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STAYING CHARGED…OR RECHARGING YOUR QA BATTERY

In our profession, there are times when we find ourselves dragging through the day in that perpetual "Groundhog Day" feeling: the same stuff, different day. We review reports and data, finding the exact same observations we have just trained our customers about or just discussed on the previous audit. Almost like a broken record. It's understandable that everyone is stressed with the current economic situation our region finds itself in and we tend to walk on eggshells not to rock that boat. I find that it can be a struggle to stay motivated through the monotony.

Then there are days when you get that breakthrough… and realize you love what you do. I find that these moments usually hit me after providing training to someone new to the regulations, working with my peers during site visits at other facilities and when we get to go to our membership meetings. When I am surrounded by such passionate individuals, I find myself recharging my QA battery, getting new information about industry happenings, learning about other regulations that I don't primarily work with and just having the opportunity to chitchat with individuals who understand that I just can't leave that write-over uncorrected in my checkbook. All this helps me to remember that I am not alone in these down-swings.

I love having the opportunity to work with QA individuals that I respect so much that I never would have met if it were not for my involvement in MARSQA and SQA. I remember my first MARSQA meeting and how I felt so nervous being surrounded by people talking and sometimes passionately debating regulatory interpretations and discussing their most recent inspectional experiences. I also remember feeling in awe, desiring to be a part of that friendly debate. Now, after 6 years, I find myself writing to the MARSQA membership as your President. I need my involvement in MARSQA to keep my QA charge up. It doesn't take much. Whether it be just going to a membership meeting and asking questions or talking with the person sitting next to you at the Cock 'n Bull, volunteering to be on a committee or running for a board position, it's a step in the direction to getting recharged and staying there.

At our May 26th Membership meeting we got to hear Ms. Carinne Park, our 2011 MARSQA SQA Award recipient talk about her experiences at the 2011 Annual SQA meeting. She was able to recharge in San Antonio…and MARSQA paid! Can it get any better?!? Here was an opportunity that Carinne would not have had if it weren't for her getting information and reaching out to our board via a letter. We have this AMAZING award to help our members "recharge" and network with other QA professionals. Our RQAP Award was also established to help enable

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qualified members to take the registration exams, which can help to differentiate you from others. Both of these awards are super simple to apply for and, in these times, can really make a difference.

I understand and know that it can be difficult to juggle our regular day-to-day responsibilities...be it at work or at home. But it doesn't take much for me to stay involved and to help regain my perspective. It takes special people to do what we do. We are a special breed. To help keep products safe for our loved ones and for the public we need to not lose that passion that can waiver during those tough times. So take the time and find what you need to recharge your QA battery.

Get involved or just come for the conversation and you may find yourself wanting to make that feeling last. MARSQA is here to keep you going and going and going…

Alyssa Colón, RQAP-GLP, MBA
2011 MARSQA President

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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Lean Six Sigma in a GLP Archive

Lindsay Nolan, Manager of Archive Services, Charles River Laboratories

The day to day operations within a GLP-compliant archive present multiple organizational and strategic challenges. Whether there are five boxes that need to be shelved or 5,000; whether management is driving the never-ending saga of maximizing revenue-generating space; or whether personnel are being utilized as efficiently as possible, the archivist is constantly searching for a better way. As daunting as our responsibilities may seem, there are basic tools available that will assist in developing more effective and efficient archival operations.

Lean Six Sigma (LSS) is a well-known approach to continuous process improvement. The numerous tools contained within both Lean and Six Sigma offer businesses the potential to transcend their capabilities from the proverbial "this is how we always did it" wasteful nightmares into innovative, customer oriented, sustainable solutions. At Charles River, we have adopted LSS in every aspect of our business and that certainly includes the archival services. Process improvement projects can consist of the sophisticated data collection and statistical analysis of Six Sigma for the ultimate goal of defect reduction. However, process efficiencies can be successfully achieved through some of the more simplistic Lean concepts of waste elimination.

