



MARSQA Monitor

NEWSLETTER OF THE MID-ATLANTIC REGION SOCIETY OF QUALITY ASSURANCE

Volume 14, Issue 3

LOOKING FORWARD TO 2011



Time does just fly on by, does it not? Summer seems like it was here just yesterday, yet the trees and my local apple orchard are long since bare. Halloween decorations have already been packed away with the thoughts of the festive holidays ahead! And I'm already wondering if I'll be as fortunate as my colleague

was back in February when she missed a nor'easter while conducting a site audit in Puerto Rico, or will I have a repeat performance of my San Antonio trip and lock the keys in the rental car again. Ah, audit travel. The collective stories we could put together!

This time of year is also an eventful one for MARSQA! Firstly, we can look forward to gathering together for our November membership meeting. It's always a great opportunity to get out of the office, re-connect with past colleagues, make new acquaintances, share experiences, and expand our knowledge base through our presenters. November also marks election time - don't forget to vote for the two open Director slots, the Treasurer and the Vice-President for 2011! With that I'd like to welcome Alyssa Colon into the position of President for 2011, and to thank all of the Board Members whom I had the pleasure to work with in 2010.

The end of the year is also a time to give and to receive... so don't forget that this is the time to begin thinking about the annual SQA Award! The 2011 SQA Annual Meeting and Training will be held in San Antonio (remember; don't lock your keys in the car!).

What an opportunity to network nationally, attend multiple sessions and view countless presentations on a wide variety of GXP topics, all under the backdrop of the San Antonio Riverwalk and the Alamo! In this economic climate, an award that potentially could cover most if not all of your expenses is a fantastic deal! And all you need to do is write a page on why you want to go! I hope to see tons of one-page letters come the beginning of next year! In the same vein, remember MARSQA also offers an RQAP award for those of you thinking about taking the exam this year! As I said in my last letter - take advantage of the perks that your membership fees offer! Read up about all of these items in our new web space on the SQA website.... Or tell your friends on MARSQA's Linked-In group page!

Being this is my last letter to everyone as MARSQA President, I can't help but look back on the past year at all of the hard work that so many people put in to make 2010 a great year for the organization. To all the Committee members and MARSQA members who worked behind the scenes to bring us our newsletters, events, trainings, elections, technological advances, implemented ideas for awards and enhanced communications, ran for office, joined a committee, helped to form a committee... thank you all for getting involved! To all that took time to volunteer to present and scribe at our March Roundtable session, as well as our July and November meetings - thank you for your time and for sharing your experiences! Bottom line is the success of MARSQA rests on the Membership's shoulders, and we did a great job in 2010. Let's keep the ball rolling! And to all MARSQA members, thank you for allowing me to serve as President. It has been an honor.

INSIDE:

SQA Special
Symposium....3

Man Overboard.....6

Pharmacovigilance
Auditing.....10

Committee Corner....12

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.



154 Hansen Road, Suite 201 Charlottesville, VA 22911
Phone: (434) 297-4772 Fax: (434) 977-1856
www.marsqa.org

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

Jane Goeke

MARSQA Newsletter Committee Chair

SQA held a special symposium on October 11/12 in San Jose, California. The theme was “Achieving Consistency in GLP Inspections and Common Regulatory Interpretations”.

The meeting was well attended (approximately 90 persons) with a mix of representatives from Pharma, Chemical, CRO and Regulatory entities.

The purpose of the symposium was to consider the manner in which varying sets of GLPs and varying interpretations of GLPs have impacted business. In addition to airing out concerns, the symposium provided regulators with the opportunity to discuss their rationale as well as ways to ameliorate conflicts.

Topics

The various presentations were interspersed with panel discussions and extensive Q&A discussions. Three key areas were focused on: 1) Differences in GLP Requirements, Enforcement and Interpretations; 2) The challenge of using accreditation groups to conduct GLP monitoring; 3) OECD, EU, EPA and FDA views on achieving consistency on mutual visits, enforcement and data acceptance.

