



WELCOME TO MARSQA 2018!

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 it's members.

Our new Board of Directors:

- President: Megan Lawhead
- Vice President: Nancy Gravino
- Past President: Stacy Wilson
- Treasurer: Tina Myers
- Secretary: Denise Wilson
- Director: Lyn Dugger
- Director: Christi Velez
- Director: Erin Range
- Director: Narith Flach

Our Committee Members:

- Computer Validation: Denise Botto, Chris Wubbolt, Calvin Kim
- Education and Program Planning: Roxanne McDonald, Tara Keener
- Historical: Nancy Gravino
- Nominating: *Open
- Membership: *Open
- Newsletter: Tina Myers, Amanda Hobson
- Technology: Kiet Luong

*Please consider volunteering for the open committees or on any of the other committees. We would love to have you on board.

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SPECIAL POINTS OF INTEREST

- Two Full Day Member Meetings for 2018
- Free Webinars Through SQA
- CSV Training
- Open Committee spots



MEET THE MARSQA PRESIDENT: MEGAN LAWHEAD

My career began at Charles River Laboratories (Horsham) over 10 years ago and in the past year, I have recently taken on the role as QA Supervisor. I also am a recent graduate of the Dale Carnegie course, being awarded the Highest Award for Achievement by my peers.

I proudly serve a MARSQA president, also having previously served as VP and am also a member of the newsletter committee. I love MARSQA because is a great organization to network and create professional relationships. MARSQA also offers exposure to a wide variety of training topics through in person meet-

“The best antidote I know for worry is work. The best cure for weariness is the challenge of helping someone who is even more tired. One of the great ironies of life is this: He or she who serves almost always benefits more than he or she who is served.”

– Gordon B. Hinckley, *Standing for Something: 10 Neglected Virtues That Will Heal Our Hearts and Homes*

PRESIDENTS MESSAGE

Hello MARSQA Members!

The beginning of the year has flown by and we are already in Spring! Or, so the calendar tells us. I have seen plenty of snow!

As your 2018 MARSQA president, I am energized to serve the membership and provide value added learning and networking possibilities. The MARSQA board has been busy behind the scenes preparing membership meetings, webinars, and committee meetings! We have a great upcoming year planned. Membership meetings at the Cock and Bull will occur on 17 May and 20 September of this year. Computer System Validation trainings are scheduled for 09-10 May and 03-04 October. Visit www.MARSQA.org for our upcoming events and registration.

I have proudly served MARSQA in various capacities over the years and my goal this year is to encourage engagement from the membership. MARSQA is full of expertise across disciplines from medical devices, bioanalytical, GLP, GCP, and academia! We are currently recruiting speakers for the 20 September 2018 membership meeting. And, I encourage each of you to attend a membership meeting and network with your fellow members. There is always lively discussion on hot topic in industry and of course delicious a delicious hot lunch.

Thank you to the 2017 MARSQA board members for their contributions to the chapter. Myself along with the 2018 MARSQA board look forward to a productive and successful year for MARSQA. I welcome your feedback and ideas for future opportunities. Please do not hesitate to contact me at megan.lawhead@crl.com with any questions or concerns.

QUALITY ASSURANCE ARTICLE

Mullin, R. (2018) The Drug Industry's Data Integrity Problem. *Chemical and Engineering News*, 96, (2). 15-17.

<https://cen.acs.org/articles/96/i2/drug-industrys-data-integrity-problem.html>

The article written by Rick Mullin for Chemical & Engineering News discusses the recent history for data integrity issues as well as current areas of concern proposed by several industry experts. In 2017, India, the United States, and China (respectively) topped the chart in FDA data integrity warnings. FDA auditors have undergone training in data integrity related processes. Industry experts throughout the article reference software limitations, scientists underutilizing software technology, academic research practices, and human error as the leading causes of the data integrity issues.

The article points to the recent guidance document by the International Society for Pharmaceutical Engineering (ISPE) titled Records and Data Integrity. The guide includes key concepts on risk management approaches, data governance, data life cycles, concepts from ALCOA and ALCOA+, as well as GxP computerized system life cycles.

<https://www.ispe.org/publications/guidance-documents/gamp-records-pharmaceutical-data-integrity>

THANKS TO THE 2017 PRESIDENT STACY WILSON!!!!

The MARSQA Board of Directors really appreciate the work that Stacy did as MARSQA's 2017 President—she implemented some new ideas and had to make some tough decisions along the way. She kept the organization moving forward and the Board of Directors look forward to her support this year in her role as past-President.

Stacy's Bio:

Stacy is currently the Manager, Auditor, Quality Assurance in the BioResearch Quality & Compliance/Quality Assurance department at Janssen.

