



## WELCOME TO MARSQA 2020!

### 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: Tina Myers**

Vice President: Amanda Hobson

Past President: Nancy Gravino

Treasurer: Gowrie Somayaji

Secretary: Julia Bernhard

Director: Denise Wilson

Director: Heidi Krueger

Director: Bethany (Davis) 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, Helen Xu

Nominating: Derek Hu

**Membership: Open\***

Newsletter: Alessio Tummolillo, Bethany Kearney, 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.

Contact the Board of directors for more information on volunteer opportunities: [board@marsqa.org](mailto:board@marsqa.org)



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#### Special points of interest

- Three Full Day Member Meetings for 2020
- CSV Training
- Open Committee Positions
- Community Service Opportunity

## MEET THE MARSQA PRESIDENT: TINA MYERS



I joined the ranks of GCP professionals in 2005 as a third career change preceded by careers in Dentistry, and Outside Sales. Although seemingly unrelated, there are common links between the three that have allowed me to develop into more holistic member of the research and development workforce: science and medicine background, people skills, attention to details, big picture thinking, business acumen and general overall interest in making sure things are done right whenever possible. I have varied GCP experience working in small, medium, and large pharma all with their unique set of requirements...

flexibility required! Currently, I am employed at Allergan (Irvine, CA/Madison, NJ) as a Sr. Manager Global R & D Quality. I am working on QARA, MS at Temple University when my travel schedule allows for class time.

I have also been on the MARSQA BoD since 2015, serving in various roles as Director, and Treasurer. In 2020 I will serve as the President for one year as preceded by the required role of Vice President.

In my spare time, I am either with my family, sketching, painting, playing the harp, or enjoying the outdoors.

### PRESIDENTS MESSAGE

## Welcome MARSQA Community to 2020.

Did you know that SQA's theme for 2020 is **Quality in Focus**?

To stay in line with that, my MARSQA's theme is: **Wear Your Quality Glasses**.

What this means to me is: use all the tools at your disposal to do the best job possible for your organization. MARSQA hopes to provide you with some new tools this year to see things more clearly.

The BoD are working on providing you, the MARSQA Community with some exciting membership activities for this year. First and foremost are the amazing face to face trainings we put together for you: face to face Membership Meetings covering various topics with various Quality-related presenters; and face to face CSV Trainings provided by our expert panel from the MARSQA CSV Committee. You will receive a certificate for fully completed attendance, and continuing education credits to be used towards your existing RQAP certification.

We are looking into furthering our mission to provide opportunities for involvement, to keep things interesting, and geographically reasonable by holding the meetings at various venues (with at least one at Peddlers Village, Lahaska, PA). The vision for 2020 includes:

- 2-3 in-person GxP trainings for the general member group
- 2 in-person trainings for CSV
- GLP and CSV forums (face to face and via teleconference)
- MARSQA Newsletter (feel free to submit your article to be published!)
- Chance for scholarship to SQA
- Opportunity to do public speaking



## MEET THE MARSQA **VICE PRESIDENT**

### Amanda Hobson

Current employment: Bristol-Myers Squibb

Years in industry: 12

Years in QA: 2.5

Hopes for this year: I am really excited to collaborate with my MARSQA colleagues over the next few years to continue traditions and make some committee updates.

Personal comment: All of my industry experience has been in a GLP setting. I entered the field as a biotechnician and then spent several years as a Veterinary Technician. In that role I was a Systems Administrator and participated in animal welfare oversight for internal and external studies. A few years ago I transitioned to the quality assurance group. I work with an amazing group of people and look forward to contributing and continuing my growth in this field.



## 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 session has 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 16 years, the last 6 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 2020 *Directors***

### **Joan Maluki**

I am a Veterinarian by training and a Quality Assurance Professional. I am currently employed at Covance Laboratories Inc. in Somerset, NJ. This site was formerly known as Envigo & Huntingdon Life Sciences. I joined industry in 2003 as an Animal Technician and moved to QA in 2004. 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 protection and animal welfare considerations for clinical trials and animal research studies in Kenya. I came back to the USA in 2017 and returned to Covance (Envigo at the time) as a QA Auditor. I am currently a Senior QA Auditor. I have been a member of MARSQA and SQA since 2004.

I began serving as a MARSQA Director in 2019. I hope that in 2020 MARSQA is able to grow its membership and to offer 3 meetings in order to provide an opportunity for learning, networking, sharing of ideas and best practices. I also hope that MARSQA is able to provide a webinar.



### **Heidi Krueger**

I am currently serving in the role of QA Director and Contracts Manager for Xybion Corporation, and have been in that role since the acquisition of Stelex by Xybion in 2010.

