



MARSQA Monitor

NEWSLETTER OF THE MID-ATLANTIC REGION SOCIETY OF QUALITY ASSURANCE

Volume 15, Issue 1

WELCOME MARSQA TO 2011!



As the MARSQA board has transitioned to the 2011 leadership, I think about how many of our members are also transitioning in their careers. As our region has been hit hard during these last few years due to mergers, staff reductions, and site closures, it is difficult to stay motivated during these transitional times. It is times like this when we have to try and differentiate ourselves from the rest. Whether this means educating ourselves in the other regulations so that we can shift between GLP, GMP and GCP, or just getting involved in organizations like MARSQA, it is important to know that we are not alone in this transition.

As I begin my Presidency, I also find the transition from Vice President to President intimidating but I know that with the support of the rest of our board

members, and with that of the membership, together we can make our 2011 society year a great and fulfilling year for all of us.

Now is a time to reach out to others, to help and support each other through these difficult times. MARSQA is here to help. By getting involved in the society, you are able to set yourself apart, to learn new things and meet great people...all of which can be so valuable, especially when many of us need that support. I encourage all of you to reach out to your MARSQA board and committees to see how we can make a difference...together. Through our membership meetings, training sessions, our new MARSQA website, and our Linked In profile, members have the opportunity to connect, get the training necessary for their transition between jobs, and support from each other. I encourage you to use these tools. Our region is so rich in talent. Use these resources to transition yourself...with MARSQA.

Alyssa Colon
2011 MARSQA President

Looking for the Right Volunteer

Jane Pasquito who has chaired the MARSQA Program Committee for many years will be leaving that post. Jane and her committee have been responsible for the many excellent membership meetings that have been held in our area and MARSQA is very grateful for their contributions.

The MARSQA Board is hoping to fill the post of Program Committee Chair over the next few months either with a single chair or two co-chairs. The position primarily requires developing the membership meeting agendas and working with the speakers. Meetings are usually held 3 times annually.

If you are interested in this role, please contact MARSQA Vice President Raneë Henry at raneë.henry@crl.com. If you would like to know more about the role, contact Jane Pasquito at jane.pasquito@sp.intervet.com.

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MARSQA MISSION STATEMENT

- 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.
- Serve as a forum for the open discussion of the theoretical, practical and ethical applications of the quality assurance profession.
- Foster a partnership between the quality assurance profession and the regulatory agencies that results in the attainment of mutually beneficial compliance.
- Support and advance the goals and mission of the Society of Quality Assurance.



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On Monday January 10, 2011, I had the opportunity to attend the American Society of Quality Northeast Pharmaceutical GMP/Quality Conference. Many informative topics on current issues in industry were presented by leading experts in the field. One presenter that I would like to focus on was Diana Amador-Toro, NJ District Director in the FDA's Office of Regulatory Affairs. Ms. Amador-Toro presented a two part session which included (I) How Pharma should monitor itself for GMP compliance and (II) How FDA inspections could incorporate pharmaceutical inspection cooperation scheme (PIC/S).

For part I of her presentation, Ms Amador-Toro discussed how Pharma should perform self inspections to reflect the inspections that will be conducted by the FDA, in order to ensure compliance with applicable GMPs. She explained how Pharma should use mock inspections for GMP purposes (system-based approach), mock inspections for pre-approval purposes (product-based approach), as well as the use of qualified external consultants to perform GAP analysis of existing quality systems. She emphasized that the FDA is not privy to internal audits but may inspect any corrective and preventative action which is conducted in response to internal audit findings. Part I of the presentation concluded with an overview of current regulatory issues, such as the use of CAPA, the evaluation of metrics, and the use of excipients. Current regulatory trends emphasize a proactive approach to CAPA to ensure a system of continuous improvement, as well as continuity across company sites for the management of CAPA. Ms Amador-Toro offered advice on the use of performance metrics as a quality management tool, explaining that metrics must ensure that the operation is in a state of control. Therefore, metrics themselves should be evaluated to ascertain that the appropriate parameters are examined, and should include any applicable calculations and analysis. Lastly, the current regulatory issues with the use of excipients were discussed. Ms Amador-Toro stressed that the company using excipients will be held accountable to ensure that there have been no changes to the origin of the material or to its packaging. She suggested that the user perform a mock interstate documentation collection to verify the identity of the manufacturer.

