



VOLUME 22,
ISSUE 1
Spring 2019



WELCOME TO MARSQA 2019!

NEW YEAR, NEW LEADERSHIP, NEW EVENTS

We are happy to welcome a new Board Of Directors and Committee Members who volunteer their time to keep the organization fully functioning, providing affordable educational events, and face to face networking/ training meetings to its members.

Our new Board of Directors:

President: Nancy Gravino
Vice President: Tina Myers
Past President: Megan Lawhead
Treasurer: Gowrie Somayaji
Secretary: Denise Wilson
Director: Lyn Dugger
Director: Christi Velez
Director: Bethany Kearney
Director: Joan Maluki

Our Committee Members:

Computer Validation: Denise Botto, Chris Wubbolt, Calvin Kim
Education and Program Planning: Roxanne McDonald, Tara Keener
Historical: Nancy Gravino
Nominating: Derek Hu
Membership: Lyn Dugger
Newsletter: Alessio Tummolillo, Bethany Kearney, Amanda Hobson
Technology: Kiet Luong

Contact the Board of directors for more information on volunteer opportunities: board@marsqa.org

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Special points of interest

- Two Full Day Member Meetings for 2019
- Free Webinars Through SQA
- CSV Training
- Open Committee spots

MEET THE MARSQA PRESIDENT: **NANCY GRAVINO**



My area of expertise is the good laboratory practices (GLPs). Over the last three decades, I have had the pleasure to meet and work with interesting and intelligent colleagues in the field of Pharmaceutical research, many of whom I feel privileged to call my friend.

I began my career working in the Inhalation lab at a CRO, and then I transitioned to quality assurance. Next, I took a giant step to work at big pharma and I have spent the last ten and a half years working at Bristol-Myers Squibb as a compliance specialist. I have inspected numerous GLP studies, facilities, systems and CRO's and I have hosted the FDA and other regulatory health authorities.

I have been a member of MARSQA since 1998, RQAP certified since 2000, I have been on the MARSQA Board of Directors filling various positions since 2008 including the Secretary, Director, Vice President positions. I am also the chair for the MARSQA Historical Committee. I enjoy the collaborations with the Board and Committees and the MARSQA membership.

PRESIDENT'S MESSAGE

Welcome to Spring 2019, MARSQA members!

One advantage to living in the Mid-Atlantic region is the ability to enjoy recreational activities at the Jersey shore, the Poconos, local parks, or even our own backyard. Although I personally was quite pleased we did not have a lot of snow accumulation this past winter, I am also hoping the weekends will be more dry this spring/summer and we can all relax and enjoy the sunshine. Perhaps you will be fortunate enough to go to the SQA Annual Meeting in Atlanta, Georgia in April.

If you are like me and will be staying closer to home this spring, your MARSQA Board and the Committee Chairs have been busy planning activities for 2019. Be alert for emails, and check out the MARSQA website for dates and registration details for the upcoming MARSQA Membership meeting at the C*ck and Bull restaurant as well as a 2 day CSV basic training course at Earl's restaurant in May. Many of you can corroborate that the food at both of these restaurants is delicious and we always enjoy spending time away from the office learning something new, while networking with our colleagues and peers. MARSQA is always looking for new speakers to present new and interesting topics. I suggest that if you are not pleased with the type of trainings or presentations that the MARSQA board has been offering to the membership over the last couple of years, then please join a committee or run for an elected position and you will discover that your opinion matters and that your ideas will be heard. Finally, if you have never attended a MARSQA training or membership meeting, there is no time like the present to start. I am committed to improving your membership and I welcome your feedback.

Please feel free to contact me at this email address: president@marsqa.org

Please also join us in a heartfelt **THANK YOU** to Megan Lawhead
The MARSQA Board of Directors and Membership appreciate all of
the work as the 2018 MARSQA President. Your work with MARSQA
has not gone unnoticed. Thank you for implementing new ideas,
making thoughtful decisions and keeping the organization moving
forward along the way.



HOW MUCH DOES A POLAR BEAR WEIGH?

As a recent addition to the QA team, my only experience previously with QA was when I was working as a Report Writer. In my role, my work was subject to periodic QA audits. These are phrases that I would hear on a regular basis, and sometimes, much to my chagrin, I would utter myself:

“Why does QA make us do this?”
“There’s no way QA will let us do that.”
“You better just do it, or QA will write you up.”

Simply put, I was part of the employee population that believed QA is a department to be feared, who lay down the law and expect to be adhered to strictly, no questions asked, like some sort of robot sent from a dystopian future to eliminate all irregularities.

