A Message from the President – Half Year Summary

Dear MARSQA members,

I would like to take the opportunity to give you an update on what MARSQA has accomplished the past 6 months as well as the remaining months of the calendar year.

1. **FREE 20th Anniversary Dinner Cruise on the Spirit of Philadelphia, June 22nd**
MARSQA held its 20th Anniversary Cruise on the Spirit of Philadelphia on June 22, 2012. **It was FREE for all current members.** The board approved this event not only as an opportunity to celebrate the success over the past 20 years, but as an opportunity for all of our members to meet each other in a more social setting. We wanted to create an opportunity to network with other members and their guests, enjoy a lovely meal and music as we sailed up and down the river. It was an enjoyable night for everyone and we thank all who were able to attend!

2. **It was a Busy Spring**
In March we had our first Membership meeting at Lahaska PA. Attendance was very good and we had three great presentations and many talented and knowledgeable speakers.

First, Richard Ciamacca, Senior Legal Counsel and Corporate Secretary from Actellion, gave a talk on “Prescription Drug Use Fee Act in 2012”. The second talk was “How Graduate Education can advance your industry career” given by Wendy Lebing MALD MS, Assistant Dean, QA/RA Graduate Program, Temple U School of Pharmacy and Peter Doukas, PhD, Dean, Temple U School of Pharmacy. Lastly, a presentation was given on “Mock Inspections and Pre-Inspection Preparation” by James Rava, Associate Director, Clinical Quality Assurance, Janssen R&D.

In April, MARSQA was well represented at the SQA Annual Meeting in Miami, FL. Myself and other board members that attended, had the opportunity to speak to other SQA members and/or other regional chapter members, discussing various things like “how to get members to join” to “how to get members to participate more” and even “ideas on different topics for training sessions and/or membership meetings”. It was a nice week indeed and I am glad I had the opportunity to represent all of you as your President. Thank you!

In May, we had our first Training Session. This time around, it was on “Basic Computer System Validation”. This training session was led by our CSV Chairs, Paula Eggert from Merck and Courtney Rodriguez from Charles River. Both did an amazing job pulling this all together. The CSV Training Team was comprised of the following individuals who contributed greatly to the training event:

- Rachel Adler, Program Manager Compliance Management, Global R&D QA, Janssen Pharmaceutical Companies of Johnson and Johnson
- Denise Botto, Principal Quality Assurance Auditor, PharmaNet i3
- Irina Colligon, Independent Consultant
- Donna Danduone, Senior Consultant, Instem
- Paula Eggert, Project Validation Specialist, Merck & Co, Inc.
• Melissa Elliott, Director of Quality Assurance, Huntingdon Life Sciences-Princeton Research Center
• Penny Jegede, Senior Specialist, Global System Quality Assurance, Global R&D QA, Janssen Pharmaceutical Companies of Johnson and Johnson
• Marlena Maier, MBA, BS, Quality Assurance Professional
• Courtney Rodriguez, Manager, Global Computer Validation Quality Assurance, Charles River
• Elisabeth Smith, Research Biologist (Compliance Specialist), Merck & Co.
• Purna Thakker, A.D.P.Thakar LLC (USA), PurnaVed (India)
• Vince Windisch, Ph.D., Associate Director Quality Assurance, Keystone Bioanalytical (formerly High Standard Products)
• Chris Wubbolt, M.S., President, QACV Consulting

On behalf of the Board, I want to thank all of our contributors, for their efforts. Both events were well received, very informative and interactive and its these membership and training meetings that convinces people that being a part of a professional organization like MARSQA, adds real value to your career and personal and professional development. If you didn’t have the opportunity to attend either, we hope you can enjoy our future events.

3. **Summer and Fall Events**

We have planned a Membership Meeting at Lahaska for **Wednesday July 25th**. Malti Parekh and Cynde Radford of Janssen Pharmaceuticals will speak to Electronic Medical Records. In this presentation they will cover the benefits of using EMRs in clinical research, as well as recent observations on EMRs and what to look for when you are auditing a clinical site that has transitioned from paper to EMRs. Also, Karen Waetjen will provide us with a reprisal of her SQA presentation regarding GLP compliance for stem cell study designs. Both of these topics will provide valuable insight into areas of Quality that many of us have never had the opportunity to be exposed to, so from the perspective of diversifying your knowledge, increasing your value as a Quality professional, and exploring areas of Quality that may be of interest to expand and transition to, this is one not to miss!

Please mark your calendars and plan to attend this half day event on **July 25th**.

We are also planning a late summer/early fall Training Event likely for “BioAnalytical for Auditors”. **On November 13th and 14th**, the same team responsible for coordinating the Basic CSV Training will be having the Advanced CSV Training at Lahaska, PA. This is designed as a follow-up for those that participated in May’s Basic Training and also designed for a broader audience that is familiar with CSV, looking for more advancement in concepts and approaches.

In the Fall, we have our Elections for MARSQA Board members. This year the positions open will be for Vice President, Treasurer, and two open positions for Directors (out of 4). On July 25th, during the Membership meeting, members of the current board are going to briefly describe their role and debunk any myths that volunteering for office is too time consuming. There really is so much more value in getting involved than it may appear. We strongly encourage all of our members to get involved more, if not for running for office, volunteering to speak at events, or write articles for our newsletters or even be our official photographer for events. There are so many ways to get involved and it truly is the best way to get the value out of your membership.
In the coming weeks, our Newsletter Committee, led by Jane Goeke, will be issuing electronically, our 2\textsuperscript{nd} Newsletter of the year. Our Newsletters are very impressive and the Newsletter Committee does an excellent job every time for you reading pleasure.

Our Website is constantly being updated with current information, thanks to Carinne Park, our Technology Committee Chair. We encourage you to visit it regularly to keep up with any new information or changes that may come up.

Thanks again for being a part of MARSQA and if you have any questions or concerns, please feel free to contact me directly.

Sincerely,

Ranee Henry
2012 MARSQA President