While many similarities were noted in various GLP models, the most significant areas of difference appear to be:

- Study director role
- Multisite studies
- Inspection types
- Level of detail
- Signature requirements
- Record retention

The differences in enforcement of GLP requirements was a somewhat more complex topic. The most troublesome areas of difference discussed were:

- Effects of enforcement differences on multinational companies. Some of the items noted include: observations not really related to regulations, observations more about business

issues than regulatory and observations based on science not compliance.

- Issues with documenting inspectional activities
- Issues with post - inspectional activities
- Differences in enforcement approaches and consequences

The presentation on Inspectors’ interpretations of GLP requirements from an industry perspective suggested reasons for the variety of interpretations and several ways this might be addressed. The presenter also suggested that these differences make it very difficult for multinational companies to do business including the ability to efficiently generate a global study report. Differences in interpretations of GLP requirements were noted to exist among countries, within countries (by state, by agency) and by investigator. Additionally, new monitoring authorities and new investigators seem to be a significant source of variance in regulatory interpretation. Some interpretations seem to arise as a response to a specific problem or situation as well as a shift in opinion within an agency over time. This situation could be improved by better training within agencies and better communication among agencies. An ICH Consensus document on GLP could also be helpful as well as interagency discussions and formal agreements..

Many countries are using accreditation bodies instead of government agencies to monitor GLP compliance. This has presented difficulties including the fact that some accreditation bodies do not understand GLP very well and often confuse it with ISO (especially ISO 17025). The ISO position is that GLP is a quality system concerned with organizational processes and does not concern itself with technical validity or laboratory competence.

The OECD/EU presentations focused on mutual joint visits and ways to achieve consistency among the European Monitoring authorities. A balanced presentation on the value of the Mutual Joint Visit Program in the EU pointed out both pros and cons including:

Pros:

- informative and educational
- some new monitoring authorities were discovered
- improved personal relationships among regulators
- advantageous to the less experienced monitoring authorities

Cons:

- violation of Mutual Joint Visit procedures during visits
- expense
- poor interactions between monitoring and regulatory authorities in many countries

The presentation on EU efforts to achieve greater consistency among European Monitoring Authorities indicated that the European Commission's GLP Working Group would be putting greater effort into harmonizing GLP interpretations. Interpretations and requirements for the following areas seemed most in need of alignment:

- multiple monitoring authorities within a country
- multiple enforcement/assessment bodies – government, accreditation and a mixture of both
- growing gap between modern IT use versus its use in a GLP environment
- test facility versus test site QAU responsibilities
- different archiving times and conflict between regulatory and commercial law
- no harmonization on certifying test facilities in non-GLP countries
- confusion about application of GLP to new research fields

There were two agency presentations, one from EPA (Frances Liem) and one from FDA (CT Viswanathan) which considered how changes in GLP are affecting enforcement and mutual acceptance of data. Ms. Liem's presentation focused on enforcing EPA GLPs in the US and other countries. The FDA presentation included very specific views on two topics:

a) Reporting Studies

1. All contributing scientist reports are to be completed and signed prior to being used by the study director to compile the final report. This applies to both internal and external contributing scientists (single and multisite studies).

2. Draft reports should not be sent to sponsors for comment until all contributing scientist reports are signed.
3. When draft reports are sent to Sponsors for comment, FDA expects the draft report and all correspondence from the Sponsor to be archived (note: EPA has always required this under section 160.90 "Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, shall also be retained").
4. Pathology Peer review should only be done using signed pathology reports. As per the pathologist exemption, only the slides and signed final report constitute the raw data. Therefore, without a signed report, there is no raw data or report.
5. Reports must be written for all studies – even those terminated or if a compound is discontinued. The concern is that many of these compounds resurface at a later date. Based upon the status of the closed study (almost complete, test article already in humans), latitude is allowed in the length and complexity of the report.

Note: These requirements appear to be driven by FDA's concern for "undue influence" being exerted upon study directors especially by Sponsors. This was seconded by several meeting attendees who have seen evidence of "undue influence". Some Sponsors complained that CROs are writing reports with almost no interpretations to avoid this.

b) Mutual Acceptance of Data

FDA has concerns regarding the OECD Mutual Site Visit Program as well as various national certification and accreditation programs. FDA feels that OECD programs are based too much on process and not enough on data quality. To support this, detail was provided about 3 recent FDA inspections conducted abroad. The labs were accredited by recently established monitoring authorities as well as by more mature authorities.

