Vol. 17. Issue 1, Mar. 2013 | New England Regional Chapter of the Society of Quality Assurance

Northern Highlights

President's Message

Chris Wubbolt, President, NERCSQA

Chris Wubbolt, QACV Consulting, Quality Assurance, Compliance & Validation Consulting

As I was preparing the President's Message for 2013 I couldn't help but reflect on the past; how I became involved in the New England Region Chapter Society of Quality Assurance; the people that came before me; and what we have planned for the future. I've been a member of NERCSQA for the past three years. I was asked to run for Vice President for 2012 after I helped to organize the NERCSQA 2011 Good Clinical Practice training event. I've always been very interested in and supportive of continuing education, training and mentorship. I remember when I first started out in industry in the early 1990's and learning so much from the training events and meetings I attended and from those with more years in the industry that offered advice and shared their experiences. So, when I was asked to run as NERCSQA Vice President, I was more than happy to give back to the industry which I have been involved in for more than 20 years now.

I knew that running for Vice President wasn't just a one year endeavor. As Vice President, I realized that in 2013 I would be the President of NERCSQA, followed by a term as Past-President in 2014. As I begin my term as President, I want to thank Manish Ranjitkar for his leadership as President of NERCSQA in 2012 and his role in promoting two successful training events (the Good Laboratory Practice training sponsored by Boehringer Ingelheim and the "Train-the Trainer" event in Mystic, Connecticut), as well as three well attended membership meetings. NERCSQA also held a meet and greet breakfast at the annual SQA meeting in Miami this past year. I am pleased that Manish will continue to serve NERCSQA this year as Past President. I also want to thank Linda Hook D'Innocenzo and Patience Miller who left the Board following the completion of their terms in 2012. Linda was the President in 2011 and served as Past President in 2012. Patience served as the Chair of the Publication Committee.

As 2013 begins, I want to welcome two new NERCSQA Board members. Aimee Altemus becomes Chair of the Publication Committee and Danielle DeOssie takes over from Jennifer Bravo as the Chair of the Membership Committee. Jennifer will take on a new role for NERCSQA as Vice President and Program Committee Chair for 2013. Katherine Connors , Christopher Braudis, and Laura Hoffman continue their terms on the NERCSQA Board as Secretary, Director of Sponsorship, and Treasurer, respectively. I know how much time and commitment it takes to serve on the Board in addition to meeting the obligations of their full-time jobs so I want to thank every one of the Board members for serving the NERCSQA membership in 2013. I know they will make my job as President so much easier.

So… what do we have planned for 2013? I

(continued on Page 10)

Inside this issue:

Past- President's Message

Manish Ranjtkar, Past- President, NERCSQA

Manish Ranjtkar is Director of QA at Cambridge Biomedical Inc. Cambridge, MA

Greetings NERCSQA members!

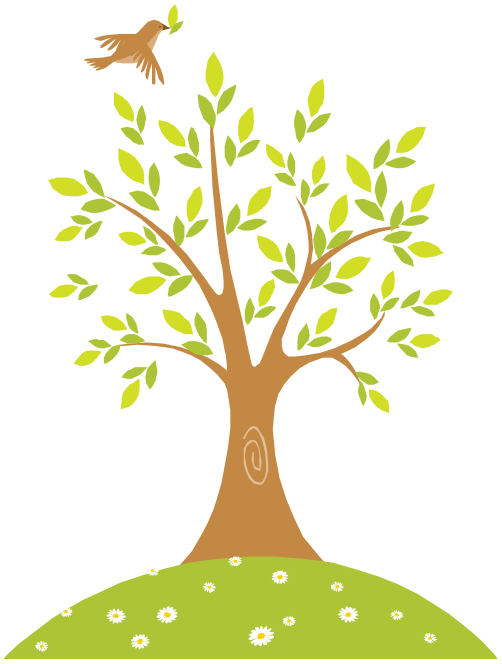
I am currently the Past President of NERCSQA, I have been involved with NERCSQA for the last 7 years starting as a member, then a secretary and slowly working up to Vice President and President. Working with NERCSQA has been very fruitful and exciting. We have put together some great training programs for GLP, GCP, Computer Validations and Information Technology Compliance. In the recent year we have also forged strong relationships with Massachusetts Biotechnology Council, offering networking events and local trainings.

