2009 Fall Edition

MARSQA Monitor

Newsletter of the Mid-Atlantic Region Society of Quality Assurance

Volume 13, Issue 3

A Busy Fall Season for MARSQA Members!

These last few weeks it seems to me that summer has quickly rolled into fall, and the fall season already has the chill of the approaching winter. For me, this is the time of year when you are still looking ahead to closing out pending projects but also the time of year to look back at what has been accomplished. As this year continues to slip by, I am looking ahead to completing the remaining projects MARSQA needs to accomplish.

Our primary task right now is to obtain candidates for the upcoming annual election. This year we need candidates for the Vice President, the Secretary and the two opening Director positions. This would be a great opportunity to step in and bring forward any ideas and suggestion for this organization. We have a diverse group of board members to work with and we look forward to adding participating members as candidates. If you think you would be interested in helping to lead the MARSQA organization in any of these positions please consider submitting your biography to the Elections Committee (jannonef@princeton.huntingdon.com).

Another project that is very near completion is the presentation of the Advanced GLP Training for Managing Multi-Site Studies course at the SQA Quarterly meeting in Philadelphia on October 28th. You can find details for attending this training at the SQA website (www.sqa.org). It has taken many months of effort to put this presentation together and I would like to thank all the members of the Education Committee for the work and effort they put into designing and presenting this course. I would also personally like to thank both Joanne Ramundo and Jane Pasquito for all the organization and behind the scenes preparation they have done for this course.

One final project we are in the process of tackling is getting the MARSQA website transitioned to run more efficiently. There have been a number of issues to resolve this past year, some resolving more easily than others. We have several Board members working on the remaining issues with the goal of having the website up and running as soon as possible.

In 2009 the MARSQA organization as a whole has been able to provide several services to the membership including selecting two MARSQA Scholarship Awardees to attend the SQA Annual Meeting in April in San Diego. We had two regional meetings, one in March another in June, covering a variety of topics on GLPs, GCPs, auditing and computerized systems. Again I would like to thank Jane Pasquito and the Program Committee for all their work putting these meetings together. Additionally, Jane Goeke and the Communications Committee have very enthusiastically put together three newsletters during this year and I greatly appreciate all the work they have put into all these publications. The Education Committee was also able to provide the Basic GLP training in May and will be following up

continued on page 2...

Inside:

with the Advanced GLP course at the end of October. The Board members have also had several behind the scenes projects they were responsible for including the transition of MARSQA's financial records to SQA headquarters (this will allow our Treasurer to use SQA's financial services for obtaining centralized financial reports, making e-payments and meeting all tax requirements); preparing a membership survey, updating operational guidelines and putting together a membership directory (still pending). I would also like to thank the MARSQA Board for all their input, ideas and deliberations as we addressed issues throughout the year. You have all helped me tremendously. I look forward to having our new candidates in place by the end of the year so that next year's president, Tony Borisow, will have a Board in place by early January.

Regards,

Lynda

Lynda Olsen
2009 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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Root Cause Analysis

Ana Maria Rodriguez Rojas
MARSQA Member

Nothing happens without a cause.

No work process can survive and nobody will stay in business very long if problems are constantly ignored. A problem might be defined as an undesired event, situation, performance trend, a deviation from a requirement or an expectation that impacts an end goal. And in root cause analysis (RCA), the best way to solve problems is by correcting or eliminating the root cause rather than merely pursuing an obvious symptom. I would like to compare RCA to the etiology of a disease in medicine: it is the removal of the etiology of the disease that has long term benefit rather than the mere treating of the symptoms.

According to "The ASQ Auditing Handbook", the process or methodology of identifying the root cause for the occurrence of an unwanted effect, consequence, condition, or problem is known as RCA. The root cause is the factor that caused a nonconformance or customer complaint, and should be permanently eliminated through process improvement.
A root cause is identified if:

- It causes the effect - either directly or through a sequence of intermediate causes and effects.
- Its controllable-intervention would change the cause.
- Its elimination will result in the elimination or reduction of the effect.

Basic RCA
RCA is an analytical tool that does not focus on statistics. Instead, it focuses on finding the causes of problems by visually mapping the cause-effect relationships within a process or system. Often, it has been labeled as "Six Sigma light", problem solving minus all the heavy statistics. RCA is the appropriate use of any of the large number of basic quality tools to examine the failure of any business process in any industry. Once those causes are identified, then corrective action to prevent reoccurrence of that problem can start Corrective Action and Preventive Action (CAPA). Organizations have access to several RCA tools, including the 5 Whys?, Fault Tree Analysis, Interrelation Diagrams, Ishikawa Diagrams (Fishbone, Cause and Effect), Pareto chart and Scatter Diagram, among others.