After starting as a lab tech basic research, I transitioned to a QC testing lab where I eventually advanced into the role of QA Officer. After working in laboratory QA, including lab method validation, and FIFRA GLP studies, as QA Manager or Director for 4 different companies over a period of approximately 13 years, I transitioned into my current industry providing end-to-end consulting services, including validation, and software to pharma and similarly regulated industries. I have been in this current industry for the past 20 years.

I've been involved with MARSQA on and off, and in a few different committees, for almost as long as I've been involved in QA, but just recently acknowledged that it was time to pay it forward by running for an open board position. My hope is that the organization can continue to grow and provide the valuable opportunities for learning and networking within the world of QA for which it is already well known. One important thing that I would like to help push forward is the value that an organization such as MARSQA can provide in encouraging use of new technologies and ideas within the highly controlled environments in which we all work.

When I'm not working, my time is divided between my two Collies, one Sheltie, a cat and a leopard gecko. One of my Collies is a certified Therapy Dog and we enjoy our visits to a local nursing home. I am also on the board for our local Collie rescue, and combine my love of learning, teaching, and kids by being active in my church's children's ministry.



## Meet the MARSQA 2020 Directors

### Denise Wilson

My area of expertise are the good laboratory practices (GLPs). I have worked at Bristol-Myers Squibb in Quality Assurance for the last 15 years and currently as a Compliance Specialist. I have previously worked in Quality Assurance at Covance (formerly Tandem Labs), BASF (formerly American Cyanamid Co.) and Envigo (formerly Huntingdon Life Sciences). 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, held the position of Secretary (2017-2019) and currently hold the position of Director 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.



### Bethany Kearney

My areas of expertise are global quality systems, compliance software implementation, clinical research (ICH-GCP); ISO 9001, 14155, 13485 and ISO/IEC 17025. I have 15 years of experience in quality compliance roles companies including Johnson and Johnson, Dr. Reddy's Laboratories, Clinlogix LLC and Confinis CPM ag. Through my experience designing and integrating complex quality management systems, she supported bringing products to market through implementation of quality by design principles and support of evidence-based safety and efficacy investigations. Currently, I am supporting the Industry Best Practice CoE at Sparta Systems to help enhance apply life science knowledge to the Trackwise product and software deployment strategy. I am excited to continue with the MARSQA board this year and I look forward to seeing you all at our meetings!



## Meet the MARSQA 2020 Secretary

### Julia Bernhard

My career began at Syneos Health in 2014 as a member of the Quality Control Department and I transitioned into Quality Assurance in 2019. My primary responsibility at the Early Stage lab is to conduct audits of bioanalytical project work, processes, and systems in accordance with SOPs and GLPs when appropriate. I attended my first MARSQA membership meeting in 2018 and fully joined the next year. To be in a room for the first time with so many people who truly care about the work we do was inspiring. I hope that as I take on this opportunity as the MARSQA Secretary, that I will continue to grow and learn more about this wonderful industry that we've all made our passion.



## **Meet the MARSQA 2020 Committee Chairs**

### **Newsletter Committee**

#### **Alessio Tummolillo**

Current employment: Covance Laboratories

Years in industry: 5

Years in QA: 1

Hopes for this year: To help continuing to improve the MARSQA newsletter and bring quality content to our members!

Personal comment: I was a report writer for 4 years before moving to QA and am now into my second year of being an auditor. Aside from Quality Assurance, I am also part of the IACUC and Safety Committee at my site (so have a vested interest in the safety of our people, our animals, and our data!). I am excited to see what new adventures time presents for me!



#### **Bethany Kearney**

Current employment: Sparta Systems

Years in industry: 15

Years in QA: 15

Hopes for this year: To reach as many of the members that we can via our membership meetings, participation at the annual meeting and with other outreach and volunteer programs.

#### **Amanda Hobson**

Current employment: Bristol-Myers Squibb

Years in industry: 12

Years in QA: 2.5

Hopes for this year: I am really excited to collaborate with my MARS-QA colleagues over the next few years to continue traditions and make some committee updates.

Personal comment: This year the Newsletter Committee would like to make some updates to our communication processes at MARSQA. Hopefully more to come from this group!



