



Northern Highlights



The Quarterly Newsletter of the New England Regional Chapter of the Society of Quality Assurance

President's Message

As I sit by the bright, calm, turquoise waters of Playa Sucia in Puerto Rico, it is hard to think of snow, winter or the hectic schedule of work. The scenery before me is picturesque and unlike anything we have in New England. The sand is fine and blindingly white below the bright sun. This beach was created by an opening between ochre and brown colored cliffs, bringing warm Caribbean waters a short distance inland, creating a small cove known as Playa Sucia. In the distance, atop the right cliff, the newly painted "Faro" (lighthouse) sits overlooking the cove and the ocean.

Alas! Vacation is drawing to an end and I soon will be back in the midst of winter. As they say, if good things didn't end we wouldn't appreciate them... With the end of vacation come the responsibilities of work and setting the 2014 goals for NERCSQA. But as reluctant as I am to leave this little piece of paradise, I am also excited by all the events and changes planned for NERCSQA this year. Among other things, we will be presenting a poster and holding a "Meet and Greet" at the Global QA Meeting / SQA Annual Meeting in Las Vegas, NV. In addition, we are planning to hold three additional member meetings as well as two day long training sessions - one on medical devices and the other one on regulated bioanalysis. Stay tuned for details on these trainings. I hope to see you at one or all of these events!

Jen Bravo
MS, RQAP-GLP
Associate Director
QA & Safety
Agilux Laboratories

All of these events are possible due to the enthusiasm of the Board of Directors. I would like to

take this opportunity to welcome the new officers to the team - Aimee Altemus as Vice President and Chair of the Program Committee, Deb Buxton as Secretary, Jessie Latchaw as Director of Sponsorship, and Lisa Kennedy as Director of Publications. I would also like to thank outgoing officers for all the time and effort they put into making NERCSQA successful last year - Kate Connors as secretary, Chris Braudis as Director of Sponsorship, and Manish Ranjitkaras Past President.

There are two people who I would like to single out for their invaluable contributions to the organization in 2013. Chris Wubbolt, as President, was instrumental in building momentum for the organization and laying out the vision for 2013. I have big shoes to fill (pun intended)!! Aimee Altemus, as Director of Publications, made significant changes to the newsletter content and managed to issue four newsletters in 2013!! Not an easy feat!

I hope to see some of you at the NERCSQA meet and greet and/or the poster session at the Global QA Meeting / SQA Annual Meeting in Las Vegas. At least as it pertains to NERCSQA, you'll be remembered for what you do in Vegas!!

Jen Bravo, President NERCSQA



Welcome New Board Members!

The results are in! Elections were held in December, and now the board welcomes:

Aimee Altemus

Vice President

- GLP Auditor IV, Boehringer Ingelheim
- 14 years in QA
- NERCSQA Member since 1999
- 2002-2003; Director, Membership
- 2009-2010; Director, Sponsorship
- 2013– 2014; Director, Publications

Debra Buxton

Secretary

- QA Consultant
- 14 years in QA and 4 years in QC
- Member of RAPS, ASQ, and PDA
- Led a FDA inspections with no 483s—go Deb! (for the latest trends in 483s, see page 5)

Lisa Kennedy

Director of Publications

- QA Auditor I, Agilux Laboratories

Interested in contributing an article, case study, or cartoon for the next issue of Northern Highlights?

Contact Lisa Kennedy at
DirectorP@nercsqa.org

For a complete list of Board Members, please see page 9

Jessie Latchaw

Director of Sponsorship

- Auditor III, Boehringer Ingelheim
- 6 years in QA
- NERCSQA member since 2008
- Member of PRCSQA and SQA
- Aims to develop NERCSQA's relationship with local pharmaceutical companies and CROs

Become a Corporate Sponsor or Corporate Member Today!