Case 1

- organs missing so unable to conduct proper histology
- study director not qualified to conduct inhalation studies

- study director knows nothing about in life facility and histology contractor (not involved in decision to use)
- no SOP to evaluate target organs
- pathology report signed by pathologist's manager who was not a pathologist
- QAU inadequate – did not note any of the above problems

Case 2

- two juvenile studies to evaluate brain exposure
- one study done in US/one study outside
- higher exposure to TA noted in US study
- sponsor accepts study done outside US
- for study conducted outside US, no validated method to evaluate exposure
- unacceptable quality control

Case 3

- spontaneous malformations in control and treated group underreported (do not match historical data)
- no explanation for lower than expected rate of malformations
- staff not trained
- affected about 100 studies

FDA does support cooperative inspections. But, there are concerns:

- not all monitoring authorities are equal and GLP principles are not effectively enforced
- compliance certificates do not guarantee GLP compliance or good science
- there is limited value to the OECD “Annual Report of Establishments”
- OECD needs to evaluate its business model
- the utility of doing joint on site evaluations every 10 years is questionable
- TK data are not looked at carefully by many monitoring authorities

Canada

A presentation on the new Canadian GLP program was given as part of the program. The two presenters were Dr. Leo Bouthillier who represented Health Canada and Rassoulou Diallo, Senior Program Officer at the Standards Council of Canada (SCC).

Canada is a long term signatory to the overall OECD program (1989). However, Canada is just getting around to establishing/implementing a monitoring authority for pharmaceuticals, biopharmaceuticals and radiopharmaceuticals. Future programs will cover veterinary drugs, food additives, animal food additives and cosmetic products. Canada already has a GLP monitoring program (using the SCC) for pesticides and industrial chemicals (2006).

GLP inspectors are from SCC and not Health Canada (a different model from the US). SCC currently also monitors standards in health, safety, worker and public welfare for the Canadian government. SCC represents Canada at ISO and has various accreditation programs.

GLP inspections in Canada will be pre announced and will occur approximately every 2 years. Fees will be assessed. Each inspection will involve 2-6 inspectors and is expected to last about one week. Inspectees are given the opportunity to object to the choice of inspectors (conflict of interest, etc.)

A Q&A information document will be developed for stakeholders.

Currently, non-GLP data are accepted in Canada. However, as the monitoring authority becomes fully functional, non-GLP data for required studies will be automatically rejected.

Efficacy data from non-clinical studies must be to GLP when the data can't be obtained from humans.

Human Bioequivalence studies may be conducted to GLP. If not, all studies must include an agreement letter between the Sponsor and the CRO to assure certain standards are met (GLP like, GCP, etc.).

Ana Maria Rodriguez-Rojas
MARSQA Member

The challenges Pharma professionals currently are experiencing while working or looking for work in this economy are the focus of this article. Specifically, close attention is placed on the human factor within this tough economic climate. On a future issue, quality systems and new Pharma business model are tied into this equation.

The challenges of working in this economy have touched everybody directly or indirectly at some point since the rumblings of Biopharma layoffs became apparent in 2007. Back then, the pressure increased dramatically to fill pipelines through true innovation and better early stage selection while drastically reducing costs. Pharmaceutical business practices adopted stringent means including downsizing in order to raise operational excellence while staying viable as a business during the global economic downturn. While Pharma profits have minimally been affected during the current crisis compared to other sectors of the economy, the industry continues to restructure in preparation for the so-called “patent cliff” when blockbuster drugs lose their protection. Similar to other industries, downsizing is one of the main tools in restructuring Big Pharma.

