Vol. 13. Issue 1, Apr 2009 | New England Regional Chapter of the Society of Quality Assurance

Northern Highlights

Past President's Message

Scott Cook, Past President, NERCSQA

Welcome to 2009!

I look back on 2008 as we move into 2009 with great memories. We really had a special year and the accomplishments speak for themselves. Exciting training that included SOP Development: Incorporating Today's Best Quality Systems Practices, presented by Vivian Bringslimark; GMP 21 CFR part 11 Computer Validation, which included new information on ISPE GAMP 5, presented by: Monica Cahilly, M.S., RQAP-GLP President, Green Mountain Quality Assurance, LLC; Improving Quality and Compliance: Toxicology Department Process Improvements by Partnering with Quality Assurance, presented by: Rob Stachlewitz, Ph.D., DABT, Principal Scientist, Toxicology and Safety Assessment-Boehringer-Ingelheim Pharmaceuticals and Everything You Ever Wanted to Know About Nonclinical QA - Finally Your Chance to Ask. What are the hard questions facing non-clinical QA professionals?, presented by: Greg Furrow, Senior Director, Regulatory Compliance – Charles River Laboratories, PCS, MA. The Board of Directors also worked diligently in implementing additional procedures this year, like the electronic balloting system for the in coming officers.

These accomplishments are really a testament to the dedication of the members of the committees and the Board of Directors as well as our membership. I would like to thank, in no particular order: Patience Miller, Linda Hook-D'Innocenzo, Theresa Donegan, Richard Shalvoy, Manish Ranjitkar, George Kuniholm, Angel Caputo, everyone who ran for an elected position, Jennifer Bravo for the Poster at BARQA, our 2008 Sponsors (Charles River Laboratories), to the speakers mentioned above, and to all the participants of training events that participated and posed great questions. I would also like to thank the talented staff at SQA Headquarters.

For 2009, we will continue to work on the remaining gaps: website design and updating SOPs and historical archives. In addition, we continue to work on developing strong programs of interest to Quality Assurance professionals in New England.

I hope everyone can see the great opportunities that our chapter has for us in 2009. We have built a great foundation that supports our vision "To serve as a focal point for Quality Assurance "GXP" professionals in the New England Region". Lets continue this momentum....I wish everyone an exciting and successful year!!

Scott A. Cook

NERCSQA's Past President Scott Cook is Associate Director of Quality Assurance at Charles River Laboratories in Shrewsbury, MA.

Inside this issue:

Patience Miller is Sr. Quality Assurance Representative at Charles River Laboratories, Shrewsbury, MA

President's Welcome

Patience Miller, President, NERCSQA

Welcome to 2009!

I want to congratulate the newly elected board members: Vice President-Cheryl McCarthy, Sponsorship Director Amie Altemus, and Publications Director- Jen Bravo. I look forward to working with you, the other board members, the program committee and members to make this year a good one.

This year there will be some changes made to the website, starting with an update to the Home Page to include more current information. We will also be adding the past issues of Northern Highlights and information from past training.

I realize that due to the financial constraints there may be less money available for training. As president I would like to hear from members on what they feel is needed to keep current. What do you feel is the best way to continue - offer 1 or 2 day training, offer ½ day training, webinars or round table discussions. These are all options.

I also want to let members know that last year we did not receive any nominees for the Ging Lee Scholarship. This scholarship is intended to help a member attend SQA training. It was created in 2007 by then President George Kuniholm in memory of Ging who was a board member and also a program committee member. I hope to see this presented this year, please go to the website for details.

In closing I would like to thank the outgoing board members, Richard Shalvoy (Treasurer) and Linda Hook-D'Innocenzo (Publications Director) for their efforts over the last two years. It was a pleasure working with them and I look forward to seeing them at future trainings.

I look forward to working with the board and the program committee in continuing to establish an environment for communication and information for industry professionals.