This year I will be the past president on the board. I have previously held the positions of Director, Vice President and President and have been a member of MARSQA since 2010.



MEET THE MARSQA *VICE PRESIDENT*:

NANCY GRAVINO

My area of expertise are the good laboratory practices and I have worked as a compliance specialist at Bristol-Myers Squibb for the last ten years inspecting 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 and RQAP certified since 2000, I am chair for the Historical Committee, and I have been on the MARSQA Board of Directors since 2008 filling the positions of Secretary, Director and my current role of MARSQA Vice President.

I love collaborating with members of the MARSQA Board and MARSQA membership who are a great group of people. I hope that MARSQA can provide plenty of opportunities for MARSQA members to get together and network at the membership meetings and various training courses that will be offered throughout the year.



MEET THE MARSQA *TREASURER*
TINA MYERS

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) in the clinical quality space. I enjoy the challenges that quality assurance brings and there truly is never a dull moment...always so many areas of risk to think about. I have worked in several therapeutic areas such as oncology, rheumatology, metabolic, viral, ophthalmic, CNS & Psychiatric, medical aesthetics, medical device, and gastroenterology. I've been to numerous interesting research centers, academic centers, and healthcare facilities, all over the United States and abroad, and have met many great, hard working people that always put in their best efforts to help society find treatments for illness and unmet medical needs.

I am proud to represent the small group of people that volunteer their time to serve on the MARSQA Board of Directors. My first post in 2015 was Director, then Treasurer. I also chair the Newsletter committee. 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.



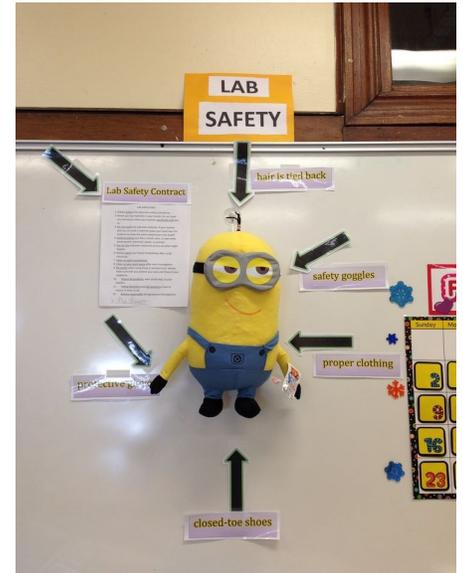
Meet the MARSQA 2018 Directors

Erin Range

I live in Bucks County Pa where I teach yoga, stand up paddling (SUP) and help manage Kind Earth Growers LLC a native plant nursery in Ottsville, Pa.

I'm currently a Director on the MARSQA board and have been a MARSQA member since 2004. For more than 14 years I have worked professionally in Quality Assurance. I started in the GLP Contract Research industry as a laboratory technician and moved into a new role as a QA Auditor in 2004 and was promoted to QA Manager in 2007. I joined the Quality Assurance department at Envigo in 2009 auditing Toxicology and Bioanalytical aspects of both GLP and GCP studies.

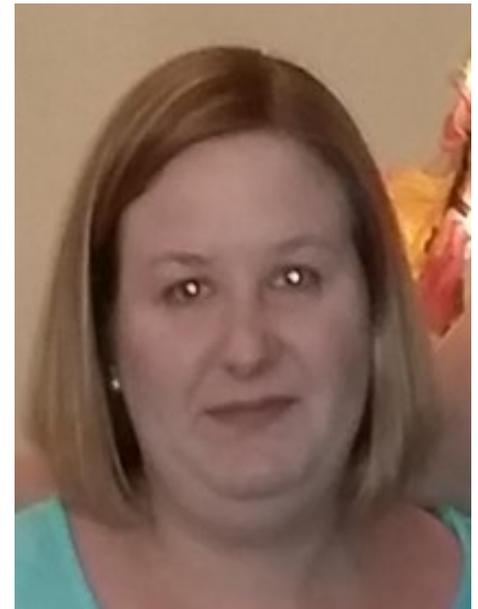
Being a member and attending MARSQA meetings have been a great way for me to network, connect, learn, and develop professionally. I am glad to be a part of supportive and dedicated organization.



Christiana 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 CRO's as an auditor before going into the pharmaceutical industry. I have experience in FDA/EPA/OECD regulations/guidance's, hosting Health authority inspections and training new auditors/ business partners in GLP's. I have also gained experience in auditing GCP and Gelp. 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



Meet the MARSQA 2018 Directors

Lyn Dugger

Many year of experience either 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. As a manager, I hosted the EPA at the knoell USA facility The audit resulted in zero findings. I also travelled to China to perform an OECD GLP audit on a chemical facility.

