

MARSQA MONITOR

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Volume 19,
Issue 1
Q1, 2016



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President's Message from Kiet Luong

On behalf of our Chapter, I would like to thank you personally for your commitment, participation, and continued support. For those who are new to the Chapter, I would like to welcome you and take a moment to briefly describe what you have to look forward to for 2016!



MARSQA is an organization that encourages interactions, networking, and knowledge sharing among members in all aspects of Quality Assurance whether in government, industry, research & development, testing, or academia. In order to achieve this goal, MARSQA will be distributing a calendar of events on our website, outlining the scheduled dates for membership meetings, usually hosted at the C*ck and Bull Restaurant in Lahaska, PA. Both members as well as non-members are invited to the membership meetings; there will be a hot lunch buffet, guest speakers presenting on a variety of topics, and networking opportunities with other colleagues in your field. The face-to-face interaction with everyone provides an invaluable experience to all.

Please visit www.MARSQA.org for upcoming events. MARSQA will also be organizing one and two day training sessions on selected topics. All members are encouraged to suggest topics for the training sessions.

I would like to take this opportunity to thank the 2015 Board Members for their continued involvement and contributions to our Chapter. I also welcome the 2016 Board Members and wish them all a very productive and successful year! [Click here](#) to view the 2016 Board Members.

The MARSQA organization is also looking for members to volunteer their time to either be a Chair, Co-Chair, or member of one of the Committees. You can find a list of the Committees and the current respective contact(s) [here](#). If you are interested in learning more about the committee or are interested in serving in any capacity, please contact the committee directly. *(Continued on following page)*

President's Message from Kiet Luong (continued)

(continued from Page 1)

As President, I will do my best to increase the value this membership brings to you. I believe together we can make a difference, and that together we can make MARSQA a professional affiliation that provides many things to many different people. I want MARSQA to be the first place you go to for all your quality needs.

The goal this year will be to enhance our service to our members, provide many opportunities for learning and development as well as variety of topics from SMEs (subject matter experts) and guest speakers. MARSQA is also an organization for growth and networking opportunities. We welcome all ideas and suggestions and will work hard to incorporate them into this year's program. As such, your input is greatly needed and appreciated.

I'm looking forward to serving the MARSQA organization as your President in 2016, and I'm committed to making this year a year filled with great possibilities! We will also be celebrating MARSQA's 25th Anniversary, so join me in looking forward to an exciting year ahead.

Please feel free to contact me anytime at kiet.t.luong@gsk.com.

Call for MARSQA Volunteers!!!

Help us have another successful MARSQA year and volunteer to be a meeting presenter!

- Are you a Quality Archives Expert?
- Do you know about Quality Risk Management?
- Do you have an interesting Quality topic you want to share?
- GLP Expert? GMP Expert? GCP Expert?



If you answered yes to any of the above questions you are ready to be a MARSQA presenter. Contact the current MARSQA Vice President, [Stacy Wilson](#) today if you are interested in being a MARSQA presenter!

GLPs and GMPs and GCPs...oh my!

MARSQA has traditionally been an organization whose membership has primarily been GLP QA focused, although over recent years we have seen a significant influx of GCP QA professionals. MARSQA still has not made significant inroads into the GMP realm, but we are hoping that will change in the future. When discussing topics for the MARSQA newsletter and MARSQA events, including the CSV training programs and MARSQA membership meetings, we always have discussions of who our potential audience may be, and typically the audience is primarily GLP and GCP Quality Assurance professionals.



The MARSQA newsletter committee felt that it would be interesting to the MARSQA membership to publish a series of articles which highlight the similarities and differences between quality systems, roles and responsibilities, and regulations that pertain to GLP, GCP, and GMP QA professionals in the pharmaceutical industry. We felt that the best place to start was to first examine what the regulations require with regards to the QA function for GxP disciplines.

GLPS! The Good Laboratory Practice regulations (FDA and OECD) have very clearly defined responsibilities for the Quality Assurance Unit (QAU). QAU responsibilities as defined within 21 CFR §58.35 ([click here for regulations](#)) include:

- Monitoring each study to assure management of conformance to the GLP regulations.
- Independence of personnel involved in the direction and conduct of studies.
- Maintaining copies of master schedules, protocols, and inspection records.
- Inspecting nonclinical studies at intervals adequate to assure the integrity of the study.
- Periodically submitting status reports to management.
- Review of final study reports for accuracy.

A key tenant of the GLP QAU is “independence.”