Patience Miller

Chapter Officers for 2009

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

President: Patience Miller, Charles River Laboratories, President@nercsqa.org

Vice President: Cheryl McCarthy, eClinical Solutions, VP@nersqa.org

Past President: Scott Cook, Charles River Laboratories, PastPresident@nercsqa.org

Secretary: Manish Ranjitkar, Vertex Pharmaceuticals, Secretary@nercsqa.org

Treasurer: Christine Garvey, Charles River Laboratories, Treasurer@nercsqa.org

Director of Publications: Jennifer Bravo, Agilux Laboratories, DirectorP@nercsqa.org

Director of Membership: Theresa Donegan, Charles River Laboratories, DirectorM@nercsqa.org

Director of Sponsorhip: Aimee Altemus, Vion Pharmaceuticals, DirectorS@nercsqa.org

NERCSQA Website Under Construction

You have asked, and we will deliver… Our website will be undergoing many changes this year. We have started with the main page and will continue to add more content as the year progresses. The goal is to make the site more user friendly and useful to our membership. Initially, the items we plan on focusing our efforts include updating the list of upcoming training events, updating the list of past training events, updating the newsletter archive and adding new links to other websites that might be of interest to our membership.

We would like to receive input from our members as to what other items should be included in the website. *Remember, we are designing the site for you. We would love to hear your suggestions and/or comments.*

The first round of edits has been submitted and we hope to have the changes implemented in the near future. Visit our website, www.nercsqa.org, often to see the progress. Please send any suggestions for content to Jen Bravo at DirectorP@nercsqa.org.

Stay Tuned for the next update!

"Visit our website often to see the progress."

www.nercsqa.org

Program Committee Update

The Program Committee is hard at work putting together sessions for later this year. We are planning on incorporating different methods of delivering these sessions to you such as webinars and ½ day and full day sessions.

The Program Committee is also planning a fun networking social event in the near future. The goal is to provide an informal forum for members and non-members (hopefully soon to become members) to meet, interact with each other, and exchange ideas. The Program Committee would also like to use this event to gain insight as to what kind of events QA professionals in this area are interested in. Keep an eye out for the networking social invitation!

If you have a topic that you are interested in learning more about or even presenting yourself, please contact Cheryl McCarthy at VP@nercsqa.org.

"Keep an eye out for the networking social invitation!"

Upcoming Training

The next proposed training event will cover auditing. The training will focus on standards and guidelines like ASTM-E2500 and GAMP5. It will address recent industry events and include hands-on exercises. After this training, you will be able to:

- Plan and prepare for an audit
- Prepare audit checklists
- Follow-up on the audit findings
- Determine when to re-audit.

The lead speaker will be Virginia (Ginni) L. Corbin. Ginni travels globally speaking on topics related to regulatory compliance and best practice. Previously Waters' Director of Regulatory Affairs, she is a long-standing member of the Audit Repository board and author of PDA Technical Report No. 32, "*Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations*". Additionally, Ginni is leading the response to the draft revisions to EU Annex 11 on behalf of the PDA .

The date and location for this training will be announced shortly..

Training on Electronic Data and Computer Systems

Katherine Connors, NERCSQA Member

"Monica's training session offered a comprehensive overview of electronic data and system compliance..."

NERSCQA's summer training was held on June 11-12, 2008 at the Sheraton Tara in Framingham, MA. Monica Cahilly of Green Mountain Quality Associates presented on the topic of *Quality Oversight of Electronic Data and Computerized Systems Compliance: Current Perspectives For U.S. FDA Compliance*. Monica's presentation began with a look at the various rules and regulations (21 CFR Part 11, Sarbanes-Oxley, HIPAA, etc.) that have defined the need for computerized systems validation. Also highlighted were some key facts that are forcing computerized systems validation and compliance to the fore front of industry; namely increasing computerized processes, greater reliance on electronic records over paper, increases in the integration of computerized systems across departments, and the movement toward globalization of computerized/ enterprised systems.