For part II of the presentation, Ms Amador-Toro explained the mission and benefits of PIC/S. PIC/S is the abbreviation of both the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme operating together in parallel. PIC/S is an international group composed of 39 participating authorities, with the FDA becoming a member January 1, 2011. PIC was established in 1970 and the Scheme was launched in 1995. The role of PIC/S is to exchange information and experience in a confidential manner, in order to provide a harmonization of technical standards and procedures regarding the inspection of the manufacturing and testing of medicinal products. The benefits of membership in PIC/S include training opportunities for inspectors, international GMP harmonization, international networking among regulatory inspectors, rapid alert and recall system, and recommendation for improvement of standards. It is also hoped that PIC/S membership will help fill a gap in the number of overseas inspections conducted by the FDA.

With the FDA's emphasis on maintaining a quality environment through proactive measures, as well as the emphasis on global harmonization, these are issues which are sure to be recurring. For more information, you can refer to the following websites:

www.picscheme.org

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM210822.pdf

www.pharmamanufacturing.com/articles/2010/041.html

UPDATE!! Links to all MARSQA Action Committees and the dates of their Meetings and TCs are now posted on the MARSQA Website at <http://www.marsqa.org/>. It's easier than ever to volunteer.

COMMITTEES

MARSQA has eight committees. They are listed below along with the Chair(s) for each.

CSV	Paula Eggert	paula_eggert@merck.com
Education	Joanne Ramundo	joanne.ramundo@sanofi-aventis.com
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MARSQA activities and projects are driven to a great extent by its committees. Please consider volunteering for one of these committees to help keep our chapter vital. In the article below, Carinne Park shares the reasons why she is a member of the Website Committee.

Introduction to the MARSQA Website Committee

Carinne Park

Co-Chair

Behind every great website is a great webmaster – one that has dedication to updates, a love of posting news, and in MARSQA's case, a desire to discuss GxPs at all hours of the day. It requires the ability to keep up with evolving technology, which in this day and age, can be an exciting challenge. Is there an 'app' yet for 21 CFR Part 11? And if so, is it validated?

MARSQA is no exception to this changing world and it is the responsibility of the website/technology committee to keep up. Recent transformations are already noticeable: the old website is being replaced with a new, user -friendly interface; forums for discussing challenges of compliance are readily available on LinkedIn; and as some of you may detect, MARSQA now widely uses electronic communication instead of paper.

As the most recent member to the technology/website committee, I can't take much credit for the new ideas or being the webmaster (thank you Anthony Borisow, Bryan Sangkavasi, and the MARSQA Board). But the exciting thing about technology is that there is always room for more ideas. For example, would it be possible to broadcast MARSQA meetings over the web? How about being able to pay for dues or meetings online? Both of these are possible endeavors we could see in the near future, and why I'm part of this team.

These changes are here to make MARSQA more accessible for the members. Please, use and access these new methods of communication we have. Check out the website to see current committee activities and how you can get involved. Send an email with your new idea for a MARSQA meeting. Or, post on LinkedIn your question about storage stability from the transport between US and China. It's all here for you!

e-Signing off for now, Carinne Park

MARSQA Word Scramble

by Rachel McGowan, Newsletter Committee

1. AARSMQ _____
2. tysud rrditceo _____
3. Odgo rtblaoyora rcscepiat _____
4. oodg nfgmancatuui rptiacecs _____
5. gsrnieltoua _____
6. drouati _____
7. Itqyiau sursaneca _____
8. rliippanc voanigtisert _____
9. Tnayonh robowis _____
10. coolport _____
11. dfoo nda gdur dmiansnoittra _____
12. remtas Icedhesu _____
13. DOEC _____
14. ddtnasar goraintpe cpoeruder _____
15. PEA _____
16. Ianiiovadt _____

Answer key on Page 7

MARSQA MEMBER PROFILE: RANEE HENRY, MARSQA VICE PRESIDENT



In your opinion what is the key to happiness?

This is something that I think I personally have asked myself many times. For many years, I thought that happiness was largely determined by one's genes, marital status, personality and material possessions.

But as I got older, I realized that happiness is entirely about our ability to make "choices". Each of us wake up each day with the choice to be happy or not be happy. We can choose to do things that bring joy and happiness into our lives or not. It is entirely in our hands. We all have the ability to change the things we are not happy with in our lives and select a path that helps lead to

achieving the right balance between work, our lifetime goals and the many relationships in our lives. My key to happiness is to make choices that feel right for me, not for what is right for someone else. I realized that sometimes (not all the time) you have to put yourself and your happiness first in order to obtain true happiness for yourself and those around you. If you're not happy, no one around you will be either.

