

MARSQA MONITOR

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by Chris Wubbolt

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There has been much discussion within industry regarding the review of electronic records. As a result of FDA, MHRA and other guidance related to data integrity, many companies are now including routine review of electronic records within their standard operating procedures. Regulatory agencies are also requesting to review electronic records during an inspection.



21 CFR Part 11 specifically allows FDA to inspect electronic records (ref: 21 CFR Part 11.10(b)). There is some debate within industry regarding how regulators may be allowed to access electronic records during an inspection. MHRA regulators are known to have asked for access to electronic systems to maneuver within the system on their own. Most companies are hesitant to allow unfettered access to their electronic systems. Instead, companies prefer instead to have a “driver” that navigates through the system to assist the regulator in accessing records within the system. This approach makes sense as it allows a trained system user to navigate through the system and also track any specific records which may be reviewed during the inspection.

A related topic, which is an open discussion point, is the ability for auditors to review electronic records during an inspection of a Contract Research Organization (CRO), with or without a “driver” to navigate them through the system. CROs are hesitant to allow review of electronic systems as they are concerned that the auditor may review confidential records that may pertain to another sponsor or client. While this concern is understandable, it also places the sponsor auditor at a disadvantage if they are not able to view electronic records during the audit.



If an auditor is only able to review printouts or reports from a system during an audit, significant quality issues may not be identified by the auditor. If the same CRO is audited by a regulatory agency afterward, the regulators (who are able to view electronic records) may identify quality issues that the auditor may have missed due to lack of access to the electronic system. (Continued on next page)

Topic for Discussion: Review of records (cont.)

(Continued from page 1)

As an example, I once conducted a for cause audit of a CRO which required review of Corrective and Preventive Action (CAPA) records that were created for a study. Printouts of the CAPAs reports were provided for review during the audit. However, when the CAPA reports were reviewed against the CAPA SOP, several sections which were described within the SOP were not included on the CAPA reports. The CRO stated that they did not include the missing sections (root cause analysis and investigation) because they felt the information was confidential and they did not want to share this information with the sponsor. As an auditor representing the sponsor, my position was that the CAPA was generated due to an issue that jeopardized the conduct of the sponsor's study, and all of the information within the CAPA needed to be assessed as part of the audit. It was the sponsor's responsibility to ensure that the issue was thoroughly and adequately investigated and that appropriate corrective and preventive actions were taken based upon the root cause analysis and investigation. The CRO finally agreed to provide all of the information associated with the CAPA during the audit. When the additional information was reviewed, it was found to be incomplete. If the CRO had not addressed the incomplete CAPA, and if a regulatory agency performed an inspection of the study and identified this issue, the integrity of the study could have been jeopardized.



Understandably, electronic review of records during an audit is a delicate subject. However, sponsors and CROs need to have an understanding regarding review of complete and accurate electronic records during an audit. Sponsors may need to include specific language within their contracts with CROs regarding review of electronic records during an audit. CROs may need to design or configure their systems to allow review of electronic records within their systems while maintaining confidentiality of other information within the system. If the purpose of an audit is to identify potential quality or compliance issues that may result in a regulatory observation, the auditors need to be on the same playing field as regulators during a regulatory inspection.



If you have thoughts or comments on this topic, please let contact us! We will publish your comments in the next newsletter. Megan.lawhead@crl.com, tina.myers@otsuka-us.com, or chris.wubbolt@qacvconsulting.com

MARSQA SQA Annual Meeting 2016 Scholarship Winner Megan Lawhead, Charles River Laboratories

I had never realized that holding and racing an armadillo in a Texas honky-tonk was on my bucket list until presented with the opportunity at the SQA Annual Meeting. Surprisingly, holding an armadillo was hardly the most interesting thing I experienced at the SQA annual meeting. I was fortunate to receive the MARSQA scholarship and dove headfirst when I arrived at the Gaylord resort in sunny Grapevine, Texas. The opening remarks started off strong with the event coordinators riding in on toy horses. I knew this meeting was going to be a fun time!



The theme of the annual meeting was “Cultivating a Culture of Quality.” I kept this in mind when selecting courses and presentations to attend. My specialty is GLP, but I chose to attend numerous presentations in the cGMP, Computer Validation, and GCP realm. As I increase my involvement with sponsor qualification audits at my facility, I enjoyed learning more about the various disciplines. I also attended a Quality College Course “No Such Thing as GxP” a full day course which focused on all of the various disciplines—similarities and differences. The presentation on business continuity in the wake of a fire at a Testing Facility was fantastic. One does not anticipate catastrophic events occurring and this presentation detailed the not only regulatory considerations, but a myriad of elements including emotional impact and business impact. I also attended the MARSQA luncheon and got to mingle with members!



The meeting also allowed for considerable networking time with regulatory experts in the field, vendors, and auditors and consultants from just about everywhere! It was especially a great experience to discuss hot topics and challenges with colleagues in the field at the opening reception overlooking a beautiful lake! I would like to extend my genuine **THANKS** to the MARSQA Board for choosing me for the scholarship and affording me the opportunity to attend as well as **THANKS** to my company’s management at Charles River laboratories.