Narith Flach

Narith is an integral part of the MARSQA organization providing feedback and voting on important issues for all MARSQA related business and membership meetings.

Meet the MARSQA 2018 Secretary

Denise Wilson

My area of expertise are the 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

410.884.9100 | qualityassociatesqa.com

Want To Get Involved With The MARSQA Organization?

Volunteers are needed for the Nominating and Membership Committees!

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

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

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

Basic CSV Course!!

We are starting to plan the Basic CSV course in May and need Presenters!!! 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.**

Community Involvement

MARSQA members lend a helping hand and talk with students at this annual event...

GETT Expo

March 17, 2018 - 1:00-4:30pm
Phoenixville Area Middle School
www.gettpa.org



The GETT Expo is an opportunity to show hundreds of girls just how fun STEM careers can be! Showcase your industry or resources to 750 girls in grades 5-10 and their parents and educators. Meet and talk with the girls to help them understand STEM through a hands-on activity. Be the real-life, successful woman who shows them how STEM is fun and can prepare them to help others and change the world.



Benefits for Exhibitors

- Visibility to approximately 1,000 people including parents, educators, speakers, students, and other employers
 - Inclusion in the program booklet
 - Access to future volunteers and interns



What Should You Bring?

- 5 minute hands-on activity that can be repeated multiple times for the 750 girls
- 2-3 women stationed at your table to carry out activity and engage attendees
- Tablecloth, posters, organization information, giveaways, etc.



What Does GETT Provide?

- 6' Table (additional tables available at \$50 each)
 - 2 Chairs
 - 8' x 6' Area
 - Setup 11:30am - 1:00pm
- For an additional fee, one standard electrical outlet (limited availability)



Expo cost is \$250 per table; non-profit rate is \$100 per table
Sign Up by January 15, 2018

Visit <https://www.surveymonkey.com/r/gett2018expo> to reserve your spot. Contact Tracey Oberholtzer (toberholtzer@ccedcpa.com) or Susan Boardman (sboardman@dasd.org) with any questions.



Interested in becoming an event sponsor? Expo table included at every sponsor level. For more information contact Tracey at toberholtzer@ccedcpa.com.

 www.facebook.com/gettpa

   GETTstem



More about GETT: Girls Exploring Tomorrow's Technology (GETT) is an all-day fun, informational event for elementary, middle and high school girls in grades 5 through 10 and their parents that features successful women in STEM. Attendees learn the facts about how STEM careers can be fulfilling, fun, and rewarding personally, professionally and financially. GETT is sponsored by the Innovative Technology Action Group (ITAG).



UPCOMING EVENTS

Full-Day... MARSQA Member Meetings

Time: 9 am—4 pm includes Hot Buffet Lunch

Cock N Bull, Peddlers Village, Lahaska, PA

Cost \$50 Members/ \$70 Non-Members

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

◆ **Thursday, May 17th**

Considerations in auditing BA work - What to look for and where in bioanalysis

Irina Colligon

Legal Aspects of Working with Vendors

Richard Ciamacca

Computer System Validation Open Forum

This hour will be open to all interested to discuss recent CSV trends, issues, and/or updates.

Biomarker Method Validation: Approaches

Dr. Sheri Lordi

GLP/Bioanalytical Open Forum

This hour will be open to all interested to discuss recent GLP trends, issues, and/or updates.

SQA Hot Topics

Megan Lawhead

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

◆ **SAVE THE DATE!**

Thursday, September 20th

Details will be provided closer to the meeting date

◆ **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

CSV CORNER TRAINING FOR 2018

◆ MARSQA Computerized System Validation

Basic Training:

Wednesday—Thursday, May 9-10th

Earl's Restaurant, Peddlers Village, Lahaska, PA

Register by logging into SQA website/SQA Store

Registration deadline is Friday, 4 May 2018

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.

<u>Registration:</u>	Register By 27 April	After 27 April
MARSQA Member	\$275	\$300
Non-Member	\$325	\$350

If you have any questions regarding the CSV training,
please contact:

chapters@sqa.org

Chris Wubbolt: chris.wubbolt@qacvconsulting.com

Denise Botto: denise.botto@syneoshealth.com

SAVE THE DATE!

◆ MORE CSV Training from the MARSQA CSV Committee

Wednesday—Thursday, October 3-4th

Earl's Restaurant, Peddlers Village, Lahaska, PA

Topics to be determined.

More information will be provided at a later date.