The current elected board members are very capable and driven individuals that will definitely forward the goal of NERCSQA to provide affordable and local training to the New England region. I look forward to working with these individuals this year providing any assistance or guidance they require.

Welcome to NERCSQA 2013 and have a great year.

Regards,

Manish Ranjitkar
Past President of NERCSQA



Chapter Officers for 2013

Feel free to contact any of the officers below, if you have questions or comments.

President: Chris Wubbolt, QACV Consulting, President@nercsqa.org

Vice President: Jennifer Bravo, Agilux Laboratories, VP@nersqa.org

Past President: Manish Ranjtkar, Cambridge Biomedical, Inc., PastPresident@nercsqa.org

Secretary: Katherine Connors, AVEO Pharmaceuticals, Secretary@nercsqa.org

Treasurer: Laura Hoffman, Covidien, Treasurer@nercsqa.org

Director of Publications: Aimee Altemus, Boehringer Ingelheim, DirectorP@nercsqa.org

Director of Membership: Danielle DeOssie, Agilux Laboratories, DirectorM@nercsqa.org

Director of Sponsorhip: Chris Braudis, Cambridge Biomedical, Inc., DirectorS@nercsqa.org

Messages from Officers…

Director of Membership

Danielle DeOssie

I have worked for almost two years as a QA Auditor at Agilux Laboratories. Prior to Agilux I worked as a GLP data reviewer at Biogen and before that worked in the GLP Bioanalysis group at Charles River Laboratories as a chemist.

I have been a member of NERCSQA since 2011 and currently serve on the Program Committee.

As Director of Membership I will find ways to maximize the benefits of membership to current and potential NERCSQA members.

Director of Sponsorship

Chris Braudis, MSc, RQAP-GLP

2013 Goals

- Further develop and create a lasting relationship between Mass Bio and NERCSQA so that future NERCSQA Board Members can easily collaborate with Mass Bio.
- Develop business relationships within local pharmaceutical, biotechnology, CRO's, etc. organizations to support and sponsor NERCSQA by contributing facility space, speakers, and marketing for NERCSQA events.
- Develop a more comprehensible position description for the NERCSQA Director of Sponsorship.

Director of Publications

Aimee Altemus

I have been a member of NERCSQA since 1999 and I'm very excited to start my new role.

My primary goal this year is to ensure we publish at least 3 high quality newsletters, however 4 quarterly newsletters is the target. I will strive to make these newsletters a useful tool for our NERCSQA members. Objectives of newsletters will be as follows:

- Inform/update members on NERCSQA trainings and happenings,
- Share experiences and observed trends in the industry, and
- Publicize the benefits of corporate sponsorship/membership.

Our newsletter will only be as good as the ideas/articles submitted so I urge you to get involved and submit an article or idea for the newsletter!

If you are interested in contributing an article, puzzle, case study, or cartoon for the next issue of Northern Highlights, contact Aimee Altemus at DirectorP@nercsqa.org

Become a Corporate Sponsor or Corporate Member Today!

Contact* Chris Braudis *at* *DirectorS@nercsqa.org

Meet and Greet at SQA's Annual Meeting in Indianapolis, Indiana

Come, meet other NERCSQA members, and learn about what we have planned for 2013, including training events and membership meetings.

Wednesday, May 1, 2013, 7:00 to 8:30 AM

BREAKFAST INCLUDED

Sponsors, laboratories and the FDA all have a common goal: to have scientifically valid bioanalytical data supporting clinical and nonclinical studies

A Critical Review of FDA Form 483 Findings for Inspections of Bioanalytical Laboratories

By David Scharberg, President Pharmaceutical Outsource Solutions, Inc

This paper was presented at the Applied Pharmaceutical Analysis Conference September 17, 2012. Printed here with permission from the author.