Whether one calls it restructuring, reorganization, downsizing or layoffs, they are just similar tools used to enhance a company’s bottom line and shareholder value but also to prepare for the changed business models. A layoff is a reactive tactical action widely utilized globally across many different industries aiming in reducing staff numbers with the purpose to lower organizational costs and adapt to changing market demands. Companies resort to downsizing with the expectation to achieve some economic benefit. In other cases it’s done as a ‘cloning response’ as firms copy their rivals. Companies that define workers based on how much they cost miss considering the value they create to the organization; such companies are more prone to layoffs. The global economic crisis has placed a significant sector of the labor force into unemployment and deep economic

problems. Three years later, the unemployed, the currently employed and organizations are still waiting for better newspaper headlines.

A great deal of action and decision making takes place in the US Northeast where many drug makers have global or US headquarters. Tough cutback decisions have been part of a wide industry trend to keep the Pharma’s boat afloat as its strategy, some may say, included throwing people overboard. While it is not a pleasant task, keeping the tally accurate and current has become something of a sport for some watching employee headcount go down these past few years. The following table shows some of the figures released on November 3rd, 2010 from the out placement consultancy company Challenger, Gray and Christmas, Inc. Pharma continues to be in second place right after the government in the total number of layoffs of 2010 in the U.S. with 45,263 positions so far this year. These figures do not count voluntary retirement, voluntary layoff in Pharma and undisclosed layoff from small Biotechs.

The 2010 situation is not at the 2009 level but this is still bad news, sign that the dust has not yet settled. And for many still out of work nothing looks different and it’s still tough times. Right now the job market is flooded with skilled and experienced pharmaceutical professionals who are eagerly searching for job openings but can’t find them. And so, conversations continue in families, between managers and direct reports, among colleagues and friends about restructuring, digging in, layoffs, restraint, reduced income, not taking chances, redundancy, health

TOP FIVE INDUSTRIES Year To Date

	2010	2009
Government/Non-Profit	128,218	160,434
Pharmaceutical	45,263	58,696
Retail	33,169	97,065
Health Care/Products	25,411	105,027
Transportation	24,004	68,768

Copyright 2010 Challenger, Gray & Christmas, Inc.

coverage, anxiety, fear, job insecurity, survivor's work effort and being understaffed and overworked. Suddenly, frugality and prudence are the new chic words in Pharma and at home.

Beyond the statistics of jobs vanished are the day to day painful chronicles of downsizedes facing their new hard reality with financial, health and personal consequences like: calculating finances, organizing files, updating résumés, cover letters, business cards and address books, putting life in order, networking, job hunting, recruiters, interviews, soul-searching, converting a 401(k) into an IRA, reducing personal debt or expanding healthcare coverage. Even though downsizedes feel so overwhelmed once the axe has fallen, they know they need to snap out of their pink-slip blues and must think selfishly in order to survive and thrive. Still, the grieving period is normal, natural and must be dealt with appropriately to heal and let go. Avoiding it can subconsciously sabotage future handshakes, interviews or new job opportunities. Too bad there is no transdermal patch for this. Establishing structure with set schedules despite a lack of employment can help to reduce the uncertainty of unemployment. A balance between looking for work, networking, continued learning, adequate sleep, healthy eating and fun activities/exercise often works for many people. Others may start a journal to help with dealing with the drama and the trauma of the job search process. Early on it is important to learn to compartmentalize so job hunting does not absorb every single waking hour or thought of the day. Joining professional support groups or associations, seeking a life coach or career counselor, or participating in an outplacement service program is often a common path taken when looking for solutions, new strategies and support at the beginning of this new life journey. This may be particularly important as many of the lost jobs may not simply return when times get better. And with thousands of skilled, experienced workers available in the North East alone, employers are very selective in hiring exactly the talent they need.

Many unemployed people spend evenings surfing the net in job boards, doing research, applying for jobs or establishing an online presence. The internet

facilitates but does not solve anybody's job search problems. During the day people may step out from the house to have informational meetings at coffee houses, join organizations or volunteer locally to best offer and convey their experience and skills and increase exposure. Whether the markets are up or down, word of mouth and somebody else's recommendation are still the best ways to put any candidate in the front and center, layoffs or not. So: network, network, network as it increases those connections and visibility in the field. And yes, you might end up batting for the other side recommending better fits for jobs for which you have a limited chance. In the long run, this establishes valuable connections for a job which you might be the best fit. The popular site LinkedIn helps professionals stay connected or start new connections for free. Unfortunately, most of the time and energy is not spent in personally nurturing those connections, a productive crucial step of any professional working life.

