



MARSQA Monitor

NEWSLETTER OF THE MID-ATLANTIC REGION SOCIETY OF QUALITY ASSURANCE

Volume 14, Issue 1

WELCOME MARSQA TO 2010!



As I begin this letter, I'm looking back at Past President Lynda Olsen's first letter to the MARSQA Monitor for inspiration, and noticed that 2009 was the Year of the Ox. I think I'm more of a lion kind of guy.... They say it's the month of March that enters like a lion and leaves like a lamb. For MARSQA, I

think the lion likes to show-up a bit early! Already, MARSQA has seen an unprecedented nail-biter of an election for the 2010 Board positions. The MARSQA Website is beginning to return to form behind the efforts of the 2009 MARSQA board, as well as the newly formed Website Committee. The competition for the Annual Award to the 2010 SQA Meeting in Cincinnati is well underway (and perhaps will be decided by the time this article hits the cyberspace newsstands), and meeting and training dates are being finalized as I write this letter. Welcome aboard Mr. President, keep your feet inside at all times, please hold onto the bars and enjoy the ride! And I sincerely thank the MARSQA membership for giving me the opportunity to do so by serving you in this position.

Among the planned meetings I mentioned above was the first face-to-face transition meeting of the MARSQA Board. That being said, I'd like to take this opportunity to thank Past President Lynda Olsen and outgoing Past President Janet Emeigh for their

efforts in steering the organization over the past couple of years. I'd also like to welcome our new Board members: Alyssa Colon will be serving as your Vice-President (and will choose whether next year's animal theme will be Tigers or Bears), and Lynne Watkins will join Ray Borysewicz, Ranee Henry and Melissa Elliott as your Directors. Also, Mike Franks will continue to serve as your Treasurer, and Nancy Beck will remain as your Board Secretary. Finally, my thanks to all the members who stepped-up to run for office, as well as the countless Committee volunteers that donate their time to plan our meetings, book our speakers, write our newsletters, bring fresh ideas to the table, and keep MARSQA young and running!

There are a lot of opportunities for forward progress in 2010. As President, I hope to continue steering MARSQA in a direction that represents the desires of the membership. Via the membership survey conducted in 2009, the board has heard the voice of the membership. That being said, we need to continue to hear your comments, concerns and ideas to make MARSQA even better. Even better, we hope that you'll decide to either join-in on or continue to support the organization through participation. Ask the Board or any Committee chair about endless, available opportunities. Career development, networking opportunities, camaraderie with your fellow QA professionals – any time you put in will pay off in dividends for both you and for MARSQA.

Tony Borisow
President

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HERE'S A CHANCE TO GET YOUR MESSAGE ACROSS



MARSQA's Program Committee organizes three excellent and well attended membership meetings per year.

Would you like to be part of this effort? Are you interested in giving a presentation? Do you have an idea that would provide a theme or topic for an entire meeting? Would you like to volunteer to help organize and manage a meeting?

If the answer to any of these questions is yes, just e-mail Jane Pasquito, Program Committee Chair at jane.pasquito@spcorp.com

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.

2010 MARSQA OFFICERS

PRESIDENT

Anthony Borisow
aborisow@its.jnj.com

VICE PRESIDENT

Alyssa Colon, RQAP-GLP
alyssa.colon@roche.com

PAST PRESIDENT

Lynda Olsen
lynda.olsen@spcorp.com

TREASURER

Michael Franks
michael.franks@qaresources.net

SECRETARY

Nancy Beck, RQAP-GLP
nancy.beck@bms.com

DIRECTORS

Raymond Borysewicz
rborysew@its.jnj.com

Melissa Elliott, RQAP-GLP
elliottm@princeton.huntingdon.com

Ranee Henry
ranee.henry@crl.com

Lynne Watkins, MS, PMP, RQAP-GLP
lwatkins@its.jnj.com

Tony Borisow, MARSQA President

Almost a year ago, a membership survey was distributed to those in attendance at the March 2009 Membership meeting hosted in Lahaska, PA. The survey was given with the hope that you would share your thoughts and opinions on a variety of topics related to the value of your membership and the direction you feel MARSQA should take..... And share you did! The results of the surveys collected were tabulated and presented at the July 2009 Membership meeting in Lahaska. With a new year upon us and a new Board in place for 2010, I'd like to re-present the results of the 2009 survey to everyone again in the Monitor.