GMPS! The Good Manufacturing Practice regulations also have defined roles for the Quality Control Unit. Although the GMPs refer to the Quality role as “QC”, the practical nature of the GMP quality role includes a significant Quality Assurance function. 21 CFR §211.22 ([click here for regulations](#)) defines the quality role responsibilities in a GMP environment to include:

- Authority to approve or reject raw materials, drug product containers, in-process materials, and finished drug product.
- Reviewing production records to assure no errors have occurred. (*Continued on next page*)

GLPs and GMPs and GCPs...oh my! (continued)

- Ensuring that investigations have occurred, when needed.
- Authority to approve or reject all procedures or specifications.

The key responsibility for the GMP QA role is the authority to approve or reject.

Interestingly, the GMPs do not discuss audits, although it is an expectation that audits are performed within a manufacturing environment.

GCPs! The FDA Good Clinical Practice regulations do not discuss or refer to a defined QA role. ICH E6, Good Clinical Practice: Consolidated Guidance ([click here for regulations](#)) states only that “The sponsor is responsible for implementing and maintaining quality assurance and quality control systems” to ensure that trials are conducted and data are generated in compliance with the protocol, GCP, and the applicable regulatory requirement(s). For GCPs, the sponsor is ultimately responsible for QA and QC, but defined responsibilities for a QA role are not specified. In practice, Clinical Quality Assurance responsibilities typically include management of the clinical quality system as well as performing audits at Investigational sites, of electronic systems, processes, study documentation and reports, and evaluating contracted study related obligations outsourced to external service providers (CROs, labs, vendors, etc.).

To summarize, the GLP and GMP regulations have very defined responsibilities for the QA organization. There are not clearly defined QA responsibilities within the GCP regulations or related guidance documents; so sponsors and clinical organizations have greater flexibility with regard to Clinical QA responsibilities.

The GLP QAU must maintain its independence; that is why most GLP QAU personnel review, but do not approve documents. GMP QA personnel are responsible for approval or rejection of materials, specifications, etc. Clinical QA personnel responsibilities are not clearly defined in regulation, but each clinical organization must define QA and QC responsibilities within their SOPs. All GxP QA groups typically perform an audit function and have some role in implementation or management of an organization's quality system.

If you have any feedback or would like to share your experiences regarding differences between GxP QA disciplines, please contact the MARSQA Newsletter Committee and we will be happy to incorporate your feedback into our next article in this series.

E-mail contacts: Megan.Lawhead@crl.com, tina.myers@otsuka-us.com, and chris.wubbolt@QACVconsulting.com

Meet the 2016 MARSQA Board of Directors

President: Kiet Luong

Company Name: GlaxoSmithKline LLC

Area of Specialty: GxP, Computer Systems Validation, Enterprise Migration/Integration, Systems Decommissioning, 21 CFR Part 11.

Favorite local restaurant: Aman's Indian Restaurant, Pho & More, Arianna Ristorante, Noboru

Favorite hobby or interest: Cooking, Growing Orchids and Hot Peppers

Describe your journey to the compliance world: My journey began in the laboratory where quality and compliance were lacking and I wanted to improve processes and procedures to ensure data quality and patient safety.

What was the catalyst for you to become more involved in MARSQA (e.g., run for board)?
It has been an honor and a privilege to be a part of the board members where we can make a difference. Learning from and sharing with members our experiences and to provide quality training sessions and materials to our members. It is very rewarding to be given this opportunity.



Vice President: Stacy Wilson

Company Name: Charles River Laboratories, Inc. (Horsham)

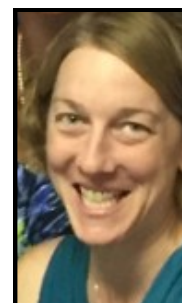
Area of Specialty: GLP

Favorite local restaurant: Ferndale Inn

Favorite hobby or interest: Reading

Describe your journey to the compliance world: Interesting!

What was the catalyst for you to become more involved in MARSQA (e.g., run for board)?
We are in a unique area with a lot of Quality Professionals. I got involved with MARSQA to help keep this great organization moving in a positive direction.



Meet the 2016 MARSQA Board of Directors

Past President: Ranee Henry

Company Name: President/Owner of [QST Consulting](#)

Area of Specialty: [Check out my company website for additional information.](#)

Favorite local restaurant: Perk Restaurant, Perkasio PA. Best Burgers in the Area!

Favorite hobby or interest: Cooking, Baking, Hosting Parties and Decorating

Describe your journey to the compliance world:

When 21 CFR Part 11 come out, and I was working at ICON Clinical Research, I was asked to develop policies and procedures to address this regulation. A Mock Inspection was scheduled months later to evaluate our readiness and we passed with flying colors. This led to me being offered a consultant position for a firm in NJ that opened lots of opportunities for me that I would not have had if I had stayed at ICON. I was exposed to variety of different compliance challenges and learned so much about our Industry and Quality and Compliance that eventually led to me opening up my own firm.

