

MWSQA



News from the Heartland

Midwest Regional Chapter: Society of Quality Assurance

Presidential Ponders

By Connie Marvel – MWSQA President

president@mwsqa.org

Did you ever just stop and think about all the different aspects of research that you are involved in as a Quality Assurance professional? Well, if not, let me provide you with a partial listing. Of course, we know about the 'Good' regulations – Good Laboratory Practices, Good Manufacturing Practices, Good Clinical Practices. But we also deal with regulations concerning Electronic Records/Electronic Signatures, Animal Welfare, Controlled Substances, and Occupational Health and Safety. These regulations cover a whole host of topics. Did you ever think you would become knowledgeable in HVAC and environmental monitoring systems, clinical chemistry and bioanalytical methods, animal care, test article preparation and dosing, field trial application, statistics, cage washers, tissue trimming and embedding, or equipment calibration? What a variety!

And, not only do we know about the regulations, but we also apply them to many different situations on an almost daily basis. QA, if it's done right, is the most sought after 'expert' around regarding good documentation practices. Of course, suggest but never dictate – leave that for the study director or principal investigator or management. As a result of our expertise in this subject, many QA groups are being called upon to introduce the concepts of good documentation to basic research laboratory personnel in an effort to improve the scientific records in those areas.

Now that you have explored some of the facets of the world of QA, hopefully you have come to appreciate your occupation even more. Being a Quality Assurance professional provides a stimulating environment with new challenges being encountered on an almost daily basis. The result of all this effort is your contribution to the marketing of a product that will be of benefit to humankind, either directly or indirectly. I don't know about you, but that's a big part of what keeps me coming to work every day.

P.S. Here's a thought – have you ever wondered why they didn't name the regulations 'Great' instead of 'Good'? Think about it – the Great Laboratory Practices! Instead, they are just 'Good', perhaps because the regulations are just the minimum requirements to be met and not the maximum. Hope to see you at the MWSQA Summer Meeting in Kalamazoo, MI on July 29-30!!

MWSQA Wants YOU!!!

Submitted by Connie Marvel, Associate Director, Bristol-Myers Squibb

The annual election for the Midwest Chapter of the Society of Quality Assurance will be held this fall, and the board is looking for volunteers! As MWSQA members, we will be casting our ballots for a Vice-President, Treasurer, and two Directors. The descriptions of these positions and their responsibilities can be found on our web site at www.mwsqa.org, so check it out! If you are interested in serving on the board, send an email to the chair of the nominations committee at nomination@mwsqa.org today!

!!ANNOUNCING THE MWSQA SUMMER MEETING!!

Submitted by Bonny Weiss, Quality Assurance Specialist, Ricerca LLC Vicepresident@mwsqa.org

Between the GxP Lines: Driving Toward Product Development

**July 29 and 30, 2003
Kalamazoo, Michigan**

The MWSQA challenges you to approach product development as a road rally to the marketing finish line! Understand how to best negotiate each GxP “leg” of the rally course as the regulatory agency “Rally Masters” intended. Determine how each “team” (study director “driver” and QA “navigator”) achieve and maintain course compliance “Time/Speed/Distance” (TSD) at every critical event “check point” through to the study completion “finish line!”

On the morning of Rally Day One, July 29th, inexperienced team members may choose to participate in the Novice GLP Auditor course, designed to familiarize them with basic regulatory road signs. More advanced auditors may choose to explore the evolution of archiving from cart path to the electronic super-highway, look at “The Mechanics of Medical Devices” or experience a fast-paced pro-rally on the “Development Cycle of Pesticides”. Tuesday afternoon, all team members will review the “Predicate Rules of the Road” and cruise through an overview of “Product Discovery, Regulatory Affairs and Due Diligence Reviews”.

Just when you think you’ve run out of gas, recharge your batteries and fuel up at the Gilmore Car Museum! Feast your eyes on vintage automobiles while you enjoy a catered barbecue. Top the evening off by taking one of these classic cars for a spin!

Wednesday, July 30th, Rally Day Two, the teams will tour the three legs of drug development: pre-clinical GLP, production cGMP and investigative GCP. Representatives from the FDA Detroit Regional Office, Ms. Nancy Bellamy, Supervisory Investigator and Ms. Kathy Quinlan, Biologics Specialist, will be on hand to present the “Rally Master” point of view. Learn to negotiate unexpected detours, avoid potholes, dangerous intersections and especially, John Law’s speed traps! Reach the finish line in optimal “TSD” compliance!

