



*“News from the Heartland”*

## Mid West Society of Quality Assurance Newsletter

August 2004

MWSQA Wants YOU!!!

By Connie Marvel

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, Secretary, and two Directors. The descriptions of these positions and their responsibilities can be found on our web site at [mwsqa.org](http://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](mailto:nomination@mwsqa.org) today!

*Just think, your name could be included on the list below...*



### MWSQA Officers

President: Bonita Weiss, Ricerca, phone 440/357-3253, [president@mwsqa.org](mailto:president@mwsqa.org)

Vice President: Debra Green, Bayer CropScience, phone 913/433-5409;

<mailto:vicepresident@mwsqa.org>

Secretary: Lea Gough, Covance, phone 608/242-7954, [secretary@mwsqa.org](mailto:secretary@mwsqa.org)

Treasurer: Deborah Little, Consultant, phone 419/289-8949, [treasurer@mwsqa.org](mailto:treasurer@mwsqa.org)

Nominations Director: Sue Batdorf, Consultant, phone 847/ 816-0109 [nomination\\_director@mwsqa.org](mailto:nomination_director@mwsqa.org)

Membership Director: Sherry Garrett, Pfizer, phone 269/833-4391, [membership\\_director@mwsqa.org](mailto:membership_director@mwsqa.org)

Audit Director: Brian Mitchell, Eli Lilly, phone 317/277-4783, [audit\\_director@mwsqa.org](mailto:audit_director@mwsqa.org)

Communications Director: Chris Carson, Consultant, phone 573/445-1755,

[communication\\_director@mwsqa.org](mailto:communication_director@mwsqa.org)

Past President: Connie Marvel, Bristol Myers Squibb, phone 812/429-8253; [pastpresident@mwsqa.org](mailto:pastpresident@mwsqa.org)

Historical Chair: Carol Thompson, Eli Lilly, phone 317/277-5233, [historical@mwsqa.org](mailto:historical@mwsqa.org)

Survey Co-Chair: Debra McMillan-Ash, Compliance Resource, phone 513/777-2823, [survey@mwsqa.org](mailto:survey@mwsqa.org)

Information Transfer (IT) Co-Chair: Paula Wehmeyer, Bioanalytical Systems, phone 765/497-5866,  
[editor@mwsqa.org](mailto:editor@mwsqa.org)

Please submit articles for the next newsletter by November 10, 2004 to [editor@mwsqa.org](mailto:editor@mwsqa.org)

Midwest Regional Chapter



*Harvest for a Crop of Knowledge*



Society of Quality Assurance

Fall Meeting

**October 5-6, 2004**

The Midwest Regional Chapter Society of Quality Assurance (MWSQA) invites you to "Harvest for a Crop of Knowledge" for the 2004 fall meeting.

Venue: Madison Concourse Hotel –reservation deadline (*reduced rate til Sept 13<sup>th</sup>*)  
*Please see end of this newsletter for additional information and registration forms*  
*And speaking of meeting attendance, here is a great opportunity!*



**MWSQA OFFERS 2<sup>nd</sup> ANNUAL SCHOLARSHIP**

The purpose of this award is to cover the registration and travel costs (a total of up to \$1,000) for a MWSQA member to attend the annual SQA meeting.

Potential recipients must meet the following requirements:

- MWSQA member.
  - Be able to attend the 2005 annual SQA meeting February 20-24, 2005 in Orlando, Florida.
- Submit the following:

A letter describing why you would like to attend the meeting and what you hope to gain from participating.

Curriculum Vitae to include current contact information and all past involvement in SQA/MWSQA (e.g., meeting attendance, committee participation, speaker, etc.)

Be willing to allow your letter to possibly be published in a future MWSQA Newsletter and/or posted to the MWSQA website.

Letters can be sent via fax, e-mail or US mail, but must be received by November 30, 2004 in order to be considered. The Board of Directors will vote to select the winner. The winner will be announced mid-January, 2005.

Please send letters or direct questions to:

Brian Mitchell – GL43

P.O. Box 708

Greenfield, IN 46140

Ph: (317) 655-9258

Fax: (317) 277-4783

[mitchell\\_brian\\_1@lilly.com](mailto:mitchell_brian_1@lilly.com)

Notes:

Winning applicant must pay for expenses and receive reimbursement after the SQA annual meeting. Receipts are required and reimbursement will be made as soon as possible following submittal of receipts. MWSQA will reimburse the winning applicant up to a total of \$1,000. The winning applicant is responsible for any expenses exceeding \$1,000.



