MARSQA MONITOR

Newsletter of the Mid-Atlantic Region Society of Quality Assurance

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Mid Year Update from 2012 MARSQA President

Well, we are half way into the year and lots to report on. I hope all of you had a chance to enjoy one of the many events we have had so far. We have a busy part of the year ahead of us and below is a summary of the first 6 months and the next.

Just recently, many of the MARSQA members celebrated our 20th Anniversary on the Spirit of Philadelphia. The night brought lots of rain unfortunately, but it didn't dampen the night at all. We ate, drank and danced well into the evening!

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.

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. I and other board members who 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.

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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. It's these membership and training meetings that convince people that being a part of a professional organization like MARSQA, adds real value to their career and personal and professional development. If you didn't have the opportunity to attend either event, we hope you can enjoy our future 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 you should not 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 for "BioAnalytical for Auditors" on either September 24th and 25th or 25th or 26th in Lahaska. 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 by running for office, then volunteering to speak at events, or writing articles for our newsletter or acting as 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.

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

A note from Krista Ehringer-MARSQA RQAP Award Recipient and MARSQA Member

As the recipient of the Spring 2012 MARSQA RQAP Award, I'd like to thank the MARSQA Board and all of the MARSQA members for the opportunity you gave me to earn my professional registration this year. I learned from other registrants that studying for the exam would be no easy feat, so I prepared by reading the regulations, the preambles, the Q&A documents, the comparison charts, and anything I could get my hands on. My advice to future candidates is to begin preparing as early as possible and be ready to apply the knowledge you've learned to answer questions about scenarios that may be unfamiliar to you. To accommodate the many different professionals in an industry as wide-reaching as ours, the exam seems to test your ability to apply what you know about the regulations rather than your ability to memorize citations. I appreciated that approach and felt that the preambles were my most helpful study tools. Although the exam was difficult and I'm glad it's over, I'm happy to report that I successfully passed and am now credentialed as a Registered Quality Assurance Professional in Good Laboratory Practice. Thank you again, MARSQA!

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MARSQA
Mid-Atlantic Region Society of Quality Assurance

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.

Global Quality Management System

Implement a Global Quality Managmeent System Sure, Piece of Cake!

Nancy Catricks
MARSQA Member

It was the summer of 09...

It was the summer of 2009 when I was blessed with the role of Validation Project Manager on our global Quality Management System (QMS). The purpose of this article is not to share how to validate a global QMS but how to implement the system once validated.

First of all, what is a QMS?

QMS stands for "Quality Management System" and is an electronic system which allows the consolidation of global GxP quality management activities using a single application. These activities include: inspection and audit scheduling; corrective and preventative actions (CAPA) implementation; compliance finding tracking and analysis; master study schedule maintenance; and compliance metric reporting activities. The list goes on and on.

There have been many lessons learned throughout the process...

Don't try to boil the ocean

Quality management systems have so many capabilities it can be overwhelming when trying to decide what to implement and when. The approach used at Charles River was to first utilize a simple work-flow to a limited audience. The GLP master schedule was the initial work-flow implemented to the QA auditors. This allows for a "quick win" and gets a small group comfortable with the application. Following the master schedule roll out, the audit manager workflow (audit documentation and routing) was implemented to the remainder of the company. By having the QA personnel already comfortable with the system, it allowed for a pool of personnel with experience in the system to assist others in the company.

If you fail to plan, then you plan to fail

Plan, plan, plan then, plan again! Once you are ready to implement it is important to develop a roll-out plan including dates and deliverables to ensure proper training is conducted, appropriate SOPs are in place, and assistance is readily available for the first few weeks after Go Live. Consider setting up on-site support centers where users of the system can come and get one-on-one assistance during the initial go live rollout.

There's always change control

Expect at least one change control within a few weeks of going live. Software is like a fine wine….. it gets better over time. I relate going live with the system like going from your Phase I and II clinical trials to your Phase III clinical trial. There will be adverse events and things you didn't think of – remember, you are going from your nice well-controlled environment to a huge population of personnel. Be prepared to prioritize each item that comes in, whether it is corrective or perfective. No matter how much time is spent trying to come up with every "what if" there will be changes that are needed.

The problem with communication is the illusion that is has occurred.

Once your system is live, it is important to continue weekly team meetings to exchange challenges and how they were overcome. This time is also useful to evaluate requested changes.
In summary, implementing a global QMS system is a huge challenge; however, when planned appropriately with realistic expectations, it can be a success!