## **Meet the MARSQA 2020 Committee Chairs**

### **Historical Committee Chair**

#### **Nancy Gravino**

My area of expertise are the good laboratory practices (GLPs) where I have spent the last three decades inspecting numerous GLP studies, reports, data, facilities, systems and CRO's as well as plenty of hours spent hosting the FDA and other regulatory health authorities. I began my career working in the field of Pharmaceutical research at an Inhalation laboratory of a CRO. Next, I transitioned to quality assurance at that CRO and then made the move to big pharma where I have spent the last eleven years working at Bristol-Myers Squibb as a compliance specialist. I have been a member of MARSQA and SQA since 1998, RQAP certified since 2000, and I have been on the MARSQA Board of Directors since 2008 filling various positions such as MARSQA Secretary, Director, Vice President, President and my current role of Past President. I am also the chair for the MARSQA Historical Committee. I really enjoy taking pictures at MARSQA events. I am not a fan of being in the picture, so if you see me walking around taking photos at a MARSQA event, say hello and get your picture taken and your picture could end up in a future MARSQA newsletter.



### **Nominating Committee Chair**

#### **Derek Hu**

Current Employment: Covance GLP Quality Assurance Officer II

Years in industry: 5

Years in QA: 3

Hopes for this year: To continually improve my auditing skills and to include Analytical auditing to my repertoire.

Personal Comment: It is an honor to be amongst all these great board members and I hope this year I can do my part and contribute to another great year in MARSQA.



## **Meet the MARSQA 2020 Committee Chairs**

### **EDUCATION AND PROGRAM PLANNING COMMITTEE**

#### **Roxanne McDonald**

**Current employment:** I am currently a Senior Auditor in Laboratory QA with GSK for 1.5 years.

**Years in industry:** I've spent the last 25 years in the Pharmaceutical industry working in Manufacturing, Raw Materials testing, Product Release, Clinical packaging, Adverse Events reporting, and Clinical and Non-Clinical Research Quality Assurance.

**Years in QA:** I had 12+ years with Merck as a Senior Specialist Quality Assurance Auditor doing GLP work and 1.5 years with GSK as a Senior Auditor in Laboratory QA doing both GLP and GCP auditing.

**Hopes for this year:** My hope for 2020 is to continue to keep the MARSQA forums a place where like-minded quality assurance professionals can meet, mingle, discuss current regulatory information, collaborate and network with each other. As the Education and Planning Co-Chair, my intent is to provide a venue to incorporate topics of interest for all members and to attract non-QA professionals who have an interest in advancing Quality Assurance concepts into the meetings.



#### **Tara Keener**

**Current employment:** I am currently an Associate Director in MRL QA GLP at Merck & co.

**Years in industry:** I've spent the last 22 years in the Pharmaceutical industry working in biological testing and Non-Clinical Research Quality Assurance.

**Years in QA:** 18 years.

**Hopes for this year:** In alignment with my co-chair, I hope 2020 continues to keep the MARSQA forums a place where like-minded quality assurance professionals can meet, mingle, discuss current regulatory information, collaborate and network with each other. As the Education and Planning Co-Chair, my intent is to provide a venue to incorporate topics of interest for all members and to attract non-QA professionals who have an interest in advancing Quality Assurance concepts into the meetings.

If you know of any great speakers or are willing to present on a topic or host a meeting at your facility, please reach out and let us know!

We're always looking for new topics, new speakers, or great venues.

Always willing to try new things to get the MARSQA community more involved.

## **Meet the MARSQA 2020 Committee Chairs**

### **Computer Validation**



#### **Denise Botto**

Current employment: Syneos Health

Years in industry: 28

Years in QA: 28

Hopes for this year: To have more people join the MARSQA CVC and to continue to have the great discussions we have during our meetings. I truly appreciate the CVC's interactions and knowledge sharing.

Personal comment: Looking forward to another great year with MARSQA.



#### **Chris Wubbolt**

Chris provides Quality, Compliance and eSystems consulting services to pharma, biotech, and medical device organizations. Chris was previously the President of MARSQA in 2014 and was also President of NERCSQA in 2013. He is also a co-chair on the MARSQA CSV Committee. Chris is a prolific speaker on various topics at industry conferences and for different groups, such as SQA, KenX, PharmEd and IVT. Chris is a Certified Six Sigma Black Belt, has a Masters Degree in Quality Assurance and Regulatory Affairs from Temple University's School of Pharmacy and a BS in Physics and Computer Engineering. Chris worked at Lancaster Laboratories, Johnson & Johnson, Aventis, and Hoffmann-LaRoche prior to starting his career in consulting. He remains active in various industry groups and was a contributing member of the DIA's "Peach Report" (Computerized Systems used in Clinical Research" as well as the original GAMP Guide on validation of laboratory systems.



