

# Northern Highlights

NEW ENGLAND REGIONAL CHAPTER of the SOCIETY of QUALITY  
ASSURANCE

Volume 10 Issue Number 2 Sept 21, 2007



## Letter from the President

*George Kuniholm, President, NERCSQA*

Wow! 2007 has been a very exciting year for NERCSQA. A year of much activity and also a year of contrasts: moving in new directions yet revisiting prior achievements, taking risks of new training formats yet having some veteran speakers return, and drumming up considerable participation from new members while longtime members continue to take leadership roles.

Early this year we were busy with the tasks required of us related to the transition from a operational model of self sufficiency to having a professional management services firm (CMG) handle most of our back office functions (membership databases, mail distribution, account management). Ironically, in order to achieve this transition we had to revive a number of Chapter Policies in various states of approval / adoption and amend (actually revise) the ByLaws. The ByLaws have been distributed to all members in good standing as of August 14, 2007 and will be voted upon at the annual members meeting.

We took on significant risk with our second training of the year was an entirely new format: a two day seminar offered by one a leading speaker on the current application of GLPs in business today, Deborah Garvin from Pacific Rim Consulting, Inc. / West Coast Quality Training Institute and former SQA President (2002). This proved to be the best received training we have ever offered with 77 individual paid registrants. For the Fall training this year, we will feature Quality Systems and Joan Covino from Strategic Quality Consulting, one of our favorite local speakers and long term members, will return to discuss Supplier Quality Management.

This year over 60% of our membership consists of new members; many have participated in Committees and provided excellent feedback that will be utilized in event planning for 2008. We are blessed, though to have a strong network of long-term and past members. I would like to thank Linda Chin from Abbot BioResearch Center and former NERCSQA President (2003), for her work on the Nominating and Teller Committees. Also, worth recognition are the efforts of Program Committee lead by Scott Cook of Charles River Laboratories. Scott first joined the chapter in 1999 and will lead as the 2008 President.

2007 has been our strongest year of overall growth. As

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of August 14<sup>th</sup> we had 133 members representing all New England states except Maine plus New York and Ohio. Financially, our operating funds have grown to about \$33K which is the most solvency the chapter has experienced. This solvency will allow us to bring before the membership for voting at the Annual Members Meeting the possibility of establishing a NERCSQA Scholarship similar to those offered through SQA. Lastly, this year we have completed elections prior to the fourth quarter which will allow a full three months of transition to next year's board. Please congratulate the new officers announced herein.

2008 is under construction. We are planning to have a symposium on Computer Validation and Part 11 featuring Monica Cahilly of Green Mountain Quality Associates which will offer basic and advanced training as well as some special interest topics. A presentation by SAFE Biopharma on Digital Reliable and Trustworthy electronic signatures at our Fall Member's meeting will server as a sampler for this event. Additionally, there is significant interest in multiple day training in cGMPs– we are currently working to identify the best speakers in this area. As always, the input of our members will make memorable events! Please let us know if you would like to participate in the Program Committee and help plan this important event.

I hope you are having an enjoyable fall and I look forward to seeing everyone at the Fall Member's meeting in Framingham.

*George Kuniholm is the Manager of Corporate Quality Systems at Millipore Corporation*

## The election results are in:

**Congratulations!** To the following NERCSQA members on their election to the Board of Directors:

**Patience Miller – Vice President**  
**Manish Ranjitkar - Secretary**  
**Theresa Donegan - Director**

Thank you to all members for your participation in this important process!



## **QUALITY SYSTEMS: “FINDING THE RIGHT BALANCE” & ANNUAL MEMBER’S MEETING**

**DATES: TUESDAY, OCTOBER 23, 2007**

**LOCATION:** SHERATON FRAMINGHAM  
 1657 Worcester Road  
 Framingham, MA 01701

**TIME:** 9<sup>00</sup> AM TO 3<sup>00</sup> PM  
**REGISTRATION:** 8<sup>00</sup> - 9<sup>00</sup> AM

### **Presentations will include**

**“Internal Audit Program”** Carlos A. Acosta, Audit Manager, Millipore Corporation

**“Effective Supplier Quality Management: Connecting the dots within your Quality System”** Joan Covino, President, Strategic Quality Consulting

**“Auditing Digital Signatures – The SAFE-FDA Auditor Familiarization Program”** Rich Furr, Director, Business, Government and Compliance SAFE-Biopharma Organization

**“Drug Safety Changes”** Donna Lyn Roman, Director, Govt Affairs and Public Policy, Boehringer Ingelheim Pharmaceuticals, Inc.

