



*“News from the Heartland”*  
**Mid West Society of Quality Assurance Newsletter**  
February 2007



***MWSQA Officers***

**President:** [president@mwsqa.org](mailto:president@mwsqa.org)

Brian Mitchell; Eli Lilly & Company, 317/ 655-9258

**Vice President:** [vicepresident@mwsqa.org](mailto:vicepresident@mwsqa.org)

Barbara Stephenson; Pfizer Animal Health, 269/833-2856

**Secretary** [secretary@mwsqa.org](mailto:secretary@mwsqa.org)

Jonathan Kreuger, Covance, phone 608/242-2712, ext. 2503

**Treasurer:** [treasurer@mwsqa.org](mailto:treasurer@mwsqa.org)

Krista Richardson, Charles River Laboratories, phone 419/647-4149

**Nominations Director:** [nomination@mwsqa.org](mailto:nomination@mwsqa.org)

Andrea Steed, Eli Lilly & Company. phone 317/ 655-9131

**Membership Director:** [membership@mwsqa.org](mailto:membership@mwsqa.org)

Steve Drzick, MPI Research, phone 269/668-3336 x1409

**Audit Director:** [audit@mwsqa.org](mailto:audit@mwsqa.org)

Janet Cunningham, Eli Lilly & Company, 317-433-4055

**Communications Director:** [communication@mwsqa.org](mailto:communication@mwsqa.org)

Celeste Rose, RoseTECH Consulting, phone 440/357-1769

**Past President:** [pastpresident@mwsqa.org](mailto:pastpresident@mwsqa.org)

Lea Gough, Covance, phone 608/242-7954

**Historical Chair:** [historical@mwsqa.org](mailto:historical@mwsqa.org)

Carol Thompson, Eli Lilly, phone 317/277-5233

**Survey Co-Chair:** [survey@mwsqa.org](mailto:survey@mwsqa.org)

Andrea K Steed, Eli Lilly and Company, phone 317/655-9131

**Editor:** [editor@mwsqa.org](mailto:editor@mwsqa.org)

Paula Wehmeyer, Bioanalytical Systems, phone 765/497-5866,

Please submit articles for the next newsletter by **May 15, 2007** to [editor@mwsqa.org](mailto:editor@mwsqa.org)



## ***Presidential Ponderings***

Brian Mitchell,  
Eli Lilly & Company

Spring is almost here! For me, the change from winter to spring evokes emotions of renewed commitment and provides for a fresh and upbeat outlook for the remainder of the year. Just around the corner, leaves will begin to appear and flowers will be blooming. This spring also marks a change in seasons for MWSQA and several other SQA regional chapters around the country.

As announced at the MWSQA 15<sup>th</sup> Anniversary meeting in Indianapolis last November, the MWSQA Board of Directors, along with other regional chapters, has decided to transition various administrative tasks to SQA HQ. Tasks making the transition include membership maintenance, financial accounting and record keeping, and website maintenance. SQA HQ will be performing these additional tasks at no additional cost to our organization, therefore saving MWSQA some money in the long run, which will be used to continue funding our chapter meetings, to continue funding the MWSQA scholarship, and to help keep membership dues the same amount they have been for 15 years...\$20.

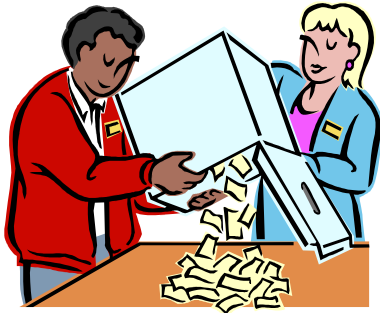
Even with the obvious financial benefits for MWSQA, the decision was not easy to make as it meant we would no longer need the services of Joyce Abad, who has been working as the MWSQA Administrator for a number of years. Joyce has consistently provided our Chapter with superior customer service and has truly been an asset to our organization! The Chapter would not be as organized and successful as it is today without Joyce's dedication and hard work. I thank Joyce for her service to MWSQA and wish her every success in the future!

Looking back on 2006, I am astonished at what a milestone year it was for MWSQA. We celebrated MWSQA's 15<sup>th</sup> birthday in style by offering our membership a week to remember in Indianapolis on November 13-17, 2006. In addition to the stimulating training and meeting sessions offered by MWSQA, the Anniversary Planning Committee joined forces with SQA to offer the RQAP-GLP professional registration exam and host the SQA Quarterly Committee, Specialty Section, Regulatory Forum and Board meetings. Both were milestones by being the first time SQA has paired up with a regional chapter to offer these opportunities. About 150 people attended, making the anniversary meeting the biggest MWSQA meeting on record. I would like to personally thank the volunteers of the Anniversary Planning Committee, the meeting sponsors, SQA HQ, and those who attended for making the meeting such a huge success. Without their amazing support, the meeting would simply not have been a possibility.

