



# MARSQA

## MONITOR

*Newsletter of the Mid-Atlantic Region Society of Quality Assurance*  
**Volume 17, Issue 1, Summer/Fall 2013**

### Mid Year Update from 2013 MARSQA President



#### **Greetings 2013 MARSQA Members!**

I hope each of you is having an excellent year. It is difficult to believe we are already at the end of August and that Autumn will be upon us shortly! I am grateful to have been given this opportunity to serve MARSQA as the 2013 President and am striving to implement some changes in the governance to allow a more efficient management of the organization.

As I find myself preparing this message for the MARSQA newsletter, I cannot help but reflect on my experiences in the pharmaceutical industry, medical device industry and MARSQA. Like many others, my career aspirations from college have taken many detours. I entered this industry looking to help patients by working as a research scientist. This provided me an opportunity to learn and embrace quality, compliance, and continual improvement. Transitioning into compliance not only changed my career path, it changed who I am as a person. A change many family members note as I apply Good Documentation Practices to correct my writing errors on birthday cards. We all have unique stories and experiences, both professionally and personally. I look forward to sharing some of my stories this year and am excited to continue to learn from your own experiences as we engage at our membership meetings.

MARSQA's vision has been to foster education, networking and support the compliance profession. We do this through periodic membership meetings and providing educational opportunities for professional development. This year we are also looking for innovative ways to expand our educational offerings in the coming years and welcome any suggestions for potential new topics. We also are interested in streamlining our procedures to alleviate some of the organizational pressures associated with hosting our membership meetings, elections, yearly transitions of elected positions and educational sessions.

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Later this year, you can also expect to see a survey requesting feedback on how well MARSQA has been performing and help identify goals or changes you would like to see. This will be a great opportunity for you to help lay down our longer term plans for the organization.

As with any volunteer organization, we cannot be successful without the support of our volunteer board of directors, committee chairs and committee members. I would like to thank each of you for the outstanding work and dedication you have exhibited in the years past and thank the 2013 volunteers for your continued support. We welcome any member with any background to become involved for your own professional development. Please feel free to contact me, a member of the board, or any member of a committee that interests you for further information.

Sincerely,

Dwight N. Crawford, III  
MARSQA President, 2013  
president@marsqa.org



## MISSION STATEMENT

Our Mission is to provide current regulatory information, education and networking opportunities for the Quality Assurance Professional. Through meetings, workshops, our Newsletter and our Chapter Website, we look to advance quality concepts and methods to members and provide a forum to interact with other professionals having the same common interest.

## MARSQA Board of Directors

### President

Dwight Crawford  
dwight.n.crawford@gmail.com

### Vice President

Chris Wubbolt  
chris.wubbolt@qacvconsulting.com

### Treasurer

Armand Spoto  
armand.spoto@lernia-ts.com

### Secretary

Amy Stawicki-Sangkavasi  
asangkav@its.jnj.com

### Past President

Ranee Ann Henry  
ranee.henry@aol.com

### Directors

Janet Emeigh  
jemeigh@morphotek.com

Nancy Gravino, RQAP-GLP  
nancy.gravino@bms.com

Malti Parekh  
mparekh@its.jnj.com

Cynde Radford  
cradfor1@its.jnj.com

# Call for Nominations!

## *Open 2014 MARSQA Board of Director Positions*

As many of you know, MARSQA is a completely volunteer organization. Without the many dedicated individuals supporting our committees and board of directors, MARSQA would not be able to serve its members. In recent years, our industry and MARSQA has changed. New demands on our time (both professionally and personally) make it difficult to balance the many tasks we face. It can be daunting to commit our valuable time to serving a professional organization. We, the board of directors greatly appreciate the past dedication and service of all members that donated their valuable time in helping us to deliver on our mission to promote the compliance profession and provide professional development opportunities.

With the approach of our election season, the board is once again happy to offer four positions for individuals to fill (Vice-President, Secretary, and Two Directors). Below you will find a description of each role, the term of the position, and expected time commitments. Serving on the board provides an opportunity to further develop your own leadership skills, networking, and public speaking. In return, MARSQA benefits from your unique contributions and ideas. If you are interested in running for one of the following positions, please look for our e-mailing coming to an inbox near your shortly for additional details! Alternative, please feel free to contact me directly at [president@marsqa.org](mailto:president@marsqa.org).

