



Northern Highlights



President's Message

Cheryl McCarthy, President, NERCSQA



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

Inside this issue:

President's Message	1
Past President's Message	2
Officers for 2010	2
Ging Lee Scholarship	3
SQA Annual Meeting	3
Benefits of Networking	4
Corporate Sponsorship	5
Upcoming Training	6

Welcome to 2010!

I want to congratulate the newly elected board members: Vice President – Linda Hook-D'Innocenzo, Secretary – Bella (Berta) Gershenovich and Director of Membership—Binesh Pradhakar. I look forward to working with all the board members this year to increase the opportunities provided by NERCSQA and to bring in more members to our association.

This past year saw some challenges in our industry and local economy that most likely affected you personally in some way. NERCSQA is looking 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) know if you have any ideas on how we can implement these activities.

We are continuing to look at opportunities for collaboration with other area quality professionals and have plans for a joint program with NEPDA later this fall. Details are being finalized so look to our website and newsletters for more information.

Speaking of the website, SQA will continue to provide our chapter with website support this year. Some new features and functionality will be rolled

out during the year that we are excited about. We'll communicate to our membership updates periodically throughout the year as these features are put in place.

Congratulations to our 2009 Ging Lee Scholarship winner Stephen Muturi. This scholarship is being provided to Stephen so that he may attend the upcoming SQA Annual Conference in Cincinnati, OH. NERCSQA will be presenting a poster there – stop by and visit us if you are attending the annual meeting.

Like many associations, NERCSQA is a volunteer organization. While it is recognized that our personal and professional lives keep us busy, organizations like ours benefit from any time you can offer to participate on our board or program committee, as a presenter at a NERCSQA session, as a host of a NERCSQA session, as a contributor to our Northern Highlights newsletter, and as an attendee at one our events. I have truly enjoyed the many opportunities, friendships and peer support I've had as a result of volunteering for NERCSQA and SQA activities and look forward to what 2010 will bring!

I would like to thank the outgoing board members for their time to NERCSQA – Manish Ranjitkar (Secretary) and Scott Cook (Past President) – your efforts are greatly appreciated!



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

Past- President's Message

Patience Miller, Past- President, NERCSQA

I want to start by thanking the following for their contributions during 2009; Cheryl McCarthy, Jennifer Bravo, Christine Garvey, Theresa Donegan, Aimee Altemus, Manish Ranjitkar, Scott Cook and George Kuniholm.

I would also like to thank the Waters Corporation for sponsoring our training last September. The training was Software and Data Auditing. - Introduction to Software Auditing was presented by Dana Yurach (Waters Corp.). Dana covered SOPs, applicable standards, assessing risks, creating audit checklists, conducting the audit and follow- up activities.

Monica Cahilly presented Auditing Validation Controls to Assure Electronic Data Integrity. Monica covered validation models, industry standards and the validation steps that are essential to data integrity.

Kudos to the staff at SQA, Jen Alluisi, Marilla Owens, Allison Travis and Nikki Edgecomb for their help with membership, annual elections, updating the website and getting information to our members.

The year 2009 was a lean year for all due to the economic changes. My hope for 2010 is that we continue to provide training in GXP with the latest information at a reasonable cost.

Best wishes, to all and here's to a more prosperous 2010 .

Patience Miller



Chapter Officers for 2010

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

President: Cheryl McCarthy, eClinical Solutions, President@nercsqa.org

Vice President: Linda Hook-D'Innocenzo, Vertex Pharmaceuticals, VP@nersqa.org

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

Secretary: Bella Gershenovich, Charles River Laboratories, 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: Binesh Pradhakar, Vertex Pharmaceuticals, DirectorM@nercsqa.org

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

Ging Lee Scholarship

Jen Bravo, Director of Publications, NERCSQA

The Ging Lee Scholarship was established in 2007 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 \$2000.

For 2009, NERCSQA received two nominations for the Ging Lee Scholarship. 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.

