Vol. 14. Issue 2, Sep. 2010 | New England Regional Chapter of the Society of Quality Assurance

Northern Highlights

President's Message

Cheryl McCatrhy, President, NERCSQA

Now that the summer is almost over and fall is upon us, we are continuing to identify ways to help our membership network to facilitate education opportunities, awareness of job openings and peer support. Please let our Program Committee chair (Linda Hook-D'Innocenzo) know if you have any ideas on how we can implement these activities.

We have some exciting events planned for the remainder of this year:

- September 8th – Joint training event with NEPDA (see page 4 for more information)
- October/ November – One day training in the Boston area – if you have a suggestion for a training topic related to Quality by Design, Regulatory Requirements, Training, etc… please drop us a line! We are always looking for additional speakers to participate in the NERCSQA events.

Like many associations, NERCSQA is a volunteer organization. Our Board of Directors for 2011 has openings for our members – see the descriptions of the positions and 2011 openings below or on our website.

We hope to see you at an upcoming NERCSQA event!

Cheryl McCarthy, CQA, CBA, is QA Manager at eClinical Solutions a division of Eliassen Group, Mansfield, MA.

Inside this issue:

Interested in Getting More Involved with NERSQA? Join the Board of Directors or Become an Officer!

The NERCSQA Nominating Committee is seeking self nominations and recommendations for candidates for the 2011 open positions listed below. Serving as an officer or as a director is an excellent way to develop professionally, interact with fellow QA professionals, and have a voice in the activities sponsored by the organization. If interested, please contact George Kuniholm at nominating@nercsqa.org.

- Vice President
  - Primary responsibility: Chair the Program Committee; organize training events
  - Term: 1 year *(Note: The incumbent of this position is also required to serve 1 year as President and 1 year as Past-President)*
- Director of Publications
  - Primary responsibility: Compile and publish NERCSQA's newsletter, *Northern Highlights*
  - Term: 2 years
- Treasurer
  - Primary responsibility: Maintain the society's finances
  - Term: 2 years
- Director of Sponsorship
  - Primary responsibility: Seek sponsors to support NERCSQA's mission and activities
  - Term: 2 years

Proposed Rulemaking for the Reporting of Falsification in Clinical Studies

By George Kuniholm, Executive Director, Quality Systems, Anika Therapeutics, Inc.

The rulemaking requires "sponsors to report information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results... involv[ing] human subjects or animal subjects conducted by or on behalf of a sponsor or relied on by a sponsor".

In the February 19, 2010 copy of The Federal Register (Vol 75 No 33), the FDA proposed rulemaking designed to require Sponsors of Clinical trials to report the Falsification of Data during the course of Clinical Studies. The Federal Register can be viewed at the following URL: http://edocket.access.gpo.gov/2010/pdf/2010-3123.pdf.

Essentially the rulemaking requires "sponsors to report information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies that involve human subjects or animal subjects conducted by or on behalf of a sponsor or relied on by a sponsor. A sponsor would be required to report this information to the appropriate FDA center promptly, but no later than 45 calendar days after the sponsor becomes aware of the information."

As stated by the FDA, the goal of such proposed rulemaking is "to help ensure the validity of data that the agency receives in support of applications and petitions for FDA product approvals and authorization of certain labeling claims and to protect research subjects." The initial comment period that closed in March was extended into May due to significant feedback by industry.

The objective of the proposed rulemaking is to create an obligation for sponsor reporting of both confirmed and suspected falsification, without mention of intent. Modifications to rules would be inserted into the CFR at multiple points in order to ensure that Clinical trials are covered for non/pre-clinical studies, new drug applications, biologics applications, new device exemptions, as well as tissue and veterinary applications.

Although introduced for the purpose of ensuring reliable and trustworthy data are submitted to the agenc, the potential implications of such rulemaking are far reaching and the potential impact could reach to GMPs and commercial operations. For this reason, SQA established a Rapid Response Team to respond to the FDA on this topic. The RRT was comprised of representatives of SQA Specialty Sections to ensure potential impacts were understood from all perspectives.

The actual response is posted on the SQA website under the URL: http://www.sqa.org/uploadedFiles/SQA_Home/documents/regulatory/FDA-2008-N-0115-Falsification20may10.pdf

The major points of the response were:

- The overall cost of compliance to the proposed rule is potentially greater than originally estimated both in time and financial aspects.
- Due to potential concerns of ways in which false data can occur, companies would like the reporting timeline to provide time for confirmation of intended falsification. Falsification through occasional oversight should not be reportable.
- 45 days to respond is too short of a timeline given the investigations that need to be done in relation to point #1. Corporate Counsel may need to get involved in this process.

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Reporting of Falsification

Continued from page 2

- There should be a uniform method to insert the reporting of the falsification of data to the FDA as the currently proposed insertion points are not uniform in their implementation of the rule.
- The reporting of falsification is legally enforceable upon the sponsors, however, there should be voluntary reporting portals for other participants in Clinical Trials including CROs and participants.
- The evidentiary threshold for falsification should be a preponderance of evidence.
- Reporting should include the legal entity (and not the individual) that was responsible for the falsification including the type of falsification event, when and where it occurred.