**Vice-President:** The office of the Vice-President is a one-year term, with primary responsibilities in overseeing MARSQA awards/scholarships and supporting the current President. The Vice-President is a voting member of the board of directors and serves for a one-year term. Once the term expires, the Vice-President transitions into the office of the President for another one-year term, and then transitions into the office of Past-President for one additional year (total of 3 years). Time commitment is typically a 1-hour monthly board meeting and approximately 2-hours per week for managing MARSQA business.

**Secretary:** The MARSQA secretary serves a 2-year term. Primary responsibilities are preparing minutes of board meetings, preparing annual reports, and maintaining chapter by-laws, policies and procedures. This position is a voting member on the board. Time commitment is typically 4 to 5 hours per month including attendance at the monthly board meeting.

**Director:** MARSQA Directors are voting members of the board and may serve on additional projects as requested. They provide input and guidance in the development of policies and procedures as well as discuss chapter business. Time commitment is typically a 1-hour monthly board meeting and approximately 1 to 2-hours per month for additional MARSQA business.

In addition to the open positions on the board of directors, we also are actively seeking volunteers to serve on our Committees as members and chairs. Please visit our website ([www.marsqa.org](http://www.marsqa.org)) for additional contact information and background on each of the following committees: Computer Validation, Education (chair needed), Historical, Nominating (chair needed), Membership, Newsletter, Program Planning, and Technology.

# MARSQA Member Profile

## Dwight Crawford, MARSQA President



*If you could meet any famous person today, who would it be? Why?*

I would love to meet Stephen Hawking who is a personal hero of mine. I greatly admire his perseverance in the face of great adversity. Many individuals significantly advanced humanity's

understanding of the world and universe, but it is the additional challenges he had to face and overcome that truly inspires me to challenge my own perceptions of my limitations.

*What advice would you give to someone starting out as a GXP (GLP, GCP and/or GMP) compliance professional?*

The compliance professional often finds herself or himself in a demanding and tasking career path. Our position requires us to be advocates for patients, enforcers of government regulations, and consultants for best business practices. To succeed in this profession, one needs to not only be well versed in the subject matter area and respective regulations, but also adept persuasive communicators. I have had some exceptional mentors that helped me develop my own communication skills and would highly recommend someone new to the area to build their own strengths and skill sets in communication. I would also highly recommend developing a strong network of peers in compliance as well as within the organization that they are auditing. Understanding a multitude of perspectives increases your own understanding and helps you become a more effective compliance professional.

*What is your favorite all time movie?*

Easy question, "Star Wars: The Empire Strikes Back". I loved this movie ever since I first saw it as a child. I will admit I may have attempted on more than one occasion to move a random item around my house using the force to no avail... yet.

*What aspect of your job gives you the most personal satisfaction?*

For me, it was always the idea that as an industry we are helping improve the lives of patients the world over. As compliance professionals, it may seem the patient is distant from our activities at times, but everything we do directly supports the compliant development of safe efficacious products. I find it very rewarding knowing I am an integral part in helping assure the industry delivers these products in a safe and compliant manner.

*What is the most challenging experience you have had in your professional life?*

One of the most challenging experiences is remaining diligent and steadfast in the face of overwhelming pressure. Many times when you challenge an existing practice that is imbedded in the culture of an organization, the stakeholders are slow to accept change (and some may be outright hostile to the mere suggestion a change is needed). At these times, it certainly is easier to stand down and assume we did enough by bringing the issue to management's attention. It is at these times that I feel we must become advocates for a better way to do business, one that benefits the patient as well as the organization. Each time I face one of these issues, I try to understand the reason behind the resistance. Understanding why there is resistance helps enlighten a path to effect the desired change.

*How do you deal with the stress of everyday life?*

Stress management is a vital part of living a healthy productive life. I find having a good friend or colleague available to vent my frustrations and receive feedback is an effective way to voice my concerns and help me articulate why I feel the way I feel. I also quite enjoy escaping from the source of the stress and doing some physical activity such as taking a walk, going for a run or even just standing up and stretching.

*What is your favorite vacation spot?*

I love the water, so anywhere near the ocean or on a lake. I am quite partial to Long Beach Island, NJ.

# MARSQA Member Profiles

## Dwight Crawford continued

*What is your dream job (other than being compliance professional, of course)?*

I always fancied being President of the United States of America. I am not yet ready to announce my campaign, but perhaps I will be ready to run in 2016 or 2020.