NERCSQA would like to take this opportunity to congratulate S. Njanju Muturi from Charles River Laboratories on being awarded the 2009 Ging Lee Scholarship.

If you would like to apply to or nominate someone for the 2010 Ging Lee scholarship, contact President@nercsqa.org. The deadline for application and/or



***Recipient of the 2009 Ging Lee Scholarship:
S. Njanju Muturi,
QA Auditor II at
Charles River
Laboratories, MA***

26th SQA Annual Meeting

Jen Bravo, Director of Publications, NERCSQA

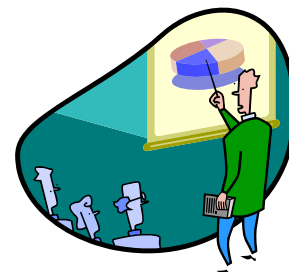
The 26th SQA Annual Meeting and Quality College will be held 25 to 30 April in Cincinnati, OH. This year's theme is "Building Bridges to Compliance". Sessions will focus on regulatory-based topics in manufacturing (GMPs), preclinical (GLP) and clinical (GCPs) research arenas.

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 going to the meeting, it would be great if you could attend the sessions and support our members! Below is a list of members who will be presenting.

- **Monica Cahilly** and Robert Tollefsen, *Electronic Records—Perspectives from FDA* (23 April)
- **Theresa Donegan**, *Critical Phase Inspections—How to Get the Most Bang*

for Your Buck (28 April)

- **Cheryl McCarthy**, *Introduction (25 - 26 April) and Advanced (30 April) GCP Quality Colleges; and Train The Trainer Program* (27 April)
- **Greg Furrow** et al., *The Use of Electronic Communication in a GxP Environment—an Expert Panel Discussion Session* (28 April)
- **Greg Furrow** and Debi Garvin, *International GLPs: Use of OECD GLPs and Guidance 13 in the United States, and Comparison of the Practical GLP Interpretation Among Tripartite Countries* (29 April)
- **Jennifer Bravo**, *Auditing Chromatographic Electronic Data* (29 April)



“Support our members!”

One way of improving one's odds of getting an interview and ultimately getting a job offer, is to make the most of networking opportunities.



Attend networking socials, meetings or other events organized by professional organizations such as NERCSQA or SQA.

Benefits of Networking

By Jen Bravo, Director of Publications, NERCSQA

In these difficult times, when lay-offs seem to be the norm rather than the exception, it is time to tap into your professional network and brush off the cobwebs from your resume.

Due to the small number of open positions in the (bio) pharmaceutical industry and the large number of currently unemployed individuals, this is an "employer's market". For any given position employers have to screen hundreds of applications until they find a candidate who is not over qualified and whose qualifications match the job being advertized.

As a job seeker, the prospect of competing with hundreds of other professionals for the same job can be daunting. One way of improving one's odds of getting an interview and ultimately getting a job offer, is to make the most of networking opportunities.

Networking can be achieved in a variety of ways:

- Call up friends and colleagues and let them know that you are looking for other career opportunities. This is an effective way of finding out about open positions that have yet to be advertized. If a position is open at your friend's or colleague's company, he/she can help you by hand delivering the resume to the appropriate person. This will typically ensure that, at a minimum, your resume is reviewed more carefully.
- Attend networking socials, meetings or other events organized by professional organizations such as NERCSQA or SQA. Remember to bring business

cards! If you are unemployed at the time of the event, bring "homemade" business cards. At a minimum, the card should have basic contact information (*i.e.* phone number and e-mail address). If possible, also highlight some of your areas of expertise directly on the card. Having a couple of bullet points about your expertise on the back of the card, for example, helps the person receiving your card remember the areas in which you are interested.