In general, most of these RCA tools share 3 basic components:

1. Problem(s) definition
2. Analysis (breaking down the problem into parts)
3. Identification of solutions (for specific actions that will take place to prevent the incident from reoccurring)

The 5 Whys?
The 5 Whys approach was created by the founder of Toyota, Sakichi Toyoda. It is a question/answer method that explores the cause-effect relationships of an underlying issue. It is the simplest way of initiating an investigation by asking 'why' and then expanding at least 5 why questions until sufficient questions are asked (and answered) to explain the incident. The 5 whys are the easiest way to get to the root of a problem but it has its limitations as well.

Using evidence to define problems and prioritize solutions
When RCA is conducted properly and in depth, it leads to corrective actions that prevent recurrence of the issue or problem that initiated the RCA. Determining how far to go in the investigation requires good judgment and common sense. Theoretically, you could continue to trace root causes back to the Stone Age, but the wasted effort would be useless. Be careful to understand when you have found a significant cause that can, in fact, be changed. Another way of focusing on the investigation is to change the RCA mindset from looking for problems into looking for solutions. When the mindset is focused on finding possible solutions, the investigation analyzes the impact the deviation has on the end goal(s). That is to say, consider the alternatives or options to control the causes (possible solutions) and continue to prioritize the possible solutions, not the causes (problems). Finally, select the best solutions to

continued on page 4...

meet the overall goals. Sometimes, the cleanest way to start an investigation is to focus first on the impact to the goals. People might disagree on what the problem is but they don't disagree about the impact to the goals. So if someone was injured or there was a production or manufacturing issue, etc., everybody can answer the question about the impact to the goals the same way.

Many times, RCA is conducted hurriedly or with the wrong tools. This results in misidentification of the root cause or failure to find the true root cause. Consequently, the corrective action applied is a "Band-Aid". Months later, the same problem recurs. This is because the symptom was corrected, not the root cause. However, if the investigation has enough time and resources to conduct RCA properly, the corrective and preventive actions will address the actual root cause. The result is a significant reduction in the potential for recurrence of the initial event, ultimately resulting in being proactive by standardizing the correct procedure to ensure a positive outcome and deepening the understanding behind the corrective action and the standard(s).

RCA and CAPA

Traditionally, RCA has been a reactive investigation because the analysis is done after the event has occurred. After gaining deep understanding in RCA, this tool becomes a proactive methodology when it is able to forecast the eventuality of a deviation prior to its occurrence. Whether the scope of the investigation is reactive or proactive, or you want to standardize good laboratory, manufacturing or clinical practices, or just to ensure everybody is following the standards and being compliant, RCA is a mindset for the quality professional (auditor or auditee). Therefore, RCA leads to effective management of CAPA. Ironically, although CAPA is only required with medical devices (QSR), it had become an expectation of the FDA that drugs (API), biologics and biotech also maintain a CAPA system. RCA has been well established in medical devices. Only recently has RCA become part of the CAPA system in pharmaceuticals. Those using RCA, as outlined in ICH Q9, GLP and GCP environments will be able to see a more forward thinking approach to embrace and implement. Many times, we react rather than plan. Through RCA, I believe that we will move forward with better planning and knowledge prior to studies.

Since RCA consists of systematic problem-solving techniques, the benefits of using RCA should be the same in all GxP areas. GLP, GCP and GMP are only stages of an integral process in pharmaceutical drug development. RCA has been mostly used in GMP environments where there is usually a strong quality systems background and people are better trained in conducting this type of trouble-shooting. It might be challenging to change the traditional ways studies have been run for years in GCP and GLP areas. Currently, the trend is shifting towards incorporating and implementing RCA especially in GCP and GLP environments. RCA can helped to map the processes better, making a system/process more robust in terms of compliance and exceeding regulatory norms in both GCP and GLP aspects. The ultimate benefit comes when the true root cause of a problem is established and corrective actions are implemented. The benefit is not only regulatory compliance but a better business solution.

Newborn Heparin Incidents: a 5 Whys Study Case

Ana Maria Rodriguez Rojas
MARSQA Member

Why were 6 newborns given adult doses of heparin in Indianapolis in 2006?