**Robust data records and accounts for all variables.** Generally, these variables consist of all the measured values and unplanned events that at the report stage support or detract from the scientific evaluation of the study. One of the basic tenets of Good Laboratory Practices is that there must be data to support the accuracy of measured values. Without this supporting the data, any data indicating a measured value is no longer robust and its value becomes questionable to the study director. Any options that are in SOPs or protocol must be recorded in the data.

**Robust data is understandable and has utility.** Data must be understandable to the average man, and be in a form that can be used and archived. In the real world, reports are written from the data, and the writer is often a person of less education than the Study Director. Obscure data, even if correct, only promotes error and inefficiency in the report writing process.

**Robust data contains a record of systematic review.** Verification of data is a Study Director responsibility, and a part of the GLPs. Oddly, review of data, which is a study function, is often done by Quality Assurance Units, which could be argued to be a non-compliant event. Nevertheless, it is critically important that robust data be "verified" in a consistent and systematic way.

These principles should provide clarity and direction when next confronted with a data issue. Just remember to focus on the data, apply the principle to the situation, and your argument will be hard to refute.



## [ENTER AND WIN - THE SQA PHOTO CONTEST!](#)

So you've captured that memorable image from the Annual SQA Meeting or other SQA-sponsored event, and are not sure what to do with it. The SQA Historical Committee invites you to submit ONE best picture from this year's SQA-sponsored events for entry in the SQA 2005 Photography Contest. The contest will be judged at the joint 21st SQA Annual Meeting and 1<sup>st</sup> International QA Conference in Orlando, FL in 2005. All entries will become part of SQA history via inclusion in the SQA Historical Photo Archive!

P.S. You can also send any other SQA-sponsored event quality photos for inclusion in the SQA Historical Photo Archive - but be sure to identify them as "archive submissions" rather than the ONE for the SQA 2005 Photography Contest.

### Photo Contest Guidelines:

- All photos *must* be taken during an SQA event: SQA Annual Meetings, SQA regional Chapter Meetings, SQA-sponsored training sessions or other SQA event.
- Photos must be of SQA members attending the event.
- Photos may be submitted in print format or in digital format (photos are recommended to be submitted in .jpeg format).
- Type or legibly print your name and affiliation, phone number, names of individuals in the photograph, (left to right and front to back) on two small sticky labels. Also, include the name/date/location of the SQA event (month and year are okay, if you do not know the full date). If the photo is submitted digitally, assemble the information and submit the label information with the digital image.
- Secure one of the labels (from step 4) to the back of the photograph and submit the other label with the photograph. The extra label (or information submitted with digital photograph)

will be used for display of the photograph.

- Photos may be submitted via mail address to the attention of: Patricia O'Brien Pomerleau, @ CIIT Centers for Health Research, PO Box 12137, Research Triangle Park, NC 27709-2137. Photos will not be returned, but will become part of the SQA Historical Photo archives.
- Digital photos may be sent via e-mail to Patricia at [pomerleau@ciit.org](mailto:pomerleau@ciit.org).
- The deadline for submission of photos via mail or e-mail is January 15, 2005. You do not have to be present at the meeting to win.
- Photos may also be submitted in a manila envelope to the SQA Historical Committee at the time of the Annual Meeting in Orlando, FL



Our 'mystery guest' last issue was Lea Gough and our first correct guess came from Virginia Alldredge.

Virginia has won a year's free membership in MWSQA. Congratulations, and 'thank you' both!

If you would like to win a free membership be the first correct guess to submit your answer to P Wehmeyer via e-mail to 'editor@mwsqa.org' (or use your MWSQA directory to contact P. Wehmeyer). Employees at the editor's site and of course, the guest are not eligible to win.

**Q: My birthplace was Detroit Michigan**

**Q: I got into Quality Assurance because I was the only one available with experience with GLP safety studies.**

**Q: My favorite quote is "Judge your success by what you had to give up to get it." - by Dali Lama**

**Q: The first job I had was as a file clerk in the local school system.**

**Q: On a cold rainy day I like to curl up on the couch and read a good book.**

**Q: My favorite food is mashed potatoes.**

**Q: The one word that best describes me is Midwestern**

**Q: One of the most memorable events in my life was birth of each of my children.**

**Q: My hobbies/favorite pastimes are gardening, travel and swimming.**

**Q: I just can't resist chocolate**

**Q: The most respected occupation should be 'Teacher'.**

**Q: My all time favorite movie character is Mel Gibson.**

**Q: My pet peeve is last minute business travel**

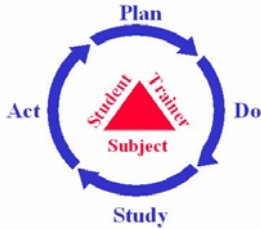
**Q: The one person I'd like to swap place with is Phyllis Diller**

**Q: If there were one thing I'd like to be remembered for in my life it would be for being**

available to friends/family.