Fast forward to my current status in QA, where my primary responsibility is auditing, I am faced with a whole new perspective.

When I walk into a room to perform an audit, I can feel the temperature in the room drop 20 degrees - *celsius*. I can see employees stiffen up, and I can hear the negative tone in their phrases, “Great, QA is here.” This isn’t always the case; there are times when auditees are just as comfortable with me being there as if I was just another member of their department. But the former situation, the cold reception towards members of QA, happens often enough that I’ve come to recognize it, and have wondered what I can personally do to change it.

As a result of the reception to QA audits, I broke this down to two key issues that I wanted to address: the lack of communication between auditees and QA; and confusion surrounding responses necessary to close out the audit findings. During my annual review, I discussed these issues with my manager who gave me a single piece of advice. She stated, “Try talking to new hires and introducing yourself as a person. Let them know that you aren’t there to point out their mistakes, but make sure that they are prepared for any regulatory or client visit. You’re there to make sure they are receiving the proper training and are as knowledgeable as they can be in their everyday duties.”

With that simple, yet profound advice, I had a whole new perspective of my value to the team. To put the advice into practice, I implemented a few changes to my auditing style.

- A warm introduction for new employees during training and prior to each audit
- Engagement the departments that I may be auditing to ask questions and show a willingness to understand and accept their perspective
- During audits, reiterate to auditees that QA is a support department and available outside of audits

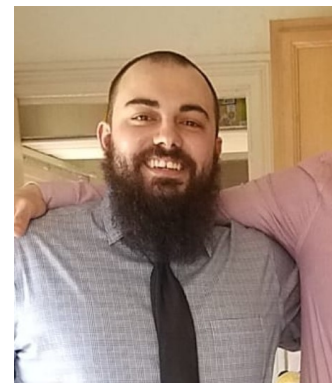
I approached these changes hopeful that these small measures will help employees understand that the QA department is made up of human beings, not T-800 Terminators, who are capable of making mistakes, and are a resource to help with any challenges, not reprimand for minor mistakes.

I have already started to see a change in the frequency of questions from the auditees prior to the audit and a genuine understanding and concern when findings are issued. I think they may have also raised the thermostat a few degrees for me...enough to break the ice.

Alessio Tummolillo, Quality Assurance Auditor II at Envigo

The changes that I hope to continue to see have inspired me to write this article and continue to delve deeper into my own working practices as an auditor.

What can you do to enhance the relationship with your auditees? Let’s discuss at the next MARSQA membership meeting!



MEET THE MARSQA *PAST PRESIDENT* : **MEGAN LAWHEAD**

My career began at Charles River Laboratories (Horsham) 11 years ago and I serve as the QA Supervisor. I am currently enrolled in the Management Development Class at DVIRC and am looking forward to being part of a podium presentation at the upcoming SQA meeting in Atlanta. I proudly serve as MARSQA past president, having previously served other executive board roles. MARSQA offers great opportunities to network and create professional relationships as well as stay abreast of hot topics and exposure to a wide variety of training topics through in person meetings.

MEET THE MARSQA *VICE PRESIDENT* : **TINA MYERS**

This year (2019) I will serve at the MARSQA Vice President under the leadership of Nancy Gravino (MARSQA President 2019). I am proud to represent this small group of people that volunteer their time to serve on the MARSQA Board of Directors. My first post to the MARSQA Board of Directors was as Director (2015-2016); then Treasurer (2017-2018). I have also worked/chaired the Newsletter Committee for the past four years.

I am thankful to all my fellow MARSQA volunteers for giving their time, energy, and ideas to keep the organization going, to keep it interesting, and to keep it a place where like-minded quality assurance people can meet, mingle, discuss, collaborate, and network with each other.

I began my career in Clinical Research, GCP, in 2005 after making a career change. I work for Allergan and have worked for three other sponsor organizations (Savient Pharmaceuticals, Bristol Myers Squibb, and Otsuka America) all within the clinical quality assurance space and have covered assignments in several therapeutic areas.

Outside of work, I enjoy spending time with my family, doing outdoor activities such as hiking, biking, and playing the lever Harp where I am currently studying for certification as a Harp Therapist.



MEET THE MARSQA *TREASURER* : **GOWRI SOMAYAJI**

I have been a member of MARSQA since 2016 and have attended the MARSQA member meetings since. I find them to be informative and helpful in understanding how the regulations are interpreted and applied in other companies. I find the topics current, relevant and interesting. My favorite sessions have always been the open-discussions - where we have the opportunity to interact with subject matter experts and experienced colleagues in the room. As the treasurer of MARSQA I intend to lend my support to the success of this organization.