In this study case, we will find out by using the Root Cause Analysis' 5 Whys methodology to look at the root causes in these incidents. Five is just an arbitrary number that reminds us to dig deeper into any issue. A brief run through this type of investigation gets to the heart of the problem. We will see what led to the morbidity and mortality of these babies. The 5 Whys figure captures in a clear and direct format the main causes that led to the overdoses. Heparin adult doses are 1000x more concentrated than infant doses. Therefore, this type of overdose critically impacts the patient safety goal because it might terminate in injury or death. There were at least 5 opportunities missed for double-checking the dosage (identified in the figure with numbers). Three of the six babies who received the heparin overdose died as a result of these unfortunate mistakes.

The failure to discover wrong drug dosage occurred when [1] the wrong dosage was removed from the pharmacy inventory [2] the bottle was placed in the cabinet [3] the bottle remained in the cabinet and was taken from it [4] the incorrect dosage was removed from bottle, and [5] the incorrect dosage was administered to the babies.

In conclusion, the wrong dosage was missed because of:

- the lack of effective double check by another staff member
- missing computer check system
- human error (assisted by the fact that the adult dosage bottle and the infant dosage bottle looked practically the same; presently this has been corrected).

Hospitals across the nation have implemented many solutions to correct this type of error (double checks by staff members is required together with the use of a computerized prescription dispensation system).

Why, such a powerful 3 letter word. Let's use it more often in our investigations.

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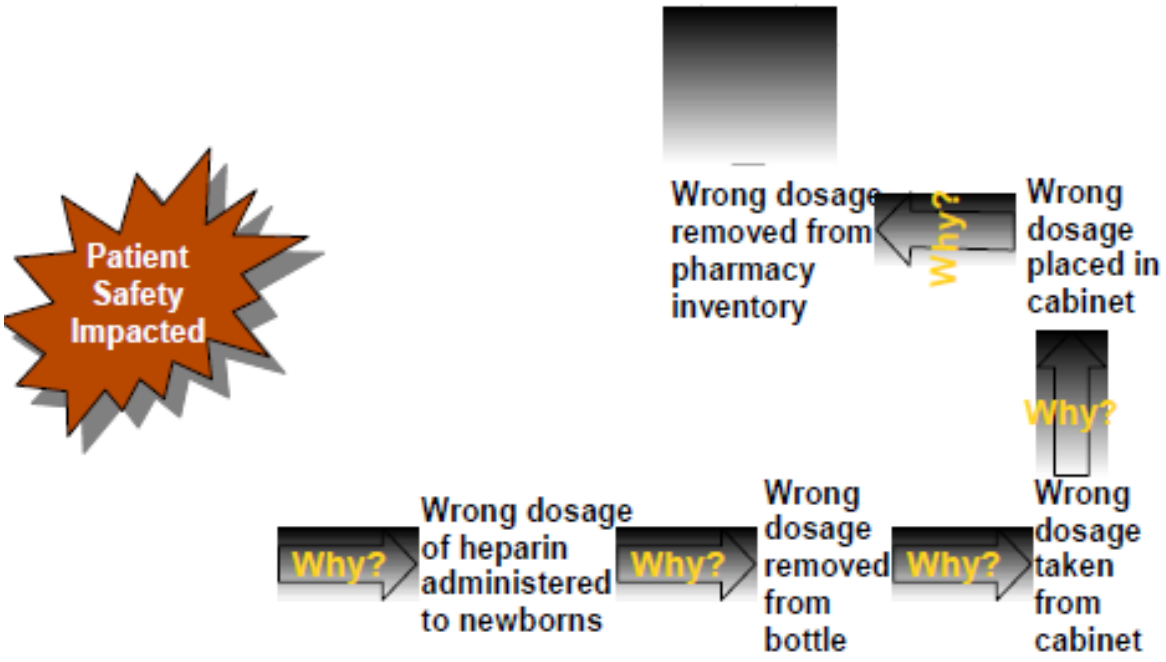

Newborn Heparin Incidents: Patient Safety Case Study Using The 5 Whys

COMPARATIVE WORK ENVIRONMENTS
CRO VERSUS PHARMACEUTICAL COMPANY

Nancy Gongliewski
Director, SQA Board and MARSQA Member

Note that this is a continuation of a theme from our previous newsletter where one of our members compared working as a consultant with working for a business.