“Between the GxP Lines: Driving Toward Product Development” is offered to MWSQA members for \$120 and non-members for \$170; or save \$\$ by joining the MWSQA team for \$140! Hosted by MPI Research of Mattawan Michigan, the meeting will be held at the Radisson Plaza Hotel, 100 West Michigan Avenue, Kalamazoo, Michigan (269) 343-3333. Room reservations will be accepted through July 15th at the MWSQA reduced-rate of \$114 a night.

Don’t fall asleep at the wheel! This will be a full 2-day meeting, so plan accordingly! Registration forms will be sent electronically to the membership soon. Look for meeting updates at www.mwsqa.org

FDA GLP Update at PhRMA BRMC Annual Meeting

Submitted by Connie Marvel, Associate Director, Bristol-Myers Squibb

The PhRMA Bioresearch Monitoring Committee Annual Meeting was held on April 22-25, 2003 in Bethesda, Maryland. James F. McCormack, Ph.D., Director of Nonclinical Laboratory Compliance, Office of Enforcement, Office of Regulatory Affairs – FDA presented a GLP update which included the following information and inspection trends:

- Coulston Foundation, Alamogordo, NM signed a Voluntary Disqualification Consent Agreement on 21Apr2003. (Reference 21CFR Part 58, Subpart K - Disqualification of Testing Facilities).
- FDA Investigators should assure the viability of the industry self-regulated quality system, which is the triangular relationship formed between Management, Study Director, and the QAU.
- Nonclinical Laboratory Inventory: FDA is attempting to update their listing in order to assure that all GLP testing facilities & contractors are subject to inspection.
- Improve the frequency of inspections: FY 1999 - 2002 resulted in 84, 74, 83, and 51 inspections being conducted. Target for 2003 is 129 inspections!
- Laboratories for inspection are being identified at the beginning of the fiscal year. Districts will be permitted greater latitude in scheduling/planning inspections.
- Emphasis being placed on improving the timeliness and quality of inspections.
- Investigator Training:
 - 2 week Basic GLP Training Course is offered to new investigators.
 - 1 week Advanced GLP Training Course focused on auditing tissue processing, histology & pathology and which also covers Tox-Path, LIMS, and HPLC systems is offered to more experienced investigators.
- Inspection Guides are being developed for auditing nonclinical laboratory studies, inspection of necropsy & histology practices, and inspection of HVAC systems.
- TURBO EIR is database for generation of the 483 & EIRs.
Presently in-use in all districts.
A portion of the regulations is cited for every finding followed by the specific incident. (Author's note: Misrepresentation and/or incorrect categorization of findings are an industry concern.)
- Active involvement by the Study Director in the conduct of a GLP study is the expectation:
From submissions, CDER is making lists of the names of Study Directors and tracking the type and number of studies for which they have served as Study Director.
Results of analytical evaluation of dosing formulations need to be provided to Study Director in a timely manner.
Study Directors need to maintain an awareness of contracted portions of a study - single point of control emphasized.
- OECD Consensus Document on Multi-Site Studies finalized on March 11, 2002 is a guidance document with emphasis on business processes of conducting a GLP study such as modes of communication.
For US-based companies, involvement with CROs in Canada or Europe will require some additional documentation requirements to fulfill the expectations of this guidance.
- FDA's Viewpoint, per Jim McCormack (and many others) -- Contracting Happens!
GLP regulations already recognize that portions of a study may be outsourced. As such, there is no need to expand the FDA GLP regulations to delineate the contractual agreements established between sponsor and CROs.
- Inspection assignments are being developed to cover projects that have had an IND or NDA submitted, thereby linking Clinical Investigator, IRB, Carcinogenicity, and Reproductive toxicology audits to a particular project.

REMEMBER TO SUBMIT YOUR PHOTOS FOR THE ANNUAL CONTEST!

Submitted by Celeste Rose, RoseTECH Consulting, Inc.

Join us in documenting SQA History! The SQA Historical Committee invites **YOU** to submit photos from any past or upcoming SQA events for the Photography Contest and for SQA Historical Archives.