What is your all-time favorite movie? Why?

My favorite movie of all time is Shawshank Redemption. I don't think I saw the movie for the first time in a movie theatre and from what I remember, it really wasn't a big blockbuster movie and hadn't heard about it when it first came out, but what a great movie indeed! I love the movie because each and every relationship in the movie you could relate to in some way. It is riveting and sad and happy all at the same time. Great great movie.

What do you like most about your current role in quality assurance?

Even though my role now is in Information Technology, it still is and always will be about assuring quality in the service we provide for others. What I like about this role is that there isn't a single person working in our field today that doesn't rely on or isn't seeking to improve existing Technology. I enjoy being in a position where the choices I make and the work I put into a project make employees' jobs better or easier by providing them with real technological advances.

What are your views on the outlook for quality assurance professionals in the future? Do you see the field as having a shortage, an over-saturation or the right amount of QA professionals?

Even with all the amazing technological advances we have seen, there will always be a need for QA professionals. With the decrease in the need for QA professionals in one area because workflows have been streamlined or improved, there is then an opposite effect in other areas. Like everything or anyone else, QA professionals will need to adopt to new types of activities or services to ensure a good and long lasting future.

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

I love helping people and in my role, I get to help people get things done or find solutions that make their job better and easier. That is very rewarding to me personally to be able to do that for people every day.

How important do you think it is to have a work-family life balance?

It is everything. You'll never be a good member of the family if your whole life is about work and you'll never be a good worker if your whole life is about family. If you choose to do both, then you must find a way to give each 100%, 50% of the time. Balance isn't giving 50%, 100% of the time. If you can do that, you will be successful at both.

Where is your favorite vacation spot?

My home! My favorite vacation spot honestly is here where I'm surrounded by people that I love and people that love me and try and do something fun every week. Either with family or friends. I love to cook, so don't enjoy eating out 3 meals a day for a whole week. I don't like sleeping away from home much, so honestly, being here every night and my weekends are my vacations.

What's your favorite hobby?

Cooking and entertaining and seeing people enjoy themselves.

MARSQA Word Scramble Answers

1. MARSQA
2. study director
3. good laboratory practices
4. good manufacturing practices
5. regulations
6. auditor
7. quality assurance
8. principal investigator
9. Anthony Borisow
10. protocol
11. food and drug administration
12. master schedule
13. OECD
14. standard operating procedure
15. EPA
16. validation

MARSQA MEMBER PROFILE: PAULA EGGERT, CHAIR COMPUTER VALIDATION COMMITTEE



In your opinion what is the key to happiness?

Good health, family and laughter

What is your all-time favorite movie? Why?

I like, *The Big Chill*, because it's a reminder of time gone by and friendships rekindled.

What do you like most about your current role in quality assurance?

Meeting and working with many different groups of people on a daily basis.

What are your views on the outlook for quality assurance professionals in the future? Do you see the field as having a shortage, an over-saturation or the right amount of QA professionals?

My personal view is that there may be an increase in Quality Assurance professionals. Current trends seem to reflect job roles with increased responsibility and fewer employees. This mindset often leads to limited time and attention necessary for ensuring the quality aspects. Increased personnel from an independent group (QA) are helpful in assisting by specializing in the quality aspects of various tasks, making it a career that could span to areas beyond regulatory concern.

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

I enjoy having the ability to convey computer system validation concepts to others as a training opportunity.

How important do you think it is to have a work-family life balance?

It's very important, although something I haven't mastered. One easy test for me is looking at how productive I can be AFTER taking a break from the job! Both my family and my job are lacking when I don't have good balance.

Where is your favorite vacation spot?

Belize

What's your favorite hobby?

Large jigsaw puzzles when time allows

SUPPORT/ADVERTISE IN THE MARSQA MONITOR!

The Newsletter Committee writes, collects and assembles the copy for the MARSQA Monitor. We are always happy to hear your ideas, suggestions and *especially* to publish your contributions in the newsletter. Just contact Jane Goeke, RQAP-GLP, Committee Chair at jane.goeke-1@gsk.com.

Please also remember that you can advertise in the Monitor. For example, the discounted fee for members is only \$75 for a full page ad for three editions. The MARSQA Monitor is published in the Fall, Winter and Spring. Contact Jane Goeke, RQAP-GLP for more information on advertising.

Routine Maintenance

A Cartoon by Eva Haszcz, Newsletter Committee Member