You work for a non-clinical CRO and life is chaotic. There are constant Sponsor visits, impossible deadlines, a tough workload and constantly changing processes – life would be much easier if you just worked for a pharmaceutical company. Having worked for both, I suggest you consider again. There are pros and cons to working in each environment

Yes, working for a CRO has challenges, but there are advantages. One of the greatest challenges is ongoing Sponsor inspection (and the resulting recommendations). Sponsor QA inspections are often more in depth and stringent than inspections by the regulatory agencies. Their inspections and recommendations lead to constantly changing processes and additional workload. However, this means CROs frequently have the best industry quality practices (automatic continuous improvement), the latest regulatory agency inspection information and expectation (CROs are privy to all the information that each of their Sponsor representatives pass on) and the highest level of inspection readiness for agency inspections (practice from all those Sponsor inspections).

In addition, an effective Quality Assurance Unit at a CRO is part of the service provided by the CRO. Therefore demonstration of an effective QAU is often a very valuable asset and marketing tool for a CRO. This situation regularly leads to quick implementation of processes addressing compliance concerns and strong support from management for this implementation. Management at a pharmaceutical company is also very aware of the importance of non-clinical safety studies and works diligently to ensure the compliance of this research to regulated standards; however the scope of their responsibility is often much wider than that of CRO management. So, the focus of their efforts is not solely directed at this area. Because of this and the sheer size of a pharmaceutical company, process improvements often take much longer to implement.

In the current environment, influenced by changes in the economy and business culture, employees in all types of businesses are being asked to work more efficiently – to do more with less. As a result, the difference in work load between CROs and pharmaceutical companies is not all that different.

One of the greatest advantages of working for a pharmaceutical company is the ability to see the drug development process in its entirety. Although you may be part of the non-clinical QA group, you are often involved in activities with other groups involved in the R&D drug development process, including the clinical area, R&D drug manufacturing, publishing and regulatory affairs. Not only does this provide knowledge but it also provides opportunities to expand your career development.

Although there may be differences, QA professionals working in both environments have much in common. We take our role seriously and work diligently to ensure data integrity and accurate reporting in the non-clinical areas we support. Throughout our day to day activities we should always be aware that what we do helps to ensure that safe and effective medicines, chemicals, devices, etc. are made available to the public.

WORD SEARCH

AUDIT
CITATION
COMPLIANCE
CRO
EPA
FDA
GOOD LABORATORY PRACTICE
INSPECTION
MARSQA
MULTISITES
OECD
PHARMACEUTICAL
PROTOCOL
QUALITY ASSURANCE
RAW DATA
REGULATIONS
REPORT
SOP
SPONSOR
STUDY DIRECTOR
TESTING FACILITY
VALIDATION

G	D	E	M	V	T	R	M	A	R	S	Q	A	O	O	T	N	I	G	F	L	S
N	O	C	U	D	R	Q	U	A	E	A	Y	D	F	O	O	L	M	S	S	O	N
P	R	O	T	O	C	O	L	R	P	E	A	F	R	I	E	S	P	N	P	A	R
M	I	N	D	Y	E	T	R	F	O	G	U	C	T	B	C	E	O	Y	I	O	E
N	S	A	U	L	D	S	P	M	R	N	G	A	P	C	L	C	E	T	U	L	C
V	A	F	G	H	A	U	D	I	T	P	T	A	R	L	O	N	C	I	T	I	N
M	A	R	B	O	S	B	F	C	G	I	Q	U	F	E	R	A	D	L	S	P	A
P	N	L	M	T	E	C	O	D	C	N	Y	T	A	O	C	R	F	I	D	P	I
H	F	H	I	P	R	O	C	R	L	M	I	E	O	N	O	U	A	C	S	S	L
A	C	T	O	D	L	S	P	O	A	R	S	I	T	M	T	S	Q	A	S	D	P
R	O	P	F	S	A	F	M	U	L	T	I	S	I	T	E	S	T	F	P	E	M
M	F	D	P	E	L	T	M	B	K	S	O	E	R	F	M	A	H	G	O	Q	O
A	P	S	L	M	O	R	I	T	F	C	M	R	O	Q	C	Y	L	N	N	P	C
C	F	L	M	O	F	D	A	O	R	E	P	H	Y	S	F	T	C	I	S	N	R
E	G	O	D	S	T	I	L	E	N	S	F	Q	A	P	O	I	I	T	O	C	A
U	S	Y	I	L	T	O	G	K	H	P	M	C	L	G	R	L	T	S	R	R	W
T	S	T	U	D	Y	D	I	R	E	C	T	O	R	F	D	A	A	E	C	M	D
I	C	R	Q	S	T	M	O	F	P	A	L	S	N	G	R	U	C	T	E	C	A
C	H	G	W	O	E	L	S	F	J	M	N	I	E	F	C	Q	I	T	M	N	T
A	R	A	D	L	N	H	E	D	P	G	R	O	L	L	B	E	O	D	I	P	A
L	P	N	S	F	R	N	O	I	T	C	E	P	S	N	I	F	N	L	Q	C	M
E	Q	T	F	O	E	S	N	O	I	T	A	L	U	G	E	R	H	P	M	O	E

Need help? Answers on page 9.

