



*“News from the Heartland”*  
**Mid West Society of Quality Assurance Newsletter**  
October 2010



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Please submit articles for the next newsletter by **November 8, 2010** to [editor@mwsqa.org](mailto:editor@mwsqa.org)



## ***Presidential Ponderings***

Darcie Verdon, Covance Laboratories, Inc.  
President, MWSQA

Here in the upper Midwest the reality of fall is upon us. School supplies are nearly cleared off the store shelves, children are back in school, football season is here, and there is a new crispness in the air. It seems like just a few weeks ago we were in the early stages of planning our 2010 annual meeting, and that too has come and gone amongst a bustling of activity.

The 2010 meeting was another success and I would like to thank the planning committee, presenters, and participants for all of their contributions in Columbia, MO and throughout the year. Greatly appreciated is the on-going support of our corporate sponsors for this year's event, and on behalf of the planning committee I would like to extend my many thanks to ABC Laboratories, Charles River Laboratories Inc., Monsanto, Pfizer Inc., WIL Research Laboratories LLC, and Leifheit & Company Inc.

In 2011 we head north as we plan for an annual meeting in the Chicago area. The host for the 2011 meeting will be Midwest BioResearch, a WIL Research Company. The planning committee intends to start planning for this meeting right away, and each member of MWSQA is welcome to participate in the planning and organization. If you are interested in participating please contact the Planning Committee to find out how!

As we begin to look ahead to 2011, I once again call on our chapter members for your continued support and participation. First and foremost, as we look toward next year, we find ourselves looking for individuals to step into leadership roles on the MWSQA Board of Directors. Leaving us this year will be Lori Rush (Secretary), Matt Hansen (Nomination Committee Director), Kathy Newland (Audit Committee Director). We will also have an opening for Vice President as Deanna Talerico assumes the role of President of MWSQA. I would like to extend my appreciation and thanks to each of these individuals as they conclude their tenure in their current role, they have been valuable assets to this chapter during this time and have gone above and beyond to share their expertise and talent to continue to build a strong Midwest chapter.

If you are at all interested in running for the Secretary, Directors or Vice President position, please contact Matt Hansen, Nominations Director at [nomination@mwsqa.org](mailto:nomination@mwsqa.org) so that he may include you on the ballot. Continuing to build on what has been established and bring new ideas and backgrounds into the leadership of MWSQA only strengthens our chapter and the support we provide to our members.

Many Thanks!



## 2010 MWSQA Annual Meeting

Deanna Talerico, MWSQA Vice President & Planning Committee Chair;  
Tony Ettwein, MWSQA Communications Director

Seventy-three people, including 20 speakers, attended the MWSQA annual meeting, which was held in Columbia, Missouri on 27–28 July 2010 at the Courtyard by Marriott. Analytical Bio-Chemistry (ABC) Laboratories in Columbia acted as corporate sponsor and host for the meeting.

The meeting consisted of two half-day pre-conference workshops: The first workshop was co-hosted by Bob Herr and Tony Ettwein (Pfizer, Inc.) who presented a forum on IT issues and computer system validation, followed by Chris Wubbolt (QACV Consulting), who addressed computerized systems used in clinical trials. The second workshop, “Principles of GMPs for the FDA Regulated Industries,” was presented by Howard Cooper (EQACT). Surveys received from attendees indicated that the sessions were generally well received.

Our Keynote speaker this year was Larry Potterfield of MidwayUSA, a 2009 Baldrige Award recipient. Mr. Potter spoke enthusiastically about the positive impact that applying the Baldrige National Quality Award principles has had on his company, and of the processes that lead to achieving the Baldrige Award, which he believes can have a dramatic positive effect on our communities, states, and country.

We were also fortunate to have Dan Meyers of the EPA’s Office of Compliance give a presentation on computer validation issues. Meyers talked about how “evidence of reliability” is key to the validation of computer systems, and described the information that EPA inspectors review during their inspections.

This year’s dinner and networking event took place on Tuesday evening at the Les Bourgeois Vineyards in nearby Rocheport. The event included a presentation by the vineyard’s winemaker, and wine tasting combined with an excellent menu. In addition, participants had the opportunity to see the sunset across the Missouri River after dinner. The evening was very relaxing and enjoyed by attendees, and surveys indicate that the food was rated above average.