Contrary to the belief of some people who never experienced long-term job loss, being out of work is no picnic, and downsizedes worry in addition to the job search about their new reality and the future. Some get by, cutting back on costs including healthcare, food and many other necessities. Older employees with 20 or 30 years of experience are especially affected. They are among the first to be laid off because their salaries typically are higher than recent college graduates. At the same time, they may not be hired for jobs requiring less experience as being "overqualified". On the other hand, they get labeled "underqualified" when retraining in a new specialty. Early retirement packages might catch those close enough to the retirement age but still, many recently unemployed are well experienced without being close to retirement. The situation is particularly distressing for this group and can have significant health consequences. Many find themselves in a hard situation where they cannot retire yet while lacking the time to start a new endeavor all over again. Some become consultants, entrepreneurs, mentors, or go back to school. While it is easier for young workers to retrain and work up the ladder, it does not make sense when only a few years are left before retirement.

MAN OVERBOARD CONTINUED

Downsizing came as an utter surprise to many loyal employees who did not prepare for the possibility of unemployment. These followed the old conventional wisdom that getting the right degree, experience and working hard will automatically translate into a promotion, dream job or lifetime job security, which is not true anymore. The new truth appears to be that nobody is indispensable and no job is safe. Others with a greater sense of awareness saw the writing on the wall prior to layoffs, made plans and prepared for the job campaign to come. Wall graffiti included signs of business slow down, disappearing raises, reviews got tougher, promotions were put on hold, some senior management found other jobs, key employees weren't replaced, positions went unfilled, more projects got cancelled, job duties merged and money got tighter.

Meanwhile, it is hard to land a new job in this climate when a company takes longer to fill a position, ships jobs overseas or postpones plans to create new jobs. Pharma job cuts spiked in September with 6,069 followed by 1,929 in October based on the Challenger, Gray and Christmas report. This drop in October job cuts and the announcement of hiring plans (300 jobs) for the month of October might be a healthy sign that a slow improving recovery is at hand and Pharma employers seem confident to start hiring once again. How fast or robust will the recovery be to our industry? It is too early to tell and there is not an easy solution for everybody's needs. Focusing on being recession proof is crucial now more than ever. CEO John Challenger advises on "the parts of the search processes the candidate can control and to maintain discipline over variables that fall under its control: (1) who you see; (2) how often you see people and; (3) what you say when you are in front of them."

Today, no job is permanent therefore the worker/job seeker should consider seeing himself as an independent consultant or a free agent, always ready to take on the next assignment. It is a totally different (and healthier) mindset when the worker/job seeker sees himself as the architect of their own life, as the creator of their own future. That means sharpen skills and knowledge and have a marketing plan ready to go. Knowledge and a good positive attitude are very good weapons to fight the unemployment war with.



Staying well connected outside the current or previous company through association meetings or networking events is the key, as well as ensuring a diverse skill set and keeping education current. Confirm that others outside your company know that you are an expert: publish articles, write for journals, present at conferences, volunteer for professional associations, etc. So, if and when the axe falls your way, execute that marketing plan. Regardless of where you are in the layoff cycle, remember that you will survive, you will move on and you will find something new if you are disciplined, prepared and nurture your network.

MAN OVERBOARD CONTINUED

References:

1. "October 2010 Job Cut Report: Are companies continuing to announce few cuts going into the fourth quarter?" Challenger, Gray & Christmas, Inc. Date Accessed: November 5, 2010. <http://www.challengergray.com/press/PressRelease.aspx?PressUid=149>
2. "The Layoff Kings: The 25 Companies Responsible for 700,000 Lost Jobs." Daily Finance. Date Accessed: October 28, 2010. <http://www.dailyfinance.com/story/the-layoff-kings-the-25-companies-responsible-for-700-000-lost/19588515/>
3. "Pfizer looking to lease out former Wyeth labs in Collegeville." Philadelphia Business Journal. Date Accessed: October 29, 2010. http://www.bizjournals.com/philadelphia/blogs/real_estate/2010/10/pfizer-looking-to-lease-out-former.html
4. "Engagement, Well-Being, and the Downturn." Quality Digest. Date Accessed: October 27, 2010. <http://www.qualitydigest.com/inside/quality-insider-article/engagement-wellbeing-and-downturn.html>
5. "2010: A Year of Big Layoffs for Big Pharma." Pharmaceutical Executive. Date Accessed: October 28, 2010. <http://blog.pharmexec.com/2010/10/19/2010-a-year-of-big-layoffs-for-big-pharma/>