I have been in the pharmaceutical industry for 15 years, the last 5 of which have been in QA. I currently work as a pre-clinical QA auditor at Janssen Pharmaceuticals, covering GLP, GcLP and Discovery QA. My previous job titles included Biorepository QA Manager at Scisafe, Inc., preceded by Scientist at Merck & Co. At Merck, I worked in Infectious diseases and Cardiovascular therapeutic areas.



Meet the MARSQA 2019 Directors

Joan Maluki

I am a Veterinarian by training and a Quality Assurance Professional. My QA profession began at Envigo (formerly Huntingdon Life Sciences) in 2004 prior to which I was an Animal Technician in the same organization. I took a break to raise my young family between 2012 and 2017. Over this time period, I volunteered (as Chairperson and Member) in various ethical and animal care review committees that oversaw human subject participant and animal welfare considerations for clinical trials and animal research studies in Kenya. I came back to the USA in 2017 and returned to Envigo in the same role. I am currently a Senior QA Auditor. I have been a member of MARSQA and SQA since 2004.

I was recently elected to serve as a MARSQA Director, a role I look forward to serving in for the best interests of the membership. MARSQA provides an excellent opportunity for networking, sharing of ideas and best practices.

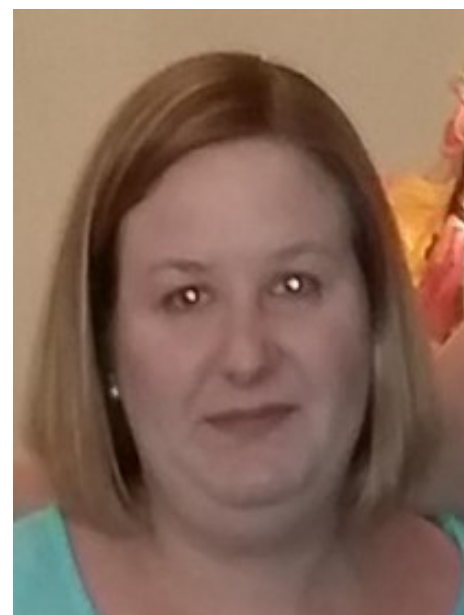
My hobbies include travelling, knitting, reading, watching movies, swimming, walking, listening to music and dancing.



Christi Velez

I have over 17 years working in the preclinical area and have worked both within the CRO and pharmaceutical industries. I currently work at Janssen Pharmaceuticals as a Preclinical Team Lead/Domain Expert. I started my career working as a laboratory technician conducting GLP and Non-GLP in-vivo studies at White Eagle Laboratories. After working in the laboratory, I transitioned to the QA department and worked at several CROs as an auditor before going into the pharmaceutical industry. I have experience in FDA/EPA/OECD regulations/guidances, hosting Health authority inspections and training new auditors/ business partners in GLPs. I have also gained experience in auditing GCP and GcLP. I attained my RQAP-GLP certification in 2005.

I have been a member of MARSQA for over 10 years. Currently, I am a Director on the MARSQA Board. What I like most about MARSQA is that they provide local forums for the QA industry to meet, discuss and learn at local events. I look forward to expanding my growth and knowledge in the regulated industry and expanding my experience by collaborating in an external environment.



Meet the MARSQA 2019 Directors

Lyn Dugger

I have many years of experience working in a GLP environment either as a Chemist in the lab, an Auditor in Quality Assurance, or as a Manager of Quality Assurance. Management experience includes managing laboratory personnel as well as QA personnel on site and at client sites. One of my moments that I am most proud of is when I hosted the EPA at the Knoell USA facility. The audit resulted in zero findings. I also have experience travelling to perform audits as far away as China.

Bethany Kearney

I have been a member of MARSQA since my SQA membership began a few years ago and thoroughly enjoy the regional meetings as well as the SQA annual meetings. This year I am very excited to serve as a Director of MARSQA.

Over the last 14 years, I have worked in large pharma, research and most recently in clinical services organizations. My expertise within quality is with the design and establishment of quality management systems within my own organizations and in support of the client organizations that I work with day to day.



Meet the MARSQA 2019 Secretary

Denise Wilson

My areas of expertise are good laboratory practices. I have worked at Bristol-Myers Squibb in Quality Assurance for the last 13 years and currently as a compliance specialist. My responsibilities include inspecting GLP studies, facilities, systems and Contract Research Organizations. Additionally I have participated in several FDA and USDA regulatory inspections.

I have been a member of MARSQA since 2005 and currently hold the position of Secretary on the MARSQA board of directors.

