President’s Message

Hello everyone,

As the year has progressed we have all been extremely busy, thus the cancellation of the NERCSQA Member meeting that was scheduled in June. While it was due to lack of participation, we look forward to rebounding with a robust attendance at our joint training event with the Mid Atlantic Regional Chapter SQA (MARSQA) at the Boehringer-Ingelheim (BIPI) location in Ridgefield, Ct., on September 22 & 23. I am confident we will rally as an organization to build on this meeting as we move forward into the final months of 2016 and beyond.

As we embark on Q4 we will hold our end of the year membership meeting on Nov 9th at the Warren Center in Ashland, Ma. At the meeting we will be introducing our new board members to the membership. We will also hear more from Linda Chin, current Vice President and Program Chair who has been working relentlessly to put together the program of events (membership meetings and training) for 2017. Linda has been a key contributor to NERCSQA for many years and I hope you share my enthusiasm in welcoming her to her new roll in 2017 of President of NERCSQA. I am confident that the quality and content of our meetings will continue to grow under her guidance.

As we turn our focus to the joint training with MARSQA planned for September, we have a very exciting line up of speakers on the following topics; Introduction to GLPs (concentration on predicate rule), Introduction to GCPs, Sponsor/CRO Readiness for an FDA Inspection, Quality risk Management as Applied to Clinical Trials, and Cultural Awareness. Please remember as you make your plans to attend the training to include registration for the wonderful social event on the evening of September 22nd, we look forward to the interactions and networking opportunities this will allow for our membership.

As for the business aspects of NERCSQA, the updated bylaws will be forthcoming soon for membership approval, both nominations and elections for open board seats in 2017 shall transpire over the coming months as well. Open board positions for 2017 are Vice President / Program Chair (3 year commitment), Treasurer, Director of Membership, and Director of Publishing (2 year commitments). Please feel free to reach out to any of the current board members to get more details on any of these positions. We are always looking for and encourage you to nominate or volunteer as soon as possible so we can make the transition to 2017 as seamless as possible.

See you all at BIPI in September....

Irma, NERCSQA President
About NERCSQA

The New England Regional Chapter for the Society of Quality Assurance

Officers & Board of Directors

President
Irma Anncharico
President@nercsqa.org

Vice President
Linda Chin
VP@nercsqa.org

Secretary
Deb Buxton
Secretary@nercsqa.org

Past President
Aimee Altemus
PastPresident@nercsqa.org

Treasurer
Brittany Medeo
Treasurer@nercsqa.org

Director of Sponsorship
Mary Donohoe
DirectorS@nercsqa.org

Director of Membership
Cindy Zisson
DirectorM@nercsqa.org

Director of Publications
Lisa Kennedy
DirectorP@nercsqa.org

Contact our Board Members to learn how you can get involved with NERCSQA.

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.

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*Special Training Event*

NERC SQA & MARSQA

Present a Special Joint GLP Training Session

The 2-Day event will include:

- An Introduction to GLP including a special focus on the Predicate Rules
  - An Introduction to GCP
- Sponsor/CRO Readiness for an FDA Inspection – presented by Mike Rashti, Former FDA
  - The Biologics Super Highway
- Unexpected Investigations in Bioanalysis
  - Data Integrity
- Quality Risk Management as applied to Clinical Trials
- Cultural Awareness – insights & benefits for auditors working in a multicultural environment
  - Proposed GLP Round Table Discussion!

22–23 September 2016
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Rd
Ridgefield, CT 06877

Register HERE!

Hotel Information & Directions

~~Sponsored by~~
Boehringer Ingelheim
FDA issues a nationwide recall of all over-the-counter dietary supplements containing >100 mg L-Tryptophan, due to a clear link between the consumption of L-tryptophan tablets and the U.S. outbreak of Eosinophilia Myalgia Syndrome (EMS). By 1990 the CDC confirms >1,500 cases of EMS, including 38 deaths, and FDA prohibits the importation of L-tryptophan.

Regulations are published to Accelerate the Review of Drugs for life-threatening diseases.

Several adverse reaction reporting systems are consolidated as MedWatch, designed for voluntary reporting problems with medical products to be filed with FDA by health professionals.

Revising a policy from 1977 that excluded women of childbearing potential from early drug studies, FDA issues guidelines calling for improved assessments of medication responses as a function of gender.

FDA declares cigarettes to be "drug delivery devices." Restrictions are proposed on marketing and sales to reduce smoking by young people.

FDA promulgates the Pediatric Rule, a regulation that requires manufacturers of selected new and extant drug and biological products to conduct studies to assess their safety and efficacy in children.

Federal agencies are required to issue guidelines to maximize the quality, objectivity, utility, & integrity of the information they generate, and to provide a mechanism whereby those affected can secure correction of information that does not meet these guidelines, under the Data Quality Act.

Nutrition Labeling and Education Act requires all packaged foods to bear nutrition labeling and all health claims for foods to be consistent with terms defined by the Secretary of Health and Human Services. The food ingredient panel, serving sizes, and terms such as "low fat" and "light" are standardized.

Safe Medical Devices Act is passed, requiring facilities that use medical devices to report to FDA incidents that suggest that a medical device probably caused or contributed to the death or serious illness, or serious injury of a patient.