We cordially welcome you to take pictures at this year's SQA-sponsored events, then submit them and/or any photos from past SQA events for entry in the 2nd Annual Photography Contest at the 2003 National SQA Meeting in D.C. The photographs will become part of SQA history via inclusion in the SQA Historical Photograph Archive!

Submit photos via mail to Celeste Rose, RoseTECH Consulting, Inc., 1135 Dorothea Dr. Painesville, Ohio 44077. Digital photos may be sent via email to crose@rosetechconsulting.com. The deadline for submission is September 15, 2003. See **page 9** of the **SQA Spring 2003 newsletter** for contest rules and details. (www.sqa.org/members/newsletters/Spring_Newsletter_03.pdf).

Vendor Audits and Risk Assessment

Submitted by Paula Wehmeyer, Sr. QA Auditor, Bioanalytical Systems, Inc.

With the new guidance out on 21 CFR Part 11 we are asked to dust off the predicate rules again and take a look at our practices as they exist in electronic media. Good business practices have long required that we consider not only the needs of compliance but also its costs. Vendor audits are among the responsibilities that are loosely structured in the regulations. They need to be addressed, but when, how and who will conduct them? The first step is to make these determinations and commit them to a standard operating procedure (SOP).

Certainly there are some categories of vendors who are not going to need any type of audit. They supply us with paper, pens, and other simple supplies. Let's call these 'no risk vendors' and identify them as vendors who do not require an audit. Next let's look at vendors who supply us with the simple laboratory needs; things that do not impact our test systems in a direct fashion. We will identify these suppliers as 'low risk' vendors. These vendors will receive at least a survey to fill out and will merit a little research on the Internet. Depending on what we learn initially we may follow up with a telephone call. A site visit is unlikely unless perhaps they are in our immediate neighborhood. Next come our 'medium risk' vendors, whose products come into immediate contact with our test systems, such as chemical reagents or animal feeds. If they have a long and good history we may be able to show due diligence with a WebEx plus telephone audit. Now to our 'high risk' vendors--these folks supply products critical to the collection or handling of our data. They may supply "data-crunching" software; they may archive our data off site, supply us with our test systems, calibrate our instrumentation at their facility or do a portion of our research for us. Here a site visit is an important consideration; although a detailed survey or Web Ex plus telephone audit may give us the information we need to assure a controlled quality product to us as the customer. We need to consider our options carefully and identify meaningful criteria to make the best choice. If the vendor makes regulatory claims, is certified by ISO for example, will this be a factor in our decision making process?

How often do we need to follow up? Is this mandated unilaterally by SOP or should this be determined when the initial audit is conducted? And how should we follow up? If we did a site visit the first time do we need to go back? Is a survey enough? Admittedly some will assert that a site visit is mandatory. It is the most certain tool for gathering information when combined with examining what is publicly available, but in the real world where we must weigh our resources carefully it makes sense to assess cost vs. risk in this arena as in any other in the business world.

Who should conduct the audit? Is quality assurance the best choice? Would a team of two or three individuals be best? Could one person go on site and with a little advance planning, make the determinations everyone needs? This is the most individualized question of all since it is built around

the personnel available and the financial flexibility of your company. You will find your own answers to these questions, once you start to ask them.

HIPAA Compliance for Clinical Research Programs

Submitted by Cynthia S. Way, CIP Manager, IRB & Research Support - Covance Clinical Research Unit, Madison, WI

Speaker at MWSQA 2003 Winter Meeting – Claudia J. Egan, Reinhart Boerner Van Deuren, S.C., Milwaukee, WI

Ms. Egan reviewed the intent and impact of the HIPAA Privacy Rule on the health care industry, in particular, medical research. She began with HIPAA privacy rule basics, and reviewed the acronyms associated with HIPAA, e.g. CE (covered entities), BA (business associate), IHO (individually identifiable health information), and PHI (protected health information).

Also addressed were the data elements that make health information identifiable under HIPAA, as well as research data that is protected, and not protected, by HIPAA. Ms. Egan discussed components of de-identifying PHI with the group, and explained that HIPAA allows individuals the rights to control their PHI.

The application of HIPAA in medical research will engage multiple stakeholders, such as research subjects, investigators, sponsors, IRBs, Human Subject Protection Offices, and Institutional Officials of covered entities. Ms. Egan helped her audience gain a better understanding of what would be required of their institutions come April 14th.