Discussion points on day one focused on the paradigm shift caused by the implementation of 21 CFR Part 11 where computerized systems could no longer be thought of as a black box. The shift in industry has been toward developing a risk based approach to compliance focusing on patient safety, product quality, and data integrity. The main points related to Part 11 compliance were reviewed; validation, checks, copying of records, archival, documentation controls, written polices, training, and security/audit trails. Monica highlighted several FDA 483's and Warning Letters focused on non compliances noted to each of the main parts of Part 11. Later topics on day one were related to the Part 11 Scope and Application Guidance and the idea of FDA enforcement discretion. Given the complexity and integration of computerized systems across business groups some in industry are moving toward an integrated model for managing risk and quality. An Enterprise Risk Management Committee composed of representatives from quality assurance, finance, legal, supported by a Global IT Risk and Quality Unit would identify and map out all business processes and offer a cohesive and centralized approach to managing computerized systems in complex regulatory environments.

Day two of Monica's training session centered on the responsibilities of Quality Assurance personnel related to auditing validation deliverables and conducting inspections of validated systems once in production. GAMP 5 and the Red Apple II Report are valuable tools giving insight into current industry computer system validation concepts and offer the Quality Assurance auditor a broad knowledge base for understanding and inspecting validation activities. Similar to a risk based approach to validation activities, Quality Assurance professionals should take a risk based approach to auditing. This approach would identify critical systems that have a direct impact of product quality, patient safety, or data integrity. Identifying a cross section of critical systems will allow for review of varying architecture and systems maintained by different users/system owners. Auditors should take time to evaluate and understand how the system works and how it will be used in order to identify the critical risks that would be associated with that system. Monica concluded with points to consider for Quality Assurance personnel when conducting facility inspections focused on evaluating electronic data and systems compliance.

Monica's training session offered a comprehensive overview of electronic data and system compliance from the years prior to Part 11 implementation to today's current complex regulatory environment along with the changes in FDA perspective and enforcement.

Katherine Connor

Ging Lee Scholarship

The Ging Lee Scholarship was established in 2007 in memory of a long time member and contributor to NERCSQA—Ging Lee. The scholarship allows a member 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 $2000.00. The scholarship is awarded on a number of factors including service to NERCSQA and SQA, financial need, and potential professional advancement from attending such training.

The first scholarship was awarded to Jen Bravo, who used it to attend BARQA's *2nd Global QA Conference* in Edinburgh, Scotland. She used the opportunity to present NERCSQA's poster. According to Jen, "The scholarship provided me with the means to attend an international meeting and interact with our European and Japanese counterparts. It was an incredible educational and networking opportunity for me."

Last year, due to the lack of applications and nominations, the scholarship was not awarded. This year, we would like to change that.

If you would like to apply or nominate someone for the scholarship, contact President@nercsqa.org. The deadline for the 2009 Ging Lee Scholarship is October 31, 2009.

"The deadline for the 2009 Ging Lee Scholarship is October 31, 2009"

SQA Annual Meeting and Training

The 25th SQA Annual Meeting and Training will be held 19-24 April in San Diego, CA. This year's theme is "*Cruising Down the Quality Highway: 25 Years and Going Strong*". Sessions will focus on regulatory-based topics in manufacturing (GMPs), preclinical (GLP) and clinical (GCPs) research areanas.

As in previous years, NERCSQA will be presenting a poster at the conference. Stop by to network and exchange ideas! Several members of NERCSQA will also be speaking at the meeting. If you are attending, it would be great if you could stop in to the sessions and support our members! Below is a list of members who will be presenting .

- **Richard Brooks**, *Archive Move* (23 April)
- **Scott Cook**, *Changing the Approach QA Management has in a Quality Organization* (21 April)
- **Theresa Donegan**, *Compliant or Not—Looking at Validation and Regulatory Requirements for Computerized Diagnostic Instruments* (23 April)
- **Greg Furrow**, *Understanding GxPs: Bridging the Communication Gap* (19 April)
- **Cheryl McCarthy**, *Intro to GCP Quality College* (19 April), *Assessing Compliance Risk Using a Clinical Mega Trial Model* (22 April), *Advanced GCP Quality C*ollege (24 April)
- **Beth Moulaison**, *Auditing a Contract Lab? Why bother!* (21 April), *Can Six Sigma Improve Everything, Even your QAU?* (22 April)

"Support our members!