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## Janet Emeigh, Director, Membership Committee Chair



*If you could meet any famous person today, who would it be? Why?*

I'm really not impressed by famous people. Most of them (with few exceptions) are just people who have done something for which I'm not so sure they deserve the spotlight.

*What advice would you give to someone starting out as a GXP (GLP, GCP and/or GMP) compliance professional?*

First and foremost, get involved as soon as possible with an organization such as MARSQA and SQA. Having a network of other professionals with different backgrounds and experiences is a great resource to turn to when you have questions. Second, do not restrict yourself to your own GxP discipline when it comes to developing your skills. There is a lot to be learned from the other GxP disciplines that you might find useful in your own field. If you are a GLP auditor, get to know the auditors in the GCP and GMP areas. Ask questions and attend training. Finally, get to know the science behind those areas that you audit. I think the only way to know if the science is being conducted in a compliant manner is to know it well enough to know where someone might try to take

shortcuts or outright commit fraud and attempt to cover it up.

*What is your favorite leisure time activity?*

Reading. I unfortunately don't have as much time to do this as I would like, but there is nothing like a good book to help you escape the world around you for a little while.

*What aspect of your job gives you the most personal satisfaction?*

Working for a fairly young company, I've actually been able to see the changes that I've helped bring about in the GLP compliance. Knowing and seeing that I've been able to make a difference I think is about as satisfying as it gets.

*What is your opinion of reality TV? Do you have a favorite or a not-so-favorite show?*

I'm not a huge fan of reality TV. How real can it be with cameras everywhere? I do enjoy the Amazing Race, not for the "reality" portion of it, but as a way for me to travel around the world. Watching it, I've made an ever growing list of those places I'd like to take more time to visit sometime in my life.

*How do you deal with the stress of everyday life?*

I'm learning to meditate.

*Where would you like to reside when you retire? Why?*

Anywhere close to family and friends. What I'd really like to do is spend as much of my retirement traveling to all the places on my ever growing list.

*What is your dream job (other than being compliance professional, of course)?*

I'd like run a bed and breakfast. I enjoy cooking for people other than myself and I'd really like an opportunity to meet as many people as possible and hear about their experiences.

# March 20 Membership Meeting Recap

## Janet Emeigh

*Director and Chair, Membership Committee*

Spring still hadn't sprung yet as MARSQA held its first membership meeting for 2013 in Lahaska, PA at the Cock 'n Bull restaurant. Sixty-two (62) members, non-members and speakers were in attendance.

The meeting began after another delicious lunch and social hour with MARSQA President, Dwight Crawford, presenting recognition plaques to the MARSQA officers whose terms had come to an end. Plaques were presented in person to Ranee Henry (President, now Past –President), Kimberly Bartelli (Treasurer) and Dwight Crawford (Vice-President, now President). Officers not in attendance, Alyssa Colon (Past-President), Marlena Maier (Director) and Stephen Simpson (Director) were also recognized.

The meeting progressed with presentations by three very knowledgeable speakers on topics centered around the theme "Regulatory Inspections: Preparing, Living Through Them, and Dealing with the Aftermath."

The first speaker, Margaret Connolly, Ph.D, a Senior Statistician with C-TASC, Inc. was not what I would have expected from a statistician. For her presentation, entitled "Improving Usability of Observations Trending for More Effective Compliance Evaluation", Dr. Connolly was provided with a portion of a redacted database of information compiled from clinical site audits. Using this information as an example, she provided us with examples of various statistical tools that could be used to help identify areas of risk. These included items such as Assessment Score Cards and Process Summaries which can be used to determine if you have any potential trends in audit observations that may need to be addressed. These problems can be identified within a site, across sites or even across processes.

Amy Sangkavasi, Manager, Safety Compliance Management at Janssen, presented "CAPA Concepts and Management in a non-GMP Environment". CAPAs are a staple in the GMP environment and to a lesser extent in the GCP environment. There has even been a growing interest in their potential utility in a GLP environment. Amy's presentation centered primarily around the use of CAPAs in the GCP and even internal quality arena.

CAPAs are a planned approach, rather than a reactive approach, to solving problems. Through investigation into the root cause of an issue, careful planning of corrective actions to address and correct that root cause and follow up to ensure the effectiveness of the corrective actions, an organization can more effectively prevent noncompliance and other undesired issues that can affect the overall quality of a study or process.