Considering that a year has gone by since the survey was initially distributed, and taking into consideration that the survey's initial distribution was limited to those in attendance at the March 2009 meeting, I invite everyone to continue to provide the Board with your valuable feedback! A copy of this survey has been posted to the MARSQA website for the purposes of providing the Board your thoughts. Better yet, feel free to contact any (and every) Board member with your ideas and opinions on things we can do to help continuously improve our MARSQA community!



Membership Survey

Background

Are you a member of MARSQA?	49	1-5 Years Experience: 18 Members
Are you a member of SQA?	39	6-10 Years Experience: 9 Members
		11-20 Years Experience: 9 Members
		20+ Years Experience: 5 Members

Average Experience: 10 Years

Please Identify Your Current Position and Responsibilities

<u>Position</u>	<u>Responsibilities</u> <i>(all that apply)</i>
1 Computer Systems Auditor	4 Animal Welfare
2 Laboratory Management	4 Controlled Substances
32 QA Auditor	18 EPA GLP
7 QA Management	39 FDA GLP
2 Validation Specialist	10 GCP
3 Compliance Manager	5 GMP
1 QA Coordinator	27 OECD
1 QC Analyst	16 Training
1 Consultant	15 Validation
1 Study Director	1 Document Control Management
1 Retired	1 Process Development

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- Do you feel the 2008 MARSQA elected board was effective in steering the organization?
 - YES 46
 - Not a Member 2

- Do you feel \$50 is a good value for your MARSQA dues?
 - YES 47
 - Not a member 2
 - Undecided 1

- For those whose company subsidizes their MARSQA membership, would you continue to renew your membership if you had to pay your dues out of pocket?
 - YES 30

WHY?
Valuable Resource and Networking
Value/Price
Keep up-to-date on current issues

 - NO 7

WHY NOT?
Current Economy
Belong to several other professional organizations

- How often do you visit the MARSQA website per year?
 - 5 – 10 times: 30
 - 11 – 20 times: 6
 - Greater than 20: 3
 - Rarely or Never 13

- How often do you usually attend MARSQA meetings in a year?
 - 1 time 6
 - 2 times 24
 - 3 times 20
 - Never 0

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If applicable, what keeps you from attending the number of meetings that you would like to attend?

- Time availability 28
- Distance 8
- Topics not interesting/applicable 11
- Weather 1
- Meetings not in scheduled early enough 2
- Limitations set by employer/management 3

If you had the option, is there something specific you would change about the MARSQA meeting format?

- Rotate meeting sites
 - Earlier start time for meetings
 - Lunch after discussions
 - More time dedicated to socializing, training / business
-
- In the past year, have you offered to volunteer in any capacity with MARSQA (committee participation, meeting presentation, etc.)?
 - YES 13
 - NO 37

 - If you did offer to volunteer your time in the past year, did a MARSQA representative contact you about your interest in volunteering?
 - YES – I was contacted 9
 - NO – I was not contacted 1

 - Did you vote in the 2009 MARSQA election?
 - YES 32
 - NO 19

If no, what was your reason for not participating this year?

- Did not know candidates
- Forgot
- Time

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• What do you feel that MARSQA is ‘doing right’ (choose all that apply)?

- Interesting topics presented at meetings 34
- Frequency of meetings is acceptable. 41
- Good diversity of courses presented 31
- Attention to evolving needs of membership 1
- Location of meetings 2
- Getting Newsletter back 1

• What areas do feel MARSQA can improve upon (choose all that apply)?