- Get involved in a professional organization such as NERCSQA or SQA. Professional organizations are run by volunteers from many different companies. NERCSQA, for instance, is run by volunteers located in the New England area, while SQA is run by volunteers spread throughout the US. Between the two organizations, volunteers and members work at a variety of companies, such as contract research organizations and (bio) pharmaceutical companies. By volunteering at a professional organization, not only will the organization benefit from receiving your input and ideas, you will also benefit by expanding your network!
- Use internet networking tools. LinkedIn, for example, is a business oriented networking site where you can invite people to be part of your "professional network" contact list. Some employers and recruiters also use LinkedIn to advertize jobs and to search for candidates. You can

It Pays To Be a Corporate Sponsor or Corporate Member

By Aimee Altemus, Director of Sponsorship, NERCSQA

Becoming a Corporate Sponsor or Corporate Member is a win-win proposition for both NERCSQA and for the Company providing the support. Your Corporate support (1) enables NERCSQA to educate Quality professionals by keeping these informative training seminars and meetings cost-effective and local resulting in affordable training fees, minimal time away from the office and minimal travel expense, (2) provides name recognition and exposure for your corporation or organization opening more doors when looking for potential job candidates, and (3) provides your employees with an opportunity to shape the current Quality dialogue in the industry.

A Corporate Sponsor will be recognized if the benefit to NERCSQA is deemed to be \$100.00 or greater and will receive:

- Recognition advertisement in Northern Highlights, the NERCSQA Newsletter
- Name listed under Corporate Sponsors on the NERCSQA web site at www.nercsqa.org with link to your company
- Recognition certificate or plaque and recognition at training / member meeting events
- Premier Sponsors (defined as companies that incur the bulk of expenses in hosting an event) will also have the option to let employees attend the event held at their site at no additional cost – 3 individuals for a half day training or 6 individuals for a full day training

Below is a list of ways that your company can become a Corporate Sponsor:

- Donate a specified dollar amount toward a NERCSQA training or expense
- Offer to pay for certain expense items for training
- Donate the use of their facilities and/or equipment including A/V equipment.
- Provide meeting / training room space at the site of the Corporate Sponsor or

cover the cost of hotel/conference center fees

- Provide tours of facilities
- Provide catering or covering the cost of meals and/or refreshments
- Provide paper supplies, printing and/or mailing expenses

Corporate Membership is another way of supporting NERCSQA. Corporate Membership allows a Company to send different individuals to different training events conducted during the course of the year. The pricing is designed to be a discount over individual training fees. Corporate membership is purchased in increments of \$500.00 each increment conferring the following benefits (increments are recognized by the level of Corporate Membership: Bronze, Silver, Gold, Platinum).

The benefits of Corporate Membership (per increment) are as follows:

- Attendance at any NERCSQA sponsored event for any individual from the Corporate Member organization. These can be different people at different events (nominal value of \$300.00 based on 3 one day seminars)
- Quarter page advertising in any NERCSQA publication (Northern Highlights and the Membership Directory) – increments can be combined or used separately. (nominal value: \$180.00 based on 3 quarter page ads)
- Three months job posting on the NERCSQA web site at www.nercsqa.org (nominal value of \$450.00 based on 3 one month postings).
- Recognition at training / member meeting events.

If your company is interested in learning more about NERCSQA Corporate Sponsorship or Corporate Membership, contact Aimee Altemus (DirectorS@nercsqa.org).

**Become a
Corporate
Sponsor or
Corporate
Member Today!**



**Contact Aimee if
interested:**

DirectorS@nercsqa.org

Upcoming Training

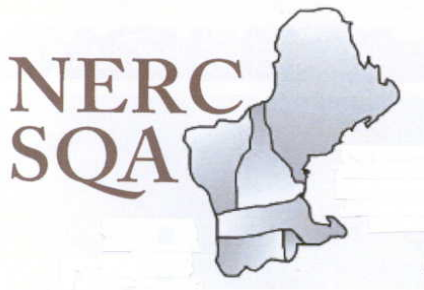
Keep your eyes open for upcoming training. This year the Program Committee is working on a Spring and a Fall training session as follows:

- Spring Training—tentatively scheduled for May. This training will be a regulatory track.
- Fall Training— combined effort with New England Parenteral Drug Association (NEPDA). Topic and date to be determined.

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.

*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