A well designed CAPA program should consist of defined phases including initiation of a CAPA based on some trigger event (deviations, audits, inspections, process improvement, etc.), investigation of the root cause of the problem, implementation of the CAPA plan and follow up to determine the effectiveness of the CAPA. Each phase should have a defined timeframe for completion to ensure the process is kept moving (eg. X calendar days from identification of trigger to initiation, X calendar days to complete the investigation, X calendar days to complete implementation of CAPA measures and review/re-audit in X months to determine effectiveness). In addition, a team approach to CAPAs is often most effective.

# Membership Meeting Recap - cont.

Root cause analysis is a key to developing an effective CAPA plan. To determine root cause, you collect data, identify possible causes, and identify the root cause. There are many ways to determine the root cause and the method used is often determined by the problem and the experience of those conducting the analysis. Examples of root cause approaches are cause and effect (fish-bone), the 5-Why's and the Is/Is not.

Once you have identified your root cause, determine the best solution to correct the immediate problem and implement corrective and or preventive measures to prevent the same problem from occurring again. Finally, you need to define clear and objective outcomes to measure the success of your corrective and preventive actions and define the criteria that will enable you to close the CAPA record. Based on the plan, follow up and compare your expected results with your actual results. Do they match? If so, your CAPA is effective. If not, then you will need to initiate a new CAPA because your original CAPA was not effective (perhaps you did not identify the true root cause or your corrective/preventive actions were not adequate).

Last but not least, Mike Rashti, former FDA investigator in the Philadelphia District Office and now an independent Consultant gave us some "Insight Into the FDA Inspection Process". Mike provided a general overview of the different FDA Centers (CDER, CBER, CDRH, CVM, CFSAN) and the goals of the FDA from the inspections perspective. The primary goal of the FDA inspectors is to ensure that the data submitted to the agency by industry to demonstrate the safety of the products they wish to market are accurate and reliable. These areas include not only human and animal drugs, human biological drugs and medical devices and diagnostic products, but also food and color additive and electronic products. Mike quoted "Of every dollar Americans spend, the FDA regulates 25¢ of it."

There are two types of GLP inspections conducted by FDA, with the majority of the assignments issued by the FDA District Office. The first is a Surveillance Inspection, which is a periodic, routine inspection to determine the compliance of a laboratory with the GLP regulations using studies that are in progress or that have been recently completed. These inspections are conducted approximately every 2-4 years and are generally unannounced. The second is a Directed Inspection. These are assigned by the Center for a specified purpose such as verifying reliability, integrity and compliance of studies submitted in support of a pending marketing application or perhaps to follow up on a complaint of potential violations or unreliable data from a whistle blower, FDA reviewer or other source. Mr. Rashti outlined the inspection process followed by the FDA, which can be found in the FDA Compliance Program Guidance Manual (CPGM) 7348.808 "Good Laboratory Practice (Non-Clinical Laboratories)" available on the FDA website.

For GCP facilities, inspection assignments are issued by the Centers (CDER, CBER, etc.). These include Routine and Directed (for cause) inspections. Routine inspections conducted on Pivotal studies pending and NDA/BLA review typically last from 3-7 days. Directed inspections are for cause and are requested for suspicion of false or fraudulent data, data that appears to be unrealistic and/or the Sponsor alerts the agency of serious problems with a site. Directed inspections typically last at least 7 days and often longer. GCP inspections are typically announced to ensure that the appropriate staff and all of the source documentation are available for review. Mr. Rashti outlined the inspection process followed by the FDA which can be found in the CPGM documents 7348.809 "Institutional Review Board", 7348.810 "Sponsors, Contract Research Organizations and Monitors" and 7348.811 "Clinical Investigators".

# Membership Meeting Recap - cont.

Finally, Mr. Rashti outlined some of the most common deficiencies found at clinical sites. These include:

- Protocol non-adherence
- Failure to report concomitant therapy
- Inadequate/Inaccurate records
- Failure to report adverse events
- Inadequate drug accountability
- IRB problems
- Informed consent

Mr. Rashti summed up his presentation by advising the audience to be prepared. Know what to expect during an FDA inspection and be aware of common deficiencies. Active involvement with your sites during study conduct can help to avoid such findings.