I have been overseeing and inspecting bioanalytical activities for the 16 years that I have been in the industry, the first 6 for my employer, ALZA Corporation, and the last 11 as an independent consultant. Over those 16 years I have performed over 85 bioanalytical inspections, averaging about 5 a year. I thoroughly enjoy this aspect of my job. Invariably, during these visits, the issue of 483's comes up -often I am asked what kinds of 483's I am seeing during my inspections.

It's not surprising that people in our industry are obsessed with 483's. They have good reason. If the FDA comes to a facility and performs an inspection – and then leaves without issuing any Form 483 findings – it is like the "Good Housekeeping stamp of approval". A facility that can point to a "clean" inspection is likely to gain new clients more easily and keep existing clients confident and happy.

Conversely, a facility that receives 483 findings may have some doubt cast upon its abilities. It might be more difficult to convince new clients to place work and existing clients may start to wonder if the work they have placed there may be adversely impacted by the same conditions that caused the 483's to be issued.

Since the labs do the work on behalf of the sponsors (or, indeed, are part of the same organization) sponsor's care a lot about 483's. The sponsor is the one with millions of dollars on the line for the submission and doesn't want anything to jeopardize that investment. As we have seen in the past, even if a sponsor's study was not directly affected by the result of a poor inspection, there could still be repercussions – as in the case at MDS and Cetero where the sponsors had to go back and invest more time and money to defend or reproduce study results.

The FDA is tasked with enforcement, and is the one that issues the 483's. The FDA has limited manpower and budget to perform this task, but is still held accountable by the public for the quality of the data supporting product approvals. It is a difficult and thankless task where inspectors are probably left wondering: If these are the things we are catching – what are the things we are not?

- Sponsors, laboratories and the FDA all have a common goal: to have scientifically valid bioanalytical data supporting clinical and nonclinical studies,
- Good bioanalytical methods, appropriately validated and applied should not yield 483's,
- The issuance of a 483 means that something has gone wrong somewhere, and
- Actions that lead to a reduction in the issuance of 483's benefit everyone.

I am sure when he asked me to make this presentation, Farhad envisioned me coming up here, showing a bunch of 483's and discussing them from my perspective. This would be easy to do because I collect current nonclinical and bioanalytical 483's and distribute them through a subscription service. While I will be showing you some 483's, I

think this type of show and tell has been overdone. I chose a different approach. I started preparing my presentation with the rather basic question: What are the circumstances that lead to a 483 being issued?

Here are some of my assumptions:

Since the impact of receiving a 483 can be so detrimental to a laboratory, it is easy to predict that the lab will do everything in its power to not receive 483's , meaning they will try to do all of their activities as correctly and compliant as possible, within the limits of their understanding of the rules and their capacity to follow them.

There are numerous contributing factors that lead to a 483 finding, many (admittedly, most) on the part of the sponsors and laboratories themselves. But that is the subject of another presentation. Today I am going to talk about how, in my opinion, the FDA's actions contribute to the circumstances that lead to the issuance of 483's.

I have arranged these actions into 3 groups:

1. Before the inspection,
2. During the inspection, and
3. After the inspection.

I also provide recommendations that, in my opinion, could help improve the situation. Some of these recommendations are drawn from my experience performing highly regulated sample analysis under the EPA Contract Laboratory Program and the Navy CLEAN program for environmental waste remediation and base conversion.

Part 1. Actions before the Inspection

When the FDA inspects a facility they are performing an enforcement action. The inspector(s) come on site and determine if the facility has met the requirements for validating and applying a bioanalytical method. If, in the inspector's opinion, there is non-compliance, a 483 finding may be issued. However, the assumption underlaying this process is that the facility clearly knows what is expected when validating and using these methods. This means that the regulations and supporting rules are clear and can be readily applied. In my experience, this is not uniformly the case. The FDA contributes to the confusion with respect to the regulations and supporting rules in several ways:

1. The regulations are vague with respect to the requirements for bioanalytical methods,
2. There is no single, enforceable document that clearly lays out the rules,
3. Some rules are not clearly defined,
4. There is no mechanism for revising or reissuing the rules as they change or are updated over time