- More relevant topics at training or Quarterly meetings 9
 - *GCP*
 - *Analytical*
 - *Incurred Sample Analysis*
 - *Biotech Studies (GLP)*
 - *Leadership*
 - *International auditing/regulatory environment*
 - *Multisite Study responsibilities*
- Monthly highlights of MARSQA’s activities from the board. 11
- More high profile speakers (e.g. FDA speakers) 32
- Ice breakers and activities aimed at networking at the meetings 14
 - *Add “Hot Topics” session for participants to discuss current issues or experiences*
 - *Roundtable meeting on selected topics*
 - *One “No” vote*
- Courses aimed at improving auditing skills 24
 - *GCP & GMP trainings*
 - *Advanced level trainings*
- Website update 19
- Discussions in lieu of talks* 1
- Annual Anniversary Meeting* 1
- Timeliness of website update and yearly agenda* 1
- 483 info on website* 1
- Involve members from outer reaches of MARSQA area* 1
- Add MARSQA to “Linked-in” as SQA is* 1

• Additional comments?

Discussion groups on MARSQA website
 Sign-up issues on MARSQA website an issue

Betty DeLise

MARSQA Member



The quality of the observation determines the quality of the corrective action. The nature of writing is a complex process, is dependent on the individual who is doing the writing, and can therefore be fraught with inconsistencies among individuals. “Inconsistency is the only thing in which men are consistent” (Horace Smith). One of the biggest challenges in QA is consistency among auditors - speaking with one voice. We’re not robots or computers – we are human. As QA professionals, we are always striving to be as consistent as possible. It’s something our Business Partners/Clients/Study Directors/Management ask of us. With organizations who are working globally, consistency can be even more critical in order for Management to assess compliance across all sites and to be assured that consistent QA technique and processes are facilitating that assessment.

For these reasons, it is imperative to establish a standard for writing observations within your quality organization. An established standard for writing observations provides for increased consistency among auditors, consistency in trending observations, consistency in what is considered an observation, improved quality of corrective actions, and ultimately a clear, consistent picture of compliance in the organization. The standard that I will be discussing is called the ANSWER Method. By following the ANSWER Method, the reader will be able to see things in their mind as clearly as if they were seeing it with their own eyes.

So what is the ANSWER Method?

ANSWER is an acronym – Activity, Nature, Sample, Where, Evidence, Requirement. It’s a standard method for writing observations that incorporates key components necessary for writing clear, concise, easily understood observations.

ANSWER

<u>A</u>ctivity	What activity is being audited?	e.g., Protocol, Protocol Amendment, In-life activity, Report/Raw Data, System, CRO/Vendor, etc.
<u>N</u>ature	What is the nature of the concern?	Detailed description.
<u>S</u>ample	What was the sample size?	e.g., 1 of 8 balances, 3 of 10 animals, etc.
<u>W</u>here	Where were these activities taking place?	e.g., Report/Raw Data Audit, System Audit, Formulations Laboratory, Experimental Phase Inspection, etc.
<u>E</u>vidence	What objective evidence has been collected?	Detailed description.
<u>R</u>equirement	Where is the requirement defined?	e.g., SOP, Protocol, FDA GLP, OECD GLP requirements with supporting text reference.

If you follow this method of writing and ensure you’ve incorporated all of the applicable components of ANSWER into your observation it will improve the quality of the corrective action, improve trending consistency, and achieve improved consistency among auditors in writing observations. The observations will speak for themselves. There will no longer be a need to have additional explanations from the auditor in order to understand the concern. By following the ANSWER Method, any reader can understand the observation and immediately visually reconstruct the situation and fully understand the significance and criticality of it. This drives improved corrective actions and relevant action from Management when warranted.

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I. Example Observation according to ANSWER:

While auditing the weighing of a test item (A) in the formulation lab (W) it was observed that 1 balance of the 5 sampled (S) has not been calibrated yearly (N) as required by SOP-001 (R). The last calibration was conducted 2 years ago (E).

Activity	What activity is being audited? e.g., Weighing of test item
Nature	What is the nature of the concern? e.g., Balance accuracy
Sample	What was the sample size? e.g., Looked at 5 balances
Where	Where were these activities taking place? e.g., In Formulation Lab
Evidence	What objective evidence has been collected? e.g., Last calibration was 2 years ago for 1 balance
Requirement	Where is the requirement defined? e.g., SOP 001 requires yearly calibration

There are some additional, common sense, items to consider when writing observations according to ANSWER:

II. ANSWER and Common Sense:

Activity	What activity is being audited?
Nature	What is the nature of the concern?
Sample	What was the sample size? Not applicable for protocol and report audits.
Where	Where were these activities taking place? Not applicable for protocol and report audits.
Evidence	What objective evidence has been collected?
Requirement	Where is the requirement defined? Not applicable for internal inconsistencies.