Further reading:

- "The Decline: The Geography of a Recession." LaToya Egwuekw. Date Accessed: October 27, 2010. <http://latoyaegwuekwe.wordpress.com/2010/10/07/the-decline-the-geography-of-a-recession/>
- "Laughing in the Face of Layoffs." StressDoc. Date Accessed: November 6, 2010. <http://www.stressdoc.com/laughing.htm>
- "Strategies for Reorganizing or Downsizing: The Stress Doc's Top Tips for Tip-Top Management." Stress Doc. Date Accessed: November 6, 2010. <http://www.stressdoc.com/cutting2.htm>
- "12 Essential Strategies for Job Hunting in a Digital Age." Make the Days Count Blog. Date Accessed: November 2, 2010. <http://makethedayscount.com/2009/07/10/12-essential-strategies-for-job-hunting-in-a-digital-age/>
- "Are You Told You're 'Overqualified'?" Make the Days Count Blog. Date Accessed: November 2, 2010. <http://makethedayscount.com/2009/07/27/are-you-told-you%E2%80%99re-%E2%80%98overqualified%E2%80%99/>

Ray Borysewicz

MARSQA Director

The majority of my QA career has been in the GLP environment with some added computer validation and GCP work. While working in the GLPs a new opportunity presented itself, a position as pharmacovigilance auditor. I found this very interesting although I was not really aware of what Pharmacovigilance (PV) entailed. All I knew was that it was associated with product safety. So, since I had been in the GLPs for years, I thought I would pursue a novel area. I did my research regarding the PV world prior to my interview and PV was increasingly gathering my interest. I decided to accept the PV auditing position and have not looked back.

Although Pharmacovigilance (PV) may seem to be a vague or nondescript word to most MARSQA members, it is a very important field in today's regulated environment. The Pharmaceutical Industry has seen a decisive upswing in the amount of health authority PV inspections throughout the world due to its obvious importance to patient safety and also due to the number of media articles being reported and as drug recalls increase. PV, in short, has everything to do with product safety. One definition of Pharmacovigilance (and there are many) "is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems" (World Health Organization 2002). PV auditing encompasses all aspects of drug safety, beginning with preclinical safety information all the way through the post marketing life of the product (and at times, years after the last mg has been sold). The initial global PV awareness and program initiation started back in late 1960s to help prevent the Thalidomide atrocities.

PV encompasses adverse events from safety case and periodic aggregate reports, safety signal detection, signal evaluation, risk assessment, and risk management from pre and post marketing development of pharmaceutical products. Adverse events can originate from many arenas including the consumer, health care professionals, literature, sales, clinical trials, marketing, the web and direct from employees. An adverse event is any undesirable experience associated with the use of a medical product in a patient. An adverse event can be categorized as non-serious or a serious adverse event (SAE). The FDA describes an SAE as a patient outcome including one of the following: 1) Death -the patient's death is suspected as being a direct outcome of the adverse event, 2) Life-Threatening- if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death. 3) Hospitalization (initial or prolonged)- if admission to the hospital or prolongation of a hospital stay results because of the adverse event, 4) Disability-if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life, 5) Congenital Anomaly- if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child, or 6)- requires Intervention to Prevent Permanent Impairment or Damage. The timelines for reporting are very stringent and reporting requirements very well defined for serious adverse events.

PV consists of both a complex and diverse set of rules and timelines. As mentioned, reporting requirement timelines for both serious and non-serious adverse events differ among health authorities and also take into account whether the product is a Pharma, OTC, device or cosmetic product. Regulations differ in each country. The product could be regarded as a cosmetic in one country and a device or pharmaceutical in another or any combination thereof. It is an ever increasing challenge when auditing PV around the globe.