Nancy Catricks before QMS


Nancy Catricks after QMS

UK and OECD GLP Update

Mark Goodwin
BARQA Board Member and Chair of BARQA GLP Committee

This article provides a UK and OECD GLP update for the period June 2011 to May 2012. In summary, the UK GLPMA has issued further guidance (new and revised), shared 2011 Inspection data and has set up a QA Focus Group. For OECD, the mutual acceptance of data status for some countries has changed, the OECD GLP Discussion Group is now well established and the proposed Pathology Peer Review Guidance is still under discussion.

BARQA ran a successful annual conference and the BARQA GLP Committee is preparing two GLP booklets.

UK GLPMA Document on Test Types Stated on GLP Compliance Statements (new document issued Dec 2011)

Following a successful routine GLP Inspection conducted by the UK GLPMA, the test facility receives a Statement of Compliance from the MHRA. This Statement lists the Test Types that are within scope. In order to clarify the meaning of each test type the UK GLPMA issued a document in December 2011. The document lists the 9 categories of 'test type' together with the meaning for each category. The 9 categories are Analytical and / or Clinical Chemistry, Ecosystems, Environmental Fate, Environmental Toxicity, Mutagenicity, Phys. Chem Testing, Residue Studies, Toxicology and Other – details to be given on the Statement of Compliance (used when a facility conducts a very specific test type).

The UK GLPMA has received many requests to add test types to the statement of compliance. The GLPMA are interested to know why as all potential categories have been included. An example of such a request was to include metabolism, however it is not a requirement to claim GLP compliance for metabolism studies.

UK GLPMA Policy on the use of non-GLP facilities for the conduct of study phases (revised in Dec 2011)

Previously it was a requirement to notify the UK GLPMA when a non-GLP facility was to be used for a phase of a GLP study. The Policy now states that the UK GLPMA only needs to be notified when GLP compliance is to be conferred (claimed) for the work performed at the non-GLP facility. Although this is the case, the test facility must have a process in place for use of non-GLP facilities and a log maintained to record every phase of a GLP study conducted at a non-GLP facility. As in previous versions, the Policy describes the strict requirements around conferring GLP compliance for a study phase conducted in a non-GLP facility.

UK and OECD GLP Update - continued

UK GLPMA Document on "Use of Test Sites in Canada" (August 2009)

This document is still current despite the announcement last year that it will be withdrawn. The likelihood is that it will be withdrawn now that the Standards Council of Canada (for Health Canada) has completed inspections of all major facilities that conduct non-clinical safety testing on pharmaceutical products. The document is concerned with multi-site GLP studies conducted at UK based test facilities that had a phase at a Canadian facility. The document states that unless the GLP status of the Canadian facility could be verified (i.e. inspection by the responsible Canadian Government Agency), then no GLP compliance claim could be made for the phase of the study.

The UK GLPMA is unlikely to issue any further national guidance in the future. Instead, the Frequently Asked Questions section of their web-site will be used more widely and if there is a need for guidance this will be considered at the EU and OECD levels.

UK GLPMA Inspection Data for 2011

65 inspections conducted (comprising implementation, compliance monitoring, triggered by facility changes and facility closures)

Total number of deficiencies:	572
Critical deficiencies:	3
Major deficiencies:	29
Deficiencies:	540

For the critical deficiencies, two related to QA and one to backdating a protocol amendment.
The number of major deficiencies in each category were: Organisation & personnel 8, QA 6, Computerised systems 6, Study Conduct 4, Facilities 3, Archiving 1 and SOPs 1.

For total deficiencies, the percentage deficiencies in each category were: Study Conduct 36%, Organisation & personnel 19%, Facilities 15%, QA 9%, Archiving 8%, SOPs 8%, and Computerised systems 5%.

UK GLPMA QA Focus Group

The Group is assessing whether or not current guidance on QA remains fit for purpose. The Group consists of three UK GLPMA Inspectors and six industry representatives. There have been two meetings to date with a focus on process-based inspections, audit of the final report, risk-based inspection programmes and quality control. The Inspectors will now consider and document the discussions to date with the aim of reconvening in the fourth quarter 2012. How the output will be issued has yet to be determined.

OECD Update

Argentina is the most recent country to become a full adherent to the OECD MAD agreement (for biocides and pesticides only).
Current provisional adherents to OECD MAD are Malaysia and Thailand. Both have been assessed (by Mutual Joint Visit) and are awaiting a decision (from the OECD GLP Working Group meeting in late May).
Russia is now striving for OECD MAD status; China has not yet approached OECD for provisional adherence status and so it is likely to be several years before China is a full adherent to OECD MAD. Chinese Taipai have a monitoring programme in place but can only seek membership with China

UK and OECD GLP Update - continued

OECD GLP Discussion Group

The general aim of the Group is around harmonisation such that international regulatory expectations for GLP compliance are consistent. Industry representatives have posted comments on the two discussion topics: Inconsistencies of international inspectorates (80 comments) and the application of GLP to emerging technologies (40 comments). The comments were reviewed by Andrew Gray (Head of UK GLPMA) and two themes seemed to emerge: Quality Assurance issues and electronic records (e.g. cloud technology, archiving). The OECD GLP Working Group will decide what topics to take forward (at their meeting in late May – no further news at this time).