III. Example Observation NOT following ANSWER:

Inspection reports were not distributed (N) to the Study Director on the dates specified on the QA Statement (N).

Option a:

The inspection reports were not distributed to the Study Director.

Option b:

The inspection reports were distributed to the study director, but the dates are not mentioned correctly on the QA Statement.

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Analysis:

Nature: There are actually 2 different potential concerns listed in this example observation. It's not clear which one is correct.

Activity: Missing.

Evidence: Not enough details (for the person who wrote the observation it's clear, however we should ask ourselves whether it is also clear to people not involved in the audit).

Requirement: Missing.

(Sample and Where: Not applicable in this case since it was a report/raw data audit; although the reader can't tell this since the Activity is missing.)

Because the observation is not described according to ANSWER, there are different options for interpretation by the reader, trending by the auditor, and corrective action from the business.

Trending:

Option a might be trended more significantly because it concerns a deviation to the GLP regulations.

Option b might be trended as less significant since it is an internal inconsistency.

Corrected Observation According to ANSWER - Option a:

During report / raw data review (A) a deviation to the GLP regulations (N) was noticed. FDA Subpart B, 58.35 on Quality Assurance mentions "Periodically submit to management and the study director written status reports on each study noting any problems and the corrective actions taken"(R). It was noticed however that the inspection reports were not distributed to the Study Director (E).

Corrected Observation According to ANSWER - Option b:

During report / raw data review (A) an inconsistency was noticed between the date when the inspection report was reported to the study director and the date mentioned on the QA statement (N). Inspection report xyz was distributed to the study director on DDMMMYYYY, however the QA statement mentioned DDMMMYYYY(E).

This example shows how the method for writing an observation can affect interpretation, trending, and corrective action received.

IV. Let's take another look at ANSWER:

<u>Activity</u>	Tells the reader what type of audit we're talking about.
<u>Nature</u>	Think BIG PICTURE when writing the observation. Is it capturing the root cause of the issue?
<u>Sample</u>	Indication of how rampant the issue is. A complete process break-down, or just 1 missed? Minor error, mistake?
<u>Where</u>	Helps with visual reconstruction for the reader, tells the story, gives context.
<u>Evidence</u>	Backbone of observation.
<u>Requirement</u>	If there's no Requirement, is it an observation? Is there a need for an SOP? This is the component that stops invalid observations from being written.

Of course consistency in observation writing can only occur after adequate preparation and skilled performance of the audit. Adequate execution of these steps is imperative to effectively evaluate the audit results and write your observations using the ANSWER method. ANSWER should be in the back of the auditor's mind while performing the audit to be sure all of the pieces required to write up an observation are gathered during the conduct of the audit. Remember, the quality of the observation determines the quality of the corrective action.

Mark Goodwin
BARQA Member

There has been a lot of GLP activity in the UK over the last few months. In particular the UK GLPMA implemented their risk based inspection strategy, issued further guidance and ran an industry symposium. BARQA issued two guidance documents and ran the successful annual conference.



UK MHRA risk- based inspection strategy

This is part of a government wide initiative aimed for better regulation. The MHRA, following industry consultation, implemented their strategy 1 April 2009. The aims were to make best use of resources for protection of public health, target poor compliance and perform no inspection without a reason. The different Inspectorates (e.g. for GLP, GCP, GMP and Pharmacovigilance) tailored the strategy to meet their own needs. From the GLP perspective, inspections of UK facilities will continue to be at least once every 2 years as this is generally the norm in OECD countries. The risk factor (derived from regulatory intelligence including inspection history, nature/volume of work and notification of significant changes) determines the frequency, duration and scope of the inspection. Some companies with a good inspection history will still be high risk due to the nature / volume of work and are inspected every year. At a recent stakeholder meeting, the following GLPMA update was provided.

