspect of starting a consulting business is making contact with prospective clients. One approach is networking with friends, peers, SQA members and/or other consultants. Secondly, one needs to determine an hourly rate that supports her/his financial needs and is acceptable to the client. This may be determined by reviewing salary surveys conducted by various professional organizations, e.g., SQA.

As with all work environments, there are pros and cons. Let’s look at the pros of consulting first. You are the boss! If you can work at your home, you can set the schedule. You can work 2 or 4 or 8 hours a day, 15, 40 or 80 hours a week, at night or on the weekend. You can get a lot done without interruption. You can take a day off; you can make appointments, etc. without having to ask permission. You do not have to participate in the dreaded annual performance review. When working at the client’s office, you do not have to be worry about office politics or attending multiple, unnecessary meetings. Depending on your client base, you get the opportunity to meet a lot of different people, learn the nuances of various companies/industries and work on projects outside your expertise.

Now for the cons. As a small business owner, the consultant is responsible for accounting, marketing, travel arrangements, insurance (health, disability and liability), contract review, etc. She/he does not get paid sick or vacation time. It is critical that the consultant stays abreast of developments in her/his field of expertise as well as changes in regulations. Attendance at professional meetings or continuing education is on the consultant’s dime. She/he also does not get paid unemployment. As such, the consultant must be continually looking ahead, either for new clients or continuing work with existing clients. When working at home, the consultant loses the socialization aspect of working with peers. This can be especially difficult for those individuals who look forward to the interactions that the workplace provides. Moreover, consultants need to budget monetarily based on the restrictions/practices of a client’s accounts payable department i.e., payment 30, 45, 60 or sometimes even 90 days after invoicing.

As mentioned earlier, the consultant is his/her own boss. However, the needs of the client usually puts them in control. There are times when every client wants the consultant to be at their site/working on their project at the same time. Juggling one’s time and handling the various aspects of her/his clients’ needs can be quite challenging.

In summary, the cons of being a consultant can be overwhelming and often take time to adjust to. After 15 years, however, I have yet to find a company that I would rather work for other than my own.

Note: Debra McDougall has been working in regulatory environments for 28 years and has had her own quality assurance consulting business, Consultant One, for 15 years. She has an MS in QA/RA from Temple University. Debra lives in Frenchtown, NJ and can be reached at 908-227-2539 or at dmcd.consult-one@att.net.

GLP Modernization Effort – Updating the Regulations for the 21st Century

Many scientific and technological advances have occurred since the Good Laboratory Practices (GLP) regulations became effective in 1979. These advances have resulted in dramatic changes to the way nonclinical studies are currently being conducted. Historical interpretations of the GLP regulations have resulted in procedures that are sometimes cumbersome and do not provide appreciable improvement for data integrity or human subject protection, and may add to the cost of drug development. Pharmaceutical Research and Manufacturers of America (PhRMA) believes the GLP regulations can be modernized without negatively impacting data integrity or patient safety assessments. FDA has also recognized the need to update research regulations and guidance documents in order to strengthen their oversight of clinical trials, in an effort to modernize their approach to bioresearch monitoring as part of the Critical Path Initiative. This same approach of updating regulatory documents can be applied to modernization of GLPs.

When considering recommendations to move forward, PhRMA Bioresearch Monitoring Committee (BRMC) utilized interpretations of the GLPs stated in published FDA documents (preamble, compliance program guides, etc.) and the Organisation for Economic Co-operation and Development (OECD) Principles of GLP.

Following much discussion and evaluation among the PhRMA BRMC members and other pre-clinical safety PhRMA committees, a list of modernization items for consideration was developed. They include:

- Allow for fully integrated study reports rather than having to append individual, separately signed, contributing scientist reports to the final report
- Allow for process-based inspections to supplement and/or substitute for study-specific inspections for repetitive study activities performed at a site
- Accept as suitable for use in GLP studies, test article that has been characterized and assayed for stability to GMP standards
- Define the role of Principal Investigator
- Allow for terminated studies to be closed without issuance of a study report if prior to the IND filing, while maintaining the requirement that all raw data be archived
- Allow for more than one individual to be assigned as Archivist
- Delete requirement for the Master Schedule to be retained/maintained by the Quality Assurance Unit (QAU)
- Delete requirement for QAU to maintain copies of protocols
- Allow for archival of study materials within a reasonable timeframe after study completion
- Remove requirement to retain test article storage containers for study duration
- Clarify that only study-specific inspections are required on Quality Assurance Statement (i.e. not process, systems, or facility-based inspections)
- Limit requirement for QAU to assure only documented deviations were authorized
- Clarify definition of control article and add definition for vehicle (carrier)
- Allow for a risk-based management approach to final study report reviews