1. The Regulations are Vague

Bioanalytical is used to support studies: clinical, nonclinical, bioequivalence, pharmacokinetic, bioavailability. The actual regulations that apply are 21 CFR part 58 (GLP's) and 21 CFR part 320 (Bioavailability and Bioequivalence). While the 21 CFR part 58 (GLP's) applies when doing Bioanalysis as part of a nonclinical study, it has very little information specifically applicable to the conduct of bioanalytical testing, and no rules for the validation of the method or sample analysis. Similarly, 21 CFR part 320.29 establishes only that the analytical methods used to support BA and BE studies be, "...demonstrated to be accurate and of sufficient sensitivity to measure, with appropriate precision, the

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A Critical Review of FDA Form 483 Findings for Inspections of Bioanalytical Laboratories

(continued from Page 5)

actual concentration of the active drug ingredient or therapeutic moiety, or its active metabolite(s), achieved in the body."

So, the actual regulations provide no specific sets of rules for validating and applying bioanalytical methods to nonclinical or clinical studies. This was the way things were until the Guidance for Industry Validation of Bioanalytical Methods was published in 2001.

2. There is no single, enforceable document.

The Guidance for Industry Bioanalytical Method Validation (2001) is the first and only description of expectations provided to the industry by the FDA on this topic. However, this document is poorly formatted and organized, leaves many requirements poorly defined and, technically, is not a document that can be used for enforcement. This is the disclaimer that is found at the front of the Guidance for Industry Bioanalytical Method Validation (2001).

"This guidance represents the Food and Drug Administration's current thinking on this topic. It does not create or confer rights for any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations."

Since it was published in 2001, there have been no revisions or updating to this document. Additional "guidance" has come out in the form of workshop and conference reports.

3. Some rules are not clearly defined

The rules for bioanalytical are found in the Guidance for Industry document. This document does not lend itself well to being a reference or enforcement document because the information in it is organized poorly, there are rules that are not clearly defined, and some have no information as to how they are to be performed.

Example: Poor organization-Stability. Stability is the title of Section D in the document, but is also covered in Section E (Principles of Bioanalytical Method Validation and Establishment) and Section F (Specific Recommendations for Method Validation)

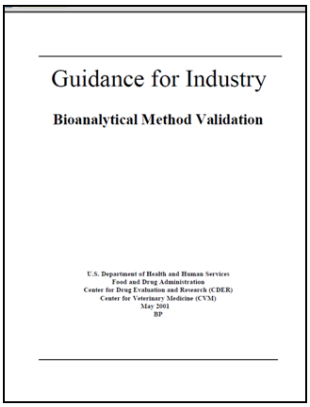
Example: Poor Definition-Selectivity. The document requires that blank matrix should be obtained from at least 6 sources. "Source" being the confusing word here, because what they really mean is non-pooled.

Example: No description of how it is to be performed-Specificity. Specificity is addressed in section F but never defined. In fact the directions for an LC-MS or LC/MS/MS method leave several unanswered questions: Would simply doing the selectivity as defined in section A be sufficient?

This is ironic when you remember that a laboratory has to take these rules and turn them into a method validation SOP or protocol which they will then be held accountable for by the FDA. In other words, they have to take these requirements and figure out, first, how to do it, and second, what the acceptance criteria will be. Why wouldn't the FDA want to simplify this process?

4. There is no mechanism for revising or reissuing the rules as they change or are updated over time.

The rules for bioanalytical are found in the Guidance for Industry document. This document does not lend itself well to being a reference or enforcement document because the information in it is organized poorly, there are rules that are not clearly defined, and some have no information as to how they are to be performed.


Guidance for Industry

Bioanalytical Method Validation

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Veterinary Medicine (CVM)
May 2001
BP

As soon as the Guidance for Industry was promulgated, the need for amendment or revision was almost immediately apparent. While it did do a good job of formalizing a number of rules, it also put some issues on the table with little or no definition.

Example: Matrix Effects. In Section E (Principles of Bioanalytical Method Validation and Establishment) the fourth bullet point establishes the expectation that LC-MS/MS methods have, "… the appropriate steps taken to ensure the lack of matrix effects throughout the application of the method…" The manner for doing this was not defined until the 3rd Crystal City conference report 6 years later (2007).