Committee Corner: find your way to join in!

COMMITTEES

MARSQA has seven committees. They are listed below along with the Chair for each.

Communications	Jane Goeke	jane.goeke-1@gsk.com
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Membership	Janet Emeigh	jemeigh@medarex.com
Nominating	Fran Jannone	jannonef@princeton.huntingdon.com
Program/Planning	Jane Pasquito	jane.pasquito@spcorp.com

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, **Denise White** reports on her experiences as a member of the **Communications Committee.**

I was seeking a volunteer opportunity last year when I decided to join MARSQA's newly re-formed Communications Committee. This dynamic group, led by Jane Goeke, consists of enthusiastic members from various sectors of the QA industry who meet approximately once a month via teleconference to brainstorm ideas for the MARSQA newsletter.

The Communications Committee was responsible for resurrecting the publication after a bit of a hiatus. With the release of the 2008 Fall Edition, the MARSQA Monitor was officially back! At that time, it was decided that one of our objectives would be to issue 3 newsletters per year and so far we are on track due to Jane's commitment and the hard work of all involved. Committee members are tasked with generating ideas that we think are relevant and would be of interest to QA professionals, then interviewing individuals, writing/soliciting articles, proofing copy and selecting newsletter design while keeping the MARSQA Board of Directors abreast of our activities and providing written reports as required.

We also work closely with SQA which provides us with many administrative services such as layout, publishing and mailing services. This allows us more time to focus on the actual content of the newsletter. The Communications Committee has frequent interactions with the other MARSQA committees as well. We often reach out to them in search of information regarding MARSQA events such as training opportunities, meetings or other initiatives.

The Committee has a great team spirit; we brainstorm ideas, eagerly accept assignments and then everyone goes off to do his/her part while keeping our common goal in mind – putting out a quality product representative of our efforts. I'm always amazed at the level of dedication everyone displays as they go about fulfilling their responsibilities, and their willingness to go the extra mile to get the story.

Committee members take great pride in having the newsletter be informative, interesting and even humorous. From time to time, you will see jokes or cartoons in the publication that only the QA professional can truly appreciate. The newsletter is also a good vehicle for advertising (e.g., consultants who wish to market their services). Ad space is available for a nominal fee.

Being a member of the MARSQA Communications Committee has been an extremely rewarding experience. I believe that the newsletter adds value. Furthermore, I enjoy the interactions with other industry professionals, and the time commitment required is quite reasonable.

MARSQA Membership Meeting Held July 21 in Lahaska, PA

▲ Jane Pasquito,Chair of the Program Committee setting up the projector for the speakers

▲ Eric Ramsey of GSK spoke on "e Archive Process Improvements and the use of SAFE-BioPharma Digital Signatures."

◀ Betty Delise from Johnson and Johnson spoke on "Consistency in Observation Writing Using the ANSWER Method."

▲ Rachel Adler from Johnson and Johnson spoke on "A Risk Based Approach to Auditing Computerized Systems in a GLP Environment."