What was the catalyst for you to become more involved in MARSQA (e.g., run for board)?

Wasn't something I would have normally have done, but was convinced by current Board Members that it was a worthwhile activity and that lots of opportunities would stem from this and they were right. I have had such a great time serving on the board, that I continue to run for office. I would encourage you all to do the same. The people I have met, the things I have learned and the experiences I have had are priceless. Thank you MARSQA for enhancing my career!



Secretary: Nancy Gravino

Company Name: Bristol-Myers Squibb

Area of Specialty: GLP, RQAP certified (GLP)

Favorite local restaurant: Any restaurant is my favorite, so I do not have to cook! But, if I have to choose a type of restaurant, then any steakhouse.

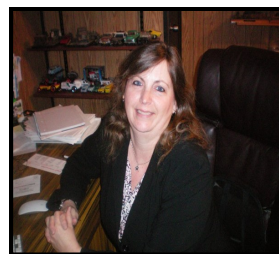
Favorite hobby or interest: Classic car shows with my husband and going to the Jersey shore (Avalon)

Describe your journey to the compliance world:

I began working as a laboratory technician in a contract laboratory and then worked my way up to quality assurance after spending 13 years in the lab. For my regulatory compliance career, I have worked for one contract lab and three pharmaceutical companies over the last 18 years.

What was the catalyst for you to become more involved in MARSQA (e.g., run for board)?

When I worked for the contract lab, management always encouraged us to attend MARSQA membership meetings and in 2008 I ran for my first position on the MARSQA board of directors and I have been on the MARSQA board for the last nine years, filling the position of secretary and director. Being a member of MARSQA and being on the MARSQA board has allowed me to meet and network with wonderful people from all the different pharmaceutical companies in the area.



Meet the 2016 MARSQA Board of Directors

Treasurer: Brittany Medeo

Company Name: QACV Consulting

Area of Specialty: GLP; however, I work across the GxP

Favorite local restaurant: Napa Flats in College Station Texas makes a great wood fired pizza.

Favorite hobby or interest: I love to be outside and hike with my two dogs and riding my horse.



Describe your journey to the compliance world:

I began working as a Research Technician for drug device combination preclinical studies at Penn Vet CORL in 2009. I moved into a QA role at Penn Vet CORL in 2010. I moved to Texas in 2014 and began working for QACV Consulting and I am currently enrolled in the MS program for Regulatory Affairs at Northeastern University.

What was the catalyst for you to become more involved in MARSQA (e.g., run for board)?

I have been a member of MARSQA since my time at Penn Vet CORL, Chris Wubbolt suggested running for Treasurer and it has been great to get to know everyone on a more personal level. The high quality training that is easily accessible is definitely one of MARSQA's strengths.

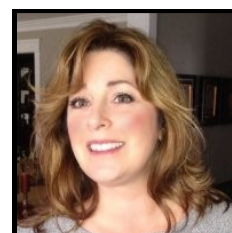
Director: Tina Myers

Company Name: Otsuka America Pharmaceutical, Inc (OAPI)

Area of Specialty: GCP, RQAP certification, in process MS, Regulatory Affairs and Quality Assurance, Temple University School of Pharmacy

Favorite local restaurant: Glasbern Inn

Favorite hobby or interest: Watercolor painting, photography, arts/design



Describe your journey to the compliance world: After thorough study, preparation and networking I transitioned from Restorative Dentistry into Clinical Quality Assurance ten years ago.

What was the catalyst for you to become more involved in MARSQA (e.g., run for board)?:

I wanted better access to people from different backgrounds and to offer whatever skills I could to help the organization run well; I also wanted to add some balance since there were no GCP people represented on the board. Lastly, I wanted to test my project management skills and exercise some creativity by being on the newsletter committee.

Director: Denise Boto

Company Name: inVentiv Health

Area of Specialty: GCP

Favorite local restaurant: The Milford Oyster House

Favorite hobby or interest: I am a Civil War buff, especially anything to do with Gettysburg. I also love to be outdoors and enjoy hiking, kayaking, riding my mountain bike and going white water rafting.



Describe your journey to the compliance world:

I graduated from college and was fortunate to start working right away at Schering Plough in Quality Assurance. From there I worked at several major pharmaceutical companies, all in QA, and got experience in GMP, GLP and GCP. With GCP being my favorite, that is where I stayed and I continue to work in this area at inVentiv Health, the CRO I have been with for 15 years.

What was the catalyst for you to become more involved in MARSQA (e.g., run for board)?

I have been involved with MARSQA and the Computer Validation Committee for over 15 years.