Recommendation: The FDA should consider adopting a document that clearly defines all of the rules for method validation and sample analysis. It should define how an action is to be performed, what the acceptable limits are, and what (if any) exceptions exist. This document should be revised or reissued periodically and serve as the basis for enforcement. An example of this approach can be found at another government agency that oversees highly-regulated analysis: the EPA. For years the EPA has administered the Contract Laboratory Program (CLP) where third-party laboratories perform sample analysis on behalf of the EPA using promulgated Statements of Work (SOW). Each SOW clearly defines the requirements for sample analysis, documentation and reporting (methods are already validated under this program). Periodically, new SOW's are issued which have changes to the requirements incorporated.

Part 2. Actions during the Inspection

An FDA inspector comes on site and at some point might decide that there is non-compliance and a 483 finding is issued. Sometimes the inspector has you dead to rights – you did it wrong, you failed to do it – whatever. Sometimes, though, it is not so cut and dried. There are circumstances where the laboratory personnel and the FDA inspector have different interpretations of rules and compliance. Personal experience has taught me that even though the Guidance for Industry makes allowance for an "alternative approach" usually when it comes down to a difference in interpretation, the FDA inspector will allow little latitude.

1. You are held to the current standards, regardless of when the actual work was performed,
2. The FDA inspects to different rules,
3. There is no way to get a 483 finding reviewed and potentially withdrawn

1. Held to the current standard

One of the most frustrating aspects of the requirements for bioanalytical methods is the expectation from the FDA that the method be up to date at the time of inspection, even if the actual activity is several years old by the time that inspection occurs.

- Under what circumstance will it not be important to assess an LC-MS/MS method for specificity?
- How would one investigate to ensure precision, selectivity, and sensitivity will not be compromised?

Example: Exclusion of calibrators. Form 483 Finding: The high calibration standards (250 ng/mL) for xxx in runs 9, 16 and 17 were excluded from the calibration response without justification. Truncation of the calibration range allowed otherwise failing runs to pass.

This was a method that was validated prior to 2000, but inspected after the Guidance for Industry was issued in

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A Critical Review of FDA Form 483 Findings for Inspections of Bioanalytical Laboratories

(continued from Page 7)

2001, in which the rule was established that the ULOQ could not be excluded from the calibration curve.

2. The FDA inspects to different rules

Failure to use independent stock solutions for the spiking of calibration standards and quality control samples during pre-study method validation for xxx.

Although the Guidance for Industry exists and other workshop and conference reports give additional guidance of rules for bioanalytical methods, these are not the only sources drawn upon by the FDA inspectors. The FDA inspectors have their own individual experience, training from the agency and agency inspection manuals. Not all of these sources are consistent.

Example: Separate stock solutions for calibrators and QC samples. 483 Finding: Failure to use independent stock solutions for the spiking of calibration standards and quality control samples during pre-study method validation for xxx.

The basis for this finding comes from the FDA Compliance Program BE Manual, "[question]…were the controls [QC's] made from a standard weight different from the standard weight used to prepare standards for the standard curve (i.e., two separate independent weighings for calibration standards and QC stock solutions)?"

The first interesting fact is that this comes from section E of the manual– Sample Analysis of Appendix A, not Section D – Analytical Methods Validation (implying that this evaluation should be made for calibrators and QC's used for sample analysis, not validation), and the second interesting fact is that this requirement is in direct opposition to the following statement from the Guidance for Industry, " Standards and QC samples can be prepared from the same spiking stock solution, provided the solution stability and accuracy have been verified."

3. No ability to request review of 483

Occasionally, there will be a legitimate difference of opinion between the FDA inspector and the facility personnel. This will usually result in a 483 finding being issued. Once the Form 483 has been issued there is no way to have the 483 finding reviewed for accuracy, and potentially withdrawn, if found to be incorrect. It is true that the facility can write a response to the effect that they disagree with the finding. Few will dare, and most are left in the position that even if they think the finding is wrong, they have to acknowledge it and take corrective action. The potential risk of not taking corrective action is that when the FDA inspects again at some point in the future, the facility will get written up again, or worse.

