

MARSQA MONITOR

MARSQA Monitor, Volume
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26 March 2015

Special points of interest:

- Presidents Message
- Upcoming Events
- *Extremely Bright Idea Corner*

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MARSQA President's Message

Welcome MARSQA Members ...to 2015!

I would like to first thank you all for the opportunity to be your 2015 MARSQA President.

My goal as your 2015 President is simple. I want to create an environment that helps all of you learn and grow professionally. I want to create an environment that facilitates good conversation and long lasting relationships that help you advance in your career and be a part of your personal and professional development.

There are so many things that I want to do this year and I know that I have only a short time to do it. My reign is short and by the time you read this, 1Q will already be in the books. I have planned for a very aggressive year with even more Membership Meetings at our favorite spot in Lahaska's C*ck-n-Bull Restaurant. We also are planning at least three 2-day Training Sessions. One in the Spring, Summer and Fall.

I'm looking forward in being your President in 2015! I take this position and role very seriously and I'm committed to making this year, a year filled with great possibilities!

Feel free to contact me anytime at
rancee.henry@aol.com



Sincerely,
Rancee Henry
President of MARSQA 2015

Greetings from the MARSQA Monitor Newsletter committee!

Happy Spring!

The newsletter committee is looking forward to providing dynamic and informative newsletters to our fellow MARSQA members.



Sincerely,
Megan Lawhead
Tina Myers
and Chris Wubbolt
*MARSQA Newsletter
Committee*

Meet the MARSQA Board

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Raneer Henry

President: Raneer Henry

Company Name:
QST Consulting, Owner

What public figure (past or present) would you like to have dinner with?

Area of Specialty:
Computer System Validation and Auditing

He isn't a public figure, but I lost my Dad at a young age. I would love to have dinner with him so he can see his little girl all grown up.

Describe one reason you enjoy being a MARSQA member:

Meeting and interacting with other professionals in the industry.



Kiet Luong

Vice President: Kiet Luong

Company Name:
GlaxoSmithKline

Describe one reason you enjoy being a MARSQA member:



Area of Specialty:
Computerized Systems Validation, Systems and Enterprise Integration, Data Migration and System Decommissioning

Personal and Professional development and knowledge transfer

What public figure (past or present) would you like to have dinner with?

Mahatma Gandhi, Audrey Hepburn, Steve Jobs, & Bill Gates



Janet Emeigh

Secretary: Janet Emeigh

Company Name:
Alliance Pharma, Inc.

Describe one reason you enjoy being a MARSQA member:

What public figure (past or present) would you like to have dinner with?:

Area of Specialty:
Bioanalytical Compliance, FDA and OECD GLPs

MARSQA has provided excellent opportunities for me over the years to expand my network of colleagues in the QA profession. As my responsibilities have changed over the years into different areas of GxP compliance, these connections have been invaluable resources to me whenever I had questions. Not only that, many have become lifelong friends.

I'd like to be able to have an in depth and honest conversation (if that's possible) with most of our political leaders and see if they truly have the best interests of our country at heart. It wouldn't necessarily have to be over dinner, but I'd really like to find out how many of our country's leaders are in the position they are in because they truly want to do what's best for this country or are they in politics for their own self-serving interests. Again, not sure if that's possible, but I'd at least like to try.

Specific Interests:
Computer Systems Validation/21 CFR Part 11, GMP and GCP



Treasurer: Brittany Medeo

Company Name: *QACVC Consulting*
Describe one reason you enjoy being a MARSQA member:

Area of Specialty : *I enjoy being a MARSQA member because of the wonderful opportunity to meet people and continue my educations in the field.*
I have a particular affinity for the GLPs but enjoy learning about all GxP areas



Brittany Medeo

What public figure (past or present) would you like to have dinner with?

Louis Pastuer due to his contribution to modern science.



"Just the Facts

Ma'am"

#1 Rule of

Objective

Auditing...

Director: Denise Botto

Company Name: *inVentiv Health Clinical*
What public figure (past or present) would you like to have dinner with?