The PhRMA BRMC has recently met with members of a Society of Quality Assurance (SQA) Task Force who have been working on a similar modernization effort. Together, the PhRMA BRMC & SQA Task Force will continue to collaborate on moving forward with recommendations to modernize the GLP regulations in hopes of bringing the regulations into alignment with the improved business environment of the 21st century. We will continue to maintain our focus on ensuring we deliver nonclinical safety studies of the highest quality, with the goal of ensuring patient safety during clinical testing.

Christiana Velez

MARSQA Member

I would like to thank the Board of Directors at MARSQA for awarding me the MARSQA scholarship to attend the 2009 SQA annual meeting in San Diego. Having been a member of MARSQA for several years and working in the Quality Assurance field, I have heard many great things about the SQA annual meeting but was never able to attend a meeting before. Being able to go to the meeting this year was a great opportunity to attend trainings/conferences and interact with other QA professionals in both a professional and social atmosphere. I feel this meeting helped me remain current on the latest regulatory requirements and trends and that I gained new knowledge in other GXP areas. I feel this was a very valuable experience and that I will be able to share what I learned at my trainings with my fellow colleagues.

While at the annual meeting I was able to attend two pre-conference workshops that included “Understanding the GxPs - Bridging the Communication Gap”, “Selected Topics in Bioanalytical Auditing” and also attended several conference sessions throughout the week. The course in Bioanalytical auditing was especially useful since it discussed a wide range of topics starting from the basics of pharmacokinetics to method validation and then further into auditing bioanalytical data. This was very informative since we broke out into groups and were able to look through actual data and try to find where the issues were and key areas to look at while auditing bioanalytical data. It was great to be able to interact with different auditors with varying degrees of knowledge and auditing experience and work together to find where the issues were within the data. I also attended several sessions that pertained to bioanalytical current hot topics, method validation and Incurred Sample Reanalysis along with various other topics. These sessions were very helpful to keep me informed on the current trends and regulatory requirements that the industry is using.

I would encourage every Quality Assurance professional to attend one of these meetings and to apply for the MARSQA scholarship; it was a great learning experience. Again thank you MARSQA for this great learning opportunity.

QUALITY QUOTES - WHEN SOMEONE ELSE HAS ALREADY SAID IT BEST

Quality means
doing it right when no
one is looking.

- Henry Ford

Everything can
be improved.

- C.W. Barron

It is easier to do a job
right than to explain
why you didn't.

- Martin Van Buren

Quality is never an
accident. It is always the
result of intelligent
effort.

- John Ruskin

Stacy Wilson

MARSQA Member

First and most importantly I would like to thank MARSQA for the scholarship I received, which enabled me attend the SQA meeting in San Diego CA in April. In these challenging economic times, this scholarship made it possible to attend and participate in the 2009 meeting. I am very grateful for the financial support. I would also encourage all members to apply for the annual scholarship in the future. I found the knowledge, experience and networking opportunities at the SQA annual meeting to be invaluable. My experience at this year’s meeting is chronicled below.

Sunday and Monday I started my SQA annual meeting experience with two pre-conference training classes “Introduction to the Principles of Computer Validation for the QA Professional” and “Continual Quality Improvement Expanding the QA Toolbox”. Both full day classes presented educational material in the morning sessions that prepared the attendees to participate in interactive afternoon exercises. These interactions allowed all participants to meet colleagues from many different areas of the Quality Assurance discipline and discuss various views and opinions. Based on these discussions, I was able to take back and propose new ideas and information with the Quality Assurance group at my place of employment. The opening reception followed the Monday course sessions and was an exciting event that featured great food, music and conversation in the beautiful poolside setting of the Town and Country Resort. Later in the week I was also able to hear SQA’s own Deviations perform. If you ever have the opportunity to hear the group, it’s definitely worth it. The SQA sponsored event to Miramar Marine Corps Air station was also a once in a lifetime experience that was enjoyed by all.