- 38 inspections subject to RBI approach – 3 facilities had next inspection brought forward due to poor compliance
- Facilities with good compliance will not see a difference until next inspection (e.g. scope and duration of inspection may change)
- Completion of ‘Notification of changes’ forms has lead to the date and/or scope of some inspections being changed
- Processes will continue to be modified in light of experience

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

This document is relevant to the pharmaceutical sector and is concerned with multi-site GLP studies conducted at UK based test facilities that have a phase at a Canadian facility. Unless the GLP status of the Canadian facility can be verified (i.e. inspection by the responsible Canadian Government Agency), then no GLP compliance claim can be made for the phase of the study.

Possible future UK GLPMA guidance on GLP compliance in a paperless environment

This guidance will not be concerned with computer validation but with how to comply with GLP in a paperless environment. Areas covered would include protocols, reports, electronic archiving and electronic signatures. There could be some form of industry involvement.

UK MHRA involvement in BARQA annual conference (GLP aspects)

The following points were personal views of two GLPMA Inspectors and a preclinical GLP assessor.

The Inspector supported a risk-based approach to QA activities (providing compliance with Regulations are maintained). This could be achieved by spending more time in areas of poorer compliance and less time in others, focusing on complex studies / processes and by QA driving quality improvement through consultancy. This could lead to more effective use of QA resource (e.g. in an area previously inspected with good compliance ask questions to verify no change in status then move on).

The second Inspector considered that the GLP Principles were out of date, particularly the QA section and the lack of information around QC. The Inspector also highlighted areas in which industry could generally improve:

- robust systems for dealing with deviations from analytical expectations

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- File notes and deviations are often poorly written; what is written down must fully reflect the situation / issue
- Ineffective QA in terms of audit findings close-out and effective use of CAPA
- Business should use QA information (audit results and trends) for process improvement
- Tools in place to support compliance status i.e. how can you demonstrate that you are highly compliant

The MHRA preclinical assessor confirmed that ADME studies do not need to be done to GLP, acknowledged that some specialist work can only be done in non-GLP labs and that they would not be too perturbed if GLP was not applied in 'grey area' situations as GLP is a means to an end. The Assessor did require clarity in reporting GLP studies, particularly around:

- responsibilities
- sub-contracting of any phases
- SD responsibility for ensuring compliance of subcontractors
- deviations and affect on validity of the study
- justification of conclusions
- whether contributing labs are party to OECD MAD

MHRA Symposium (20 – 21 January 2010)

Day 1 was dedicated to GLP and Day 2 to GCP for Clinical Laboratories. Key points from the GLP day are given below.

Risk-based QA program – documentation should be in place to support the program particularly for a 'reduced' program; consider both the likelihood of compliance issues occurring and the consequence of compliance issues if they did occur; consider wider implications of findings to prevent repeats in other areas/studies. Five minutes of QC could save an hour later down the line. QA role is a positive, proactive role.

UK GLPMA Interactions – impart knowledge to the six UK Receiving Authorities (annual meeting); interact with industry in various ways (e.g. training, conferences, annual GLP Consultative Committee meeting; correspondence); representation on EC and OECD GLP Working Groups. Q&A section is soon to be added to GLPMA web-site.

Multi-site studies – ensure the part of the test site that will conduct the study phase is on the GLP footprint
UK GLP Deficiencies (2009 up to November)

- Five critical deficiencies (2 study conduct; 2 organisation & personnel and 1 QA)
- 26 major deficiencies (6 QA; 5 archive; 5 computer systems; 4 study conduct; 4 organisation & personnel; 2 facilities)
- Deficiencies: 31% study conduct; 23% organisation & personnel; 18% facilities; 10% QA; 8% archives; 7% computer systems; 3% SOPs
- In recent years there has been escalation of major deficiencies to critical deficiencies and of deficiencies to major deficiencies due to agreed CAPAs not being implemented

BARQA GLP Activities

Two BARQA Guidance Booklets have recently been published:

- *A Guide to the Role & Responsibilities of GLP Management*
- *Hosting an External GLP Inspection*

OECD Update

Health Canada has sanctioned the Standards Council of Canada to assume responsibility for the GLP compliance monitoring of facilities that test pharmaceutical products from 22 June 2009. Inspections began in August 2009.