There are a number of individuals, corporations, professional societies, and educational institutions that have commented on the docket. These comments are available at the FDA URL: http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-N-0115

It is not clear how long the agency will take to consider all of the submitted comments and we cannot be certain if the final rulemaking will actually take place. In general the principles contained in this rulemaking are already recorded elsewhere in the CFR, and this proposed rulemaking is just to make the regulations more explicit and enforceable.

All entities should create and implement internal mechanisms that detect falsification whether intentional or unintentional and handle it in a proactive manner. Ultimately, the reporting of falsification will ensure safe and effective treatments for patients and in general protection of human clinical subjects, and both accidental as well as intentional falsification should be dealt with in a responsive manner, although the course of action may be substantially different. Accidental falsification may lead to additional training, further automation, and maybe the reprimand of personnel. Intentional falsification requires stern internal policies for investigation and consequences and may be reportable under current standards, so entities should take the time to understand both current and proposed regulations.

The goal of the proposed rulemaking is "to help ensure the validity of data that the agency receives in support of applications and petitions for FDA product approvals and authorization of certain labeling claims and to protect research subjects."

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 Jen Bravo at DirectorP@nercsqa.org.

NERC SQA

Cost per person
(If registered by noon Sep 3, 2010)
- Members : $50
- Non-members: $75

Cost (late registration)
(If space is available)
- Members: $60
- Non-members: $90

For questions about the meeting, contact:

Cheryl McCarthy
508-594-6353
president@nercsqa.org

Register NOW at:
www.NERCSQA.org

Mark Your Calendars — Upcoming Training Event

NERCSQA and the New England Parenteral Drug Association (NEPDA) Present:

cGMP Compliant Personnel Training Systems

Does your training program constitute reading and understanding your company's Standard Operating Procedures? Is the program effective? How many of your process failures involve lack of effective training? This meeting will provide an overview of new training paradigms including On-the-Job Training and Train-the-Trainer programs.

As part of the NERCSQA's continuing training program, this meeting will be a joint meeting of our chapter with the New England Chapter of the Parenteral Drug Association (NEPDA). Here is a great opportunity to learn the latest trends in training from our panel of experts.

Featured Speakers:

Because 'Read & Understood' Isn't Good Enough: How to Build an Effective OJT Program

Presented by Joanna Gallant, Unit Manager, Framingham Quality Training, Genzyme Corporation

Train the Trainer: Basics for Implementing a TTT Program

Presented by Cheryl McCarthy, CQA, CBA, Associate Director, Quality Assurance, eClinical Solutions, President NERCSQA and
Linda Hook-D'Innocenzo, Associate Director, Quality Partnership Management, Vertex Pharmaceuticals Inc., Vice President/Program Committee Chair NERCSQA)

This event includes a facility tour of Genzyme's new $170 million, 60,000 square-foot manufacturing facility located at New York Avenue in Framingham, MA. Construction began on the project in 2008 and the company hopes to gain FDA approval for manufacturing Fabrazyme® by the end of 2011.

The tour is available to the first 15 NERCSQA members that register!

Wednesday September 8, 2010

Dinner & Meeting Location:
SHERATON FRAMINGHAM HOTEL & CONFERENCE CENTER
1657 Worcester Road, Framingham, MA
www.sheraton.com/framingham

Genzyme Facility Tours (*pre-registered only*): 4:00 p.m. – 5:00 p.m.
Registration and Social Hour: 5:30 p.m. – 6:30 p.m.
Dinner & Presentation: 6:30 p.m. – 9:00 p.m.

Ging Lee Scholarship—Call for Nomination

Please consider nominating a fellow NERCSQA member for the Ging Lee Scholarship!

The scholarship was established in memory of a long time member and contributor to NERCSQA—Ging Lee. The scholarship allows the recipient to travel to a SQA sponsored educational event, such as the upcoming SQA Annual Meeting, and it covers the cost of registration, airfare and lodging up to $2,000.

Due to the down turn in the economy, many companies have cut their spending budgets. Unfortunately, for many companies this has translated into a loss of funding for training and attendance to conferences. So as a QA professional, one has to find creative ways to remain current and obtain the training necessary to continue doing one's job appropriately. The Ging Lee Scholarship is an excellent way of obtaining money for continuing education or training for a deserving member of the community.

The decision for awarding the scholarship is based on a number of factors including service to NERCSQA and SQA, financial need, and potential professional advancement from attending a NERCSQA / SQA sponsored educational event.

If you would like to nominate someone for the 2010 Ging Lee scholarship, contact President@nercsqa.org.

The deadline for nominations to the Ging Lee Scholarship is October 31, 2010

Join Today!!!

CHAPTER INFORMATION

Contacts:

secretary@NERCSQA.org
VP@NERCSQA.org

NERCSQA Mission Statement:

"To serve as a focal point for Quality Assurance "GXP" professionals in the New England Region by establishing a forum for education, training, communication and information exchange among QA professionals in the environmental, pharmaceutical and biotechnology fields of government, private industry, research and academia."

As a member of NERCSQA , you will receive:

- *Our newsletter, Northern Highlights*
- *A discount on training sessions*
- *An annual membership directory*
- *End of the year social following the Chapter's Annual Meeting*
- *Opportunity to network with other Quality Assurance professionals*