Contact Jessie Latchaw at
DirectorS@nercsqa.org

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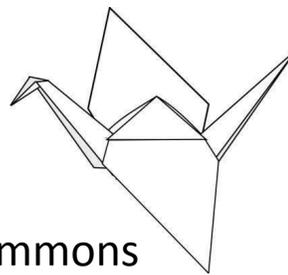
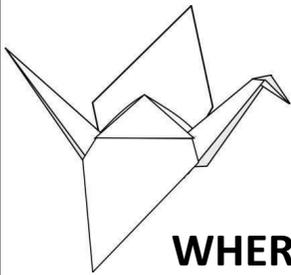
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At the SQA Conference?
Need a break from blackjack?

Come check out the NERCSQA Poster

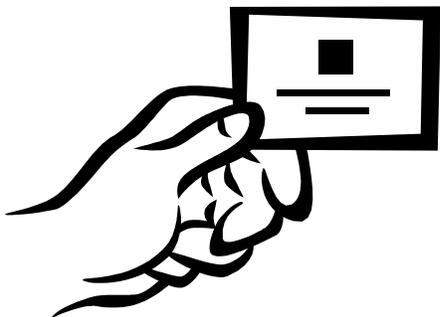
See how NERCSQA is “Gaining Momentum”
in 2013-2014!



WHERE: Gracia Ballroom and Commons
The Cosmopolitan of Las Vegas

WHEN: Tuesday, April 8th, 7:30 am - 5:00 pm &
Wednesday, April 9th, 7:30 am - 3:30

Check out our
“Origami of the
Day”



Enter your
Business Card for our
Daily Give-Away!



Meet and Greet
at SQA’s
Annual
Meeting in
Las Vegas, NV

Come, meet other
NERCSQA members, and
learn about what we
have planned for 2014,
including training events
and membership meet-
ings.

**Tuesday, April 8,
2014, 7:30 to 8:30
AM**

**BREAKFAST
INCLUDED,
SLOTS EXTRA**

Looking forward to
seeing you there!

A Brief Visit to the FDA Website

By Lisa Kennedy, QA Auditor, Agilux Laboratories

In the light of my election to NERCSQA Director of Publication, I drafted a quick email to the FDA webmaster and the few contacts I could muster from FDA the website; because what would be more interesting to QA professionals than a short article on some basic FDA statistics? Well, they never got back to me (surprise!) but luckily the FDA website is an absolute wealth of statistics, so here are a few things that I found interesting

Compared to the rest of the country, the North East experience the fewest FDA inspections

Being a regional publication, I thought a geographical approach to the data would be appropriate. At 17.2%, the North East made up the smallest percentage of the 102,000 inspections performed by the FDA since 2008¹. The South, on the other hand, accounted for the most, at 26.5% of all audits, followed by the Midwest and the West. International and sovereign territories made up 9.4% and 1.3% of audits, respectively.

So what are the results of these inspections? Compared to the rest of the country, compa-

nies in the North East have received fewer OAI's (Official Action Indicated) outcomes (3.0% vs 3.7%) from inspections, but less FDA visits have ended NAI (No Action Indicated, 60.9% vs 63.6%).