Current provisional adherents to the OECD Mutual Acceptance of Data Agreement are Argentina, Brazil, Malaysia and India. India was subject to a mutual joint visit in 2009 and will be re-assessed. China is not a provisional adherent but is starting to work with OECD to progress the process.

Alyssa Colón, RQAP-GLP

MARSQA Vice-President

On October 28, 2009, I attended MARSQA's Advanced GLP Training for Managing Multi-Site Studies session. This one-day training assisted in identifying and developing solutions to global compliance issues that many of us face in our day-to-day work. Although the GLP regulations have remained the same, compliance has become more challenging due to the global nature of the industries governed by the regulations.

Some of the topics and issues discussed included:

- A review of the roles and responsibilities outlined in: “OECD Principles on Good Laboratory Practice (Number 1) and “ The Application of the OECD Principles of GLP to the Organization and Management of Multi-site Studies” (Number 13)
- Planning and preparing for a multi-site study
- Challenges in study conduct and communication
- Data Management and Archiving
- Establishing Lead and Test Site QA roles
- Evaluation of Part 11 Compliance
- Inspection Readiness
- Utilizing non-OECD member facilities

Some of the lessons that I took away from this training were:

- Communication is critical between all the participants on the studies; this includes QA!
- Ensuring Study Director awareness on the study is key! Documented evidence of this awareness is critical to assuring Study Director involvement.
- OECDs are not regulations. They are a guidance on how to achieve the goals of the GLPs, especially in a global business environment. The OECD guidances only become regulations/law when adopted by a country.
- Be in a constant state of inspection readiness!

Overall, the session and the presenters were very interesting, however the participation from the trainees was probably one of the highlights from the meeting. The questions and dialog between the audience and the presenters brought this training to, in my opinion, that next level. As we all sit in various training sessions, we tend to hear all about the problems we face within our industry, but we rarely hear how others are solving these problems. This training started that dialog. The QA world is filled with so many individuals that have valuable experiences, so to see the ideas being shared outside of a structured presentation was the most valuable thing I took away from this meeting.

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 seven committees. They are listed below along with the Chair(s) for each.

Communications	Jane Goeke	jane.goeke-1@gsk.com
CVC	Ranee Henry	ranee.henry@crl.com
	Paula Eggert	paula_eggert@merck.com
Education	Joanne Ramundo	joanne.ramundo@sanofi-aventis.com
Historical	Fran Jannone	jannonef@princeton.huntingdon.com
Membership	Janet Emeigh	jemeigh@medarex.com
Nominating	Fran Jannone	jannonef@princeton.huntingdon.com
Program/Planning	Jane Pasquito	jane.pasquito@spcorp.com

Additionally, a committee is being formed to oversee the website. For information contact Tony Borisow at the hyperlink on the MARSQA website.

MARSQA activities and projects are driven to a great extent by its committees. And, most of the members of these committees are volunteers. For this edition of the MARSQA Monitor, Paula Eggert reports on her experiences as a member of the Computer Validation Committee.