Example: ISR. 483 Finding: For study number xxx Incurred Sample Reproducibility (ISR) was not demonstrated with a sufficient number of samples. Only xxx samples out of xxx (7.5%) samples were reanalyzed for ISR.

In the workshop Report on ISR (2009) under selection of ISR samples it recommends 5%-10% of total sample size with 5% as the minimum for larger studies. An approach based upon 7.5% would seem to fulfill this expectation and it is hard to figure out why the 483 finding was issued.

Recommendation: If the FDA adopted a clear single document as recommended above, the requirements would be clear for everyone – laboratory and inspector alike. This document could be revised to incorporate changes periodically. Methods validated or applied would be held to the version of the document

that was in force during that time of the activity. There should be a mechanism put into place that would allow laboratories to request a review of individual 483 findings by a single authority in the FDA.

Part 3. Actions after the Inspection

Once the FDA has finished up with an inspection, there are two sources of information that would be very meaningful to the community: any 483 findings that may have been issued and any new enforcement issues that may have come to light during the inspection. Both of these represent information that is useful, but only if available in a timely manner. It is a shame that this information is not shared more quickly with the community, especially because the information could allow laboratories to evaluate their own practices, and then take proactive measures to ensure compliance.

1. New enforcement issues are not communicated well or in a timely fashion by the FDA,
2. Form 483 findings are not readily available

1. New Enforcement Issues

A lot can be learned during an inspection. The facility learns about things it's doing or not doing to the FDA' satisfaction, in some cases it receives specific recommendations. Sometimes the FDA inspector's eyes are opened to new or unexpected enforcement issues. Unfortunately, all of that learning and information stay within that group of players: the larger community does not receive the benefit of this until a) they receive their own inspections, b) the FDA decides to share this information at a conference or workshop, or c) in the case of truly egregious issues, the FDA issues and posts a Warning Letter.

Example: The Cetero Warning Letter. As we all know, the FDA became aware of a number of new and alarming compliance issues during the inspection it performed at the Houston facility in May 2010. These issues were confirmed in the follow up inspection in December 2010. This information was only made available to the community at large when the FDA issued and posted a Warning Letter in July of 2011, more than a year after the issues first came to the FDA's attention.

While the Warning Letter provided information about the nature of the compliance issues, what would have been very helpful would have been information from the FDA giving explanation of the underlying causes, how these affected compliance, and how this would affect enforcement going forward. And it would have been useful if this information were available earlier.

Recommendation: The FDA should consider publishing and communicating to the community at large new developments in enforcement in a timely manner. One mechanism could be to publish and post a memorandum listing the issue, how if came to light, and the FDA's interpretation of compliance. These should be rolled into updates of the rules on a timely basis (as described above).

2. Form 483 Findings are not readily available

If 483's are instructive and give a good glimpse into the current enforcement actions, then it follows that people in the industry would want to see current 483's. However, the FDA does not post Form 483's like it does Warning Letters. The FDA does maintain a website listing the Active Labs Inspection List, but a recent glance shows that the list is only

New enforcement issues are not communicated well or in a timely fashion by the FDA,

Form 483 findings are not readily available

A Critical Review of FDA Form 483 Findings for Inspections of Bioanalytical Laboratories

(continued from Page 9)

updated through August 2009. From this information, one could request through FOI the Form 483 or even the EIR. However, information from this posting yields you inspection results from 3 years ago or older; not very current. This listing is made more confusing because bioanalytical inspections are not differentiated from the larger population of nonclinical inspections.

Recommendation: The FDA should, at a minimum, routinely update the Active Lab Inspection List and categorize the inspections as to nonclinical or bioanalytical. A better approach would be for the FDA to post the actual 483's on their website in a timely fashion (i.e. no more than 6 months after they are issued).

Conclusion: I would like to conclude by reasserting one of my starting assumptions: actions that lead to a reduction in the issuance of 483's benefit everyone. If the FDA adopts my recommendations, I have no doubt there will be better compliance and we will see a decrease in the number of 483 findings issued. Those recommendations are, once again:

1. Adopt a single document that clearly defines all of the rules for method validation and sample analysis.

- It should define how an action is to be performed, what the acceptable limits are, and what (if any) exceptions exist.
- It should be revised or reissued periodically and serve as the basis for enforcement.
- Laboratories should be held accountable for the requirements in place (revision) at the time the action was performed.

