



“News from the Heartland”
Mid West Society of Quality Assurance Newsletter
July 2009



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Please submit articles for the next newsletter by **September 21, 2009** to editor@mwsqa.org



Presidential Ponderings

Timothy Valley, Covance, Inc.
President, MWSQA

For as long as I can recall in my work life, as soon as the weather gets nice and warm, things pick up at work and you're not able to get out and enjoy it. Once again the weather has improved, summer has finally come and things are busy. Busy would also accurately describe the MWSQA planning committee. This team of high energy, innovative thinkers is finishing up the planning of this year's summer meeting.

This year's meeting will kick off with three concurrent workshops. The workshops were selected to better accommodate the diversity of the MWSQA membership. Feedback received at the national meeting indicated workshops and presentations beyond basic GLP are also desirable. This year's workshops include the following; cGMP Quality Systems Approach for the Medical Industry, Problem-Based Learning for GLP training, and GLP in the Bioanalytical lab, an Intended Purpose Approach for Good Science Toward Compliance.

Tuesday afternoon Debbie Green will provide an SQA update. Chris Coburn, Cleveland Clinic's Chief Technology Commercialization Officer, will present on innovation and its application at the Cleveland Clinic. Finally, Kim Quaintance, Associate Director for Regulatory Affairs, Office of New Drugs, CDER, will present on review issues that may lead to inspection.

Once business is over, the fun will start. This year's evening activity will be one for the ages. Attendees will have exclusive access to the Rock and Roll Hall of Fame. The hall is home to exhibits describing the birth of rock and roll and everything leading up to today's popular rock stars. Dinner and a few drinks are included, so get ready.

Three tracks of presentations will take place on day two of the summer meeting. As mentioned before, greater diversity of subject matter was one of the considerations for this year's presentations. Topics include automating the computer validations, the GLPs in China, international GCP experiences, regulatory audits, and import/transport issues.

A lot of careful thought went into the design and planning for this year's meeting.

In light of the poor economy this year, the aim of the planning committee was to keep costs low, including those of the evening event. Due in part to the savings the chapter has grown over the last few years, this goal was met! The committee also tried to put together a series of workshops and speakers as excellent as those at the national meeting. I sincerely hope the membership takes advantage of the meeting.

Finally I'd like to thank all our sponsors for their financial contributions to this year's meeting, as well as all the speakers who are traveling on their own dime. Were it not for your generosity and commitment to MWSQA none of this would be possible.

Have a great summer, and I hope to see you all in Cleveland.

Tim



“Purposeful Documentation for Computer Systems”

Bob Herr
Sr. Manager
Pfizer Animal Health Business Technology

Documentation and the act of documenting have gotten a bad rap. Documentation has been classified by many people as a “necessary evil” that serves no purpose other than risk mitigation (e.g., avoiding an auditor’s or investigator’s wrath). This is especially true in the information technology (IT) realm. IT people are not historically known for producing good documentation (or any documentation in some cases!). Perhaps that’s why people who own and operate computer systems in a regulated environment feel the need to create additional documentation after IT has done their thing so they can confidently declare the system validated. What a shame.

All too often I hear people in the Life Sciences industry say that the main purpose of computer system documentation is to prove to regulatory authorities that a computer system was developed and is maintained in a state of control (i.e., it is validated). While this is a valid reason for documenting, it should not be the first and certainly not the sole reason. There are several more important and practical reasons to document.

One of the most practical reasons we create a document is to help secure agreement between people. Such agreements usually call out roles and responsibilities of the involved parties and/or include information to help define the scope and boundaries of the agreement. For computer systems this agreement is mainly between the IT group and the business group. Examples include the project plan, requirements document, test scripts, project closure report, and the system support plan. The project plan sets the timelines, key deliverables and roles for the project. The requirements document sets the expectations for the IT system that will be delivered by the project. These two agreements are validated as part of the project to make sure they are kept. Documented test scripts are used to validate the requirements to make sure

the customer got what they asked for. The project closure report validates that the project was executed according to the project plan. Finally, the system support plan includes expectations, roles, and responsibilities for maintaining the system once it is put into production use.

Another important reason we create a document is to provide some information that will help someone else do something. For computer system development work, the specifications document is created to provide information to developers who subsequently build the computer system. It's been said that requirements exist to make sure we build the correct system, and specifications exist to make sure we build the system correctly. As with the requirements document, the specifications document is validated through execution of test scripts. The user manual, training materials, and technical support documentation are normally written by technical writers to help users and support personnel use and maintain the system once it is in production.

Other practical reasons to document include communicating project status to stakeholders, and providing support statistics after the computer system is in production.

So, you can see that there are many great reasons to document other than simply proving to someone else that you did something. When we clearly understand the purpose and value of the document we're creating, we're more likely to produce a quality document. I recently had someone in IT tell me that she likes documentation; she just doesn't like to write it. That's encouraging, but irresponsible. I'm totally convinced that if IT people better understood the practical value for documentation (other than just to prove they did something), they'd get a lot better at creating and maintaining it. Then maybe, just maybe that would naturally produce documented evidence that provides a high degree of assurance that the computer system does what it was designed to do (a.k.a., validation). But let's leave that for another article.



Note from your Editor

Dear Friends and Colleagues,

I am delighted to present Bob Herr's article in this edition. Does it spark some thoughts for you? Is it really that difficult to put 'pen to paper' or, more likely, fingers to keyboard? There are so many interesting questions to ask or debate, so much information out there that helps us do our jobs – please step up and share some of that 'know how' with your colleagues, or present us with a puzzle or dilemma. It won't hurt your resume any, either!

Thank you,
Paula

Paula N. Wehmeyer, BASi
Editor, *News from the Heartland*, MWSQA newsletter

Thank You to All Who Contribute to Our Newsletter

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