Over the past year, we were faced with a major archive transfer of over 15,000 boxes that required a new home in our facility. Charles River has transferred the contents of many archives to the Horsham facility and this larger than average transfer, combined with a short time-frame, gave us the opportunity to create new processes in order to manage the seemingly-overwhelming logistics. This project would require additional, temporary staffing, moving contractors and carefully planned systems. Enter Lean! Utilizing numerous Lean tools, we were able to break down all the necessary steps it would take to get the job completed. Once we had processes in place, we could then project where problems could occur and how we could potentially deal with those issues. Our team met and ran our new process through a Failure Mode and Effect Analysis or FMEA. This incredibly useful tool enabled the team to share their ideas and eventually identify potential set-backs long before the trucks backed into the loading docks. As solid as our plan was, the FMEA revealed three areas that could be improved upon.

First, we discovered that our plan to deal with "problem boxes," that is boxes that were mislabeled, missing paper work, etc., was not sufficient. Second, the team noticed that personnel were not appropriately distributed throughout the necessary work stations. Finally, moving contractors could be better utilized with explicit instructions. With these potential set-backs now out in the open, the team came together to develop solutions. A separate area was designated to place those "problem boxes" so that appropriate personnel could concentrate on resolutions. Personnel were assigned to smaller teams each with specific roles within the process. The team then developed a list of specific instructions for the moving contractors in order to maximize their time and effort while practically eliminating interruptions to our team.

Taking the time to examine our new process, we greatly improved our chance to be successful; and successful we were. Problem boxes became no problem; movers were a huge help, not a hindrance; and the team took a once complex project and leaned it into a streamlined success story. From the most overwhelming dilemmas to the more trivial setbacks, Lean Six Sigma can guide you through. Continuous process improvement drives us towards higher levels of compliance, customer satisfaction and of course a stronger archives.

UK and OECD GLP Update

Mark Goodwin, Chair BARQA GLP Committee; Member BARQA Board

This article provides a UK and OECD GLP update for the period June 2010 to May 2011. In summary, the UK GLPMA has made some changes to their risk based inspection programme and has issued further guidance (new and revised). For OECD, the mutual acceptance of data status for some countries has changed, an OECD GLP Discussion Group is to be 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 risk-based inspection programme

All facilities within the UK GLP Compliance Monitoring Programme are subject to routine inspections by the UK GLPMA. The frequency of inspection and number of Inspector days required for each facility is determined by a risk based inspection approach that was implemented 1 April 2009 as part of a government wide initiative aimed for better regulation. The risk-based programme is now well embedded but has been subject to some recent changes following review. Up to April 2011, manual means were used to make risk-based decisions from the available intelligence (including volume of work, type of work, inspection history). During April 2011, an automated system was introduced (Excel spreadsheet) following a 6 month trial. This calculates the risk score for a facility and hence determines the frequency of visit and number of Inspector days required. This removes the subjective elements of the risk assessment although there can be manual intervention in exceptional circumstances. There is an approval process for any interventions made. Information entered into the Excel spreadsheet includes inspection details / findings and background information around risk factors. Any new information gathered is entered on receipt and this could change the risk score. For example, in the UK it is a requirement for GLP facilities to submit a change notification form to the GLPMA when there has been significant change at the facility. Facilities that have historically been inspected every 12 months can still expect to be inspected on an annual basis (due to the background score resulting from the nature and complexity of the work and due to practicality reasons) but there is the possibility for some relaxation for facilities with an excellent compliance record. Low risk facilities that have a good compliance history could be inspected at a frequency of around 30 months rather than the previous 24 months.

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

This document 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 was concerned with multi-site GLP studies conducted at UK based test facilities that had a phase at a Canadian facility. The document stated 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.

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UK GLPMA Guidance on the use of non-GLP compliant facilities for the conduct of study phases and notes on the intention not to claim GLP compliance for parts of regulatory studies

This Guidance was revised in October 2010 and included a significant change. If, at the planning stage, it is known that part of an in-house GLP study will be performed in an area that is not on the GLP footprint then the UK GLPMA will need to be informed. Some parts of industry misunderstood elements of the revision and the GLPMA have acknowledged this and plan to update the document for clarity.

