Vol. 17. Issue 2, Sep. 2013 | New England Regional Chapter of the Society of Quality Assurance

Northern Highlights

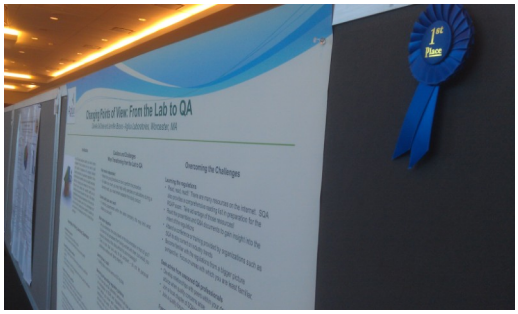
President's Message

Chris Wubbolt, President, NERCSQA

Chris Wubbolt, QACV Consulting, Quality Assurance, Compliance & Validation Consulting

2013 has been an exciting year for NERCSQA with a lot of activities and events and increased attendance and participation from the NERCSQA membership. We started out 2013 with a Meet and Greet at the SQA Annual Meeting in Indianapolis. About 20 NERCSQA members attended the SQA Annual Meeting and 10 members attended the Meet and Greet.

We had a second member meeting on May 21 at John Harvard's Brewery & Ale House in Framingham with about 15 members attending. A review of the SQA Annual meeting was presented based upon summaries provided by Paula Picton, Boehringer Ingleheim, and Danielle DeOssie, Agilux Laboratories. Speaking of Danielle, she and Jen Bravo, also of Agilux Labs, won first prize at the SQA poster session for their poster on "Changing Points of View: From the Lab to QA." The poster described the advantages of having laboratory experience when moving into a QA role. It also described the cautions and challenges when making the transition and how to overcome those challenges. Congratulations Danielle and Jen!!



NERCSQA's first training event in 2013 occurred on June 17 when "Auditing Computer System Validation and Electronic Records" training was provided by Chris Wubbolt and Binesh Prabhakar to almost 20 NERCSQA members at the Mass Bio facility in Cambridge.

NERCSQA's third member meeting of 2013 occurred on September 12 and was attended by almost 30 people! Synta Pharmaceuticals sponsored the event which featured a presentation by Mike Rashti, ex-FDA investigator. Thank you to Synta for hosting the event at their facility in Lexington!

In March we also issued our first NERCSQA newsletter which was very well received and included articles, puzzles, and news pertaining to NERCSQA. This issue of the newsletter includes our first member profile, featuring Melissa Jensik from Vertex Pharmaceuticals. Thank you to Aimee Altemus from Boehringer Ingelheim for leading the Publications Committee to publish the newsletters. It takes a lot of time and it is very much appreciated.

Inside this issue:

Scholarship Opportunity

Continuing NERCSQA's mission to provide educational opportunities to its members

Ging Lee Memorial Scholarship

Purpose

The purpose of the Ging Lee Memorial Scholarship is to recognize an individual that has contributed to the NERCSQA and to the Quality Assurance Professional in general. Financial need may be taken into consideration if selecting amongst equally deserving candidates.

Scholarship Use

The scholarship will be used to enhance the education or quality interests of the individual receiving the award by funding their attendance at any national or regional chapter of SQA event inclusive of travel and accommodations. Meals and other incidental are not included.

Applying / Nominating a member for the scholarship

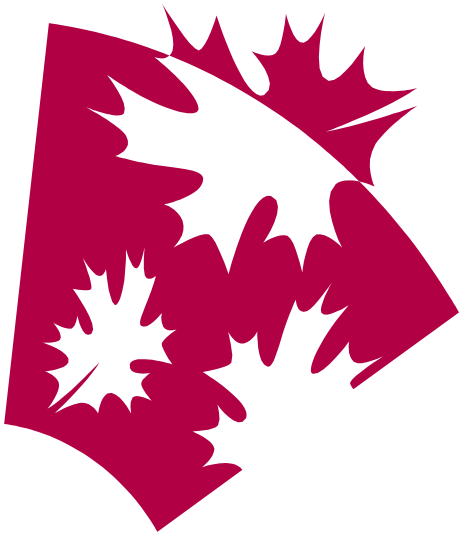
Candidates may be nominated by another NERCSQA member or may apply for the scholarship by completing the Ging Lee Memorial Scholarship Application / Nomination form available through the NERCSQA website and submitting the completed application to the NERCSQA Board of Directors for consideration.