#### **Calvin Kim**

Current employment: Bayer, Director Digital GxP Compliance Manager

Years in industry: 25, GxP

Years in QA: 7, Specifically in GxP IT Audit Management

Hopes for this year: Further collaborate with the GxP industry colleagues, in establishing regulatory compliant best practice implementation of new / emerging tech utilized in digital transformation

Personal comment: Fav quote, "*Live as if you were to die tomorrow. Learn as if you were to live forever.*" -Gandhi



## MARSQA Board of Directors and Committee Chairs Annual Holiday Dinner



### **THANKS TO THE 2019 PRESIDENT NANCY GRAVINO!!!!**

**A Big THANK YOU** to Nancy Gravino for her service as MARSQA President in 2019!!! I had the opportunity to work closely with Nancy this past year and watched her tirelessly work on all the numerous MARSQA business matters at hand. It is a big pair of shoes to fill and she did it impeccably well.

I will be hard pressed to meet the same level of detail that she was able to maintain in her communications to the BoD, MARSQA Committees, and to SQA liaisons. Of note, she has been supporting MARSQA for many years (BoD Member since 2008) in numerous roles and I commend her for her commitment and service to this organization.



**Thank you to our Sponsor In Kind, Syneos Health for  
hosting the Computer Validation Committee's Face to  
Face Meeting in April 2019**



# Syneos<sup>TM</sup> Health

**Thank you to our Sponsor In  
Kind, GSK for hosting the  
Fall Meeting in 2019.**



Today millions of people have no access to basic healthcare, millions more suffer from everyday ailments and there are thousands of diseases without adequate treatments. So we're working to develop tomorrow's treatments and to find new ways to get today's treatments to those who need them.

Want To Get Involved With The MARSQA Organization?

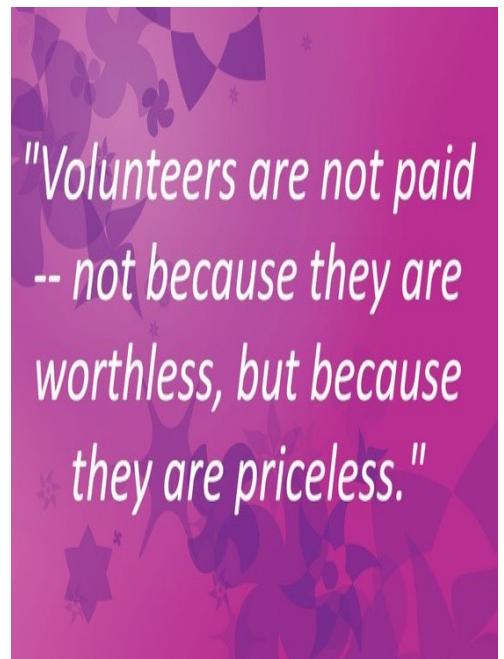


### Nominating Committee

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.



If you are interesting in participating in either Committee please contact the Board of directors for more information: [board@marsqa.org](mailto:board@marsqa.org)



*MARSQA Member Meetings*

**May 14, 2020**

**September 17, 2020**

**November 13, 2020**

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Girls Exploring Tomorrow's Technology (GETT) is an annual event in the spring for girls in grades 5-10 and their parents to learn about career opportunities in a broad scope of STEM related industries. The day is filled with exciting, enlightening and experiential activities led by successful women in STEM fields.

**Please volunteer to join us in Malvern, PA on Saturday, March 28, 2020 from 12-5pm**

**Please contact Kiet to volunteer ([kiet.t.luong@gsk.com](mailto:kiet.t.luong@gsk.com))**

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**The SQA Annual Meeting has been cancelled, so we won't see you at our MARSQA Lunch, but we hope to see you at next year's SQA Annual Meeting!**



## Computer System Validation Events



***CSV Face to Face Meeting***

***March 10, 2020 from 1-3pm***

***CSV Training Events will be held at Earls in Peddler's Village***

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.

### **Basic Training**

May 19-20, 2020

### **Advanced Training**

October 27-28, 2020

**The CSV monthly teleconference scheduled the last Monday of each month at 12pm**

Teleconference number: 888-684-2443, conference code: 453 261 5272

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

[chapters@sqa.org](mailto:chapters@sqa.org)

Chris Wubbolt: chris.wubbolt@qacvconsulting.com

Denise Botto: denise.botto@syneoshealth.com

Calvin Kim: Calvin.Kim@bayer.com

### ***Workshop Discount Offering***

GMQA's highly interactive one and two-day workshops focus on data integrity assurance and investigations, including current perspectives for cGxP compliance.

Please take advantage of the discount code **MARSQA25** through December 13, 2020 .

Register at:

<https://greenmountainqa.com/workshops>