UK GLPMA Information document: Retention of study data and supporting records for inspection purposes

This document issued in March 2011 indicates that UK test facilities / test sites must retain data for at least one UK GLPMA inspection cycle (27 months) before sending back to the sponsor / test facility. If data is sent back within this period copies of the data should be retained. The reason for this is to ensure there is data for the UK GLPMA to review during their routine inspection of any particular facility.

OECD Update

India became a full adherent to the OECD MAD agreement on 3 March 2011. Regulatory Authorities are now obliged to accept studies conducted in India (studies started from 3 March 2011). Brazil is also a full adherent to the MAD agreement but only for pesticides and industrial chemicals (from 29 March 2011).

Current provisional adherents to OECD MAD are Argentina, Malaysia and Thailand. Argentina has been assessed (by Mutual Joint Visit) and is awaiting a decision (the scope will be for pesticides and industrial chemicals only). Mutual Joint Visits for Malaysia and Thailand are planned for 2011.

China has not yet approached OECD for provisional adherence status to the MAD agreement; it is likely to be several years before China is a full adherent to OECD MAD.

OECD GLP Discussion Group

Building on the 2008 OECD GLP Event in Frascati, Italy an OECD GLP Discussion Group is to be set up with representation from each member country. The aim of the group is to ensure there is a level international playing field in terms of GLP compliance (to ensure no countries are disadvantaged by local expectations). Each country will have industry representation. In the UK, a representative from BARQA will be in the Group. Representatives will be charged with canvassing their memberships for examples of local interpretation that puts facilities within that country at a disadvantage; the group will then confirm / discuss different areas of expectation; the group will also consider GLP in areas of emerging technologies. The group will operate by means of a password protected OECD web-site. If any proposals for change are recommended it could take about 18 months for changes to go through the approval process.

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OECD Guidance on pathology peer review

A large volume of comments was submitted on the draft document. In addition to industry comment there were differences of opinion among the GLPMAs in some areas of the process. As a consequence, the document will not be issued at this time but will undergo revision prior to circulation for consultation. If agreement can be reached the document will be issued (no sooner than April 2012), otherwise the document will not go forward.

BARQA GLP Activities

In November 2010, BARQA held a successful Annual Meeting in Leeds. GLP highlights included Sponsor / CRO interactions, differences in GLP interpretation and risk-based approach to QA activities. The latter was covered by a presentation and a Workshop in which delegates considered risk-based approaches to critical phase / process-based inspections, internal / external facility inspections and document reviews (protocols and reports).

The BARQA booklet on GCLP has been revised and the revision issued earlier this year. Two other BARQA booklets are in preparation:

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

The BARQA GLP Committee has submitted comments through EQAC (European Quality Assurance Confederation) on the following documents:

- EMA reflection paper on guidance for laboratories that perform analysis or evaluation of clinical trial samples.
- FDA Docket-2010-N-0548 (FDA seeking comment on whether to amend the GLP Regulations)

Be Audit You Can Be

An original cartoon by Carinne Park

Editorial Correction

The cartoon, "Routine Maintenance," published in the Winter 2011 issue of the MARSQA Monitor was contributed by Carinne Park, not Eva Hascz.

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Nominating Committee Update

Fran Jannone, RQAP-GLP, Committee Chair

I volunteered to serve as the Chair of the Nominating Committee in 2006 and have remained in this position ever since. Basically, my responsibility is to provide the MARSQA Board of Directors with a slate of candidates for the open board positions.

There are always two positions open each election for Director and one for Vice President. The Secretary and Treasurer positions alternate each year with an opening for Secretary available for the 2012 election. For those unfamiliar or new to MARSQA, an email notice is sent by the Society of Quality Assurance (SQA) to each MARSQA member seeking volunteers to run for one of the above positions.