2007 will also offer additional opportunities to attend a MWSQA meeting. Please consider joining us for our next meeting in July, 2007 hosted by MPI Research Inc. in Kalamazoo, Michigan, which surely will be another fun educational and networking event.

I hope to see all of you in Kalamazoo in July! Until then, I hope you enjoy the change in seasons!





## ***Election Results for the 2007 MWSQA Board of Directors – And the Winners are...***

L. Lea Gough,  
Covance, Inc.

I would like to congratulate our new Board members and extend a thank you to them and their organizations for agreeing to serve on the Board. They are:

- Vice President/Planning Committee Chair – Barbara Stephenson (Pfizer Animal Health)
- Secretary - Jonathan Kreuger (Covance Laboratories Inc.)
- Director – Andrea Steed (Eli Lilly)
- Director – Janet Cunningham (Eli Lilly)

The new Board of Directors are:

- Lea Gough - Past President
- Brian Mitchell - President
- Barb Stephenson - Vice President
- Jon Kreuger - Secretary (2007 - 2008)
- Krista Richardson - Treasurer (2006 - 2007)
- Celeste Rose - Communications Director (2006 - 2007)
- Steve Drzick -Membership Director (2006 - 2007)
- Andrea Steed – Nomination Director (2007 - 2008)
- Janet Cunningham – Audit Director (2007 - 2008)
- Barb Stephenson - Program Planning
- Celeste Rose - Web Liaison

I want to take this opportunity to thank our officers and their organizations who left the Board of Directors at the end of 2006 for their service to the organization. They are:

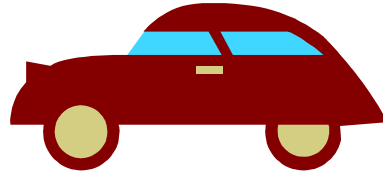
- Past President - Debra Green (Bayer CropScience)
- Director – Dee Talerico (Charles River)

I would also like to thank the other candidates for running for office and I hope to see them continue to be involved with the MWSQA and run again for office next year. They are:

- Vice President - Lisa Fink - Baxter Healthcare Corporation
- Secretary - Stephanie Clemons - Charles River Laboratories, Preclinical Services
- Director - Howard Cooper - EQACT, Inc.

Finally, a special thank you to our returning newsletter editor, Paula Wehmeyer, who will be working with us for another year.





**Midwest Regional Chapter Summer Meeting, Kalamazoo  
17-18 July 2007**

Barbara Stephenson,  
Pfizer Animal Health

**Save the Dates** - 17-18 July 2007: The Midwest Regional Chapter of the Society of Quality Assurance (MWSQA) summer 2007 meeting will be hosted by MPI Research Inc. and held in Kalamazoo, Michigan. We are planning GLP training and sessions on toxicokinetics, reproduction/teratology, computer validation, risk assessment, modernization of the GxPs and more. One evening will be dedicated to a cook out at the Gilmore Car Museum where we will have the opportunity to step back in time and drive a vintage car <http://www.classiccar.com/museums/gilmore.php>. Come join us for an educational experience, networking and fun. Our website will be updated in the spring to include the meeting agenda. MWSQA website can be found at: <http://www.mwsqa.org>

If you or your company are interested in financially contributing to the meeting by sponsoring a break, special event or meal, contact a member of the MWSQA Planning Committee, Barbara Stephenson (+1.269.833-2856, [barbara.a.stephenson@pfizer.com](mailto:barbara.a.stephenson@pfizer.com)) or Steve Drzick (+1.269.668-3666, [Steve.Drzick@mpiresearch.com](mailto:Steve.Drzick@mpiresearch.com)).





## **MWSQA CELEBRATED 15TH ANNIVERSARY IN STYLE**

Brian Mitchell,  
Eli Lilly & Company

The Midwest Regional Chapter of the Society of Quality Assurance (MWSQA) celebrated its 15<sup>th</sup> anniversary November 13-14, 2006 in Indianapolis, IN at University Place Conference Center and Hotel. As evidenced by the great attendance, the planning committee worked hard and attracted a great line-up of training, speakers, exhibitors and sponsors. About 150 people attended, making this the biggest MWSQA meeting on record. Please see the end of this article for a list of the anniversary planning committee volunteers as well as the list of meeting sponsors. Without their support, the meeting would not have been a possibility.

On Monday morning, November 13, 2006, the RQAP-GLP exam was offered for the first time at a regional chapter meeting. About 25 people registered for the RQAP-GLP exam, and once the exam proctor finally showed up to administer the exam (she mistakenly thought it was scheduled for Tuesday, November 13<sup>th</sup> and was about 2 hours late!), the rest of the meeting progressed very smoothly. In addition to the exam, Monday morning offered three concurrent training workshops covering Basic GLPs, GMP Regulations for GLP Auditors and Getting Medical Devices to Market. Monday afternoon and Tuesday were filled with fantastic presentations and speakers as indicated by the overwhelmingly positive surveys from meeting attendees. About 50 brave souls tried their luck Duckpin Bowling during the special event on Monday night. No high score records were set, however, a few sore muscles were evident the next morning!

