



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



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Please submit articles for the next newsletter by **August 27, 2010** to editor@mwsqa.org



Presidential Ponderings

Darcie Verdon, Covance Laboratories, Inc.
President, MWSQA

Things are heating up!!!! Both outside and with the MWSQA planning committee as they continue to charge ahead with planning this years meeting under the leadership of our Planning Committee Chairperson, Dee Talerico. This year MWSQA will be visiting Columbia, Missouri for our meeting and registration is underway. If you have not yet made plans for the meeting please do so as the registration deadline is July 16th. The first day will begin with a choice of 4 hour workshops in the AM followed by the keynote address from, SQA update, and a presentation from Dan Meyer of the EPA in the afternoon.

That evening we will have the opportunity to enjoy some dinner and enjoy a sampling of local wines at Les Bourgeois Vineyards Winery, a beautiful venue at the 3rd largest winery in Missouri.

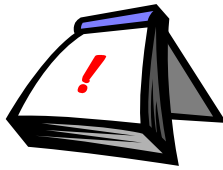
Day 2 will provide a selection of presentations aimed at meeting the needs of all the variety of knowledge and experience that exist within the membership of this amazing chapter. Again we have made every effort to include a broad scope of topics in this years meeting and feel we have successfully achieved that.

There has been much activity to increase the connectivity between the MWSQA members. Progress is being made to put in place a members only page accessible via the SQA website through the efforts of Tony Ettwein, Communications Director, and starting a group site through the LinkedIn networking connection an initiative driven by Christina Hamm, Membership Committee Director. Their efforts to bring our members closer and open avenues of communication have been an exciting effort to witness and I commend them for all their efforts.

As always the success of our annual meeting is a direct reflection of the willingness of sponsors to provide financial contributions toward this event and I would like to extend my sincere appreciation for their continued support.

I look forward to seeing you all in Columbia!

Darcie



MWSQA 2010 Annual Meeting

Save the Date! The Midwest Regional Chapter of the Society of Quality Assurance (MWSQA) Annual meeting will be held on July 27th and 28th in Columbia, Missouri. Our Titanium host for this years meeting is ABC Laboratories. As always we are aimed at offering an array of training and sessions to provide our members a variety of learning opportunities. The Conference will be held at the Courtyard by Marriott in Columbia with additional details to follow. Our website will be updated regularly to reflect the planning of this meeting. The MWSQA website can be found at: www.mwsqa.org. Registration deadline is **16 July 2010**.

If you or your companies are interested in financially contributing to the meeting by sponsoring breaks, meals or other activities please contact a Deanna Talerico at Deanna.Talerico@crl.com.



Graduate Programs in Regulatory and Quality Compliance

Lori Rush
WIL Research Laboratories, LLC

Purdue University offers graduate programs in Regulatory and Quality Compliance (RQC). These are science-based programs aimed at providing relevant graduate education in drug development and registration. The graduate programs are designed to fit the work-life balance of employed professionals. A Graduate Certificate and a Master's Degree are options in the RQC program. Both programs are part-time, with most courses taught in an executive style format. Students attend class for three weekends during the semester. Classes run ½ day Friday, all day Saturday, and ½ day on Sunday. Our graduate certificate courses are taught at the University Center of Lake County in Grayslake, IL.

The Graduate Certificate brochure can be viewed at <http://www.ipph.purdue.edu/graduateprogram/cert-rqc/brochure.pdf>

The master's degree brochure can be viewed at <http://www.ipph.purdue.edu/graduateprogram/ms-rqc/brochure.pdf>

It is recommended that an application should be submitted by July 1, 2010 for the next program, which begins September 10, 2010. Applications must be submitted online through the Graduate School at the following URL: <http://www.gradschool.purdue.edu/programs>.

If you have any questions contact Mary Speer at mspeer@purdue.edu or phone at (765) 494-9001.



FDA Announcement at SQA Annual Meeting in Cincinnati: CDER Part 11 Inspection Initiative

Matthew J. Hansen, Supervisor, Global QA Support
Covance Laboratories, Inc.

SQA's 26th Annual Meeting and Quality College was held 25-30 April at the Duke Energy Convention Center in Cincinnati, OH. The 2010 edition proved to be another successful conference with numerous educational presentations and informational discussions. One of the most talked about topics was the FDA's announcement of targeted inspections related to 21 CFR Part 11.