The logistics of compiling the ballot, biographies, obtaining board approval (by vote) and sending the entire package to SQA Headquarters staff, who in turn email the members, are fairly simple these days in comparison to my first few years. My first year was quite a learning experience and rather time-consuming, so much so that I used vacation days from my job at Huntingdon Life Sciences to complete the mailing packages. Of course, that was when all the ballots, biographies, envelopes, mailing labels and return address envelopes were prepared by a printer such as Fed Ex Kinko. Afterwards, it was up to myself and a volunteer or two to ensure that each member received the entire contents of the package (ballot, biographies, instruction for voting) and return envelopes for casting their votes. Once the ballots were returned to the President, the Tellers Committee which consisted of the President and Immediate Past President manually counted all the votes independently.

Much has changed since my first year, and all notices and ballots are mailed and tallied electronically. With this improvement, I now can use vacation time as vacation time and MARSQA saves on the expense of printing and mailing.

I would have to conclude that the hardest part of my job on this committee is finding volunteers willing to participate in the election. For those members who have considered running for one of the available positions, I will say that with the support of the current board members the acclimation to the MARSQA board is relatively easy and relaxed. Through the years, I have enjoyed my communication with all those who have taken the initiative to run for office.

One last reminder to all, please remember to keep your email and/or mailing addresses current in order to receive all MARSQA notices.

It's Not Too Early to Think About the 2012 MARSQA Board of Directors Elections!

The 2012 MARSQA Board of Directors Election process will officially begin in August – however it's not too early to start considering whether you would like to run for the 2012 open offices of Vice President, Secretary, and Director (2).

Visit the MARSQA website for the responsibilities and estimated time required for each position, or contact Alyssa Colon, President to discuss these important roles. MARSQA has an experienced group of officers already in place to guide those of you who may be concerned about being new to the Board.

The MARSQA Board of Directors encourages individuals at all levels of experience to consider running for election; all that is needed is a commitment to participate. Note: candidates for VP and Secretary must also be members of SQA to qualify for the ballot.

More information to come starting in August!

Upcoming Membership Meeting!!!

The next MARSQA Membership Meeting will be on September 7 with lunch starting at noon and the event starting at 1pm. The location is the Cock 'n Bull Restaurant in Lahaska, PA. Speakers and topics include:

Nancy Gongliewski, GlaxoSmithKline
Changes in the Skill Sets Required for GLP QA Professionals In The Past 15 Years

Leila Scott, Charles River
Digital Imaging-Validation Challenges in a Regulated Environment

Courtney Rodriguez, Charles River
Challenges Validating and Implementing Global Technologies

Upcoming Membership Meeting: September, 7, 2011 Reserve the Date!!!

Committee Corner: UPDATE!!

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

CSV	Paula Eggert	Paula_Eggert@merck.com
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	Carinne Park	carinnepaige@gmail.com

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!

Congratulations to New Committee Chairs! Thanks to Departing Committee Chairs!

Two of MARSQA's committees have new chairs. The Program Committee, which is responsible for MARSQA membership meetings, will be co-chaired by Tony Borisow and Ranee Henry. The Education Committee which manages MARSQA training sessions will be co-chaired by Stephen Simpson and Dwight Evans. These are very active committees which are responsible for many of MARSQA's key activities.

MARSQA extends sincere thanks to Jane Pasquito (Program) and Joanne Ramundo (Education) who successfully chaired these Committees for many years. Both of these MARSQA members have played a key role in sustaining the society.

PROFILE – Jane Pasquito, Chair Program Committee

Q In your opinion what is the key to happiness?

A I believe the key to happiness is having a positive attitude. I think once you have a positive attitude you draw happiness to yourself. I also believe that by surrounding yourself with friends and family who also have a positive outlook in life, you share in the energy from their happiness as well.

Q What is your all-time favorite movie? Why?

A It Could Happen to You, with Nicolas Cage and Bridget Fonda. It's a feel good movie about a down to earth cop who doesn't have money for a tip but tells the struggling waitress he will split his winnings if his lottery ticket is a winner. Well of course the cop wins, but due to greed, the money is lost to the cop's wife. The cop falls in love with the waitress, both of them now having nothing, when money suddenly pours in from people who read their story of love and hardship in the newspaper…and they lived happily ever after.

Q What do you like most about your current role in QA?