MWSQA GLP Roundtable at Winter 2003 Meeting

Submitted by LeAnn Kerney, Associate Auditor and Connie Marvel, Associate Director, Bristol-Myers Squibb

The MWSQA Winter Meeting provided some excellent sessions with one of them being a GLP Roundtable where all topics/questions were welcomed and openly discussed. This session was lead by Debbie Little of DLL Consulting and Connie Marvel of Bristol-Myers Squibb. The following is a synopsis of the discussion items and the consensus achieved. As a disclaimer, the following is not intended as legal regulatory advice.

Discussion Item: Pre-test study events conducted prior to signed protocol

Response: Most facilities are conducting some pre-test study events prior to having a signed protocol; however, it was stressed that communication processes should be in place for relaying the type and timing of events to applicable personnel (including the QAU) and that prestudy SOPs on animal care are followed. CROs generally try to have a signed protocol for contractual reasons but have no control on when the sponsor signs. It was generally accepted that procedures conducted prior to animal randomization are not considered study specific. Special consideration should be made for the definition of “experimental start date” under OECD guidelines.

Discussion Item: Handling of reports for cancelled/terminated studies

Response: General consensus was that an amendment is issued to terminate the study; however, many felt this is not adequate as the Regulations specify a report must be generated for each study (most importantly are those in which the compound has been introduced in man). QA should review each study report, even if it is just a brief memo. CROs assign study directorship back to the sponsor if the sponsor chooses not to have the contract facility prepare the report. It was suggested that the final compliance statement could indicate that the final report is not compliant in cases where there is no actual report. No response was made on whether terminated studies were being handled similarly under EPA regulations.

Discussion Item: Documentation of study director involvement in data and observation of study events

Response: Visits to animal study rooms are documented on the room log. Some organizations indicated that their procedures dictate the study director sign every page of documentation, while others mentioned a log maintained to document the study director's periodic review of study data. In many cases, supervisory personnel review data.

Discussion Item: Timing of Sponsor/Study Director signature on reports/protocols

Response: It is generally accepted that the study director should sign the final report last as this officially closes the study and will aide in overseeing prompt archival of study data. Mostly for contractual reasons, CROs generally obtain sponsor signatures on protocols prior to the study director signing. The study director will sign first in some cases in order to begin pretest events; however, the date of sponsor approval may be included in the protocol. There was no comment on a recent issue raised by the FDA as to having contributing scientists sign their individual reports prior to sponsor/study director review in order to maintain the integrity of the scientists' original interpretations.

Discussion Item: Testing facility management, to whom the contracted QA reported, had direct involvement with the study

Response: Obviously there is a conflict with true separation of QA and management. The sponsor could have been asked to provide QA oversight in this situation. This possible conflict should be documented and explained up front.

Discussion Item: If temperature ranges are not specified in the protocol, is it necessary to report actual values?

Response: Actual values should be included in the final report if such was stated in the protocol. However, most rely on SOPs for stating ranges and keep the protocol vague. Data from temperature monitoring should be maintained continuously, not just when equipment is used on a particular study (assure that it is operating properly prior to use).

Discussion Item: Electronic SOPs

Response: Many organizations are moving away from paper copies of SOPs. For some, email notifications are proof of distribution and eliminate the "read and understood" documentation. Originators of SOPs determine whether or not additional training is needed and may be asked to submit questions for testing (generally in the GMP arena with passing as 80%). Hard copies of SOPs should be available in each building for use in the event the electronic versions are unavailable. Procedural controls should be in place for printing copies of SOPs for general use. MSD sheets are being handled similarly to electronic SOPs, but generally fall under the responsibility of corporate safety personnel.

Discussion Item: QA auditing of electronic data

Response: Although most data is now collected electronically, many QA groups rely on paper, as they do not have access to the electronic data partially due to software systems set up and licensing issues. Bioanalytical data appears to be the most readily available electronic format to review. How much auditing of validated systems should be done was also questioned. Some companies have reduced the amount of review for validated systems based on documentation of QC, limited amount of word processing manipulation of original files, and how comfortable auditors are with the systems.

Discussion Item: Documentation of QA disagreement with both study director and management

Response: When GLP issues arise, always refer to the regulations. One company periodically meets with management to discuss outstanding items that the QA tracks through a database and doesn't sign the QA statement until all issues are resolved. Disagreements with management put consultant QA auditors in a precarious position. If seeking out higher management doesn't work, contract auditors may include written documentation that they are signing the statement although there are outstanding items.

