



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



MWSQA Officers

Past President: pastpresident@mwsqa.org

Darcie Verdon, Covance Inc., phone 608/242-2712 ext. 7314

President: president@mwsqa.org

Deanna Talerico, Charles River Laboratories, phone 419/647-8463

Vice President: vicepresident@mwsqa.org

Angela Eichelberger, WIL Research Laboratories, LLC, phone 419/289-8700, ext 2091

Secretary: secretary@mwsqa.org

Anne Carlson, Pioneer Hi-Bred International, Inc., phone 515/535-4247

Treasurer: treasurer@mwsqa.org

Kelly Baird, MPI Research, phone 269/668-3336, ext 1727

Nominations Director: nomination@mwsqa.org

Matt Bruns, Charles River Laboratories, phone 419/647-8464

Membership Director: membership@mwsqa.org

Christina Hamm, Cellular Technology Limited (CTL), phone 216/791-5084, ext. 117

Audit Director: audit@mwsqa.org

Steve Camarato, Covance Inc., phone 608/242-2712

Communications Director & Web Liaison: communication@mwsqa.org

Tony Ettwein, Pfizer Inc., phone 269/833-9479

Historical Chair: historical@mwsqa.org

Steve Drzick, MPI Research, phone 269/668-3336 ext. 1409

Survey Chair: survey@mwsqa.org

Gregg Gazvoda, Covance Inc., phone 608/242-2712 ext. 1267

Editor: editor@mwsqa.org

Paula Wehmeyer, PW Quality Consulting, LLC, phone 765/538-2478

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



Presidential Ponderings

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

Fall can be such an invigorating time of year and the year has definitely been a whirlwind. As we observe the glorious colors of fall all around us, I reflect back upon the last several months. The frenzy of activity associated with the scheduling of the annual MWSQA meeting, the networking of colleagues at the meeting and now into the search for the new board members to begin the process all anew. It seems as though we have just gotten started and it is time for transitioning into new roles and activities.

A special thanks goes out to Midwest BioResearch, LLC, a WIL Research Company, for being the 20th annual MWSQA meeting Titanium Sponsor. Other companies sponsoring this year's annual meeting included Monsanto, Charles River Laboratories, Inc., Pfizer, Inc., Ricerca Biosciences, LLC and Leifheit & Company and all deserve thanks for their contributions as well. Not only does a successful meeting need sponsorship but also a strong planning committee. This year's planning committee was led by Angela Eichelberger along with sturdy support from Lucy Podbielski, Nina Sahay and Sara Rybak who all worked very diligently to assure the meeting went without a hitch. Finally, thank you to the meeting speakers/presenters and the meeting attendees. As we all know it takes many volunteers and the support of our members to assure an educational experience and networking opportunity for our membership. Keep in mind for the 2012 meeting we are in need of meeting Sponsorship and volunteers. The meeting is scheduled to be in the Chicago area. Stay posted for additional updates throughout this year and next regarding the meeting progress. We hope to see you there!

I would also like to express a thank you to the MWSQA board for their efforts throughout the year. Again, it takes willing and active volunteers to steer the organization through the year. With the quickly approaching end of the year, comes the changing of the guards for our chapter. Again, thanks to Darcie Verdon, Past-President, Kelly Baird, Treasurer, Tony Ettwein and Christina Hamm, Directors, for all of your dedication over the past couple of years. You all leave great shoes to fill in the forthcoming year and we will miss you greatly.

So what will 2012 bring us you ask?...Angela Eichelberger will be transitioning into the President's role while Deanna Talerico, Anne Carlson, Matt Bruns and Steve Camarato will remain on the board. We will see new faces in the positions of Vice President, Treasurer and Directors (2). Please contact Matt Bruns if you or anyone you know is

willing to accept the challenge to run for one of the open board positions. We need volunteers to step up and complete our ballot. So with that in mind, please heed the following advice...

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.

Again, thank you all for your commitment to our chapter and assuring a strong foundation.

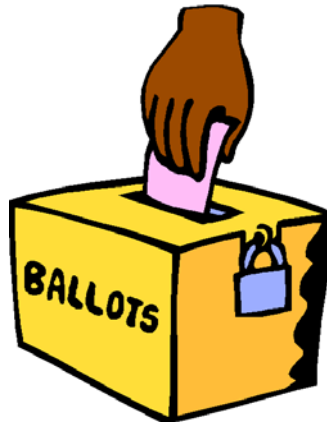
Respectfully submitted,
Dee



MWSQA Officer Elections

Matt Bruns, MWSQA Nominations Director/ Chairman
Charles River Laboratories

ATTENTION MWSQA members! Elections will be held this coming November and we would like all members to consider becoming involved in our organization.