Area of Specialty or area of interest: *Computer System Validation*
Describe one reason you enjoy being a MARSQA member: *Joshua Lawrence Chamberlain who defended Little Round Top during the battle of Gettysburg. I am a big Civil War buff.*

Being able to meet, interact and share Computer System Validation information with individuals in the Pharmaceutical industry.



Denise Botto

"Failing to Plan is Planning to Fail"

-Winston

Churchill

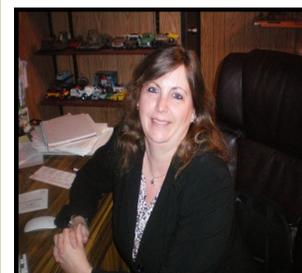
Director: Nancy Gravino

Company Name: *Bristol-Myers Squibb*
Describe one reason you enjoy being a MARSQA member: *because the organization elects well qualified and caring individuals who volunteer their time and commitment to making a well run organization. that your opinion matters and you will be heard.*

Area of Specialty or area of interest: *Auditing Cardiovascular Safety Pharmacology studies and auditing the analytical portions of Drug Safety Evaluation studies (the Dose formulation analysis and TK sample analysis / Bioanalysis).*
I enjoy being a MARSQA member because of the size of the organization and because of its charismatic members. Plus, who doesn't like networking with your colleagues and peers and the food at the events is always great! Since the organization is not too large, it is easy to get to know the MARSQA members that regularly attend the membership meetings a few times each year. I also enjoy working with the MARSQA board members

What public figure (past or present) would you like to have dinner with?

Missionary Mother Teresa, because of her compassion for others and her humanitarian work.



Nancy Gravino

Meet the MARSQA Board

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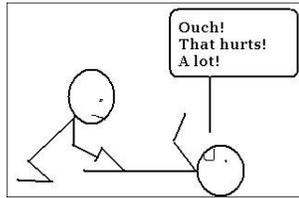


Tina Myers

Director: Tina Myers

Company Name:
Bristol-Myers Squibb

Area of Specialty :
Good Clinical Practice



Describe one reason you enjoy being a MARSQA member:

I enjoy the interaction and Intellectual engagement with those outside of my work bubble! MARSQA makes it easy because it is local, inexpensive, and informal enough to give everyone an equal opportunity to contribute ideas and experiences.

What public figure (past or present) would you like to have dinner with?

Jesus or Cary Grant



Stacy Wilson

Director: Stacy Wilson

Company Name
Charles River Laboratories, Horsham

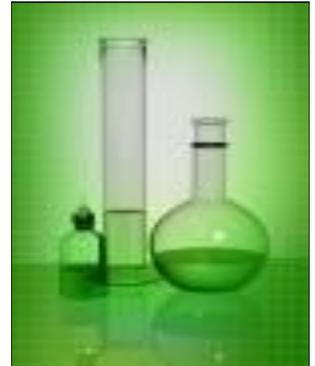
Area of Specialty or area of interest
GLP

Describe one reason you enjoy being a MARSQA member:

Interact with other members in field

What public figure (past or present) would you like to have dinner with?

Chris Rock



Chris Wubbolt

Past President: Chris Wubbolt

Company Name
QACV Consulting, Principal Consultant

Area of Specialty or area of interest

Computer System Validation, Compliance, Auditing, Training, Quality System Development

Describe one reason you enjoy being a MARSQA member:

MARSQA provides opportunities for networking, continuing education, sharing of experiences, mentoring, and the opportunity to give back to new Quality Assurance professionals. I would not be able to do what I am doing now if it wasn't for my experiences with MARSQA dating back to 1992.

What public figure (past or present) would you like to have dinner with?

I would want to have dinner with someone interesting and possibly outrageous for their time who I could ask questions that no one else but me would know the answers to. So, I would have to pick someone like Edgar Allen Poe, Oscar Wilde, Raymond Douglas Davies, Leonardo Da Vinci, or Leo Trotsky. Someone who looked at the world a little bit differently.