Discussion Item: QA challenge of archived electronic data and report retrieval

Response: It was recommended that QA should periodically challenge archived electronic data by retrieving files and comparing them to the paper form. This proves readability of data and that no changes have been made since finalization of the study. In some instances, the original software may have to be available. Certain types of data may not actually be archived with the study, but rather grouped together with similar data to make it easier to locate.

Discussion Item: Unscheduled observations occasionally recorded but the study director does not want to report because they were not “required by protocol”

Response: Often unintended observations are documented separately from the routine collection. Some QA groups have seen this type of data being deleted from the final report. General consensus was that if it was collected it should be reported. Otherwise, explanation of why the observations were not reported should be addressed by amendment or deviation.

Discussion Item: Regulatory concerns with regard to inspecting against the OECD Multi-site Document

Response: This was a general discussion as to how many facilities were functioning under OECD guidelines. Many CROs are currently implementing programs as they may most likely encounter foreign sponsors. One U.S. pharmaceutical company indicated that they are working toward compliance under these guidelines in order to prevent confusion since they work with several European CROs.

Institutional Review Boards: “If It’s Worth Doing, It’s Worth Doing Right!”

Speaker at MWSQA 2003 Winter Meeting and Author – Cynthia S. Way, CIP, Covance Clinical Research Unit

Ms. Way went back in time to emphasize the progression of human subjects protection in the United States and abroad. Historical cornerstones in research history had impact on the current regulations, and several important stories were revisited such as the Nuremberg Trial in Germany, the Syphilis Study in Alabama, the Jewish Chronic Disease Hospital Cancer Study in New York, and the Willowbrook State School Hepatitis Study in New York.

She then asked the participants to consider modern-day research tragedies, and reviewed the research misconduct involved in the Jesse Gelsinger (University of Pennsylvania 1999) and Ellen Roche (Johns Hopkins 2001) cases.

Hoping to have set the stage for comprehensive ethical and scientific considerations, Ms. Way gave an overview of guidance documents relevant to the protection of human subjects in research. Special emphasis was given to elements of informed consent. Ms. Way asked the group to consider that true “informed consent” is an ongoing process and not just a document called a consent form.

The expectations of an FDA audit were covered as well in this workshop, and Ms. Way shared excerpts from real and current Warning Letters.

Beyond Words: Non-Verbal Communication

Submitted by Connie Marvel, Associate Director, Bristol-Myers Squibb

The MWSQA 2003 Winter Meeting held in St. Louis, MO on March 11-12 began with a half-day training symposium led by Patti Wood, a Body Language Expert. There were many laughs, chuckles, smiles and raised eyebrows as Patti provided insight on understanding deception and credibility cues. The following highlights represent just a smattering of the information provided by Patti and demonstrate just how much you missed if you did not attend this presentation! For more information on this subject and others that Patti presents, visit her website at pattiwood.com!

Handshakes:

- ◆ First impressions are made in just 1/30th of a second!
- ◆ A good handshake is 3-5 pumps.
- ◆ Historically, handshaking began as a weapons check.
- ◆ Women began participating in handshakes in the mid-1980's.
- ◆ The most effective way to establish rapport. Without a handshake, it takes 3 hours to establish the same level of rapport.
- ◆ A palm-to-palm handshake indicates a willingness to be honest and self disclose.
- ◆ Maintain eye contact during the handshake.
- ◆ Shake hands at the beginning and end of meeting.

Nonverbal Deception Cues:

- ◆ The Nine Month Pregnant Pause – Liars have longer pauses, shorter answers and longer times between a question and a response than someone who is merely nervous. It makes sense that liars need time to create the lie. Recalling the truth takes less time; honest people answer spontaneously.
- ◆ The Eyes Have It – Check to see where their eyes go after you ask the question. People tend to look up to the right to visualize or create a new response or down to the right to create the sounds of a new response. We recall information that occurred in the past by looking LEFT - up to the left or down to the left.
- ◆ The Hands Say It: Excessive Gesturing – When people lie spontaneously, they tend to spend more time gesturing with their hands. On the other hand, the rehearsed or practiced liar, who has planned the deceit ahead of time, will try to control gestures and look stiffer and less natural. Spot a liar by their excessive gesturing or by looking for someone who is too stiff and still.
- ◆ Excessive Confidence – Have you ever experienced a super smooth salesperson? He may have over enthusiastically praised the product and you felt uncomfortable about his pitch? Then you have deciphered a lie by noting that the person sounded too good or too confident. Nonverbal communication, which includes such things as voice, tone, volume, and speaking rate, that sounds over confident or overacted is read at the subconscious level as out of the norm. Spot a liar by going with your gut impression. Your instincts can read a fake at a hundred paces.
- ◆ Smile and the World Smiles with You – A smile is the most common facial expression to mask emotions. It is often used to mask displeasure and anger. A real smile changes the entire face. The eyes light up; the forehead wrinkles; the eyebrows and cheek muscles rise; skin around the eyes and mouth crinkles; and, finally, the mouth turns up. In a masking smile, nothing moves but the corners of the mouth, and often they curve down rather than up.

Who's Who in MWSQA?

No one correctly guessed the identity of the 'mystery guest' in the last issue of the MWSQA newsletter, although someone did try. Our last guest was **Virginia Alldredge of Bristol Myers Squibb**. The first person to guess who the mystery guest in each issue is will win a free membership to MWSQA in the year 2004. Your 'guess' can only be submitted via e-mail to Editor@MWSQA.org. Employees at the editor's site, BASi -West Lafayette (and of course the individual his/herself) are not eligible to participate. Let's exercise that QA curiosity!

- Q: My birthplace was Des Moines, Iowa.
- Q: I got into Quality Assurance because I was actually applying for a job in Pharmacy, which was my previous occupation, and my employer thought I would be better suited for QA.
- Q: The first job I had was as an employee in a hospital kitchen.
- Q: On a cold rainy day I like to sit by the fireplace.
- Q: My favorite food is anything Mexican.
- Q: The one word that best describes me is honest.
- Q: One of the most memorable events in my life was the birth of my children.
- Q: My hobbies/favorite pastimes are bowling and watching sci-fi.
- Q: I just can't resist spending time with close friends.
- Q: The most respected occupation should be There isn't just one.
- Q: My all time favorite movie character is Maria, from Sound of Music.
- Q: My pet peeve is being dishonest.
- Q: The one person I'd like to swap place with is Don't know of anyone.
- Q: If there were one thing I'd like to be remembered for in my life it would be for being a loyal friend.
- Q: The person who had the most impact on my life was... I can't narrow it down to one. Many people are very special, depending on the situation. Friends that have helped me with difficult decisions in recent years have really made me understand how important good friends are in our lives.
- Q: One thing that really makes me laugh is letting it 'all hang out' with good friends, and realizing I have done something stupid, but being able to admit it and learn from it.

Editor's Note

You've probably noticed the new look of our newsletter. These changes have been made to save costs, which typically run over \$200 per issue for printing and mailing, to increase the speed of delivery to your 'doorstep' and to save trees! It also allows us to send out more information in a single issue, when all of you are inspired to present it. The simpler look helps facilitate distribution. You should still find it packed with useful and interesting information. Please keep that information coming and heartfelt thanks as always, to those who have contributed. The deadline for the next newsletter is **September 30, 2003**.

Thanks Again,
Paula N. Wehmeyer, Senior Quality Assurance Auditor, BASi



In Memory

Ms. Kathleen Pease, longtime member of the Society of Quality Assurance and Midwest Regional Chapter, died on June 7, 2003 following a 5-year battle with breast cancer. Ms. Pease was formerly the Director of Quality Assurance at BASi in West Lafayette, Indiana.

After becoming a member of the Society of Quality Assurance in 1992 and the Midwest Regional Chapter in 1993, Kathy gave as much to the society as she received. She participated on the SQA Nominating Committee (1998) and Program Committee (2000), presented a poster at the 1997 SQA Annual Meeting, and created the Mock Analytical Chemistry Inspection that was displayed at both the 1997 MWSQA meeting and the 1998 SQA Annual Meeting. Kathy served as a Director for the MWSQA in 1995-1996, and was instrumental in hosting the February 1995 MWSQA meeting held in West Lafayette, Indiana.

She left behind her husband Gary Williams, her daughter Kate (20) and son Nicholas (18). She will be greatly missed by all who knew her.

Memorial contributions may be made to the American Cancer Society, if desired.



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