Margaret Connolly



Amy Sangkavasi



Mike Rashti

# March 20 Membership Meeting Photos



Dwight Crawford presents himself with Vice President plaque



Dwight Crawford presents Kimberly Baratelli with Treasurer plaque



Dwight Crawford presents Ranee Henry with President plaque

# 17th Annual GLP Meeting with Belgian GLP Monitoring Authority

## Meeting Update

### Eva Haszcz

*MARSQA member and Newsletter Committee Member*

The Scientific Institute of Public Health is a Belgian national scientific institute. In 1988 a section of Scientific Institute of Public Health, Bureau of Quality Assurance has been appointed to monitor GLP Compliance in Belgium. Belgian Monitoring Authority is a non-profit and fully independent organization having eighteen Belgian and eight Chinese test facilities under their program. I had the honor to be invited by the Bureau of Quality Assurance to the 17th Annual GLP meeting in Brussels. The meeting took place on 16-May-2013 and was attended by 10 representatives from Belgian GLP Authority and 58 guests from the industry. The agenda encompassed feedback from the EU and OECD GLP Working Groups' meetings and included several interesting presentations. Below are the main items from the update of the EU and OECD GLP Working Groups' meetings.

- Malaysia became a full adherent to MAD<sup>i</sup> on 29 March, 2013. The country entered OECD's GLP system with two national programs: Standard Malaysia and National Pharmaceutical Control Bureau.
- Thailand remained a provisional adherent after an on-site evaluation lead by the Belgian Monitoring Authority in January 2012. It was concluded that the country is not ready to enter MAD and revisit is foreseen in 2014.
- Russia is in the process of becoming an OECD accession member. Russia has asked to be taken into the MAD system with the target for the end of 2014. Russia is pressing but the country has no GLP system and no GLP inspectors yet.
- Israel is now a full OECD member.
- USA Monitoring Authorities continue to be absent from the Working Group meetings.
- Collaboration between monitoring and receiving authorities is increasing in Europe and in 2012/2013 more dossiers underwent a GLP compliance check. EFSA<sup>ii</sup> is planning to increase the number of study audit requests in 2013. In 2012, seven of twelve conducted audits requested by EFSA resulted in the study being withdrawn. ECHA<sup>iii</sup> requested to be alerted by the monitoring authorities when severe problems are found during GLP inspections.
- In November 2011, a debate was organized by a political group in the European Parliament regarding validity of the open scientific literature versus GLP research. GLP research is criticized as not being independent since it is paid by sponsors. In contrast, university research is considered to be independent. EFSA reported that it is required to take into account information from the open scientific literature. The EU GLP Working Group made recommendations to ease entry of independent scientific research laboratories into a GLP monitoring program.
- The new European Union regulation<sup>iv</sup> concerning marketing and use of biocidal products will apply from 1 September 2013.
- The new guideline on bioanalytical method validation entered into force in Europe in February 2012.

i Mutual Acceptance of Data

ii European Food Safety Authority

iii European Chemicals Agency

iv EU Regulation No 528/2012 of the European Parliament and the council of 22 May 2012

# MARSQA Programs and Training in 2013

## A Retrospective and Future View

### Irina Colligon

*Chair MARSQA Panning Committee*

#### **2013 has been a good year for membership events.**

- Attendance at the Winter/Spring meeting in March reached 60.
- Over 110 attended the Summer webinar in June. This was MARSQA's first fully virtual event.
- Two more meetings are planned for the remainder of this year both in Peddlers' Village, Lahaska, PA:
  - o A Membership Meeting on Wednesday, September 18
  - o A Membership Roundtable Discussion on Wednesday, December 4

**Please watch the MARSQA Website ([www.marsqa.org](http://www.marsqa.org)) for updates.**

#### **Program Preview Details:**

- **Wednesday, September 18 in Peddler's Village, Lahaska, PA. Originally, this entire meeting was set to focus on "Legal Implications of Noncompliance". Due to scheduling difficulties, only one hour of this educational meeting will focus on the original topic. The rest of the meeting will be dedicated to an exciting new interactive workshop. Here is the preliminary agenda:**
  - o First two hours- "The Investigator is Here to See YOU", a unique interactive program led by a former FDA investigator. Most inspection preparation programs focus on what to do before an investigator arrives, how to fulfill investigator's requests and events that occur during the inspection. What makes this session different is that it focuses on giving the attendees the experience of how it actually feels to be inspected and to interact with the investigator, including how to behave and respond (and the consequences of both).
  - o Third hour-"Legal Implications of Noncompliance"-presented by a former FDAer
- **Wednesday, December 4 in Peddlers' Village, Lahaska, PA. The last meeting of the year will be the Fourth Annual Roundtable Discussion.**
  - o In preparation for this event, the program Committee is asking MARSQA members for any major topics they would like to have discussed. Please forward your suggestions to Irina Colligon at [Irina.colligon@gmail.com](mailto:Irina.colligon@gmail.com). Please make your suggestions more specific than simply "GXP". In addition the committee is looking for volunteers to moderate the discussions.