Photos courtesy of Jane Goeke

Answers to Word Search on page 7

G	D	E	M	V	T	R	M	A	R	S	Q	A	O	O	T	N	I	G	F	L	S
N	O	C	U	D	R	Q	U	A	E	A	Y	D	F	O	O	L	M	S	S	O	N
P	R	O	T	O	C	O	L	R	P	E	A	F	R	I	E	S	P	N	P	A	R
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H	F	H	I	P	R	O	C	R	L	M	I	E	O	N	O	U	A	C	S	S	L
A	C	T	O	D	L	S	P	O	A	R	S	I	T	M	T	S	Q	A	S	D	P
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M	F	D	P	E	L	T	M	B	K	S	O	E	R	F	M	A	H	G	O	Q	O
A	P	S	L	M	O	R	I	T	F	C	M	R	O	Q	C	Y	L	N	N	P	C
C	F	L	M	O	F	D	A	O	R	E	P	H	Y	S	F	T	C	I	S	N	R
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U	S	Y	I	L	T	O	G	K	H	P	M	C	L	G	R	L	T	S	R	R	W
T	S	T	U	D	Y	D	I	R	E	C	T	O	R	F	D	A	A	E	C	M	D
I	C	R	Q	S	T	M	O	F	P	A	L	S	N	G	R	U	C	T	E	C	A
C	H	G	W	O	E	L	S	F	J	M	N	I	E	F	C	Q	I	T	M	N	T
A	R	A	D	L	N	H	E	D	P	G	R	O	L	L	B	E	O	D	I	P	A
L	P	N	S	F	R	N	O	I	T	C	E	P	S	N	I	F	N	L	Q	C	M
E	Q	T	F	O	E	S	N	O	I	T	A	L	U	G	E	R	H	P	M	O	E

Temple University's QA/RA Program: A Look Back and Ahead

Janet Emeigh
MARSQA Past President

Let me start with the obligatory disclaimer. The views and opinions expressed in this article are those of the author and have not been reviewed or endorsed by Temple University or the Temple University School of Pharmacy QA/RA program.

As I write this, I find it hard to believe it's been a little over 4 years since I completed my Master of Science degree in QA/RA from Temple University. In some ways, it seems like yesterday that I received my diploma and in others, it seems like a lifetime ago. A lot has happened in my career in the past few years which I can directly attribute in part to the fact that I obtained the degree. About 18 months ago, I was hired by a small biotech firm in NJ to be the first manager of their GLP audit program. At the beginning of this year, I was also asked to manage their GMP audit program due to some staffing changes. Not too bad for someone who started in the Pharmaceutical business a little late in her career approximately 17 years ago as an entry level bioanalytical chemist, later switching to the "dark side" by becoming a GLP auditor of bioanalytical and dose formulation analysis laboratories about 11 years ago and then an auditor of all aspects of GLP study conduct a little over 8 years ago. The transition from analytical chemist to auditor was due in part to on the job training but also in a large part to the experience and knowledge I gained at Temple.

I started the program in September of 2000 with much trepidation. It had been quite some time since I had been in a classroom and I had never thought of attending graduate school after college. Therefore, I had never taken the GREs. Part of the application process for entry into the QARA program was to take the GREs. On top of that, my college grades, while respectable, were not what many would consider graduate school material. How much weight would be placed on my GRE scores and undergraduate grades? Would I even get in and if I did, would I have what it took to go all the way for a degree? Fortunately, Temple permitted students to take up to 3 courses before they actually had to apply for matriculation into the program.

I started in September 2000 with one of the required core courses, Food and Drug Law. The teacher believed the best way to learn the law was to actually experience it. We had a text book, but we were also required to bring in a newspaper or magazine article to every class that dealt with some aspect of food and drug law. We would read some of the articles and discuss them. We were also divided into small groups of about 3 and had to work together on a project related to the course work. This enabled us to get to know some of our classmates and taught us how to work on cross functional teams since not everyone worked in the same discipline or even pharmaceuticals for that matter. We also held a mock hearing before congress at the end of the term on whether or not the FDA should be given the authority to regulate tobacco, which as many of you know, just recently occurred in congress this year. We also spent a lot of time in class reading and discussing the cases that led to the modern day food and drug laws and regulations. This particular class made a lasting impression on me and alleviated much of the fear I had in proceeding with the program. Many of my later courses were your traditional instruction, coursework and examinations. I wanted to illustrate that program hires a wide variety of faculty, many who are considered experts in industry, who offer a wide variety of teaching styles. I ended up taking 3 classes before I applied for matriculation into the program. I took the GREs and I guess did well enough that along with the very good grades I got in those 3 graduate courses and the recommendations I received from people for whom I had worked, that I was accepted into the program without any trouble.

It took me the 5 years allowed to complete the program. Part way through, I decided I wanted to take as many different courses in quality and regulatory affairs as possible and the only way to do that at the time was to take courses during the week. I searched for and was lucky enough to find a job located closer to the Fort Washington campus that made this possible. The change in jobs meant a one semester delay in my studies. I was also fortunate to have worked for 2 companies during my course of study that offered tuition reimbursement. Along the way, I met a lot of different people, many of whom I maintain a friendship with today. It was a lot of hard work, working full time and attending school at night and on the weekends, but in the end, it was all well worth it!