Scholarship Criteria

Candidates must meet the following criteria:

- The candidate must be a NERCSQA member in good standing
- The candidate must not be a member of the Board of Directors

Applications are due by August 15 and should be sent to the Director of Membership, Danielle DeOssie at DirectorM@nercsqa.org.



WELCOME NEW MEMBERS!

Peter Antoniuk, Antoniuk Consulting Services LLC

Adrine Beurklian, Immunetics

Taylor Burtis, RQC Navigation

Maryse Constant, Boston Scientific

Melissa Jensik, Vertex Pharmaceuticals

Fraser Macdonald, Millennium Pharmaceuticals

Frances Nolan

Samantha Scull-Lopez, Genzyme Corporation

Edwin Sopp, Concert Pharmaceuticals

Margaret Sweeney, Biogen Idec

Khonesavanh Vilayphone, Vertex Pharmaceuticals

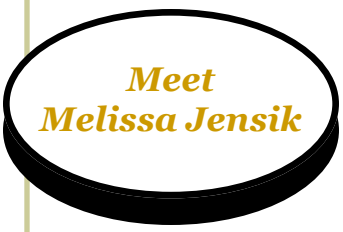
Lisa Kennedy, Agilux Laboratories

NERCSQA Member Profile Corner

The goal of the Member Profile is for the NERCSQA member community to learn a little more about its members. The questions are a mix of professional and non-professional.

Melissa Jensik (RQAP-GLP) is the first to step up to the plate! THANKS MELISSA!

1. Current Company: *Vertex Pharmaceuticals*
2. Current position: *Quality Lead - Quality Compliance Management*
3. How long have you been in your current position and how long have you been a Quality Assurance professional? *Current Position – 4 months QA Professional – 13 years*
4. How long have you been a member of NERCSQA / SQA? *Re-established SQA membership in 2013; NERCSQA membership new starting 2013*
5. How has NERCSQA or SQA helped you develop professionally? *Providing classes in Current Topics is a good way to keep apprised of recent issues. Also, administration of the RQAP exam as a means of testing one's understanding and application of the regulations.*
6. *What types of activities do you find most rewarding at your job? Reviewing procedures and practices to help departments streamline processes where possible.*
7. *Have you had any mentors or teachers that have helped you develop professionally? For my first job, I worked with a wonderful group of professionals – QA, scientists, technicians. They always made time to educate; provided opportunities for, and encouraged, professional growth; and fostered an environment of mutual respect.*
8. *What advice would you give to someone new to the Quality Assurance field? Knowledge is power. Don't be afraid to ask a question.*
9. *What types of activities do you find most challenging? Stepping outside of your audit comfort zone and getting involved in less familiar areas.*
10. *What educational opportunities would you like to see offered by NERCSQA in the future? None yet (new to NERCSQA).*
11. *What do you enjoy doing outside of work? Traveling to new places.*
12. *What is your favorite vacation spot? Probably most anywhere. I really enjoyed my trip to Poland and the Baltic States.*
13. *What is your favorite North American city? Why? I don't have a favorite, but I have always found the Seattle skyline to be very picturesque at night.*
14. *What are your favorite restaurants in the New England area? No favorite, but the Salty Dog in Faneuil Hall has a delicious swordfish fillet sandwich.*
15. *What is your favorite season? Why? Definitely autumn – the changing colors, Halloween, cider donuts, and fresh apples from the orchard.*
16. *Have you read any (non-QA) books lately? Do you have any you would recommend? "Timeline" by Michael Crichton was good. I read a lot of military history – "Masters of the Air" about the Eighth Air Force in WWII was an excellent account.*
17. *Do you have any pets? Not currently*
18. *What is your philosophy of life or work? Life is full of opportunity, if you're willing to take the risk.*



YOU COULD BE NEXT!

