



“News from the Heartland”
Mid West Society of Quality Assurance Newsletter
April 2011



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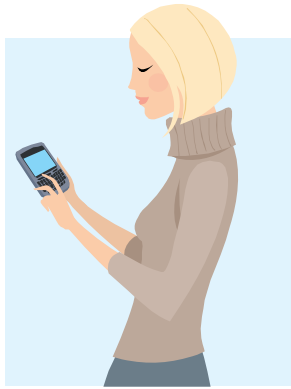
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Please submit articles for the next newsletter by **May 30, 2011** to editor@mwsqa.org



Presidential Ponderings

Deanna M. Talerico, RQAP-GLP, Charles River Laboratories, Inc.
President, MWSQA

With the ending of a very active winter, we are all eager to welcome spring. With daylight becoming longer, snow melting away, and temperatures beginning to rise, the hope of a refreshing new season is becoming a reality. Saying goodbye to winter, and the past year, can often seem bittersweet—causing us to tuck away fond memories of working with great friends and colleagues, while also making us take inventory of our successes and challenges we have made and overcome. But, with one door closing, it always means another is opening. I am both eager and excited for what the new season and year will bring for us all.

First, I'd like to take a moment to reflect. The founding member of MWSQA, Anita Bosau, RQAP-GLP, retired from Charles River Laboratories, Inc. in late fall 2010. Anita was elected as the first President of MWSQA in the early 1990's, and maintained a career in GLP regulatory affairs for over 30 years. She was a very strong pillar in the world of GLP regulations for CRO's and she is and will be greatly missed, both at Charles River and in the GLP QA community.

I would like to take this opportunity as well to welcome all our new members to MWSQA. We hope our communications, website, and conferences provide you with great resources and connections to supplement your auditing needs. I'd also like to thank all our current active members for making 2010 a great year, and for all your contributions and active participation. Remember that this is ***your*** MWSQA—you are the reason why we exist! I encourage all members to actively participate and feel free to provide any recommendations that you believe will make our organization stronger and more beneficial.

With a new year brings a new “changing of the guard” at MWSQA. I'd like to thank our outgoing officers, (Tim Valley, Lori Rush, Matt Hansen, and Kathy Newland) and say goodbye and thanks to our previous past president, Tim Valley. All of them have selflessly volunteered their time and efforts to our organization. You will be missed!

We welcome all of the newly elected board members and remind everyone of our current MWSQA Officers:

2011 MWSQA Officers

- Darcie Verdon - Past President
- Deanna Talerico - President
- Angela Eichelberger - Vice President
- Anne Carlson - Secretary (2011-2012)
- Kelly Baird - Treasurer (2010-2011)

- Tony Ettwein - Communications Director (2010-2011)
- Christina Hamm -Membership Director (2010-2011)
- Matt Bruns - Nomination Director (2011-2012)
- Steve Camarato - Audit Director (2011-2012)
- Angela Eichelberger - Program Planning
- Tony Ettwein - Web Liaison

The 2011 national SQA meeting was held in San Antonio, TX March 27th through April 1, 2011. For those members who were unable to attend the SQA meeting, please keep in mind that the annual MWSQA meeting is currently in the planning stages.

The MWSQA planning committee is excited to announce and are diligently beginning to sketch out the details for our 2011 annual meeting under the leadership of newly elected Vice President Angela Eichelberger as well as members from our 2011 Titanium Sponsor company, Midwest BioResearch, a WIL Research Company. This year our annual meeting will be held in the Evanston, Illinois area September 19-21, 2011. The planning committee is also finishing up on the details surrounding the evening event which will comprise of a Dinner Tour in the Chicago area. We are looking for volunteers – workshop/training presenters, speakers, or anyone who has ideas to share for the meeting. Please contact Angela if you are interested in volunteering your time and services. We look forward to seeing you all at the meeting!

In closing, I would like to take the opportunity to wish all the membership a very successful and rewarding year. I look forward to the year ahead and hope to provide to the membership an organization that is beneficial, prosperous and resourceful.