The program itself has continued to evolve. When I started in 2000, there were only 2 Pre-Masters certificate programs, one in Regulatory Affairs with the other in Quality Assurance. To obtain a certificate, you needed to complete 4 defined courses. Now, there are 7 Pre-Masters and 6 Post-Masters certificate programs. I was fortunate enough to work for companies that provided very generous tuition reimbursement programs, but many students I met in the course of my studies were paying for the program themselves. In 2006, Temple received an endowment from the FDA Alumni Association (FDAAA) creating the first scholarship for students for the School's graduate program in Quality Assurance/Regulatory Affairs (QA/RA). The scholarship is awarded annually in the fall to a student who is not eligible for tuition reimbursement and is awarded on the basis of both financial need and academic merit. I pretty much had to attend classes in person, but near the end of my course of study, distance learning became an integral part of the program. Several of my classes were attended from as far away as Puerto Rico by video conferencing and webinars. Some of the classes were videotaped and sent to students. Two or three years ago, Temple began offering courses on a regular basis in Tarrytown, NY. They also have offered courses off campus at hotels in Paoli and Malvern, PA. Starting in January of 2010, students from the National University of Singapore will be able to attend classes and receive a degree from Temple due to an international relationship agreement between Temple and the National University of Singapore. The program continues to grow and gain national and international recognition and prestige.

I ask you, are you at a cross road in your career? With the recent consolidation of the industry occurring once again, are you facing the possibility of a downsizing and wondering what you can do to make yourself more marketable in this highly competitive atmosphere? Do you simply want to learn a little more about your chosen field and perhaps other areas of quality assurance and regulatory affairs? If you answered yes to any of these questions, I would strongly recommend that you consider looking in to the QARA program at Temple. The top notch faculty and course offerings as well as the friendships and contacts you will make along the way are I believe highly valuable. I'm even considering a return to obtain a certificate in Global Pharmacovigilance: Benefit-Risk Assessment and/or Clinical Trial Management. More information on the program can be found by visiting the Temple QARA webpage at www.temple.edu/pharmacy_qara/.

Hot Topics/Trends in SQA Through the Years
(based on GLPSS poster presented at the 2009 SQA Annual Meeting[1])

Kimberly Evans
MARSQA Member

Since the inception of the FDA GLPs in 1978, SQA has met annually starting in 1980 to discuss topics related to the GLPs. The first official SQA Annual Meeting was held in 1985. Through the years, more areas of interest have been discussed within SQA. Today there are topics ranging from various GxPs to veterinary care to medical devices. It is fascinating to see when some topics were introduced and how long the focus remained. The GLP Specialty Section created a poster for the 2009 Annual meeting in San Diego, CA to show some of the hot topics through the years. A hot topic is a topic that is either discussed almost every year or consecutively for several years and may fade away and/or come back again. Looking at the tabulated summary, you can see some of the topics that have come and stayed/gone through the years at the annual SQA meetings. **See pages 13-14 for the full tabulated summary**.

[1]Kelly Andrew, Kimberly Evans, Sandy Harvey, Angela Lowell and Patricia O'Brien Pomerleau. SQA GLP SPECIALTY SECTION: A TRIP DOWN MEMORY LANE…PERSERVERING 25 YEARS OF GLP TWISTS, TURNS, ROCKY ROADS AND HIGHWAYS

Why Join MARSQA?

Simply put, it's a good deal!

Many of you already realize this because you've paid your dues for 2009 ($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

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**. Welcome to our community.