Prescription Drug User Fee Act requires drug and biologics manufacturers to pay fees for product applications and supplements, and other services. The act also requires FDA to use these funds to hire more reviewers to assess applications.

Uruguay Round Agreements Act extends the patent terms of U.S. drugs from 17 to 20 years.

Animal Medicinal Drug Use Clarification Act allows vets to prescribe extra-label use of veterinary drugs for animals under specific circumstances. In addition, the legislation allows licensed veterinarians to prescribe human drugs for use in animals under certain conditions.

Federal Tea Tasters Repeal Act repeals the Tea Importation Act of 1897 to eliminate the Board of Tea Experts and user fees for FDA's testing of all imported tea. Tea itself is still regulated by FDA.

A final rule mandates that all over-the-counter drug labels must contain data in a standardized format. These drug facts are designed to provide the patient with easy-to-find information, analogous to the nutrition facts label for foods.

Check out the next issue of Northern Highlights for more dates in US drug history!
Framingham State University’s Graduate Certificate in Quality Assurance (QA) for Biotechnology offers life science professionals foundational training for a role in quality assurance. The certificate combines training in QA with applicable scientific concepts and regulatory affairs, providing a foundation for successful liaison with the various departments involved in QA within an organization. The certificate program can also be completed as part of the Professional Science Master’s Degree in Biotechnology.

Upon completion of the program, students will be able to:

- Apply an understanding of common laboratory techniques used in the production and assay of biological products to roles in QA
- Apply an understanding of statistical analyses used in QA
- Evaluate the quality of life science products
- Evaluate compliance with regulations
- Integrate, synthesize, and relay information from a variety of sources, including scientific reports, regulatory requirements, and organizational goals

Admissions Requirements:
Applicants must have earned a bachelor’s degree from a regionally accredited college or university and must submit an official transcript from each college or university attended.

Program Requirements:
The Graduate Certificate in Quality Assurance for Biotechnology consists of five (5) courses:

- Biotechnology Laboratory Techniques under GLP
- QA and QC for Biotechnology and Biopharmaceuticals with QbD
- Business Operations Management in Biotechnology
- Drug Development: Process and Regulations under GMP
- Advanced Biostatistics in GCP

To enroll into this program or attend a class, please contact Sunny Tam, PhD at 508-626-4912 or stam@framingham.edu or go to: www.framingham.edu/biotech
**NERCSQA Member Profile Corner**

Lisa Kennedy  
*Agilux Laboratories – QA Auditor II*

**Job synopsis:** Performing compliance audits of regulated studies and related operations

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**at WORK...**

**How long?**
- At your current position: 3 years
- In the QA/QC profession: 4 years
- Member of NERCSQA: 3 years
- Member of SQA: 1 year

**How has SQA/NERCSQA helped you in your career?**
I’m obviously new to this scene, so NERCSQA has been my introduction to the QA world outside of work. I love attending the trainings and meetings when I can and I remember. Life can be crazy! I make the Newsletter.

**What types of activities do you find most rewarding in your job?**
When I get to do the “right thing” and really help someone or make a positive difference/change. I also find goofing off or being myself incredibly rewarding.

**What types of activities are most challenging in your job?**
Processing massive amounts of data and processes into a comprehensive, hopefully coherent audit report. Not having auditor blinders.

**Have you had a mentor along the way, and how did they help you?**
I try to learn the lessons that others have to teach me. Some make it easier. For three years I have had a boss that supports my career development and that’s nice.

**Three other jobs I’ve had:**
- SCUBA Diver/Myriophyllum spicatum destroyer
- Bartender and graduate student/teaching assistant
- Home healthcare provider

**A favorite “Quality” quote or philosophy:**
There is nothing convenient about auditing.

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**and at HOME...**

**Where were you born?**
Keene, New Hampshire

**Where do you live now?**
That’s classified

**What is your favorite hobby or pastime?**
Playing with my cats

**Three favorite travel/vacation spots:**
- Mountains
- A body of water
- Beaches

**Three favorite TV shows:**
- Jeopardy
- Cartoons for adults
- The Wire

**Three favorite foods:**
- Beer
- Bacon
- Cheese

**A favorite life quote or philosophy:**
I am he as you are he as you are me and we are all together
Winter Crossword SOLVED

Why were the chemists fed up with Bioanalysis?

Too Many DOUBLE STANDARDS!
Life in QA

Because Life happens in-between audit reports

It is easier to do a job right than to explain why you didn't.

Martin Van Buren

When you skimp on reviewers

Photo courtesy of Ashley Plumb
## Upcoming NERCSQA Events

**CLEAR YOUR CALENDARS!**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Location</th>
<th>Topic/Speakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept 22 and 23 2016</td>
<td>8am-4pm</td>
<td>Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT</td>
<td><strong>CLICK HERE!</strong></td>
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<tr>
<td>Training Event</td>
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<tr>
<td>November 9</td>
<td>6-8 pm</td>
<td>Warren Conference Center and Inn, Ashland, MA</td>
<td>TBD</td>
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<td>Member Meeting #3</td>
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## ~IN CASE YOU MISSED IT~

**A MODEST PROPOSAL BY THE FDA!**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**FOOD AND DRUG ADMINISTRATION 21 CFR Parts 16 and 58**

**GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES**

**FOOD AND DRUG ADMINISTRATION, HHS**

**PROPOSED RULE**