2. Communicate new developments in enforcement in a timely manner by publishing and posting a memorandum listing the issue, how if came to light, and the FDA's interpretation of compliance.

3. Routinely update the Active Lab Inspection List and categorize the inspections as to nonclinical or bioanalytical, or post the actual 483's on their website in a timely fashion.

4. Put into place a mechanism by which a laboratory may request the review of individual 483 findings.

President's Message (continued from Page 1)

look at organizations such as NERCSQA as great venues to provide opportunities to our membership. To me, these opportunities include networking, mentoring, training, and continuing education. In addition, I feel we should also offer opportunities for our membership to become involved in NERCSQA – to give a presentation at a membership meeting, to write an article for the newsletter, to join a committee, to share their experiences and their expertise to others in the organization, including members that are new to the industry. To me, that's what an organization like NERCSQA is all about; to learn, to volunteer, to support, to network, and to give back.

So, in 2013 we are hoping to continue our momentum from 2012. We are planning on at least two training events and three membership meetings throughout the year. We want to publish at least three, possibly four newsletters. We want to provide the NERCSQA membership with opportunities to develop professionally by offering low cost, professional training, as well as networking events. We want to see the membership continue to grow. It is our goal that our members benefit professionally from all that NERCSQA has to offer.

Here's looking forward to 2013!

Thank you,

Chris Wubbolt

NERCSQA 2013 President

NERCSQA WORD SEARCH																					
I	N	S	P	E	C	T	I	O	N	X	R	S	A	Y	T	I	L	I	C	A	F
N	E	Q	O	N	O	I	T	A	D	I	L	A	V	R	E	T	U	P	M	O	C
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CFR
Compliance
Computer Validation
Date
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EPA
Equipment
Facility
FDA
Food and Drug
Good Laboratory Practice
INDA
Indianapolis
Inspection
List
Maintenance
Master Schedule
Mentor
NDA
NERCSQA
Networking
NonClinical
OECD
Principal Investigator
Protocol
QAU
Quality
Raw Data
Records
Reports
Review
Science
Society
SOP
Specimen
Sponsor
Study Director
Test Article
Time
Training

Answer key for the word find puzzle will be in the next NERCSQA newsletter.

Interested in becoming a member of NERCSQA?
Go to http://www.nercsqa.org/membership.htm

Program Committee Update

By Jennifer Bravo, NERCSQA Vice President

I have been a member of NERCSQA since 2007. During that time, I have served as Director of Publications and Membership. I am honored and excited for the opportunity to now serve NERCSQA in the role of Vice President and Chair of the Program Committee. We have several activities tentatively scheduled for 2013— see below. The agenda, location and cost for these events will be determined in the coming months. Stay tuned!

Date	Time	Location	Topic
1-May-13	7:00 to 8:30 am	JW Marriott Indianapolis	NERCSQA Meet and Greet (with breakfast) at SQA's Annual Meeting in Indianapolis, Indiana
End of May, 2013	TBD	Framingham	NERCSQA Member Meeting and Highlights from SQA's Annual Meeting
June, 2013	TBD	TBD	Corrective Action / Preventative Action (CAPA) in a GLP Setting
September, 2013	TBD	TBD	Computer System Validation
October, 2013	TBD	Cambridge	NERCSQA Member Meeting
November, 2013	TBD	TBD	NERCSQA Annual Meeting

Are you interested in being part of the Program Committee? Do you have suggestions for topics or speakers? Are you interested in presenting or volunteering at one of the NERCSQA events? Please contact Jen Bravo at jbravo@agiluxlabs.com.

Northern Highlights Contributions Welcome!

Contributions to the newsletter are always welcome. If you would like to submit a general interest article, provide a summary of a recent training event or conference, or just to satisfy your creative writing abilities, please contact Aimee Altemus at DirectorP@nercsqa.org.

Are you interested in contributing an article, puzzle, case study, or cartoon for the next issue of Northern Highlights?
Contact Aimee Altemus at DirectorP@nercsqa.org