The anniversary meeting was also the first time SQA Quarterly Meetings were held in conjunction with a regional chapter meeting. SQA Quarterly Meetings were held at the same facility November 14-17, 2006. Quarterly Meetings included Committee, Regulatory Forum and Specialty Sections. SQA members who attended the MWSQA meeting were granted the MWSQA member registration price. Likewise, MWSQA meeting attendees were allowed to attend the SQA Quarterly Meetings without having to be a member of SQA.

Thanks again to all those who made this meeting such a huge success!! Please consider joining us for our next meeting in July, 2007 hosted by MPI Research Inc. in Kalamazoo, Michigan, which surely will be another fun educational and networking event. Stay tuned to future newsletters and communications for details on this upcoming meeting.

### **MWSQA 15TH ANNIVERSARY PLANNING COMMITTEE**

Howard Cooper EQACT Inc	Barbara Stephenson, RQAP-GLP Pfizer Inc	Andrea Steed Eli Lilly and Company
Lea Gough Covance Laboratories Inc	Celeste Rose, RQAP-GLP RoseTECH Consulting Inc	Brian Mitchell Eli Lilly and Company
Jonathan Kreuger Covance Laboratories Inc	Vicki Smith Eli Lilly and Company	Steve Drzick, RQAP-GLP MPI Research
Debra Green, RQAP-GLP Bayer CropScience	Krista Richardson Charles River Laboratories	Dee Talerico, RQAP-GLP Charles River Laboratories

**MWSQA 15<sup>TH</sup> ANNIVERSARY**  
**MEETING SPONSORS**



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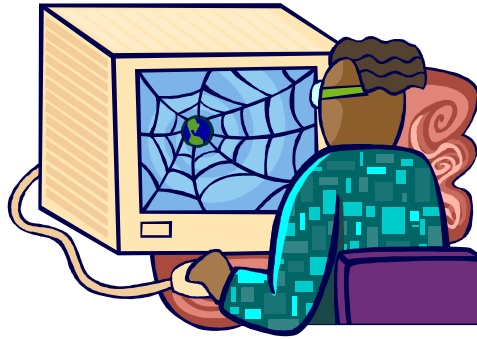
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## **MWSQA Website**

Celeste Rose  
RoseTECH Consulting

The MidWest Regional Chapter of the Society of Quality Assurance web address is [www.mwsqa.org](http://www.mwsqa.org). The website has been updated with information and calendar dates for the 2007 year ahead. Details on the July 17-18, 2007 Summer Conference in Kalamazoo, Michigan, will be added as the conference plans unfold.

### **NEW Resource Link Additions**

This year I would like to make the MWSQA a better resource tool for our members. Resources such as the following are being added to the MWSQA website Links page:

- History of FDA
- FDA News Releases
- Sign up for FDA's Free E-mail Lists
- Warning Letters and Notice of Violation Letters to Pharmaceutical Companies
- Comparison Chart of FDA and EPA GLP Regulations and OECD Principles
- FDA Glossary of Terms
- FDA CDER Guidance Documents
- FDA Guidances for Pharmacology/Toxicology
- FDA CBER Guidance Documents
- EPA OPPTS Harmonized Test Guidelines

What would *you* like to see on the MidWest SQA website? What information or resources do *you* think would be valuable?

Over the next several months more changes will be coming down the road. MWSQA will be using services provided to SQA headquarters. Some of these are already in place. MWSQA membership application forms can now be sent directly to SQA headquarters. This means that now MWSQA membership dues can be paid via credit card as well as by check. Conference dues will also be able to be paid by credit card.

Remember the [www.mwsqa.org](http://www.mwsqa.org) website is OUR member website. If you have any suggestions or recommendations that you would like to share for additions or improvements to the website, I encourage you to send them to me at [crose@rosetechconsulting.com](mailto:crose@rosetechconsulting.com).



## ***Note from your Editor***

Dear Hard-working Colleagues,

There have been many wonderful articles for this newsletter. Has yours been among them? Please give some serious thought to writing an article to keep *your* newsletter interesting. If you think you don't have anything interesting to contribute it's only because you haven't seen it in print yet. Take a look at any of the regulatory forum lists for a 'hot' topic, or keep your ears open at the next society meeting. We all have something worthwhile to contribute to *our* community. We have brand new auditors with fresh perspectives and seasoned auditors with lots of experience to share. Please contribute to help make these pages interesting.



Your pleading editor,

Paula

Paula N. Wehmeyer  
Bioanalytical Systems, Inc. (BASi)

**Thank You to All Who Contribute to Our Newsletter!!!**

*Opinions are those of the authors and not necessarily those of MWSQA.  
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