Hot Topics/Trends in SQA Through the Years

	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Organization of QAU	X							X								X				X				X					
Agency Inspections	X							X	X	X	X				X				X		X			X		X		X	
Training and Documentation	X	X					X								X	X	X			X					X				
Sponsor Responsibility	X	X														X		X							X			X	
Statistically- based monitor program	X	X																											
Validation		X		X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Redefining scope of QA			X	X																X									
QA of Pathology			X		X		X					X		X															
QA Image			X		X												X			X				X	X				
Ethics/Legal/ QA/Integrity			X	X								X	X	X	X		X	X	X	X						X			X
Redefining GLPs				X						X																			
Redefining GCPs				X						X			X	X	X														
International GLPs problems					X			X	X		X	X	X		X	X	X	X					X						
EPA & GLPs					X	X	X	X	X	X	X	X				X								X		X	X	X	X
Toxicology Studies (various types)					X				X			X		X			X	X					X	X	X				
Regulatory Visions/Perspectives						X						X							X	X									
Analytical Chemistry						X	X					X	X		X	X		X	X		X		X						
RQA Trends						X																							
Historical QA/GLP							X						X																
QA Innovations							X	X																					X
Management commitment								X								X		X										
FDA 483s								X									X		X										
QA Training								X				X	X			X	X			X	X	X			X	X		X	
Metabolism, Residue, Chemistry								X			X	X	X	X			X												
Animal Welfare/Health								X	X		X	X	X	X	X		X				X	X		X	X		X	X	
QA Effectiveness								X									X			X									
Computerized Perceptive on GLP Findings								X																					
Robotics								X																					
Expanding role of QA professional									X	X						X				X									
Biotechnology										X				X					X	X	X	X				X			
Protocol Review											X					X													
QAU Inspections											X	X	X		X	X		X											
Data Audits												X	X		X	X				X		X							
Report Audit & Archive Verific.											X	X				X				X									
Total Quality Management											X	X	X	X	X	X		X		X									
Science vs Compliance											X																		
QA/Study Director											X	X	X									X							
Contract Lab QA											X					X		X					X						
Mock Inspections (Auditonium)											X		X																
Field Studies											X	X	X	X	X						x								
FDA and GLPs											X							X		X	X								
Food Supply/Food Animal Study											X		X																
Pharmacological Efficacy/GLP											X																		
Conflict Management												X																	
GALPs												X	X																
ISO 9000												X	X			X		X	X	X									
QC												X									X								
OECD GLP												X				X	X	X	X			X	X			X			
GMP												X	X	X	X	X		X			X	X				X	X		X
Large Animal Study												X	X	X															
Agricultural Chemicals SS												X	X	X	X		X												
Tours of Lavs												X			X														
Compliance Education												X								X									
Pharmacokinetics												X	X																
Facility Assessment													X	X	X	X					X		X	X	X				
Scientific Information													X																
Risk Assessment													X								X		X				X		
Environmental Studies													X	X				X											
Certific. Research QA Professnal													X																
FDA State of Affairs/Challenges													X	X	X		X		X			X	X	X	X				
EPA State of Affairs/Challenges													X	X	X							X	X	X	X				

Hot Topics/Trends in SQA Through the Years
(Based on GLPSS Poster Presented at the 2009 SQA Annual Meeting)

	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
University/IR4														X	X		X	X	X										
Medical Devices														X										X	X	X	X	X	X
Center for Veterinary Medicine														X															
Transgenics														X			X												
Worker Exposure														X															
Product Registration/Accredit.														X	X														
People Skills															X				X										
S/Contractor/Consultant Interact.															X			X											
Archiving (paper and electronic)															X	X				X			X	X	X	X	X	X	X
Regulatory Submissions															X														
New Animal Drug/Clinical Invest.															X														
NIOSH															X														
Working more effectively with people																					X								
Establishing a QA program																					X								
Getting and keeping customers for life																					X								
Fraud and non compliance																					X	X					X		X
Data Migration																					X								
Bringing nonGLP lab to compliance																						X							
Chromatography																							X						
Misconduct																							X						
Telemetry studies																							X						
Electronic SOPs																								X					
Clinical Research and Medical Records																					X	X	X	X				X	
Internatinal Submissions																									X				
Biopharmaceuticals																									X				
21 CFR Part 11																X			X							X		X	
40 CFR Part 3																											X		
Audit Plans and Auditing																				X							X		
Bioanalytical																				X			X			X	X	X	X
Bioequivalence																											X		
China																										X			X
Due Diligence																													X
E-system Compliance																			X	X							X		X
GCLP																										X		X	
GCP											X								X		X	X	X			X	X	X	X
GLP																					X					X	X	X	X
Integrating Quality Systems (GLP/ISO/GMP)																X				X						X			
Japan (GLP,GMP, GCP)																		X								X			
Managing GLP during aquistion/merger																										X			
Mentoring and Job Searching																													X
Multi-site Studies																	X			X			X	X	X	X		X	
OHRP(Office of Human Research Protections)																												X	
OECD/GLP w/ ISO/IEC																		X								X			
QA for non-GxP facilities																												X	
QA in LCMS/MS and Immunoassay																										X			
QA in PK data																												X	
Quality Management Systems																				X							X		
Qulaification in PV																										X			
Risk Management/ Knowledgement																										X		X	X
SOP audits																										X			
South America Auditing																													X
Statistics																										X			
Turbo EIR																												X	
Value added auditing																											X		
Veterinary Clincal																			X									X	