Positions that will be available this election:

Vice President (3 year position, one year as vice president , one year as president, one year as recent past president, 2012-2014)

Treasurer (2012-2013)

Communications and Membership Directors positions (2012-2013)

If you are interested please contact Matt Bruns at nomination@mwsqa.org



Twenty Years of Quality Meetings

Angie Eichelberger, MWSQA Vice President & Planning Committee Chair,
WIL Research Laboratories, LLC;

This year's meeting was a celebration of Quality, as MWSQA celebrated 20 years of annual meetings! The celebration consisted of 3 workshops, 10 sessions, a cupcake reception, and the unveiling of the new MWSQA logo. The meeting title was "Quality Bears Repeating!" Sixty-five members, including 19 speakers, attended the annual meeting, which was held in Evanston, Illinois on September 20-21, 2011 at the Hilton Orrington/Evanston. Midwest BioResearch, a WIL Research Company, acted as corporate sponsor and host for the meeting.

The meeting consisted of three half-day pre-conference workshops: The first workshop was hosted by Howard Cooper (EQACT, Inc.) who presented "Principles of Good Manufacturing Practice for the Drug & Medical Device Industry." The second workshop, "Lead to Exceed!," was co-presented by Matthew Bruns and Deanna Talerico (Charles River Laboratories, Inc. Preclinical Services, Ohio). The third workshop, "Applying risk Management to Your Quality Program," was presented by Steven Rogers (Pfizer Animal Health). Surveys received from attendees indicated that the sessions were educational and engaging.

Our Keynote speaker was David Spaight, CEO of WIL Research Company. Mr. Spaight spoke about his work history and education with Quality. He also provided results on two surveys a coworker had done a couple of years prior from labs within the industry. The first survey was Management's top 10 complaints about QA, and the second was QA's top 10 complaints about Management. Many members stated that his speaking style and presentation were very interesting.

The chapter was not able to secure an FDA speaker for this year's meeting. Many attempts were made, but in the end it came down to the budgets. In place of a speaker, both FDA and EPA updates were provided during the opening session.

This year's dinner and networking event was a progressive dining tour of Chicago. This event was complimentary and paid for by the chapter and meeting sponsors. The members were picked up in a charter bus and escorted to three different fantastic restaurants. Appetizers and wine were served at the first stop where fantastic pizza and salads were ready and waiting our arrival. The second stop served up the main course which consisted of a giant bowl of chicken alfredo. The third stop offered decadent desserts and coffee overlooking Lake Michigan. Unfortunately the evening event start time was delayed due to the unexpected arrival of Vice President Joe Biden in

downtown Chicago. Because of the delay, some sightseeing was limited because of sunset. The Chicago Dine Around did provide free wine for supper for the delay.

On Wednesday of the meeting, 10 other presentations were offered. The sessions covered topics such as Laboratory Expansion/Renovation and Testing Prior to Use, An Overview of GMP Requirements for Combination Products, Trends in FDA GLP Enforcement: Impact on Data Quality and Study Integrity, Immunogenicity Testing for Protein Biotherapeutics: What's it All About Anyway?, Purdue University's Regulatory and Quality Compliance Graduate Certificate Program, Work Instructions, Guidelines, and memos to the File...the Monitoring Authorities Agree there Shall be One Study Protocol, Auditing a Statistical Report: Pointers, Pitfalls and P-values, Comparing the FDA Quality Systems Approach to the GMP's and ICH Q10, Pharmaceutical Quality Systems, QA Consultant's Corner, and Nonclinical Research Activities Supporting Clinical Drug Development.

Initial review of the surveys has been conducted. Overall attendees felt the meeting was a success with excellent food, beautiful conference facilities, a convenient location, and meeting sessions. One survey stated that this was the best annual meeting they had attended in 14 years! The BOD and planning committee 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.

MWSQA is still looking for a Titanium Sponsor for the 2012 annual meeting. Unfortunately, because of the economy and other conferences, the meeting attendance was down from previous years. Because the contracted numbers were not met, the MWSQA chapter owes the hotel the loss in revenue. The hotel has agreed to apply half of what is owed as a credit if the chapter schedules next year's meeting at the same facility before the end of the year. 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 2011 annual meeting a success! We look forward to seeing you again next year.



Note from your Editor

Dear Friends and Colleagues,

It's already fall and hinting of winter, where does the time go? It's nice to think of grabbing a steaming mug of hot chocolate and huddling around the warm glow of your ...computer screen to write an article for **your** MWSQA newsletter! You'll feel cozy as you view your updated resume or list your professional accomplishments for your employee review. You can even include writing an article in your goals for the coming year!

I hope to hear from you soon, I'm sure you have something valuable you can contribute. We are "wide open" for topics and article lengths.

Did you know you can advertise your company in the newsletter and/or on the MWSQA website?

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.
The editor, MWSQA and national SQA are not responsible for any damage.*