Respectfully submitted,
Dee





2011 MWSQA Annual Meeting - **CALL FOR SPEAKERS!**

Angela Eichelberger

The planning committee is currently looking for speakers for the 2011 Annual Meeting, MWSQA's 20th Anniversary! The meeting will be held **September 20-21** in **Evanston, Illinois** at the Hilton Orrington/Evanston. Speaking is an excellent way to share your individual knowledge with the organization. The committee would like to offer a variety of sessions so all GCP, GLP, and GMP topics are welcome! Session presentations are 30 – 40 minutes with potential time for questions/discussion. Workshop presentations are 4 hours long. Keep in mind that speakers have their **registration fees waived!**

Potential topics include: the modernization of FDA GLPs, Submission process and product development for EPA/FDA, ISO, Statistics, Digital Images, Pathology Peer Review, Part 11, GLP Advanced, GCP, GMP, Risk assessment, Electronic data, Analytical/Bioanalytical data auditing, Reporting, Animal Welfare 9CFR, how to handle a 483 or warning letter, Immunotoxicology or an open Q&A session.

If interested or have additional questions please contact Angie Eichelberger at aeichelberger@wilresearch.com.



Win Free Lodging at the Evanston Hilton during the 2011 Annual Meeting!

The MWSQA Board of Directors would like to commemorate the 20th MWSQA annual meeting in style by announcing a Logo Contest. The Board invites MWSQA members to design a new chapter logo! The winner will be revealed during the annual meeting. All logo designs must be received by Friday June 24th, 2011. The Board of Directors will choose the top three designs and the membership will vote for the winning entry. Submit entries in PDF format to aeichelberger@wilresearch.com.

The winner will receive one free night stay at the Evanston Hilton to be used during the 2011 MWSQA annual meeting. Winner will be notified by August 15, 2011.



FDA Part 11 Inspection Initiative: Update

Tony Ettwein, Pfizer Global Systems Compliance
MWSQA Communications Director

In last summer's MWSQA newsletter, Matt Hansen of Covance Laboratories, Inc. told us about the FDA's announcement of targeted inspections related compliance with 21 CFR Part 11, FDA's rule on electronic records and electronic signatures. Matt's article described the discussion with FDA's Robert Tollefsen at last year's annual SQA meeting, which indicated that in conjunction with inspections that CDER would normally perform, they will also "inspect Part 11 controls relating to drugs as they are described in the guidance document 'Part 11, Electronic Records; Electronic Signatures – Scope and Application' (August 2003)." Mr. Tollefsen indicated that FDA intends to perform a series of audits to help them evaluate industry's current understanding and level of compliance with Part 11, as related to the Scope and Application guidance. The Agency's findings from these inspections, now being called "tagalong" inspections by some, may be used by FDA to re-evaluate Part 11 and related guidance. Additional FDA staff will be enlisted to perform the Part 11 portion of these inspections, and "FDA may take appropriate enforcement action on issues raised during these audits." At the time of this presentation, Mr. Tollefsen did not have additional details about the tagalong program; however, he did state that the program could involve approximately 30 inspections, which were then expected to be performed in late 2010.

Update: On November 11th of last year, regulatory consultant John T. English provided an audio conference, in conjunction with FX Conferences, to provide participants with an update on the CDER Part 11 tagalong program.

According to Mr. English, who is also part of an FDA-PDA Task Force, the CDER Part 11 tagalong program was delayed, but will still take place. He stated that the reason for the delay was that because of the length of time planning the tagalong inspections, some inspections that had been planned as tagalong inspections had already begun. CDER has therefore canceled the original tagalong assignments of the field force, and new assignments will be provided soon. During the audio conference, Mr. English said his expectation is that the inspections will be completed by mid-2011, and that it could be late 2011 before industry hears back from FDA, "depending on what they find." Mr. English stated that violations of Part 11 that "do not fall within the (Scope & Application) guidance's discretion can lead to enforcement action."

Recent instructions from the FDA ORA to the field force indicate that inspectors "should not personally access a firm's databases," and that they should have the inspected firm generate

the data or reports to be copied to CD or other medium or should have them copied to paper. Mr. English shared FDA's intent to focus on "user access to computer systems with raw data," with an emphasis on controlling access to those data. Mr. English also said that related training must not only be performed, but it must be effective. In addition, he stated that "workarounds" for Part 11 issues should be the exception and not the rule.

Mr. English suggested that participants be ready for inspection and that they learn from their own regulatory history.



Note from your Editor

Dear Friends and Colleagues,

Here we are 'springing forward' into another year. Maybe this will be the year that you get an article off to the MWSQA newsletter? I hope so. We will have a better newsletter with your input and after all, it is *your* newsletter!

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

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