The remainder of the meeting was also jam packed with extensive and valuable information. My focus was GLP however, I attended as many sessions as possible to expand my Quality Assurance knowledge base. As a poster presenter, I was also able to experience and interact with many individuals during that scheduled poster session.

With all of the classes, sessions, and poster exhibits, I still had time to meet many new colleagues as well as reconnect with old friends. There was time to squeeze in a visit to the amazing San Diego Zoo and see the sunset over the Pacific Ocean. All this in just six days. Exhausting– yes. However as I mentioned previously, this was an amazing experience in which I would encourage others to participate. Thanks again MARSQA!

Quality begins on the inside...and then works its way out.

- Bob Moawad

Quality is everyone’s responsibility.

-W Edwards Deming

QUALITY IS NOT AN ACT. IT IS A HABIT.

- ARISTOTLE

Quality is a proud and soaring thing.

- Jessica Julian

Kim Evans

MARSQA Member

Want a way to enhance your resume while gaining more knowledge but can't pursue a higher educational degree? SQA offers two professional examinations; one for GLP and one for GCP professionals. These examinations require an in-depth knowledge of your area, but in passing, you will have proven that you have a great understanding of your area. Having these credentials following your name, would indicate to everyone that you have an in-depth knowledge. This could enhance your current relationships or could help you secure future positions you may want to acquire.

These tests are offered both in written and electronic form. The written test is offered once a year at a time usually coinciding with the annual SQA meeting. There are several locations where the test may be taken at that time. The electronic version is now being offered twice a year (spring and fall) and can be taken at many more locations than the written test. An advantage to taking the electronic version is that you will know if you passed or failed at the completion of the exam. You will have to wait for the results of the written test to be graded and results sent in the mail.

Sample questions (taken from RQAP candidate handbook):

GLP

1. Study inspections should be scheduled
 - A. before the test initiation date.
 - B. before the test subjects are euthanized.
 - C. at intervals adequate to ensure integrity of the study.
 - D. at intervals adequate to ensure the study director is meeting responsibilities.
2. An SOP specifies that approximately 150 mL of a reagent will be added to another reagent. However, a technician mistakenly adds 90 mL instead. This should be documented as
 - A. an SOP revision.
 - B. an SOP deviation.
 - C. a protocol deviation.
 - D. a protocol amendment.

GCP

3. Documentation of the education, training and experience that qualify an investigator to assume the responsibility for the proper conduct of a clinical trial should be provided in:
 - A. a protocol
 - B. a curriculum vitae
 - C. an investigator's brochure
 - D. a study-specific monitoring plan
4. A protocol specifies that a subject should have a physical examination at visit 2. However, the investigator forgot to complete the physical examination at this visit. This should be documented as
 - A. an SOP revision.
 - B. an SOP deviation.
 - C. a protocol deviation.
 - D. a protocol amendment.

Answers: 1. C, 2. B, 3. B, 4. C

For more information and a list of study materials, visit www.sqa.org.