Society Quality Assurance MARSQA Scholarship Winners!

Lisa Zaborowski
Charles River Laboratories



Lisa said “I am very excited to have the opportunity to attend this year’s SQA meeting and this was only possible since MARSQA offers this scholarship. I am looking forward to interacting with other QA professionals and obtaining insight into other Regulatory environments. I plan on attending one of the Quality College training workshops and I am excited about the variety of QA sessions/topic offered and the knowledge that I will acquire at the SQA meeting.”

Tony Borisow
Actavis



Tony said aside from warm temperatures, “it will be great to reconnect with so many colleagues that I haven’t seen in years as well as have the opportunity to meet new people and share ideas. Also, the last time I attended the SQA annual meeting several years ago, I had just begun working in the GCP arena. So it made sense at that time to put all of my focus on any offerings that were GCP-related to help augment my fledgling skills. This time around I’m really looking forward to exploring the different offerings across all of the GxPs for a well-rounded learning experience.”



*“The
Happiness of
your life
depends upon
the quality of
your thoughts”*

-Marcus Aurelius

MARSQA Mission Statement

The Mission of MARSQA (Mid Atlantic Region Society of Quality Assurance) is to provide current regulatory information, education and networking opportunities for the Quality Assurance Professional. MARSQA will continually strive to advance the research quality assurance professions by providing the resources, programs and training necessary for the professional development and recognition of its membership through various meetings, workshops, our Newsletter and our Chapter Website. MARSQA will serve as a forum for the open discussion of theoretical, practical and ethical applications of the quality assurance profession and 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 will foster a partnership between quality assurance profession and the regulatory agencies that results in the attainment of mutually beneficial compliance and will support and advance the goals and mission of the Society of Quality Assurance.

To advertise in
the newsletter,
please contact

newsletter@marsqa.org



*"Quality is
not an act,
it is a
habit." -
Aristotle*

To contact the entire
MARSQA board
please e-mail
board@marsqa.org

For individual Board
Member e-mail
addresses, please see
[http://
www.marsqa.org/
board.shtml](http://www.marsqa.org/board.shtml)

MARSQA Committee Chairs

Computer Validation:

Chris Wubbolt
Denise Botto
Brittany Medeo

Education and Program Planning:

Ranee Henry
Kiet Luong
Stacy Wilson

Historical:

Nancy Gravino

Nominating:

Penny Jegede

Membership:

Janet Emeigh

Newsletter:

Megan Lawhead
Tina Myers
Chris Wubbolt

Technology/Website:

Jodi McComb

2014 Year End Summary, Chris Wubbolt, *past President*

MARSQA accomplished several objectives in 2014. Two member meetings were held, including meetings in May and October at Peddler's Village in Lahaska, PA. The October meeting included presentations by Lindsay Nolan, from Charles River Laboratories and Dr. VT Viswanathan, former Associate Director, Office of Compliance, CDER, FDA. Lindsay spoke on "Maintaining Compliance Throughout a GLP Archive Move" and Dr. Viswanathan spoke on the "Dynamics of FDA Inspection and Regulatory Issues". The October meeting included over 90 attendees, which is the largest member meeting of any regional chapter in the last several years. The Computer System Validation Committee also provided a successful training course on Advanced Computer Validation topics. The MARSQA Board also developed and approved a Sponsorship Policy (see below) which provides guidelines for member companies to sponsor MARSQA events and activities. The MARSQA Board also worked on organizational changes on how the Board operates which will allow it to serve the MARSQA membership better in the future. I am sure that 2015 will bring in many more opportunities as new Board members have been elected that will bring new energy and enthusiasm to lead MARSQA moving forward.

Become a MARSQA Sponsor!