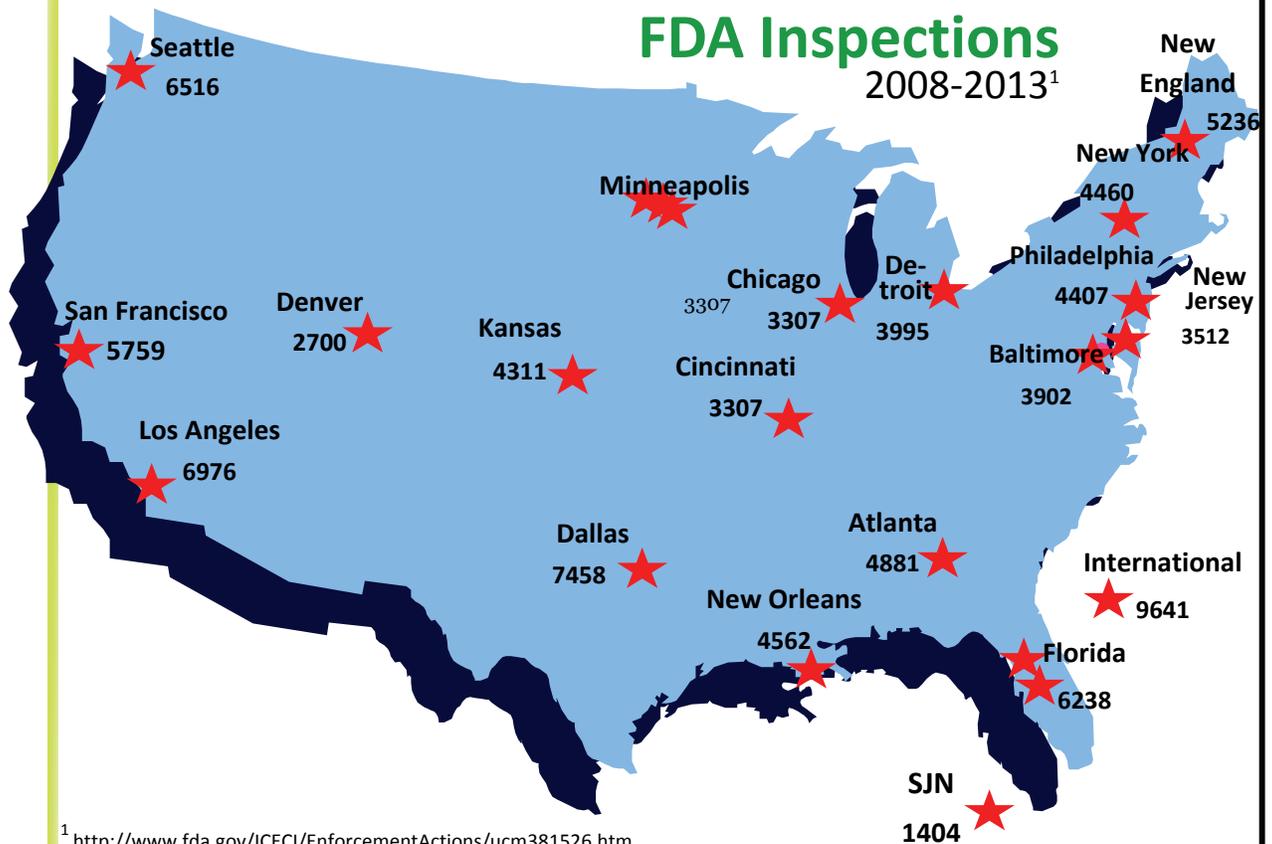
By far the most unexpected piece of this geographical puzzle were the industries that were inspected in each region. Looking at device, drug and food inspections only, New England actually had fewer drug and device related inspections but 6.5% more food-related audits (72.3% opposed to the national 67.9%).

Every American pays ~ \$8/year for the services of the FDA

See page 5 for more on the FDA budget

FDA Inspections

2008-2013¹



Recycle Me!

¹ <http://www.fda.gov/ICECI/EnforcementActions/ucm381526.htm>

What's Trending Now?

The Five Most Frequently Issued 483s of 2013¹

Bioresearch Monitoring

Short Description	Total
• Protocol compliance	47.3%
• Case history records inadequate	31.1%
• Minutes of IRB meetings.....	11.0%
• Accountability records.....	8.8%
• IRB has no/did not follow procedure for conducting review of research.....	8.4%

Devices

Short Description	Total
• Lack of/inadequate procedures..	34.4%
• Lack of/inadequate complaint procedures.....	23.3%
• Documentation.....	12.1%
• Lack of/inadequate process validation.....	11.6%
• Lack of Written MDR Procedures	11.3%