# CSV Committee Report

## Chris Wubbolt

*Vice President*

The MARSQA Computer System Validation Committee will be offering two training courses in November at the C\*ck and Bull Restaurant in Lahaska, PA. The first course is a two day “Basic Computer Validation Training” that will be offered on November 5 and 6, 2013. A one day course on “Computer System Validation Audits” will be offered on November 7, 2013. The two training courses are related and it is recommended that they be taken together although they can certainly be taken individually.



MARSQA’s CVS Committee will be offering additional CSV related courses in the future. If you have any topics that you would like to see covered in a training program or as part of a MARSQA member meeting, please contact Chris Wubbolt at [chris.wubbolt@QACVconsulting.com](mailto:chris.wubbolt@QACVconsulting.com) or by phone at 610-442-2250.



# Why Join MARSQA?

It's a good deal and costs are reasonable. **Dues for 2013 have been reduced by 40% from \$50 to \$30!**

Here's what you get for your annual dues of \$30.

- Low cost half day membership meetings (3-4 times/yr) which include lunch and professional presentations relevant to your job. (\$20 for members; \$40 for non-members) **It is now possible to attend some of these meetings by webinar.**
- Low cost professional training classes (e.g., GLP Fundamentals, Principles of Computer Validation, Analytical Chemistry for the QA Professional). These classes last from one half day to several days, have a limited number of students and allow for a great deal of interaction with the trainers and other attendees.
- Website and contents (e.g. ListServ, past newsletters, online registration and payment for MARSQA training and membership meetings).
- Electronic newsletter 2x annually with useful industry and society information
- Low Cost Advertising Rates in the newsletter and on the website.
- Awards to defray the cost of attending the annual SQA meeting. For 2013, MARSQA will award 2 members \$2000 each to attend the annual SQA meeting in Indianapolis.
- Awards to pay the cost for taking the SQA Registered Quality Assurance Professional (RQAP) examinations (GLP or GCP). The current award is \$350.
- Opportunities to network, form communities of interest and keep up with the latest industry trends.

So, if you're not a MARSQA member and think you'd benefit from all these offerings, contact our website at [www.marsqa.org](http://www.marsqa.org) and hit the "join" tab on the upper right of the page. Welcome to our community.

## Quality Quotes

**The main thing is to keep the main thing the main thing.** Stephen Covey

**Find the qualities in your people and you'll find the quality in your company.** Sir Simon Hornby

**Quality is the result of a carefully constructed cultural environment. It has to be the fabric of the organization not just part of the fabric.** Philip Crosby

**Our business is not to get ahead of others, but to get ahead of ourselves—to break our own records, to outstrip our yesterday by our today.** Stewart B. Johnson

**Quality is everyone's responsibility.** W. Edwards Deming

**Improvement begins with I.** Arnold H. Glasow

# MARSQA 2013 Committee Chairs

MARSQA has eight committees which are listed below along with the Chair(s) for each. Please consider volunteering for one of these groups.

## CSV

Chris Wubbolt [chris.wubbolt@qacvconsulting.com](mailto:chris.wubbolt@qacvconsulting.com)

## Education

VACANT

## Nominating/Historical

Fran Jannone [jannonef@princeton.huntingdon.com](mailto:jannonef@princeton.huntingdon.com)

## Membership

Janet Emeigh [jemeigh@MORPHOTEK.com](mailto:jemeigh@MORPHOTEK.com)

## Newsletter

Jane Goeke [jgoeke1@verizon.net](mailto:jgoeke1@verizon.net)

## Program

Nancy Gravino [nancy.gravino@bms.com](mailto:nancy.gravino@bms.com)

## Planning

Irina Colligon [irinacolligon@gmail.com](mailto:irinacolligon@gmail.com)

## Technology

Carinne Park [carinnepaige@gmail.com](mailto:carinnepaige@gmail.com)  
Marlena Maier [oriziba77@yahoo.com](mailto:oriziba77@yahoo.com)