THE SOCIETY OF QUALITY ASSURANCE PRESENTS

GLOBAL
REGULATORY
COMPLIANCE
CHALLENGES
SYMPOSIUM

26 - 27 OCTOBER 2009
PHILADELPHIA, PA, USA

SPONSORED BY THE
REGULATORY FORUM OF SQA

GLOBAL SYMPOSIUM PRELIMINARY PROGRAM

TITLES AND SPEAKERS SUBJECT TO CHANGE

- **Plenary Speaker on Cultural Awareness:** Robert R. Stewart, PhD, Technology Science Group, Washington DC, USA
- **GLP Systems in China and Challenges of Implementation:** Bo Li, MD, PhD, SFDA, China
- **Establishing a GLP Laboratory in China and Obtaining GLP Certification:** Dr. Xigeng Bai, Shenyang National Laboratory for Material Science, China (China QA Society)
- **China Update:** Mr. Haizhou (Joe) Zhang, Shanghai Chem Partner Co Ltd, China
- **Multisite Study Issues in a Global Study:** Ms. Katherine Ertz and Ms. Martina Preu, Bayer CropScience
- **India Update:** Dr. Labhu Sanghani, Jai Research Foundation, India
- **EPA Cooperation with Asia and Latin America on GLP:** Ms. Francisca Liem, US EPA, USA
- **Global Comparison of GLP Implementation:** a JSQA international committee project report, Mr. Yoshikazu Hasegawa, Japan (JSQA)
- **Establishing a GLP Laboratory in South Korea:** Il Je Yu, PhD, South Korea (KSQA)
- **Update from Brazil:** Beryl Packer, PhD, Monsanto
- **Update from Africa Biosafety Network of Expertise:** Dr. Allan Liavoga, Kenya
- Other topics and speakers still to be confirmed

TWO HOT TOPICS:

Full afternoon of in-depth discussions on

1. computer system issues world-wide and
2. issues related to shipping materials globally for GLP research.

VISIT WWW.SQA.ORG FOR UP-TO-DATE
SYMPOSIUM INFORMATION!

Registration is required
and will open in July.

Registration Rates

Government/Academia
employees:
\$475 early, \$550 late

SQA members:
\$575 early, \$650 late

Symposium co-sponsor
members:
\$615 early, \$690 late

All other non-members:
\$695 early, \$770 late

Hotel

**Hyatt Regency Philadelphia
at Penn's Landing**

201 South Columbus Blvd.
Philadelphia, PA, USA 19106
Tel: +1 215 928 1234

SQA has arranged a special
rate of **\$159 per night**, please
contact the hotel to reserve
your room.

Janet Emeigh

Chair, SQA Bioanalytical Specialty Section



BioAnalytical Specialty Section Society of Quality Assurance

The SQA Bioanalytical Specialty Section, aka BASS, was formed in the spring of 2004 at the SQA Annual meeting in Reno, NV. Two SQA members, Margaret (Peggy) Beamer and Carol Reber, both members of MARSQA at the time, recognized the need for a group to get together to discuss the many grey areas of the regulations as they pertain to bioanalysis. They had hoped to get at least 10 people interested in forming this new specialty section. They were pleasantly surprised when 32 “fry”, I mean interested SQA members, showed up to the very first face to face meeting at the SQA Annual meeting held in Reno and were somewhat shocked when the membership of the “school” reached nearly 80 by the end of that year.

It's now a little over 5 years since that very first meeting and there are almost 150 members swimming in our pool. Over the years, we have discussed such issues as whether or not bioanalytical samples generated from a clinical study can or should be analyzed under GLP regulations, validation of analytical methods, validation/qualification of analytical instruments, and the Crystal City III meeting held in May 2006 in which a very hot topic of incurred sample reanalysis was heavily discussed and debated. Now three years since it was discussed, many companies are still struggling with how to implement procedures to conduct these analyses to meet agency expectations. Members have also shared their FDA inspectional experiences as they relate to bioanalytical issues.

BASS began to serve the SQA membership as more than just a discussion group as our membership grew. With some guidance from members of specialty sections that were more seasoned, BASS has:

- Published one white paper in the *QA Journal* and another in the SQA newsletter, *Quality Matters*.
- Provided answers to questions specific to bioanalytical issues submitted through the SQA Regulatory Forum Q&A process.
- Arranged to have Dr. Viswanathan from FDA speak at the SQA Regulatory Forum meeting in November 2005.
- Offered training at SQA Annual meetings and/or fall training sessions starting in 2006.
- Participated in the SQA Annual meetings as presenters and/or session chairs starting in 2007.
- Worked with the SQA Clinical Specialty Section on a process map for the analysis of bioanalytical samples generated from clinical studies; the process map is available on the SQA website.
- Worked with the SQA GLP specialty section and the CVIC on the development and presentation of a one day symposium in January 2008 on analytical instrument validation/qualification.
- Worked with the SQA Biotech Specialty Section and presented a 30 minute podium session at the SQA annual meeting in San Diego in 2009 on Immunoassays, which is a topic that is common to both specialty sections.
- Facilitated a round table discussion on incurred sample reanalysis (ISR) at the Regulatory Forum meeting in January 2009. This generated some lively discussion that perhaps will be the foundation for a future article or presentation.