Q: The person who had the most impact on my life was my husband.

Q: One thing that really makes me laugh is the movie “Escanaba in the Moonlight”.



**TBD Enterprises,**  
**“Training by Design”**

A business without a reputation is like a sailboat without a sail – dead in the water! So don’t sail your “ship” with non-compliance.

The best way to assure compliance with GLP regulations is with quality training.

*We teach what you want to know in a way you want to learn it.*

In addition to workshops with attendees from different companies, we provide custom workshops at your location to meet your company’s needs.

Our workshops are scheduled as follows:

“Good Laboratory Practices in the Analytical Laboratory,” October 14-15, 2004, Philadelphia, PA

“Achieving a Competitive Edge with Good Laboratory Practices,” Nov. 18-19, 2004, Boston, MA

“Good Laboratory Practices in the Analytical Laboratory,” February 17-18, 2005, Orlando, FL

For additional information and workshops see our website: [www.trainingbydesign4u.com](http://www.trainingbydesign4u.com)

Contact: Harvey Mathason at (215)752-5117, Email [HMathason@aol.com](mailto:HMathason@aol.com)

Deepak Doshi at (267)918-0623, EMail [acelab4u@aol.com](mailto:acelab4u@aol.com)

TBD Enterprises, “Training by Design ,” 3219 Leeland Drive, Bensalem, PA 19020

# Midwest Regional Chapter Society of Quality Assurance

## **“Harvest for a Crop of Knowledge”**

Fall Meeting

**October 5-6, 2004**

Madison Concourse Hotel  
1 West Dayton  
Madison, WI 53703

(608) 257-6000  
Reservations: 1-800-356-8293

(Deadline for room reservations at the reduced rate is September 13, 2004)

### **Program Highlights**

*“Ripe for the Picking”*

**Tuesday, October 5, 2004**

### **High-Impact Communications Styles, Skills and Strategies**

Presented by Pat Alea

### **Sponsor/CRO Relations**

followed by:

**QA Roundtable and Hot Topics Discussion**

Presented by Connie Marvel/Lydia Dickrell

**Wednesday, October 6, 2004**

### **Conflict Resolution**

Presented by Scott Hunter

The registration desk will be open at **7:00** each day, and the meeting will begin at **8:00**.

There will be a one-hour break for lunch, and sessions will resume at **1:00**

Social Event information will be sent with another registration packet form via e-mail.

## *A few words about the fall meeting Sponsor:*

### Covance Inc.

Covance is a leading drug development services organization, providing a contract services encompassing nonclinical development, clinical trials, central laboratory and commercialization services to the world's pharmaceutical, biotechnology and medical device companies.

The MWSQA is **inviting your organization** to participate as a sponsor in this meeting. Sponsors may earmark their contribution for a meeting break or towards the special event. Sponsors will be recognized in the program book and throughout the meeting for their generosity in helping to defray the costs of this event.

For more information on participation as a sponsor, please e-mail any Board of Director member at [bod@mwsqa.org](mailto:bod@mwsqa.org)

### **Membership Information**

Membership information for the Midwest Regional Chapter, Society of Quality Assurance is included in this registration packet. **Join the MWSQA** when you register for the meeting and **save \$30.00** off the non-member registration fee! If you elect this option, please be sure to complete the enclosed membership form and return it along with your meeting registration.

### **Message Board**

A message board will be available for job openings and positions being sought. Take advantage of this opportunity to connect employee candidates with potential employers.

### **Accommodations**

A block of rooms at the reduced rate of \$95.00 per night will be held until **September 13, 2004**. Please make your hotel arrangements directly with the Madison Concourse Hotel at 1-800-356-8293. Be sure to mention that you are a Midwest SQA meeting attendee.

### **Transportation Information**

Shuttle service is available free of charge from the Madison airport.

### **Meeting Registration Fees**

The MWSQA is offering several attendance options for this meeting. Join the MWSQA when registering and save \$30.00 off the non-member meeting fee!