I enjoy being part of a professional organization where I can find out information about the latest regulations, technology, etc. in order to help me in my current position. MARSQA is made up of so many great people with wonderful backgrounds and experience which allows me to learn from them and know that I have all of these individuals there to help me if I have work related questions/concerns.

Director: Debra Parker

Company Name: Bristol-Myers Squibb Company

Area of Specialty: GLP, with scientific expertise in Bioanalytical; member of Toastmasters International, a Certified Massage Therapist in NJ, and TESOL-certified (Teaching English to Speakers of Other Languages)

Favorite local restaurant: Firkin Tavern in Ewing NJ

Favorite hobby or interest: Planning for a B&B in Western NY for when we retire

Describe your journey to the compliance world:

I've spent 19 years in the laboratory, running RIAs, Enzyme Inhibition assays, ELISAs, HPLC and

LC-MS/MS. Most of that time has been in a regulated environment. The transition to QA occurred 10 years ago, and it was the best career move I ever made. While I am in a GLP compliance organization, our group primarily focuses on analytical, bioanalytical and TK audit functions. In addition, I support clinical bioanalysis audits for BE, Biocomparability/Bridging Studies, Pediatric and Special Population studies. We are also moving into the GCLP space, as we partner with clinical discovery labs doing Biomarker analysis. What an exciting time to be in QA!

What was the catalyst for you to become more involved with MARSQA (e.g., run for board)?

One of my strengths is in teaching/sharing with colleagues and stakeholders the knowledge I've acquired over the past 3 decades. I am concerned, when I look around the MARSQA membership meetings, that we do not have enough young leaders in the room with us. As a Director, I hope to inspire younger folks, and pass on what I have learned. There is always something new you can learn, and I also believe that I will be learning a lot from my fellow board members. If we are going to live in interesting times, it helps to have a strong network to you help you weather whatever life throws at you. Let's all keep each other afloat!



Scientific Word Scramble!

Word	Clue
OLCULELSE	The primary substance that makes up the cell walls and fibers of plant tissues. The material is important in the manufacture of a variety of products including paper, fabric and medications.
LCLE LLAW	the thick covering of a plant cell made from non-living fibers
LARPO ECLMLEUO	A molecule that carries unevenly distributed electrical charges
ERPEAATVO	To change from liquid state to a gas
UOLVE	The inner part of an ovary that contains an egg
UNTRIBE	A machine with turning, fan like blades that runs a generator
AALLLEPR IITURCC	An electrical circuit arranged in such a way that current passes through more than one pathway simultaneously
LRMAEMPEBIE	Not allowing substances to pass through

Answers:

1. CELLULOSE ; 2. CELL WALL
 3. POLAR MOLECULE ; 4. EVAPORATE
 5. OVULE; 6. TURBINE
 7. PARALLEL CIRCUIT; 8. IMPERMEABLE

Advertisements and MARSQA Contact Information



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*Or contact us at:
Telephone: 610-442-2250
Email: contact@qacvconsulting.com*

To contact the entire
MARSQA board please e-mail:

board@marsqa.org

For individual Board Member
e-mail addresses, please see:

<http://www.marsqa.org/board.shtml>

MARSQA Disclaimer:

Please note, during membership meetings, photography during the meeting may occur. If you do not wish your photograph to be included in upcoming MARSQA newsletters, please e-mail newsletter@marsqa.org

Upcoming Events

MARSQA Spring Membership Meeting

15 March 2016

12:00-4:30pm

C*ck and Bull Restaurant
Peddler's Village, Lahaska, PA

11:00-12:00pm:

- Computer System Validation Quarterly Meeting
- GLP Open Discussion

12:00-1:00pm: Lunch

1:00-4:30pm: Meeting/Presentations

- Presenter: Shawna Jackman, Charles River Laboratories, Inc.
Topic: Stem Cells as Drug Therapies
- Presenter: Al Letchak, Director, 3rd Party Resourcing,
Quality Risk Management
Topic: Quality Risk Governance in Outsourcing (An Oversight Model)

See www.marsqa.org for meeting details and registration information

CQA Discussion Group Meeting

May 10th, 2016
11:30-4:00

Peddler's Village, Lahaska, PA

Meeting facilitators are Stan Szpindor, Joan Versaggi.

Meeting Topics:

- Issue Management/Escalation
- REMS

Upcoming MARSQA Membership Meetings

June 23, 2016

September 22-23, 2016 (Joint Meeting with NERSQA)

October 6, 2016

December 6, 2016

MARSQA Computer Validation Training

18-19 May 2016

C*ck and Bull Restaurant
Peddler's Village, Lahaska, PA

Check back on www.marsqa.org for information regarding this upcoming training!!