A good pharmacovigilance system must have exceptional practices with well defined processes. These well designed processes need to effectively detect potentially important information regarding adverse events and any one step in the process cannot stand alone. You can breakdown each step in the process and audit each as part of a PV system audit, but the entire process must also be measured with the final result being the reporting and assessing of safety information and safety signal detection. The ultimate goal is patient/consumer safety. A sampling of the effectiveness of a functional PV system could be viewed when conducting country office audits. Here you will look at the process of how/when/where AEs have been received and following the processes/steps to health authority submission and identifying safety concerns. Areas that an auditor would review in a country office audit would entail but not limited to: Local Drug Safety Unit, Clinical Research, Medical Affairs, Medical information/Customer Services, Product Quality Complaints, Regulatory, QA, Sales and Marketing, Contracts/Agreements and Customer Call Centres to name a few.

A typical Pharmacovigilance Quality Assurance (PVQA) auditing group would also include auditing Safety Systems and Processes, Central Drug Safety Groups, Clinical Trial AE Reporting and Marketing/Business Partners. PVQA is also involved in the usual QA activities, supporting Regulatory Authority Inspections, mock Inspections, consultation and review of documents, etc. Some of the basic objectives for a Pharmacovigilance Quality Assurance Audit Department include:

- To ensure that processes for the collection, evaluation and dissemination/handling of adverse events meet international/local and sponsor(s) requirements
- To ensure that the PV obligations and Marketing Authorisation Holder (MAH) responsibilities are being met
- To ensure that personnel are appropriately trained and qualified to perform PV specific job functions
- To assess delegation and oversight of any third party PV contractual obligations
- To assess that the responsibilities of the Qualified Person (QP) for PV and the deputy QP are being performed in accordance with European and Global regulatory requirements and expectations.

What do PV Audits Involve? The basics are to see whether system/process/trial has been conducted to company SOPs, international regulatory and local guidelines; to review procedures, talk/interview people, review supporting documentation pre/during and post audit and to review procedures. It is the basis for any auditing program.

PV audits and PVQA Departments are quite divergent in the types and location of audits. It is an ever changing environment with new regulations being developed in countries worldwide. Our first goal in PV is patient/consumer safety! This is first and foremost! PV is a challenging arena to be an auditor, but I suggest it a great area for anyone who is up for a challenge!

COMMITTEE CORNER: FIND YOUR WAY TO JOIN IN!

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 for each.

CSV	Ranee Henry Paula Eggert	ranee.henry@crl.com 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
Newsletter	Jane Goeke	jane.goeke-1@gsk.com
Nominating	Fran Jannone	jannonef@princeton.huntingdon.com
Program/Planning	Jane Pasquito	jane.pasquito@spcorp.com
Website	Tony Borisow Carinne Park	aborisow@its.jnj.com carinnepaige@gmail.com

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.

Introducing three members of the newsletter committee who all work hard to assure an interesting and exciting *MARSQA Monitor*.



Kim Evans

Rachel McGowan



Denise White



Why Join MARSQA? Simply put, it's a good deal!

Many of you already realize this because you've paid your dues for 2010 (\$50). However, there may be some readers who are considering membership who don't have a good idea of what they'll get for their money. Here's the list of benefits.

- Low cost half day membership meetings which include lunch and professional presentations relevant to your job
- Low cost professional training classes (e.g., GLP Fundamentals, Principles of Computer Validation, Analytical Chemistry for the QA Professional). These classes last from one half day to several days, have a limited number of students and allow for a great deal of interaction with the trainers.
- Newsletter 3x annually with useful industry information
- Membership Directory
- Low cost advertising rates
- Scholarships to defray the cost of attending the annual SQA meeting
- Opportunities to network, form communities of interest and keep up with the latest industry trends
- Fees for credit card payments not passed on

So, if you're not a MARSQA member and think you'd benefit from all these offerings, please email MARSQA HQ at MARSQA@sqa.org.