BASS has accomplished a lot in the 5 years since its inception and we have no plans to slow down. Future BASS projects include:

NAVIGATING THE GLOBAL REGULATED ENVIRONMENT: ADVANCED GLP TRAINING FOR MANAGING MULTI-SITE STUDIES

Presented by the Mid-Atlantic Region Society of Quality Assurance

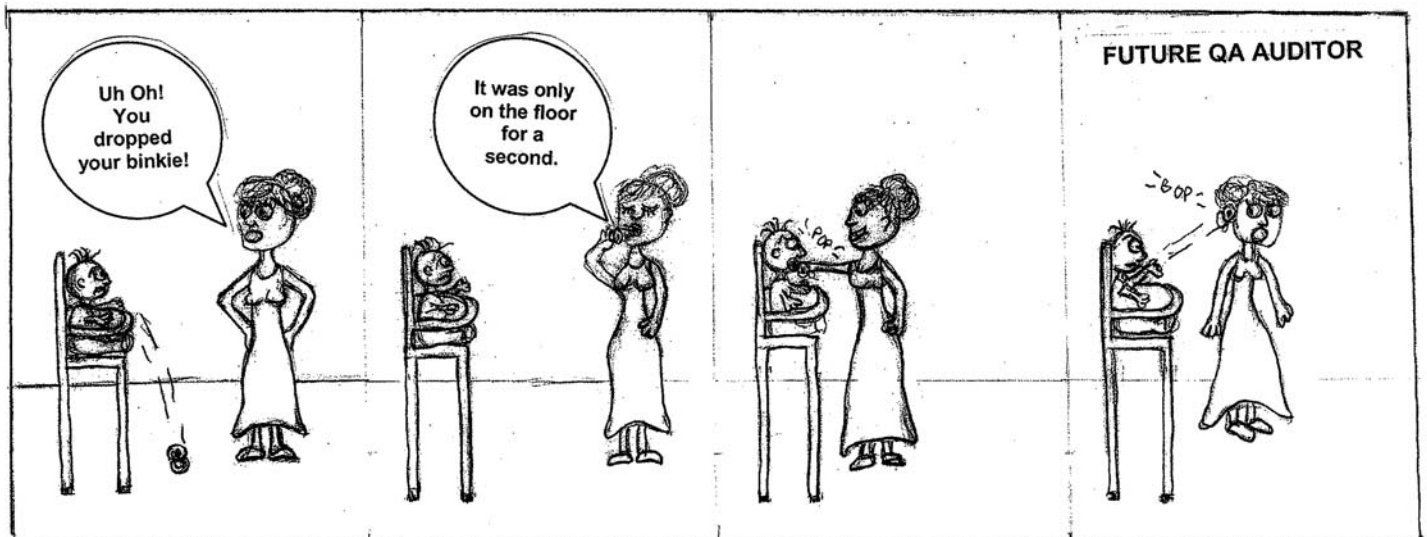
Although the GLP regulations have remained the same, compliance has become more challenging due to the global nature of the industries governed by the regulations. This training will assist in identifying and developing solutions to global compliance issues and will include:

- Working with multiple SQA specialty sections on a symposium to be presented in October in Philadelphia October 26-27, 2009. It should be noted that MARSQA will be co-sponsoring this symposium as well as offering a one day advanced GLP training session on Managing Multi-Site Studies on October 28, 2009. Stay tuned for more information.
- Working with the Biotech Specialty Section on training courses and/or presentations for the annual SQA meeting.
- Publication of additional white papers on topics such as incurred sample reanalysis, QC and acceptance criteria, and others.
- New and improved training sessions.
- Providing advice and information to those less experienced in bioanalytical regulatory issues.

- A review of the roles and responsibilities outlined in “The Application of the OECD Principles of GLP to the Organization and Management of Multi-site Studies (Number 13)
- Planning and preparing for a multi-site study
- Challenges in study conduct and communication
- Data Management and Archiving
- Establishing Lead and Test Site QA roles
- Evaluating Part 11 compliance
- Inspection Readiness
- Utilizing non-OECD member facilities

BASS has come a long way in a relatively short time. Membership is currently available only to SQA members, but if you have questions of a bioanalytical nature or you are just fishing for information, please feel free to contact me at jemeigh@medarex.com and I will do my best to hook you up with what you are looking for.