Congrats to Tina Myers!!

Tina presented at SQA!! Her presentation was entitled “Safety in Transition - From Managing Subject Safety and Safety Data During Clinical Trials to Processing Post-Approval Safety Information for Ensuring that Patients are Safe.”

Remember Yesterday

Summary by Megan Lawhead

George Santayana said “those who do not remember the past are condemned to repeat it.” It is vital to reflect on where we as an industry began and why the GLPs and all other regulations are so important. Why does it matter that we initial and date everything? Why are there so many rules? In its height of popularity and success, Industrial Bio-Test Laboratories, a CRO, conducted at least 35-40% of all studies in the US and conducted studies for the U.S. government and chemical and pharmaceutical companies (1).

Horrifying conditions for the animals were noted at IBT leading to significant death in what was referred to as “the Swamp.” “Water streamed off cages and racks, submerging the floor under a four-inch deep pool. Mice regularly drowned in their feeding troughs. Rats died of exposure. No technician entered the Swamp without rubber boots, and many wore masks to protect themselves from the hideous stench of disease and death.” (2).

In addition, poor caging equipment led to escapes, mating with wild rodents, and a monthly mouse hunt and mass euthanasia. Not surprisingly, “fabrication of data, removal of health effect findings from reports, replacement of dead study animals with healthy ones that had not received drug treatment, changes in the interpretation of histopathology slides and changes in report conclusions” were made “to make them look more favorable were repeated occurrences.” (1,2).

A study of TCC (trichlorocarbonilide) for Monsanto highlights a myriad of issues including the pathologist being intimidated to modifying test article-related pathology findings stating that many tissues could not be evaluated due to decomposition, even though the pathologist had not reviewed those slides. “The Environmental Protection Agency's study examined I.B.T.'s data on 200 pesticides. So far 66 percent of the tests have been judged invalid, only 19 percent acceptable. (3).” What is disturbing is that many of the drugs tested by IBT are still on the market with the true effects on humans and environment are not known (1,2). Please refer to the articles on the following page for additional information and chilling details regarding studies run at IBT and the legal ramifications of these atrocities against science and animal welfare.



Remember Yesterday (continued)

References:

1. Baldeshwiler, A.M. History of FDA Good Laboratory Practices. The Quality Assurance Journal, 2003; 7, 157-161.
2. Schneider K. Faking it: the case against industrial bio-test laboratories. The Amicus Journal 1983; Spring: 14-26.
3. <http://www.nytimes.com/1983/05/16/opinion/the-scandal-in-chemical-testing.html>



Call for MARSQA Volunteers!!!

Help us have another successful MARSQA year and volunteer to be a meeting presenter!

- Are you a Quality Archives Expert?
- Do you know about Quality Risk Management?
- Do you have an interesting Quality topic you want to share?
- GLP Expert? GMP Expert? GCP Expert?

If you answered yes to any of the above questions you are ready to be a MARSQA presenter.

Contact MARSQA Vice President, [Stacy Wilson](#) if you are interested in being a MARSQA presenter!



Computer System Validation Committee Update

The MARSQA Computer System Validation Committee held another Basic Computer System Validation Training at Earl's Restaurant in Lahaska, PA on May 18 and 19, 2016.

Approximately 15 people attended. The CSV Committee also welcomed two new presenters, Frank Moschetto and Narith Flach, who both did an outstanding job with their presentations.

Please join the CSV Committee on **October 5, 2016**, for a one day training program on Advanced Special Topics, including updates on current industry guidance documents related to computer validation and data integrity. If you are interested in joining the CSV Committee, please contact Denise Botto (denise.botto@inventivhealth.com) or Chris Wubbolt (chris.wubbolt@qacvconsulting.com).



Chemical Reactions Word Search

Bicarbonate
Bubbles
Chemical
Combine
Dissolve
Evaporate
Experiment
Hypothesis
Irreversible

Measure
Millilitre
Mixture
Pop
Procedure
Reaction
Reversible
Test
Variable
Vinegar

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*For more information, visit our website
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Or contact us at:

Telephone: 610-442-2250

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To contact the entire
MARSQA board please e-mail:
board@marsqa.org

For individual Board Member
e-mail addresses, please see:
<http://www.marsqa.org/board.shtml>

MARSQA Disclaimer:

Please note, during membership meetings, photography during the meeting may occur. If you do not wish your photograph to be included in upcoming MARSQA newsletters, please e-mail newsletter@marsqa.org

Upcoming Events

Upcoming
MARSQA
Membership
Meetings

C*ck and Bull
Restaurant
Peddler's Village,
Lahaska, PA

- September 22-23, 2016 – This meeting will be a joint meeting between NERSQA and MARSQA. More information to come!
- Upcoming MARSQA Membership meetings
 - October 6, 2016 @ Peddler's Village
 - December 6, 2016 @ Peddler's Village

See www.marsqa.org for meeting details and registration information.

Winter
MARSQA
Membership
Meeting

December 6, 2016

Come celebrate MARSQA's 25th anniversary. Pre-registration is required. A Murder Mystery luncheon with the theme "Murder at the Malt Shop" will be held. More info coming soon!!