- MWSQA Member - \$100
- Non-Member - \$150
- New Member - \$120

If you need additional information or require arrangements for special or dietary needs, please contact [treasurer@mwsqa.org](mailto:treasurer@mwsqa.org)

### **Cancellation Policy**

Notification of meeting cancellation must be received in writing by September 25, 2004 in order to receive a refund. Correspondence should be mailed to Debbie Little, 724 Hale Avenue, Ashland, Ohio 44805 or submitted by FAX at (419) 289-6805. Meeting registration may be transferred to another individual with written notification.

**MEETING REGISTRATION FORM**

**Midwest Regional Chapter Society of Quality Assurance  
"Harvest for a Crop of Knowledge"**

October 5-6, 2004

Name: \_\_\_\_\_

"Name Badge": \_\_\_\_\_

GXP Specialty \_\_\_\_\_ GLP \_\_\_\_\_ GCP \_\_\_\_\_ GMP

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Phone: \_\_\_\_\_ FAX: \_\_\_\_\_ E-mail: \_\_\_\_\_

**Optional Social Event:** Please indicate if you will or will not attend the scheduled social function. There is no charge for meeting attendees. Guests are welcome at an additional cost of \$25 each. Also, indicate if you or your guest will require a vegetarian meal.

\_\_\_\_ Yes, I will attend.                      \_\_\_\_ Yes, I require a vegetarian meal.

\_\_\_\_ Yes, I will bring a guest.            \_\_\_\_ My guest requires a vegetarian meal.

\_\_\_\_ No, thanks.

\_\_\_\_ I am a current MWSQA member

\_\_\_\_ I am joining the MWSQA (*membership registration form must be included*)

\_\_\_\_ I am not a member of the MWSQA

Attendance Option(s)	MWSQA Member	New Member	Non-Member
Meeting (Social Event @ no charge)	\$100.00	\$120.00	\$150.00
Social Event Guest	\$ 25.00	\$ 25.00	\$ 25.00
<b>Total Amount Enclosed</b>			

***Please, make check or money order payable to  
Midwest Society of Quality Assurance (MWSQA)***

***Meeting Registration Deadline is September 20, 2004***

**PRINT COMPLETED REGISTRATION FORM(S) AND RETURN WITH FULL PAYMENT TO:**

Debbie Little  
724 Hale Avenue  
Ashland, Ohio 44805  
Fax: 419-289-6805

**Reminder: The deadline for hotel reservations at the reduced rate is September 13, 2004. Please make arrangements directly with the Madison Concourse Hotel at (800) 356-8293**

**MEMBERSHIP REGISTRATION FORM**

**Midwest Regional Chapter Society of Quality Assurance**

***This form must be completed and returned if you elected the  
"New Member" meeting option for \$120.***

**(The 2004 membership fee is \$20.00)**

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Phone: \_\_\_\_\_ FAX: \_\_\_\_\_ E-mail: \_\_\_\_\_



Please send me email updates regarding chapter events

<b>My regulatory interests are (Check all that apply):</b>			
<input type="checkbox"/>	FDA GLP	<input type="checkbox"/>	Veterinary GCP
<input type="checkbox"/>	EPA GLP	<input type="checkbox"/>	Pharmaceutical GMP
<input type="checkbox"/>	Human GCP	<input type="checkbox"/>	Medical Device GMP
<b>My occupation is oriented towards (Check all that apply):</b>			
<input type="checkbox"/>	Human drugs, vaccines or devices		
<input type="checkbox"/>	Animal drugs, vaccines or devices		
<input type="checkbox"/>	Agricultural products (including pesticides)		
<input type="checkbox"/>	Contract Research Organization		
<input type="checkbox"/>	Educational Research Organization		
<input type="checkbox"/>	Innovator pharmaceutical, vaccine or device firm		
<input type="checkbox"/>	Generic pharmaceutical, vaccine or device firm		
<b>Professional Affiliations (Please list)</b>			
<b>I would consider future participation in the MWSQA as a (check all that apply)</b>			
<input type="checkbox"/>	Meeting Attendee		
<input type="checkbox"/>	Meeting Presenter - List Topic(s)		
<input type="checkbox"/>	Elected Officer (preference?)		
<input type="checkbox"/>	Committee Member (preference?)		

**PRINT BOTH COMPLETED FORMS AND RETURN WITH FULL PAYMENT TO:**

**Debbie Little  
724 Hale Avenue  
Ashland, Ohio 44805  
Fax: 419-289-6805**