A I really enjoy what I do as an Animal Health Quality Assurance auditor. We don't run the same battery of studies over and over again like they do in human studies. We may want to use the same compound in several different species so our studies always vary. In animal health we audit both GLP and GCP studies. One day we may inspect dogs being infested with fleas and then the next inspection we are at a farm trying to get pigs to eat medicated feed. Didn't think pigs could be so picky…did you? There are even studies where we use mannequin hands to pet dogs to see how much of a topical product could potentially transfer on to a person's hand. It's really spooky

sitting in a conference room with 75 cotton gloved mannequin hands. So what I'm saying is there is always something different to learn in this area, and a lot of different characters to deal with. A farm director (aka farmer) may run the studies while cowboys (just like in the movies) ride horses and collect the data. It's nothing like the controlled laboratory environment of a human study!

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

A It seems to me like quality and compliance in the pharmaceutical world come in waves. Quality and compliance are built up and Big Pharma is doing well. Because they are doing so well they then say, "Why are we paying all this money for quality and compliance," and then they drastically cut these departments. Next you hear in the news of drug recalls and consent decrees and the pattern starts again. I think right now due to the economy we are at a dip in the wave pattern. We are lacking in quality and compliance personnel. I believe in the near future we will see our profession begin to pick up and begin to build again.

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

A It's nice to know I play a role in providing drugs that improve the lives of animals.

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

A I feel it is very important to keep the work and family life balanced. It's very easy to get sucked in to the fast pace of work. But, to keep your sanity you have to balance it out by spending time with the people you care about the most.

Q What's your favorite vacation spot?

A I need three ingredients; the sun, the beach and a drink with an umbrella in it and I am happy!

Q What's your favorite hobby?

A I love to garden. I'm a slave to my yard all summer long. This year my house is on a garden tour and I am freaking out because of the rainy, cold spring and not being out there working enough. The highlights of my yard for the tour are my koi pond and my bird garden.

PROFILE – Ray Borysewicz, Past Director

Q In your opinion what is the key to happiness?

A Health is first and foremost, without health you have nothing. A close second is family and close friends. You need to share your health with people you are close to. Wealth is an added bonus that makes life easier, as long as you have the above. All the wealth in the world can't buy you health and true friends.

Q What is your all-time favorite movie? Why?

A This is an easy one…."Field of Dreams." I love baseball, and this is one of maybe two movies that can moisten my eyes (not fully teared up though ☺)!

Q What do you like most about your current role in QA?

A I work in the Pharmacovigilance arena and also perform GCP system audits. It is a diversified position and I have found PV to be challenging. It is totally global which also allows me to travel the world and to try to understand other cultures. It also gives me a better understanding of the back end of Pharma compared to GLPs. It is a totally different world from what I have audited in my career, it has been an exciting challenge.

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

A This is a tough question in an ever changing environment. At the moment I believe it is a fantastic field to be in. As the economy picks up I already see many more job postings. Also with the added Investigators to the FDA means more inspections, and this has been seen already. A double edged sword of sorts……we don't want to see more inspections, but due to them, the QA function becomes that much more important.

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

A The interaction with our business partners and colleagues has always been an area I enjoy and always try to improve. I always am on a constant learning curve and there is never too much down time. The days fly by and in the PV world there always seems to be new challenges.

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

A I have always thought of this as extremely important, and more so as I move on in years. Family is always first! Without family and health, you really have nothing! I also believe that more companies feel this way as well. The availability of technology has aided in the work-family balance. Many of the meetings today are teleconferenced and global in nature. Working from home, at least part-time seems to becoming more the norm than the unusual. This is great in helping balancing life and saving money to both the employer and employee!

Q What's your favorite vacation spot?

A Any where it is warm, has an ocean/water and is tropical. The older I get the more I dread cold. I have been going to Florida for the past 15 years in November to play in a baseball tournament. This has been fun; we have a great bunch of guys on the team and the wives also come down to enjoy themselves.

Q What's your favorite hobby?

A I still play baseball. I dabble in golf. I also am into aquariums (freshwater). And love pirate history!