Drugs

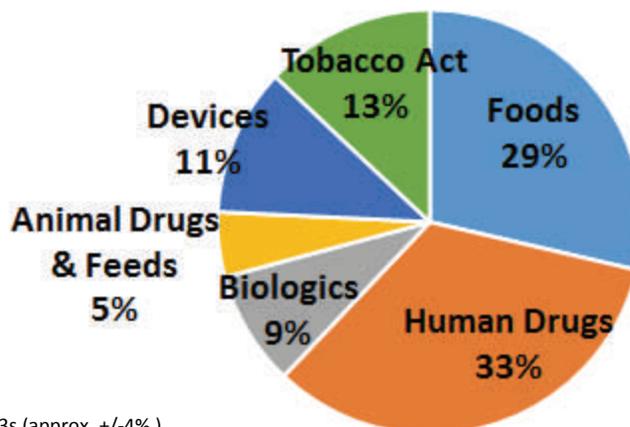
Short Description	Total
• Procedures not in writing/fully followed.....	22.5%
• Investigations of discrepancies, failure to review.....	19.0%
• Absence of Written Procedures....	15.4%
• Scientifically sound laboratory controls.....	14.3%
• Written procedures not est./ followed for cleaning/ maintenance of equipment, used in drug manufacturing	11.2%

*Get Writing!
Lack of procedures is among the top FDA findings for all three Centers*

*The Five Most Frequently Issued 483s represent 80-90% of the citations issued for each center**

FDA Budget 2014

~\$4.65 billion²



* does not reflect manually issued 483s (approx. +/-4%)

¹ <http://www.fda.gov/ICECI/EnforcementActions/ucm381526.htm>.

² <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM347422.pdf>



Recycle Me!

*For a complete list
of upcoming
NERCSQA events
see page 9*

Interested in Sharing Your SQA Experience?

There are two ways to contribute:

♣ **Present at our May 14th member meeting**

- Hone your public speaking skills
- Present to a group of career-oriented individuals

Contact Jen Bravo or Aimee Altemus for More Details

♣ **Submit an article for “Northern Highlights”**

- Not in the mood for a speech?
- Feel the pen is mightier?
- Tired of my rhetorical questions?

Email submissions to lkennedy@agilux.com

NERCSQA RQAP Study Group

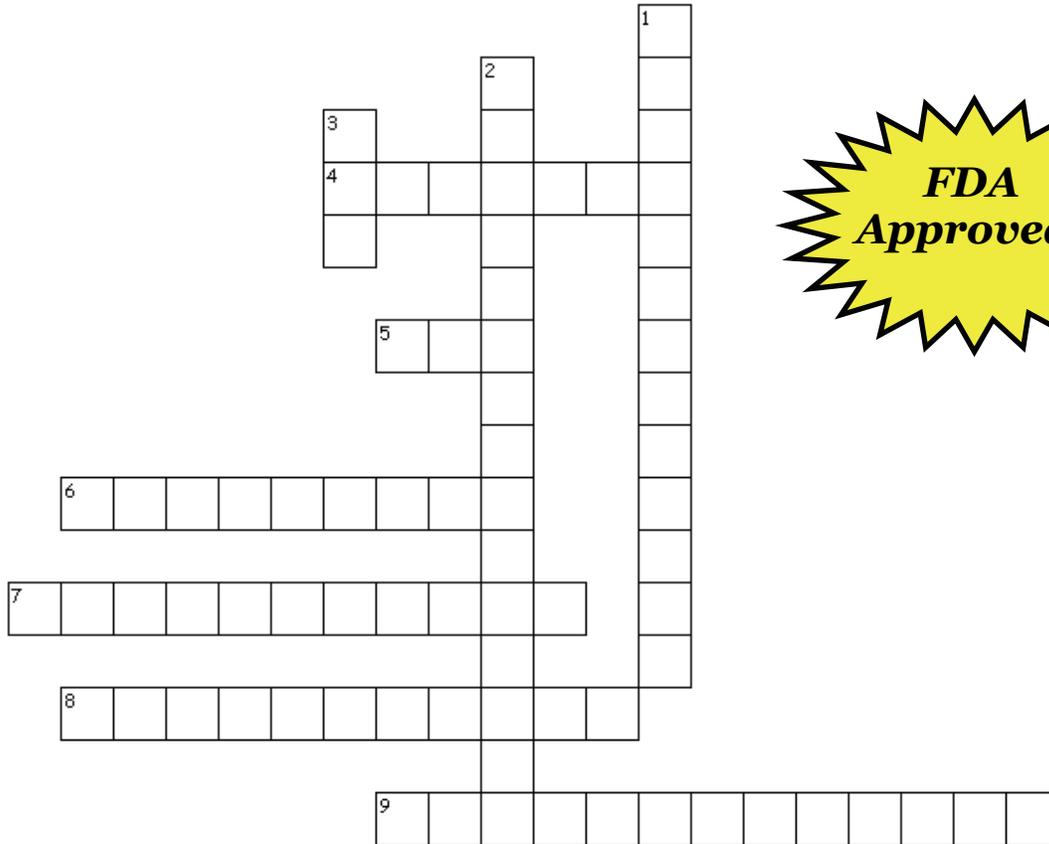
- Signed up to take the RQAP exam?
- Drowning in all of the study reference material and don't know where to start?
- Interested in joining a study group?