**Registration must be completed by**  
**October 17, 2007.**

*Members will also be voting on the NERCSQA By-Laws amendment and on a proposed NERCSQA Scholarship.*

*To become a member and receive the benefits you can fill out a membership form at [www.NERCSQA.org](http://www.NERCSQA.org)*

**For additional information please contact**  
**VP@NERCSQA.org**

### **SQA Publication Policy**

“The information contained herein are the opinions of the authors but not necessarily the opinions of the society of quality assurance (SQA). The information may not be reprinted without the approval of the author.”

## Getting Ahead: Taking Charge of Your Career

By: Scott M. Szczesny & Jillian Savoy

Stan O. Practice, QA Manager, was known around the office as the man with the plan. While most of his colleagues were hoping for the best, S.O.P. spent his time anticipating the worst. He knew that the cornerstone of any successful Quality Program relied on a well-developed and executed plan. Stan spent countless hours developing systems ahead of time that were specifically designed to handle crises that were bound to surface at the worst possible moment. When FDA inspectors showed up for a surprise facility visit, his colleagues could have sworn that Stan knew they were coming that very day. It was almost as if he had predicted it and it was clear that he had prepared for it. So when the company eventually restructured and his position was eliminated, Stan's co-workers were stunned to realize that he had not done any contingency planning for his most important project...his own career.

In the following paragraphs, we will outline some simple strategies for advancing your career through a continuous process of proactive job searching. Most people think of job searching as posting a CV on the Monster board or submitting resumes to companies via on-line methods. A better approach is much more strategic and involves a career long process which can be broken down into five simple steps:

- (I) Establishing an individual development plan;
- (II) Gaining new experience to improve your marketability;
- (III) Creating opportunities within your current company;
- (IV) Establishing and maintaining an active professional network to create external opportunities; and
- (V) Evaluating your progress throughout the process.

This might seem like an overwhelming process at first glance but as you will learn, it really involves some simple action items that anyone can follow. Whether your long term career goals involve moving up the company ladder, making lots of money, ensuring your own job stability or a combination of these things, following this process will allow you to attain your goals quicker and will help you to avoid getting stuck in a professional rut.

### **I. Establishing an individual development plan**

The individual development plan is your roadmap to success. It is essentially an outline highlighting your current strengths along with the experience you need to gain in order to attain your long term career objectives. Just as you plan for an audit or anticipate every last

detail of an upcoming inspection, it is imperative that you develop a plan for your career.

**Can I get that in writing?** The first step in establishing your development plan is to set personal goals. This task seems obvious but not many people actually take the time to physically write down their career goals.

- Where do you want to be in 5 years?
- How about in 10 years?

When your long term career goals are written down in black and white, it is much easier to evaluate what you can do this year to get yourself a step closer to reaching them. You may not achieve that Director or VP title that you desire immediately, but the steps you take now will better position yourself to attain that goal in the future. Another benefit of actually writing down your goals is that it will be much easier to realize when you are veering slightly off course. When you recognize a deviation early, a slight reorganization of your priorities can usually get you back on track. Conversely, if you are slow to recognize even a small variance from the course, you will end up having to do some major backpedaling.

**Time to polish up the old resume.** Once you have established your career goals, the second step in creating your individual development plan is to update your resume. Do not wait until you are applying for a new position in order to do this. You should update your resume at least once per year. Include new certifications and title changes that you have received and significant accomplishments that you have been a part of. Now is the time for some honest self-evaluation.

- Does your resume look more qualified for that Associate Director role you desire today than it did a year ago?

Share your resume with a colleague whom you respect and ask them to evaluate it critically.

- If you were to apply for a senior position in their organization, what would they say about your experience?

Do the same with a recruiter that you trust.

Use your own judgment as well as these second and third opinions to identify the experiences that you are lacking. Identifying your career goals and updating your resume allows you to build your individual development plan and begin to monitor your progress. Because you know where you want to go (career goals) and where you are (current resume), you can map out the experience you need to gain and interim positions that must be attained in order to reach your long term objective. Your plan should include any training and coursework needed to gain new skills and projects in your company that can expand your knowledgebase. Write out the actions you intend to take to move along your path to advancement including steps to strengthen the weaknesses you have diagnosed.

## **II. Gaining new experience to improve your marketability**

Your career goals are established, you have identified your weaknesses and outlined a development plan. That plan likely includes gaining exposure to new things. Why is this important? The more experience and responsibility that you can demonstrate on your resume, the more attractive you become to both your current employer as well as other companies. Read the biographies of executives in your field and you will likely see experience in a breadth of areas and within companies both large and small. This is not a coincidence. Dynamic leaders seek new opportunities for growth and hiring managers seek candidates whose resumes demonstrate accomplishments in a variety of settings.