OECD Guidance on pathology peer review

A large volume of comments was submitted by stakeholders on the initial draft document. As a consequence, the document was revised with several significant changes. The second draft will be discussed at the OECD GLP Working Group meeting in May. If agreement is reached at the meeting the document will be shared with key stakeholders for further consultation. If agreement cannot be reached the document will not be taken forward.

BARQA GLP Activities

The BARQA web-site has been revamped. It has several new features including a regulatory roadmap for Human Medicinal Products within Europe.

In September 2011, BARQA held a successful Annual Meeting in Bristol with the theme of Quality Connections. GLP highlights included GMP supplies to GLP studies, (is there) a level playing field for international compliance, preparing for regulatory inspections and top tips for auditors. There was also a lively workshop during which the audience had to select the correct answer (from 3 possibilities) over a number of topics.

Two BARQA booklets relating to GLP are in preparation:

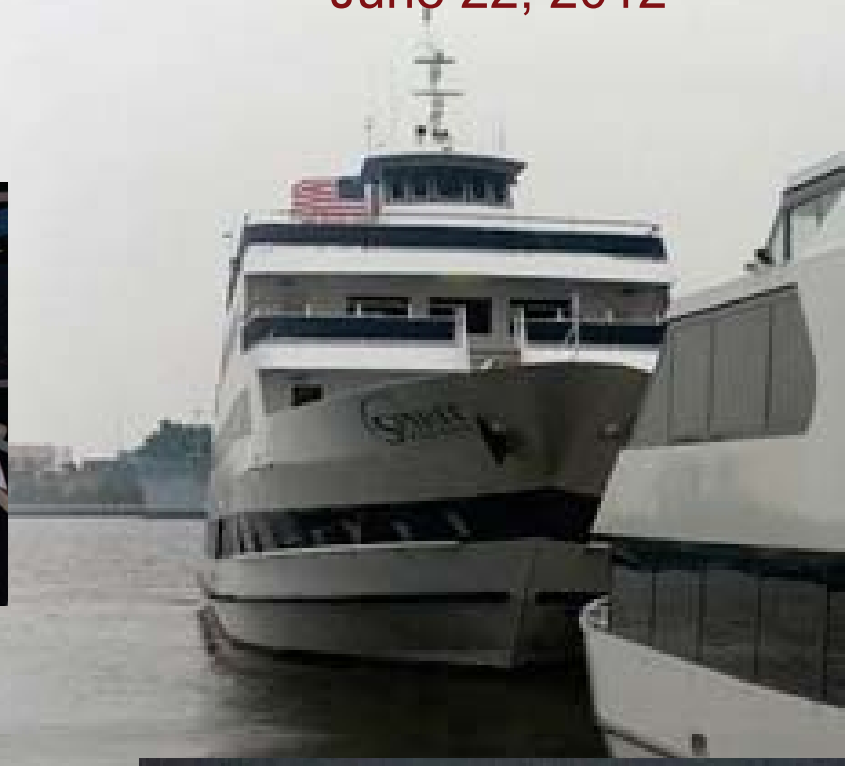
- A Practical Guide to the Role & Responsibilities of the Study Director
- GLP in the Analytical Laboratory

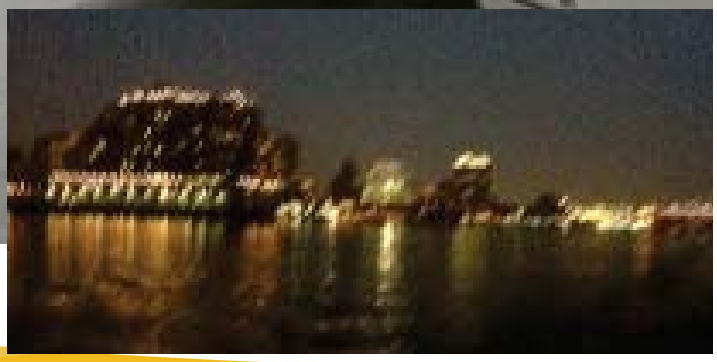
The BARQA GLP Committee was approached by the European Bioanalysis Forum to submit a joint comment through EBF / EQAC (European Quality Assurance Confederation) on the EMA Guideline on bioanalytical method validation. Industry had concerns over a section of the Guideline that could be interpreted as meaning that a claim of GLP compliance is required for analytical method validation. A response has yet to be received from the EMA.