Contact [Jen Bravo](#) or [Aimee Altemus](#)



The Northern Highlights Crossword

(some say it's better than the New York Times)



Across

- 4. Throw this away and you will regret it
- 5. A visit from them is best and the end of the fiscal year
- 6. If a problem still occurs, you haven't addressed this
- 7. Property of a substance that causes structural or developmental malformations in an embryo or fetus that are not heritable
- 8. Term for a medical device that does not comply with GMPs
- 9. The process in which a chemical mixture is separated into its component parts by passing through a solid or liquid phase

Down

- 1. Legislation that intended to prohibit cancer-causing food additives and pesticides; repealed in 1996
- 2. A daily publication of federal regulatory actions, proposed rules, final rules, and notices
- 3. Committee that is formally designated to review, approve, and conduct periodic reviews of biomedical research involving human subjects

Created by Puzzlemaker at DiscoveryEducation.com



Life in QA

“The Auditor”

Data on my desk

Data on the floor

Clipboard in my hands

Could a scientist fear more?

- Anonymous

TALES FROM QA "QA ON VACATION"

BY LISAKENNEDY



Northern Highlights Contributions Are Welcome!

Are you interested in contributing an article, puzzle, case study, or cartoon for the next issue of Northern Highlights?

Contact Lisa Kennedy at DirectorP@nercsqa.org



Upcoming NERCSQA Events

We're still working out some details, but good things are planned, so stay tuned.

Date	Time	Location	Topic/Speakers
April 08 th Member Meeting #1	7:30 to 8:30 am	Cosmopolitan Las Vegas, NV	NERCSQA Meet and Greet (with breakfast)/ NERCSQA Board Members at SQA
May 14 th Member Meeting #2	5:30 to 8:00 pm	Synta, Lexington, MA	Recap of SQA Session/NERCSQA officers and members
June 24 th Training #1	TBD	TBD	Medical Devices/Scott Cook and FDA Medical Device Speaker (invited but unconfirmed)
September Training #2	TBD	TBD	Regulated Bioanalysis/Richard LeLacheur (Agilux Labs) and Dr. Viswanathan (Ret. FDA)
Early October Member Meeting #3	TBD	TBD	TBD
November Member Meeting #4	TBD	John Harvard's, Framingham, MA	TBD

Contact Us,

We'd Love to Hear From You!



NERCSQA Officers and Board of Directors

President – Jen Bravo, jbravo@agiluxlabs.com

Vice President – Aimee Altemus, aimee.altemus@boehringer-ingelheim.com

Past President – Chris Wubbolt, chris.wubbolt@QACVConsulting.com

Secretary – Deb Buxton, dkbuxton@yahoo.com

Treasurer – Laura Hoffman, laura.hoffman@haemonetics.com

Director of Sponsorship – Jessie Latchaw, jessie.latchaw@boehringer-Ingelheim.com

Director of Membership – Danielle DeOssie, ddeossie@agiluxlabs.com

Director of Publications – Lisa Kennedy, lkennedy@agiluxlabs.com

Interested in becoming a member of NERCSQA?

You know you are!

Go to <http://www.nercsqa.org/membership.htm>



Seriously, you should Recycle Me!