If you are interested in being interviewed for the NERCSQA Member Profile Corner, contact:

Danielle DeOssie,
DirectorM@nercsqa.org

2012 FDA Bioanalytical Inspection Findings

By Jennifer Bravo, Associate Director Quality Assurance and Safety, Agilux Laboratories

Data quality and integrity are at the core of inspections performed by FDA.

Of the 180 inspections started in 2012, form FDA 483 was only issued for 39% of those inspections.

The Chief for the FDA's Bioequivalence Branch (Office of Scientific Investigations, Division of Bioequivalence and GLP Compliance), Dr Sam Haidar, Ph.D., R.Ph., presented the "Most Recent Audit/ Inspection Bioanalytical Findings from the US FDA" at the 7th Workshop on Recent Issues in Bioanalyisis (WRIB) which took place in Long Beach, CA, on April 9-10, 2013. Dr. Haidar's presentation provided an overview of bioanalytical inspections performed by the Center for Drug Evaluation and Research (CDER) in 2012, an analysis of form FDA 483 inspectional observations and recent proposed changes to bioequivalence (BE) investigations program. This article provides a summary of Dr. Haidar's presentation.

Bioanalytical and Bioequivalence Inspections

Data quality and integrity are at the core of inspections performed by FDA. The main objectives of inspections performed by CDER include:

- Evaluate adherence to statutes and regulations to ensure data quality and integrity
- Reconstruct the study based on paper and electronic documentation
- Perform a facility tour and follow the "sample" through the company's processes
- Assess whether equipment and instrumentation used were tested and perform as intended
- Evaluate procedures used such as handling of samples
- Perform a data audit to assess assay validation and compare the data submitted by the sponsor to the records available on site, among other things

Of the 180 inspections started in 2012, form FDA 483 was only issued for 39% of those inspections. Most of the inspections performed (60%) were triggered by bioequivalence studies for generic drugs. See Tables 1 -2 below for more details.

Table 1: FDA Inspections in 2012 (Bioanalytical)

Description	Number
Inspections started in 2012	180
483 Issued	70 (39%)
Unique applications	**107**
ANDAs	64 (60%)
NDA	41 (38%)
IND	1
BLA	1

Table 2: FDA Inspection Type (2012)

Inspection Type	Total No. of Inspections	No. of 483's Issued
Clinical	101 (56%)	32 (32%)
Bioanalytical	71 (39%)	34 (48%)
Clinical / Bioanalytical	8 (4%)	4 (50%)

Using internal databases, Dr. Haidar evaluated 483 observations for inspections performed in 2012. Highlights are presented in Table 3 below.

Table 3: Bioanalytical inspections performed in 2012: 483 observations

Bioanalytical Observations	
Category	**Common Observations**
Inadequate Documentation (most common)	Failure to document time quality controls, calibrator and subject samples were removed and returned to freezers Number of times samples were thawed and frozen Failure to verify weighing of reference standards by balance printout or initials of witness Number of hemolyzed samples not documented on any of the sample transfer forms
Quality Control (QC) / Calibrators	Failure to use independent stock solutions for QCs and calibrators Freshly prepared QCs and calibrators were not used for stability testing Failure to adjust QCs and calibrators for endogenous levels (e.g. testosterone) Anti-coagulant in QCs and calibrators not the same as in subject samples
SOP Deficiencies	SOPs absent (e.g. sample reanalysis) SOPs not followed No SOPs pertaining to computer system / software validation
Miscellaneous	Inconsistent manual integration Relatively large number of manual integrations Failure to resolve interfering peaks Implausible concentrations not investigated Failure to report all validation experiments containing valid data
In Vitro Bioequivalence Observations	
Category	**Common Observations**
QCs / Calibrators	Full set of calibrators not used in each run QCs not used to monitor performance for each run
Miscellaneous	Frequency of calibration of instrument not adequate (laser diffraction) Reserve samples not retained cGMP regulations followed, instead of bioequivalence regulations (this is considered to be a serious deficiency and may result in rejection of data)
BE Clinical Observations	
Category	**Common Observations**
Inadequate Documentation	Randomization codes for blinded studies not maintained at clinical site Failure to maintain complete and accurate case histories
Informed Consent	Informed consent deficiencies Inadequate information about risk Initiating study prior to obtaining consent from all subjects
Miscellaneous	Reserve samples not retained or inadequate number retained