MARSQA Computer Validation Committee

Paula Eggert

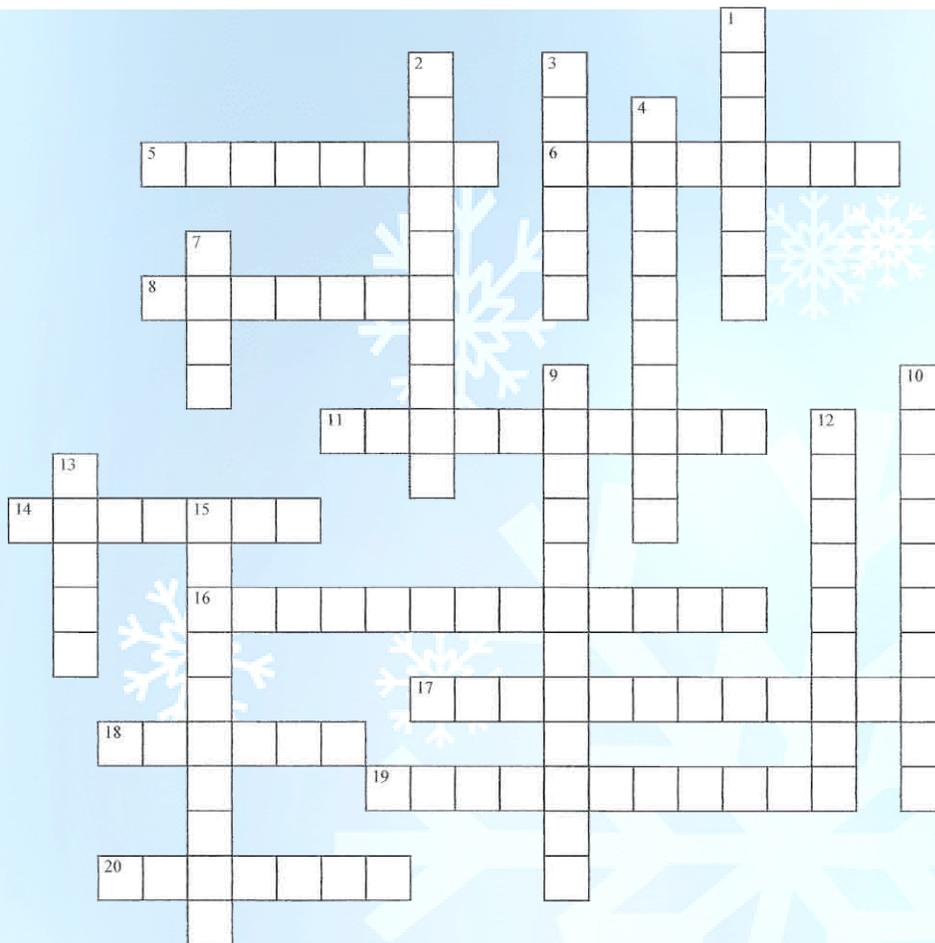
MARSQA Member

The MARSQA Computer Validation Committee (CVC) contains members from a wide spectrum of businesses in the industry. Some examples include personnel from pharmaceutical companies, contract lab organizations, hospitals, consultation firms, and research and development laboratories, just to name a few. The group generally convenes once per quarter via teleconference with document-sharing technology as needed. We are given the opportunity to create a meeting agenda that may encompass presentations as well as discussions regarding issues or interpretation of regulatory expectations for computer validation.

The time commitment for participation in the committee is minimal with a beneficial return on investment since the member interactions provide a resource of information outside your own company. The discussions may offer a new viewpoint, recommendation, or even an industry best practice that may be useful for implementation in my own job. The group encourages the sharing of opinions and experiences, and are instrumental in offering alternative solutions for issues. In addition to our quarterly meetings, some members of the team will send out a group e-mail requesting opinions on an issue. Resources gained from the team are really invaluable to me in order to keep current with computer validation in the industry!

MARSQA CROSSWORD PUZZLE

ANSWER KEY
ON PAGE 15



ACROSS

- 5** Practice of taking selected items or units from a total population of items or units.
6 Criterion or level of requirement, excellence or attainment used as the basis for the audit.
8 Permission to proceed to the next stage of a process.
11 Fulfillment of a requirement.
14 Degree to which a set of characteristics fulfills requirements.
16 Document stating requirement.
17 Confirmation through evidence & fulfillment of requirements.
18 Document stating results achieved or providing evidence of activities performed.
19 Need or expectation that is stated, generally implied or obligatory.
20 Set of related activities which transforms inputs into outputs.

DOWN

- 1** Results of a process.
2 Coordinated activities to direct & control an organization.
3 Set of interrelated or interacting elements.
4 Confirmation through the provision of objective evidence that requirements for a specific intended use have been fulfilled.
7 Determination of one of more characteristics according to a procedure.
9 Ability to trace the history, application or location of that which is under consideration.
10 Relationship between a result achieved and resources used.
12 Set of notes or instructions about specific things with specific questions to ask and specific techniques to use during an audit.
13 Systematic independent documented process to obtain evidence & evaluate it objectively.
15 Conformity evaluation by observation & judgment followed by measurement, testing or gauging.