This training will be offered on October 28, 2009, following the 2-day SQA Symposium: Global Regulatory Compliance Challenges.



An original cartoon by Rachel McGowan, MARSQA Member

Fran Jannone

Chair, Historical Committee

COMMITTEES

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

When I volunteered to serve as Chair of the Historical Committee, in March 2004, it seemed to be an easy job in the MARSQA organization. After all, I did not think it was difficult to collect the meeting minutes, committee reports, treasurer's report, programs printouts and various other records from the committees and file them with the collection of records dating back to 1991. So far, it hasn't been time consuming nor have there been many requests for retrieval of documents from archives.

Currently, the historical file has accumulated four boxes of records with one entire bankers' box alone devoted to membership renewals and meeting receipts all of which are currently stored in the archives of my employer, Huntingdon Life Sciences. I can now appreciate the advancements made in computer technology for the reduction of paper records generated for annual membership renewals among other documents to say the least.

In the process of organizing the accumulation of records, I thought it would be interesting to trace MARSQA's earliest records to see just how this organization started to give all of our newer members some perspective on the history of MARSQA. What I discovered from review of the meeting minutes was that the very first organizational meeting was held on November 14, 1990 at Bio/dynamics, East Millstone, N.J. (now known as Huntingdon Life Sciences).

The attendees were various individuals from several companies who were also members of SQA seeking to form a local chapter. It was decided to call this Chapter the Mid-Atlantic regional chapter since the chapters forming in Boston and North Carolina would be the northern and southern chapters, respectively. The MARSQA 'Kickoff Meeting' was held on May 2, 1991 at Bristol-Myers located on U.S. Highway 202/206 Somerville, N.J. with 127 registrants.

Unlike our membership meetings today held at hotel or restaurant sites, earlier Board and membership meetings were generally held at company sites of the Board or committee members, rotating so as not to wear out their welcome within one company and to vary the travel distance for meeting attendance. Additionally, MARSQA received support from companies such as Allied-Signal, Dupont, Exxon, FMC, Mobil, Product Safety Labs and Wyeth-Ayerst during 1991 for the purchase of supplies or services provided.

It has been an interesting experience reading the meeting minutes much like looking at an old photo album. **On the next page, I've included a copy of the announcement for MARSQA's first membership meeting in 1991. Enjoy!**

MARSQA

MID ATLANTIC REGION SOCIETY OF QUALITY ASSURANCE

KICKOFF MEETING

Date: Thursday, May 2, 1991

Time: Registration begins 1:30 PM
Program 2:30 - 5:00 PM

Location: Bristol-Myers Products
Somerville, NJ 08876

PROGRAM

- Pam Errico President - Qualtech, Inc.
SQA and Regional Chapters
- Joe Townsend Director, QA - Bio/dynamics, Inc.
Evolution of QA
 - Dr. Dexter Goldman President - Goldman Associates International
Good Automated Laboratory Practices (GALPs)
 - Alan Samel QA Specialist - Dupont Co. - Agricultural Products
GLPs in Perspective
 - Social Hour Refreshments Courtesy of Bristol-Myers Products

REGISTRATION FEE: \$15.00

Includes 1991 MARSQA Chapter Membership

Travel Directions and Registration Form on Back

Please R.S.V.P. Bob Barkalow (908) 851-6046 with number of persons from your company that plan to attend.

CALENDAR OF EVENTS

21 July 2009

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

21 - 25 September 2009

SQA Quality College
Minneapolis, MN

26-27 October 2009

SQA Symposium
Global Regulatory Compliance Challenges
Philadelphia, PA

28 October 2009

MARSQA Workshop
Advanced GLP Training for
Managing Multi-Site Studies
Philadelphia, PA

29 - 30 October 2009

SQA Quarterly Meetings
Specialty Sections, Regulatory Forum
and Board of Directors
Philadelphia, PA

Mid-Atlantic Region Society of Quality Assurance



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