I am looking forward to MARSQA continuing to provide opportunities for members to meet, interact and share information through membership meetings and various training courses/webinars. These activities also help promote personal and professional development.





**QUALITY
ASSOCIATES
INCORPORATED**

A KONICA MINOLTA COMPANY

Quality Assurance & Scientific Support



Quality Associates, Inc. (QAI) was established in 1986 to provide regulatory consulting services to the pharmaceutical and agrochemical industries. From inception, QA programs have been the cornerstone for providing services for both GLP and GCP studies.

- Establish GLP/GCP Programs
- Independent QAU, Full Time, Part Time, as Needed
- Conduct All Types of Study Audits, Both GLP & GCP
- CRO, Test Site, and Vendor Audits
- SOP Development
- Training Programs
- Validation Audits
- 21 CFR Part 11 Support
- CRO and Vendor Qualification Audits
- GLP Archiving

Want To Get Involved With The MARSQA Organization?

Nominating Committee

The Nominating Committee is responsible for recruiting the slate of candidates for Officer and Director Positions open for election. The Nominating Committee prepares the slate of candidates and sends it to the Board for approval. Once approved, the Committee emails the ballots to SQA for formal voting.

Membership Committee

The Committee serves as the coordinator and liaison between the MARSQA Board of Directors and the general membership of MARSQA. The Committee works to attract new members, retain current members, and complete member surveys. In addition, take suggestions and make changes for improvements.

Historical Committee

The Nominating Committee is responsible for collecting and maintaining information and artifacts related to the establishment and progression of the Chapter. Presents historical perspectives of the Chapter at Regional and National SQA meetings

Technology Committee

The Committee serves as the coordinator of content and oversees the MARSQA website and other uses of technology to advance the Chapter's mission.

*"Volunteers are not paid
-- not because they are
worthless, but because
they are priceless."*

**If you are interesting in participating in any Committee please
contact the Board of directors for more information: board@marsqa.org**

Are you interested in being a presenter?

This is a great opportunity to brush up on your presentation skills.



We also need volunteer assistance with planning the course, reviewing presentations, helping with registration, etc.

**If you are interested in volunteering please reach out to Denise Botto:
denise.botto@syneoshealth.com.**

UPCOMING EVENTS

MARSQA Member Meetings

Time: 9 am—4 :30pm includes Hot Buffet Lunch

C*ck N Bull Restaurant, Peddlers Village, Lahaska, PA

Register through SQA/SQA Store: “MARSQA” in search box

Thursday, May 16, 2019

MARSQA Member (and onsite student rate)	\$60
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Nonmember	\$80
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2019 Membership + Meeting	\$90
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Featured Speakers:

Stacy Wilson and Christina Velez of Janssen Pharmaceuticals
A Global Sponsors Perspective Managing an Internal & External Risk Based Audit Program

James C. Canterbury of Ernst & Young LLP
Blockchain – Reshaping the way we share and trust data

Dr. Elise Lewis of Charles River Laboratories
Current Perspectives on Microsampling in Small Laboratory Animals

Gowri Somayaji of Janssen Pharmaceuticals
Inducing Quality Culture in Discovery Research – Why Data Integrity at the Bench Matters

Full Agenda is available here: <http://marsqa.org/events.shtml>

We look forward to seeing you at the Annual Meeting!

Look for the MARSQA luncheon and the sponsored head shots booth



COMPUTER SYSTEM VALIDATION COMMITTEE EVENTS



Our Spring Face to Face at-Syneos Health was successful! Thank you to all of the attendees who were able to come.

We look forward to seeing you in October!

CSV BASIC TRAINING

May 7-8, 2019 at Earl's Restaurant, Peddlers Village, Lahaska, PA

Training Objective:

The training will cover various topics related to regulatory requirements for data integrity and security, and CSV fundamental topics, including validation planning, user requirements, specifications, risk assessment, testing, validation reporting, change control and maintenance practices.

RQAP re-registration units will be requested.

Registration:

	Register By 27 April	After 27 April
MARSQA Member	\$275	\$300
Non-Member	\$325	\$350

SAVE THE DATE!

- ♦ Monthly CSV Teleconferences: Last Monday of every month 12-1pm
- ♦ CSV Face-to-face: October 15, 2019 at Bayer Corporation in Wippany
- ♦ Membership meeting September 19, 2019 to be held at GSK in Collegeville, PA
- ♦ CSV Special Topic Training October 29-30, 2019
- ♦ Webinars: **free** to SQA/MARSQA members:

Webinars are announced ad-hoc throughout the year to all members via email. Registration is completed through the SQA/SQA Store