On Wednesday of the meeting, 12 other presentations were offered. The sessions covered topics such as Bioanalytical 101, Designing a Quality System, IT and QA interactions, Compliance in dealing with Site closures, QA GMP responsibilities, SOP management, Archive considerations, ICH Q10 overview, Management’s perspective on Quality, obtaining and maintaining USDA permits, <sup>14</sup>C radiolabeled drug candidates for Clinical Studies, and introducing GLP programs to non-GLP colleagues.

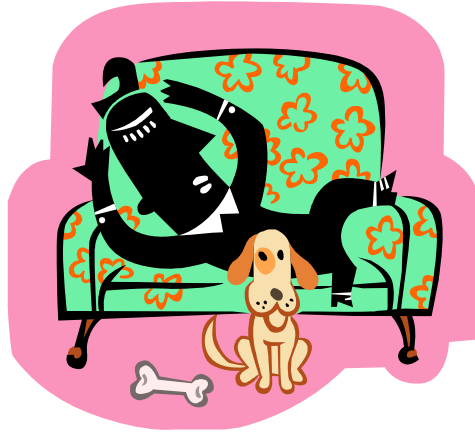
The MWSQA Board of Directors and Planning Team, led by our survey analyst Gregg Gazvoda, have had an initial, high-level discussion of the ~ 40 surveys we've received to date. We welcome your continued feedback at any time. We want MWSQA members and all other participants to know that we'll continue to analyze your responses and act on them appropriately. We want our own continuous improvement process to be as transparent to you as possible. Responses to date were either positive or offered good, constructive criticism. Among the suggestions under discussion:

- There were not enough printed surveys. For next year's meeting, we'll have more available.
- The workshops were generally successful.
- A number of people indicated that they'd like the speaker grid ahead of time, as well as printed copies of some materials. (In part, the lack of materials this year were due to an attempt at saving paper; in addition, a number of speakers were not able to complete their presentations very far in advance – this seemed to be an especially busy year for many of us, perhaps because of the poor economic climate.) The planning team will discuss better ways of distributing materials next year, and will schedule due dates for activities further in advance.
- There were a number of IT-oriented workshops this year. Although they were appreciated, a number of attendees are looking for more intermediate-to-advanced GxP sessions (particularly GLP and GMP, with a few requests for GCP sessions). We'll take these comments into account for next year's meeting. In addition, there has been discussion that next year's sessions might be longer (e.g., 90 minutes instead of 60 minutes), but would also include 5-10 minutes between sessions for people to move between rooms.
- A number of attendees commented on room temperature, with most of them saying rooms were too cold. We'll try to monitor room temperature more continuously next year.
- Some food allergy needs were not met, for example, dishes did not always list whether they contained foods such as peanuts. This will be addressed for next year's meeting.

We think next year's MWSQA meeting will be a good one, and the Planning Committee is already looking forward to it. Next year's meeting will be in the Chicago area, and will be hosted by Midwest BioResearch, a WIL Research Company. Please note that we tentatively plan to have next year's meeting a little later in the year than usual, probably in the September-October timeframe, with the current target being mid-September. It's not too early for you to submit topic suggestions for next year. Look for a request for submission of "hot topics" in advance. We continue to welcome any suggestions for next year's meeting, and also invite anyone reading this article to participate on next year's planning team. Planning for next year's meeting has already begun, and the more people we have involved in the planning, the easier and better things will be. It's a fun committee to work with.

Many thanks to our sponsors, exhibitors, consultants, meeting presenters, the Planning Committee, and all meeting participants for making the 2010 annual meeting a success. We look forward to seeing you again next year in the Chicago area.





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

Dear Friends and Colleagues,

Looks like we've 'fallen' into another season, ready or not. Did you attend the MWSQA meeting this year? It's not too late to send an informative article about your experiences. Did you present a session? Why not add an extra feather to your cap with a companion article- the hard work is already done.

Please note, Word or email format is much appreciated.

Thank you,  
Paula

Paula N. Wehmeyer  
PW Quality Consulting, LLC  
Editor, *News from the Heartland*, MWSQA newsletter

## **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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