We are excited to provide this newsletter to the organization to celebrate the events that have occurred, share information with our membership and upcoming experiences we wish to share with you.

“MARSQA envisions an atmosphere of collegiality that advances the Quality Assurance profession by fostering dialogue, providing avenues of ownership and satisfying educational needs for all Chapter members.”

- MARSQA Vision
Thank You Attendees of the 2019 SQA Annual Meeting

MARSQA was represented at the annual meeting with an informational poster, sponsorship of the headshot photo booth, numerous presenters and a luncheon for MARSQA members.

Annual Meeting 2020 Preparations

Abstracts for the upcoming meeting are due September 30, 2019

We look forward to seeing you at our MARSQA Luncheon!
Scholarships and Awards
In 2020, MARSQA plans to continue sponsoring scholarships totaling over $3450 in funds for certifications and annual meeting expenses.

“Continuing education is one of the most important ways to enhance your career and keep abreast of current trends and happenings within your field of expertise. The RQAP Examination not only tests the knowledge of regulations/guidelines and how they are applied, it also ensures that continuing education is completed in order to maintain certification. These principals will help to ensure a commitment to a high quality standard in the QA industry and I would be honored to have the privilege to be among this group of dedicated individuals.”

Excerpt from the Application Letter of Ashley Cousineau, Winner of the 2019 RQAP Award

Upcoming Elections: Board Positions Available

See MARSQA website for additional details of the duties and time commitment for each open board position and be on the lookout for the MARSQA email of appeal for the 2020 election

Vice President

The Vice President shall serve for one year, succeeds to the office of President, and then shall succeed to the position of Past President for a total of three years in office. The Vice President is an advisor to the Program Committee and member of the Finance Committee.

Secretary

The Secretary will serve for a term of two years. The Secretary prepares for board meetings and is responsible to maintain meeting minutes and an up to date membership list. The Secretary manages the maintenance of chapter bylaws, operating guidelines and the MARSQA Annual Report.

Director (2 positions)

The Director will serve for a term of two years. The Director may serve as a chairperson or a working member of committees and as a liaison with committee chairs for special projects and assignments.
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 QA, 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
A Look Back on SQA 2019 Annual Meeting

SQA 2019! What an interesting meeting this was! To make it even more exciting, I attended as the 2019 GLPSS (Good Laboratory Practices Specialty Section) Scholarship Recipient!

The fun began on Monday, 29th of April with a turbulent morning flight from Newark, New Jersey. Upon arrival at the Hartsfield-Jackson Atlanta International Airport, I quickly forgot the scary experience after bumping into my former Supervisor who had just arrived in Atlanta but was on her way to catch her flight back to New Jersey because the FDA had arrived at the facility where she now works. Unfortunately, she missed the meeting. However, this article is dedicated to her and all other QA professionals who were not able to attend the meeting.

Upon arrival and check-in at the Marriott Marquis, we quickly and pleasantly discovered that the area around the hotel had nice restaurants and convenience stores within a walking distance. The hotel itself is very beautiful and boasts over 1,600 rooms, a dizzying (approximately) 50 floors and a large atrium that spans the entire height of the building and consists of two vertical chambers divided by elevator shafts and bridges.

To kick off the meeting, there was the Opening Reception on the evening of Monday 29th April from 5:30 pm. It was a wonderful evening of reconnecting with fellow attendees and making new acquaintances while enjoying the beautiful view of downtown Atlanta.

Tuesday 30th April 2019

On the first day of the meeting, I attended the GLPSS breakfast where members introduced themselves and gave a summary of their background, experience and where they work. At this point I was introduced as the 2019 GLPSS Scholarship recipient.