MEET MARSQA MARTHA!



Introducing the new Dear Martha (MARSQA Martha) column!

Do you ever have those questions about quality assurance that you are dying to ask, but you don't have the guts to stand up at meetings and ask or you feel uncomfortable asking a peer or boss or do not have the time to research and find an answer on your own?

Now is the chance for you to ask those questions — Ask MARSQA Martha! Just send your questions to askmartha@marsqa.org

You can request that your question be included in the newsletter anonymously or signed by a name of your choosing. The Communications Committee will research and MARSQA Martha will answer your questions in the next MARSQA newsletter.

FORWARD PROGRESS FOR THE MARSQA WEBSITE!

It's a New Year! And through the efforts of dedicated MARSQA Members and SQA, the MARSQA Website is charging back!

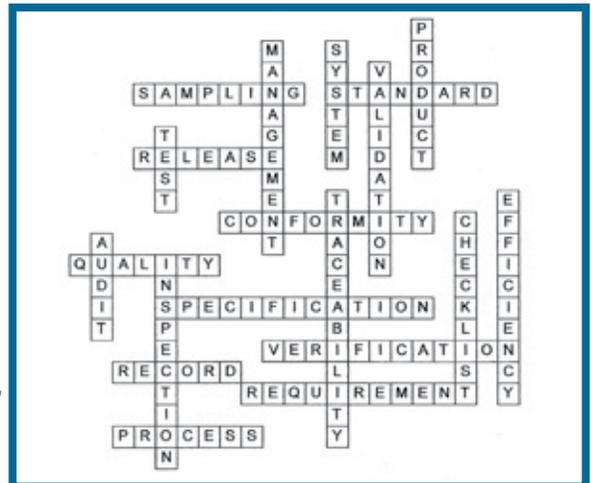
- The 2008 and 2009 issues of the MARSQA Monitor have been added in the Members Section
- Board and Committee rosters have been updated and Email hyperlinks repaired on the Home Page
- MARSQA's Operating Guidelines have been updated



Check out the MARSQA Website, and keep checking back for further progress at <http://www.marsqa.org/> !

Want to help keep the website charging ahead?
Join the newly formed Website Committee!
Contact the MARSQA President, Tony Borisow
(aborisow@prdus.jnj.com) for more details!

MARSQA Crossword Puzzle Answers



Announcements

UPCOMING MEMBERSHIP MEETINGS

MARCH 16, 2010- MARSQA Membership Meeting at Cock'n Bull in Lahaska, PA. For more information download the meeting agenda at <http://www.marsqa.org/meetings/2010/MARSQAFlyer-Mar10.doc>

MAY 18, 2010. Personal Development and Effectiveness for Quality Assurance Professionals at Cock'n Bull Restaurant in Lahaska, PA. This training is presented by Tony Jones and Krystyjana Dwyer, Taylor Technology, Inc. a Pharmanet Company. For more information download the flyer at <http://www.marsqa.org/meetings/DevTraining2010.doc>

MARSQA AMBASSADOR AWARD

Read all about it! Nominate that deserving someone.

Did you know that MARSQA offers an annual recognition award to members who have performed notable and continued service to the organization? To qualify for the award, the recipient must have been a member of MARSQA for at least five years, must have served as an Officer, Director or Committee Member within the last five years and must have made a significant contribution to MARSQA that resulted in positive growth and development of the organization.

The award is presented at the last membership meeting of the year. Nominations must come from current MARSQA members and should be addressed to the MARSQA President no later than August 15. No self nominations, please.

All nominations go to Tony Borisow at aborisow@its.jnj.com

SUPPORT/ADVERTISE IN THE MARSQA MONITOR!

The Communications 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, Communications Committee Chair at jane.goeke-1@gsk.com. Other members of the committee are: Kim Evans, Kimberly Lytle, Rachel McGowan, Myhan Nguyen, Ana-Maria Rodriguez-Rojas and Denise White, RQAP-GLP. Ray Borysewicz the board liason.

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.