**What's it worth to you?** We advise all of our candidates to treat their resume like an investment. Every day that you go to work is a little more time and energy invested into your long-term return. We firmly believe that the experience you gain, especially during the earlier portion of your career, is significantly more important than the wage you are receiving. That is to say, the difference between making \$90K or \$100K this year is insignificant when compared to what you will earn over the course of your career. Of course, all things being equal, everyone would like to make more money today. However, if you are accepting more money to remain in a job with limited growth or learning opportunities, you are hampering your ability to increase your earning potential in the coming years. You should focus on building your resume and expanding your skill set such that you can command more money over a longer period of time. It would be great to earn \$5K or \$10K more this year but if that money comes with the handicap of allowing your resume to become stagnant than it is certainly not a sound investment decision. Your earning potential over a period of 5, 10, 15 or more years is significantly greater than the extra \$5K or \$10K you would earn this year. The more skills that you can add to your repertoire the more marketable your resume becomes and the greater your future earning potential will be.

## **III. Creating opportunities within your current company**

Now that you have scoped out your individual development plan, evaluate the plan against your current position and the potential to grow internally. Understand how far you can advance within your firm. Think this through ahead of time so that you will anticipate when it is time to move on. Take the initiative to create opportunities for yourself within your current role. These opportunities can range from promotion or transferring into a new group to simply adding additional responsibility to your current tasks or gaining a new skill by working on a particular project.

**Excuse me boss, can we talk for a minute?** The best managers have development plans for each of their employees. But, the most successful employees make sure that their boss is aware of their goals as well. For instance, discuss your desire to get involved in an upcoming project or to broaden your horizons by taking part in the next GCP audit.

We constantly hear from candidates who are frustrated that they are not being considered for an open position within their company. However, most of these same candidates admit that they have not expressly made their interest in the position known. Make sure that your boss or the senior management team is aware of your desire to be considered for a particular opening or that you would value the chance to work in a different part of the organization. If they do not respond positively about your candidacy, find out what experience you would need to gain in order to be considered for similar positions in the future. Do not rely on your boss to present these opportunities to you. Stand up and create them for yourself. Timing is everything and the right time to take on a new challenge is always now. This is a powerful statement but rings true in most situations. This includes both taking on new responsibilities within your current company and making a move to a new position externally.

## **IV. Establishing and maintaining an active professional network to create external opportunities**

Many employees do not think about searching for a new job until they get passed over for a promotion or their company goes through a restructuring. This is a tragic mistake. The best time to look for a new job is when you are happily entrenched in your current position. It is highly unlikely that the right next career step will present itself at the exact same time that you decide that you want to leave your current company. This is why you should always be actively listening for the right opportunity even though you may not necessarily be looking.

**Advancement has a price.** The most successful people identify and accept their next position before they ever bump up against a glass ceiling in their current role. The truth of the matter is there is really never a convenient time to change jobs. Professionals on the fast track are always willing to accept a new challenge. You can be sure that the Vice President of Quality at your company did not get there by chance. There were strategic career moves and goal oriented time lines set in place that specifically justify their elevated position. There were likely also times when they chose to strike when the iron was hot rather than to wait because the timing was not convenient. It is important to note that these moves often came along with significant short-term sacrifices to reach their long-term goal. Such sacrifices include relocation to a new city, accepting a lateral salary move or the potential risk of joining a start-up firm or company in transition. These sacrifices can be worthwhile and are often necessary in order to continue advancing on your projected career path.

**Tap into those connections!** Maintaining an active professional network is the most obvious way to increase the likelihood that you will hear about interesting opportunities outside of your company. Everybody knows that networking is something that they should be doing but many people are not sure how or why. One of the most common mistakes that people make is to only think about networking when they need something. If you are only touching base with your former colleagues, bosses and professors when you want a new job or need specific answers to a problem you are facing, your network will not bear the fruit you desire. You should keep your network organized in a contact management system to ensure that you have current phone numbers and email addresses and to remind yourself to check in with your peers periodically. Place a call or drop an email when you read news about their company or before heading to a conference. Make them aware of opportunities that exist in your company and they will do the same for you. Networking is a two way street, it cannot be all take and no give.

To keep your network growing, it is vital to get out and meet new people. Be active in your local PDA, SQA, ISPE, RAPS, AAPS chapters or whichever organizations align closely with your interests. Do more than just attend meetings for the free cocktails. Write a paper or present on a topic. Volunteer to work a show or lead a discussion group.

This makes it much easier to meet new and successful people and to get your name out among your peers.