Is your company interested in becoming a MARSQA sponsor? To become a sponsor you can host a MARSQA meeting, provide catering, or support to MARSQA. Benefits include:

Advertise in the MARSQA newsletter, acknowledgement on the MARSQA website and member meetings, free job postings, and free registrations are MARSQA member meetings or training events. Sponsorship Levels include:

- ◆ Platinum
- ◆ Gold
- ◆ Silver
- ◆ Bronze
- ◆ In Kind

For more information, contact a MARSQA Board Member or review the Sponsorship Policy on the MARSQA website.

Upcoming Events



<p>MARSQA Spring Conference</p> <p>March 26, 2015</p>	<p style="text-align: center;">C*ck and Bull Restaurant</p> <p style="text-align: center;">Peddler’s Village, Lahaska, PA</p> <p style="text-align: center;">See www.marsqa.org for meeting details and registration information</p>
<p style="text-align: center;">MARSQA Meet and Greet Event at SQA Conference</p> <p>Tuesday, 14 Apr 2015</p>	<p style="text-align: center;">SQA 31st Annual Meeting and Quality College</p> <p style="text-align: center;">Tuesday, 14 Apr 2015</p> <p style="text-align: center;">Tampa Convention Center, Room 9</p> <p style="text-align: center;">12:00p.m. to 1:30p.m. Lunch included</p>
<p style="text-align: center;">Upcoming MARSQA Membership Meetings for 2015</p>	<p style="text-align: center;">June 25</p> <p style="text-align: center;">October 1</p> <p style="text-align: center;">December 8</p>
<p>MARSQA Training</p> <p>May 19-20, 2015</p>	<p style="text-align: center;"><u>Basic Computer System Validation Training</u></p> <p style="text-align: center;">Accenture, Berwyn, PA</p> <p>The curriculum is organized by system life cycle phases; provides a focus on selected advanced concepts of computer validation activities in accordance with each phase. The program is geared towards individuals who work in the GxP regulated environment.</p> <p>Fee: \$200 for Regional SQA Chapter Members and SQA Members (\$175 Early Registration (by April 19, 2015)) \$250 for Nonmembers (\$225 Early Registration (by April 19, 2015)) \$25 per person discount for multiple attendees from same company!</p> <p><u>Registration deadline:</u> May 15, 2015</p>

What Benefits Do You Receive For Your \$30 Annual Membership?

- The opportunity to interact with Mid Atlantic Region Quality Assurance professionals from different backgrounds, such as government, academia, and industry. Expand your knowledge in areas of regulated research to which some of us may not otherwise have an opportunity to be exposed.
- Three or 4 membership meetings per year: Our half-day membership meetings are preceded by a hot buffet luncheon. Chapter business is discussed, and training presentations and discussions are provided at a cost of only \$20 per MARSQA member (\$40 for non-members).
- Multi day training seminars are offered several times a year on current topics by leading industry experts at great rates (\$250/member/day, \$350/non-member/day).
- Access to the MARSQA members listserv-forum and document library.
- Each year of MARSQA membership provides you with .25 unit for RQAP re-registration. You also earn .25 unit with each attendance at a MARSQA meeting.
- The *MARSQA Monitor*: As a supplement to the MARSQA website, MARSQA provides a more personal, quarterly hard copy newsletter. Both the website and the *Monitor* provide updates on MARSQA happenings and interesting articles from both industry experts and membership, advertisements and career opportunities and listings of available MARSQA training courses.
- A \$2000 award to the SQA Annual meeting is presented to a MARSQA member each year to help defray the cost of travel and attendance.
- An Annual hardcopy Membership Directory.
- Our chapter works to provide links to resources in Quality Assurance for Mid Atlantic Region QA professionals.

SAVE BIG!

40% OFF

ORGANIZATION NAME

Discount
SAVINGS

Expiration Date: 31Dec 2015

Dues for
2015 have
been
reduced
from
\$50 to \$30!

The Extremely Bright Idea Corner **Share Your Brilliance with the MARSQA Monitor!**

Offer to do a presentation on an interesting topic at one of our upcoming meetings

Suggest topics of interest that you would like to hear at our upcoming meetings

Share an experience that can be published here in the next newsletter