Job Opportunities

ARIAD Pharmaceuticals, Inc. Cambridge, MA

Position: Quality Assurance Auditor or Sr. Auditor (GCP)

Summary

This position is responsible for the planning, delivery and execution of the Good Clinical Practice (GCP) QA program on assigned projects/products and global GCP audit activities. The role is responsible for GCP oversight, and for assuring the compliance of clinical trial projects to ARIAD Standard Operating Procedures (SOPs) & Policies, and applicable worldwide regulations and guidelines (e.g. US FDA, EMEA, ICH, and country-specific regulations). This position offers a significant opportunity for growth.

This position, reporting to the Assoc Director, GCP Audits & Compliance, will require 25-30% travel for conducting audits, including international travel. You must possess excellent oral and written communication and interpersonal skills, as well as computer proficiency. You should have a demonstrated ability to work independently.

Training & Education Preferred:

- Bachelor's degree is required.
- Equivalent relevant professional experience may be considered.
- A medical related degree is a strong plus.

Preferred Prior Experience

- Three to five (3-5) years experience in drug development, clinical research, regulatory compliance, and clinical study monitoring or equivalent.
- Minimum of two (2) years previous clinical Quality Assurance (GCP) experience independently conducting a broad range of audits including investigator sites, vendors, processes, databases and regulatory submission documents.

Competencies

- Knowledge of the drug development process, GCP/ICH guidelines is essential.
- Understanding of or experience in Pharmacovigilance is a plus.
- Strong quality orientation including the ability to focus on details and adherence to standards while maintaining a balanced business perspective.

Duties

- Assist in developing SOPs for the management and oversight of GCP activities.
- Develop written QA plans for assigned projects/products.
- Assess compliance of clinical investigator sites, vendors, and ARIAD programs to FDA, ICH, and other government agency regulations/ guidelines.
- Conduct GCP audits of clinical studies at Clinical Investigator sites
- Conduct audits of regulatory documents, sponsor processes/procedures, clinical trial databases and vendor/ services providers (CROs, Clinical Labs etc).
- Report results to project team personnel and management, and interact with various teams to ensure corrective actions are taken and to bring audit observations to closure.
- Participate in special assignments on various projects (including inspection readiness) as determined by QA management.

To apply, please visit ARIAD's site: http://www.ariad.com/wt/tertiarypage/jobs/job/TA_GCP

Membership Update

If you haven't renewed your membership for 2009 or are interested in joining us as a new member – please use the membership form at www.nercsqa.org to join today! We will be surveying members later this Spring to find out what you have been up. We would like to highlight member successes and accomplishments in the website and newsletter..

If you are presenting at industry conferences, authoring books or articles – we want to hear from you!

Newsletter Update

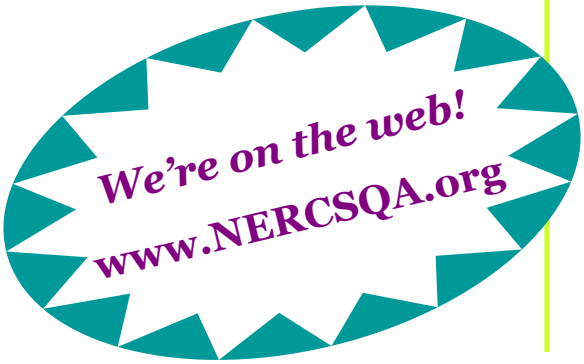
As you may have noticed, we have changed the design of the newsletter. Please let us know what you think of the new format! We would also like to include letters and articles from members in the upcoming issue of Northern Highlights. If you would like to contribute, please contact Jen Bravo at DirectorP@nercsqa.org. Deadline for submission is June 30, 2009.

Are you interested in contributing an article for the next issue of Northern Highlights? Contact Jen Bravo at DirectorP@nercsqa.org

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*

JOIN TODAY!