**Those pesky recruiters can be a big help.** You should also make an effort to establish and maintain relationships with recruiters who specialize in your field. Take their calls and share information when you can. After a conversation or two, it is easy to differentiate between the couple of recruiters who truly know your field and can be a valuable resource to you versus the ones whose messages can be ignored. Bear in mind that this relationship is a two way street as well. A recruiter's livelihood is based entirely on networking. If you share information and leads with them they will certainly return the favor. When recruiters get a new and exciting search assignment, the first people they call are the ones they know and who have been helpful to them in the past. Monitor the progress of other companies in your locale. Let your colleagues and recruiters know of your interest in a particular firm and you are much more likely to hear about the opportunities that do exist but do not pop up on their website career page. Recruiters really value relationships with candidates and view them as a partnership. They spend a lot of time specifically targeting companies to uncover or create opportunities for candidates based on the information that they share about their interests. More often than not, a good recruiter will have the appropriate contacts to get your resume the desired exposure at companies that intrigue you. Giving them the chance to make confidential inquiries into specific companies is a fantastic way to create opportunities for yourself. As always, staying

proactive is the key to moving forward and achieving your goals.

#### V. Evaluating your progress

Taking the time to evaluate your progress along the way is absolutely crucial. You will already be doing this formally at least once per year when you update your resume. This can also be done as a part of an annual review with your boss. As you review the steps in this process, you will notice a common theme, the need for self-evaluation. In fact, continuously assessing your progress is imperative and is something you should be conscientious of throughout your working life.

- Did you reach this year's goal?
- Have you attempted to step outside of your immediate comfort zone at work to get exposed to something new?
- Did you gain the experience you desired during a particular project?

Setting a goal is the first step but is pointless unless you are going to judge your progress against each goal.

**It is a long and winding road.** Remember that job searching is a career long process that will evolve over time. Your goals will likely change over the course of several years and that is okay. You should be constantly planning your development path, creating opportunities to gain new experience and evaluating your progress to make the necessary adjustments.

*Scott M. Szczesny is the Head of Quality & Compliance Recruiting at PharmaLogics Recruiting and Jillian Savoy is an Executive Recruiter at PharmaLogics Recruiting*

Have an Idea or question or like to write an article?

Contact Publications: [DirectorP@NERCSQA.org](mailto:DirectorP@NERCSQA.org)

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**New England Regional Chapter Has Record Breaking Turn Out for the Two Day GLP Training Held in June by Patience A. Miller**

June 12<sup>th</sup> & 13<sup>th</sup>, 2007

**Day 1: Quality Assurance Audits, Inspections and Responsibilities**

**Day 2: GLPs for Study Directors and Scientific Staff**

As presented by Deb Garvin of Pacific Rim Consulting, WCQTI and former SQA President

The planning for this event started two years ago with the idea to have a well renowned speaker provide in depth training. At the time we immediately thought of Deb Garvin, one of the most knowledgeable professionals in the field of GLP regulations. The training was a huge success. There were many new member enrollments due to the draw of this two-day program. Professionals attending the training came from as far as Canada and New Jersey. This proved to be the best attended training program conducted by NERCSQA to date.

There were approximately 38 people that attended both days; Day 1 on QA Audits, Inspections and Responsibilities had an additional 15 attendees for a total of 53. Day 2 on GLPs for Study Directors and Scientific Staff had an additional 24 attendees for a total of 62. The combined total of 77 paid registrations was astounding.

Deb discussed the finer points of who is responsible for what in the GLP's. Her presentations were informative and engaging. Her experience added some reality to the presentations as she had an interesting story to stress the point she was making. Deb did quote from the preambles and the FDA Question and Answers. If you asked questions or commented you were rewarded with chocolate bars or a small gift.

Deb really tried to stress that quality is everyone's responsibility whether you are a QA auditor, Scientist, Study Director or Chemist. For the system to work we all must look at the piece we are contributing and how it helps to provide quality we can trust in the products that are being researched or produced.

From the responses on the June program evaluations we hope to conduct the next program on Computer System Validation and Quality Assurance. As membership grows into new areas it will give us the opportunity to expand our speaker base and continue to grow. If you are a new member to NERCSQA please join in the planning process by attending our conference calls.

We are in the process of recruiting members to volunteer some time on the NERCSQA program committee. Our success this year has truly been the efforts of our creative and inspiring program committee.

We would like you to be part of this exciting team. Please contact Scott Cook at [scott.cook@crl.com](mailto:scott.cook@crl.com) for more information.

*Patience A. Miller is the Quality Assurance Supervisor for Cambridge Biomedical Research Group and our newly elected Vice President.*

**NERCSQA Mission:**

*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.*

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