At the meeting, Mr. Robert Tollefsen provided FDA regulatory information and updates. During his presentation, Mr. Tollefsen discussed FDA's upcoming CDER Part 11 Inspection Initiative. In this effort, the FDA will be inspecting 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). It is the Agency's intention that this initiative will help them to evaluate industry's current compliance and understanding of Part 11 related to the guidance. Inspectional findings from these audits may be used by the Agency in its reevaluation of Part 11 regulations and guidance.

The Agency has indicated that these Part 11 inspections will be performed in conjunction with regular CDER audits and additional staff will be tasked to support the Part 11 portion of the assessment. The FDA may take appropriate enforcement action on issues raised during these audits. At the time of this presentation, Mr. Tollefsen did not have information regarding the planned number of targeted Part 11 assessments nor the expected timeframe for this initiative. However, he did indicate that the effort may involve approximately 30 inspections performed over the second half of 2010.

Further details of this initiative are being defined by ORA and CDER representatives prior to implementation. SQA's Computer Validation Initiative Committee (CVIC) has provided feedback and questions to Mr. Tollefsen for consideration during his discussions and planning with CDER.



Building Bridges to Compliance

26th Annual SQA Meeting and Quality College, April 25-30, 2010 in Cincinnati, OH, USA

Lori Goodrich, Group Supervisor, Quality Assurance
WIL Research Laboratories, LLC

I was awarded the MWSQA Scholarship, which paid up to \$2000.00 toward expenses, for attendance at the 26th Annual SQA Meeting and Quality College (Addressing Challenges to Achieve High Quality GLP and vGCP Animal Studies), held April 25-30, 2010 in Cincinnati, Ohio, USA. Due to this generous award, I was not only able to attend, but was able to take an additional session at Quality College, and attend the Dinner event held at the Cincinnati Aquarium.

Sessions were divided into 5 tracks this year, and training sessions included Bioanalytical, GLP, Clinical, Computer Validation, Animal Health, Medical Devices, University sections as well as a new Roundtable Discussion track. With so many sessions available at once, it was hard to choose, especially when several interesting sessions were held concurrently.

On the first day, I spent some time considering the theme of this year's meeting "Building Bridges to Compliance." I pictured myself on a "coastline" (at the SQA meeting) looking out on many small "Islands of Knowledge" (sessions covering many areas of compliance). With so many choices, I could either work on building small bridges to many areas of knowledge by making diverse choices in sessions, or I could work on enhancing my existing "bridge" to GLP compliance. Small walkways are usually eventually replaced by sturdy bridges which are much more helpful. This got me thinking that by selecting the sessions that would be most helpful to me, I would be adding to my small walkways and turning them into bridges.

There were many chances to explore all areas of compliance as this year's meeting provided ample opportunities for training. I chose to follow the sessions that would be most helpful to me in my position as a QA professional in a GLP environment, with just a few sessions in other areas to get a broader view of compliance in other areas.

I especially enjoyed the EPA/GLP Update and SQA-FDA Updates, Pathology peer review and Quality Systems sessions, which all provided valuable information that I was able to provide to my co-workers as well as management when I returned to work. When I was not absorbing new information, I was reinforcing knowledge that I already had in place. I came away with some thought-provoking information and ideas that will be useful to me at work. I feel that I can creatively relate the information that I learned from the Quality College session and the Improvement sessions that I attended to my coworkers and add value to our auditing processes. I had the chance to meet up with QA professionals I am already acquainted with, and met some fun and interesting new people during lunches and the dinner at the Cincinnati Aquarium. Cincinnati is a wonderful place – the hotels were very nice and the dining choices were great. Cincinnati would be a great place to return to for a few days of vacation!

Overall, I had a great experience at the SQA meeting, gained a new perspective, added to my knowledge in several areas and essentially worked on building my "bridge" to compliance. This was a wonderful opportunity to attend on scholarship funds and I appreciated the opportunity provided to me.

Calendar Note:

BioOhio Regulatory Forum

August 17, 10am - 4pm, Holiday Inn Cleveland-Strongsville
<http://www.bioohio.com/news/Events-Calendar.aspx>



Note from your Editor

Dear Friends and Colleagues,

Here we are in the midst of summer, hopefully enjoying ourselves! Please take a minute to write an article for our newsletter. Remember, it's only as good as you make it.

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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