The BARQA GLP Committee has representation on the OECD GLP Discussion Group and the UK GLPMA QA Focus Group.

MARSQA's 20th Anniversary Dinner Cruise

on the *Spirit of Philadelphia*
June 22, 2012





Photos from the 20th Anniversary Dinner Cruise- continued

Photos from the 20th Anniversary Dinner Cruise- continued

Recap of Basic Validation Training Event

Paula Eggert
Co-chair CSV Committee

The MARSQA Computer Validation Committee (CVC) training team provided Basic Validation Training on 15-16 May 2012 at the Cock n Bull Restaurant in Lahaska, PA. Paula Eggert, one of the co-chairs of the CVC hosted the training. A total of 30 participants attended the two-day sessions.

Multiple presenters provided insight to basic topics of interest that included: definitions/terminology, system life cycle development, team roles and responsibilities, relationship of GxP regulations to validation, system validation maintenance, data migration, good documentation practices, and explanation of validation deliverables. Both days concluded with a group exercise to utilize those concepts that were presented. The training session was recognized and granted RQAP certification credits of 3.5 GCP or GLP units for the two-day training. Overall comments from the attendees were positive on the materials provided. There has also been interest in providing this training via webinar as well as providing additional training sessions for Basic Validation Training in the future.

The MARSQA CVC training team would like to extend a sincere "thank you" to the MARSQA Education Committee and those members of SQA that provided support and assistance in making this event successful.

The CVC training team is in the early stages of planning the upcoming Advanced Computer Validation Training which will take place on 13-14 November 2012. Please check the website for upcoming details regarding this training opportunity.

AMERICAN COLLEGE OF TOXICOLOGY
Call for Abstracts

33rd Annual Meeting of the American College of Toxicology, November 4-7, 2012.
For more information, registration forms and program online contact www.actox.org or call 301-634-7840.

AMERICAN COLLEGE OF TOXICOLOGY 33rd ANNUAL MEETING
NOVEMBER 4 – 7, 2012
Omni Orlando Resort
Championsgate, Florida

MARSQA 2012 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.

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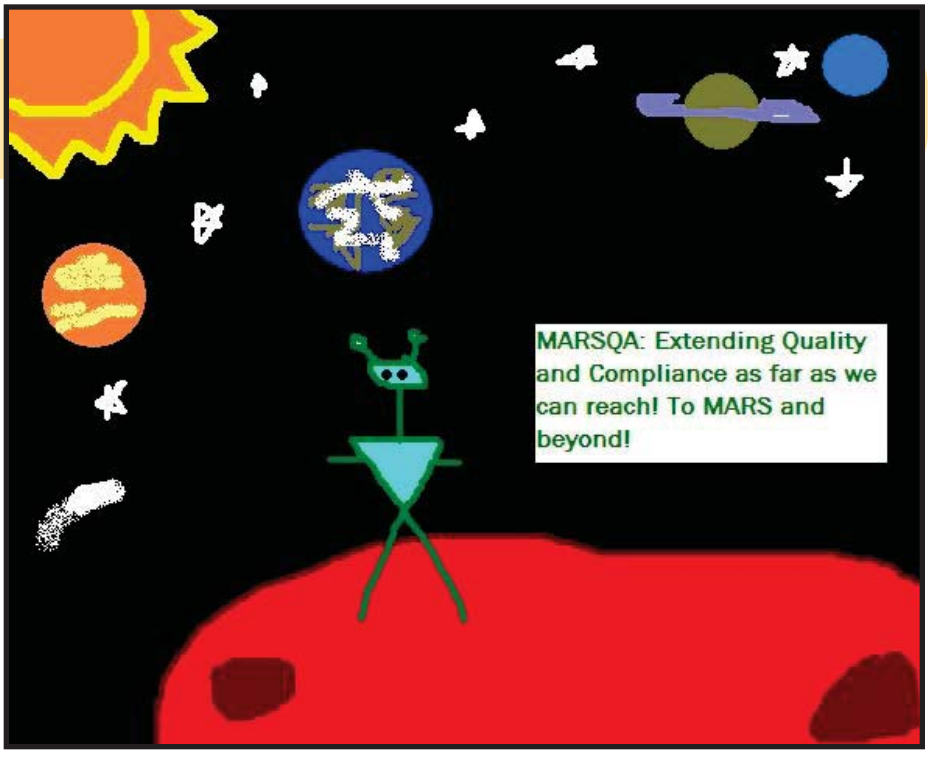
cartoon submitted by Carinne Park, Chair of the Technology Committee



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