At 8.15 am, the fun begun with a welcome speech and announcements by the SQA President, Steve Rogenthein. He talked about the theme of the meeting which was “Quality on My Mind,” a play on words of the song “Georgia on My Mind.” He told the audience about what we were looking forward to and this included five concurrent tracks consisting of 70 different presentations covering a diverse series of topics. He told us that there were also over two-dozen vendors and 53 posters on display in the Exhibition Hall. We would also be graced by the presence of a dozen members from various regulatory monitoring authorities who were there to present and participate in the meeting. Also included were peripheral meetings for 13 Specialty Sections, seven Regional Chapters as well as several committees such as the Council of Professional Registration, the Education Committee and the first ever meeting of the Early Career Professional Development (ECPD) group. He announced that for the first time in its Annual Meeting history, SQA would be live streaming the opening plenary!

…please visit the SQA website, where the entire article will be released this month!

Joan Maluki
Sr. QA Auditor, Covance
Fall Membership Meeting: Emerging Technology
September 19, 2019
GlaxoSmithKline
1250 S. Collegeville Road Collegeville, PA 19426

Featured Topics Include

- **Key Connections Between General Data Protection Regulation (GDPR) and ICH GCP**
  
  *Speakers: Allison Merrell and Jennifer Van Ekelenburg*

- **Presentation on Oncology/Biomarkers**
  
  *Speaker: Greg Stella*

- **The Importance of a Robust Pharmaceutical Quality System (PQS)**
  
  *Speaker: Mike Labruto*

- **Emerging Technology Initiatives in Preclinical Immunogenicity**
  
  *Speaker: Scott Hottenstein*

- **SQA STEM Learning Foundation, and GSK Future Leaders Program**
  
  *Speaker: Kiet Luong*

- **Data Integrity and New Technologies**
  
  *Speaker: Lorrie Schuessler*

- **Internal Control Framework (ICF): A GSK Perspective**
  
  *Speaker: Kevin Wilk*

- **23andMe: Utilizing Human Genetic Insights; How the Biobank and Other Sources Can Generate New Targets, Prioritize Indications, and Accelerate Clinical Development**
  
  *Speaker: TBD*

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**Advanced Registration Required**

*Please refer to MARSQA Fall Membership Meeting email for registration information.*

**MARSQA Members: $30 , Non-Members: $45**

**Lunch and snacks are provided**
Computer System Validation Special Topic Training

"Don't Let CSV Scare You!"

October 29-30, 2019
Earl’s in Lahaska, PA

Registration will open in September with the final agenda. CSV Discussion topics include: Data Integrity, Audit Trail Review, Approaches for Auditing Software Vendors and Observation Writing Best Practices. Attendees are encouraged to wear costumes!

Face to Face Computer Validation Committee Meeting

October 15, 2019
Bayer in Wippany, NJ

These meetings are always very valuable with great round table discussions. Registration for this meeting will open in September. The event is free and lunch can be purchased at the Bayer cafeteria. If you would like to be a presenter at this meeting, please contact the CVC Co-Chairs.

Monthly CVC teleconferences take place the last Monday of every month from 12-1pm. Please bring with you any topics you would like to discuss. The MARSQA toll free teleconference number dial in is 888-684-2443. The conference code is 4532615272.

Please reach out to your MARSQA CVC Co-Chairs with any questions!

Denise Botto, Calvin Kim and Chris Wubbolt
MARSQA
By the Numbers

100+
Board members to date since MARSQA was founded in 1991

7
Active committees of volunteers

600+
Members of the MARSQA regional group

$3450
In scholarships and awards donated to members annually

Thank you to our presenters at the Spring Membership Meeting!
Christina Velez, Gowri Somayaji, James Canterbury, Dr. Elise Lewis and Stacy Wilson

Doing Your Part

MARSQA is currently looking for Committee and Board Members. Please reach out to the corresponding email for questions or membership.

- Computer Validation Committee cvc@marsqa.org
- Education and Program Planning Committee education@marsqa.org
- Historical Committee historical@marsqa.org
- Newsletter Committee newsletter@marsqa.org
- Technology Committee technology@marsqa.org
- Membership Committee membership@marsqa.org
- Nominating Committee nominating@marsqa.org