(article continued on Page 6)

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 Aimee Altemus at DirectorP@nercsqa.org.

Are you interested in contributing an article, puzzle, case study, or cartoon for the next issue of Northern Highlights?
Contact Aimee Altemus at DirectorP@nercsqa.org

2012 FDA Bioanalytical Inspection Findings (continued from Page 5)

Proposals under Consideration

Dr. Haidar discussed proposals under consideration at FDA:

Surveillance inspections: There is a proposal to develop a surveillance model for bioequivalence studies in addition to application based inspections. There appears to be a push to develop inspectional quantitative measures that can be used for trending and training purposes and to improve consistency between inspectors. These quantitative measures would also be used to rate inspected entities to help FDA prioritize routine inspections.

FDA/EMA initiative: FDA expects to increase collaboration with EMA in the area of bioequivalence inspections. This is driven primarily by increased globalization and the need for more foreign inspections. Under this increased collaboration, the agencies may conduct joint inspections when needed and will be sharing inspectional reports and site information. Dr. Haidar emphasized that the exchange of information would be conducted under confidentiality agreement.

Bioequivalence regulations: The agency's regulatory counsels are in the process of evaluating approaches to update the bioequivalence regulations. Dr. Haidar warned that depending on resource availability, any changes to the regulations may take years.

JOB POSTING Senior Quality Assurance Engineer – Full-Time,

Amazing Charts.com, LLC, North Kingstown, RI

Job Description: Amazing Charts.com, LLC is seeking a Senior QA Automated Test Engineer to help drive an automated test framework in support of regression testing and validation of the Amazing Charts application. To reduce test times and improving test coverage. This individual will have proven experience developing an ATE test suite from the ground up and have experience with various automation tools and scripting languages.

- Lead the development of an automated test framework and test suite in support of the Amazing Charts application using a .net framework
- Set and communicate overall test strategy as it pertains to automated testing
- Investigate new ATE technologies and processes to identify the necessary tool suite and scripting languages necessary to implement the ATE framework
- Work with the development and QA teams to break down complex software architecture and feature sets in support of developing automated tests
- Prioritize features as candidates for automation depending on ROI analysis to reduce test time, improve test coverage and avoid wasted effort
- Mentors QA team members in automated testing techniques to improve their skills and facilitate their contribution to the ATE suite
- Function as team member for new development projects to develop, document and update test scripts for new and changing features
- Work with the Development team to capture and reuse automated Unit Test Cases, Test Stubs and Drivers, and other Development test objects
- Support and maintain an automated smoke test to validate incremental builds

Desired Requirements:

- Bachelor's Degree in Computer Science or Engineering discipline.
- 7+ years of software development experience with a minimum of 5 years proven success in leading the creation and implementation of an automated test framework.
- Working knowledge of WinForms applications and web services, utilizing the .NET framework (C# and VB.Net) and SQL Server.
- Working understanding of different automated test tools (TestComplete, Squish, QTP) including open source.
- Experience with designing, writing, implementing different scripting languages such as Ruby, Perl, TCL.
- Experience with different SDLC frameworks with previous hands on participation within an agile development projects.
- Solid understanding of Quality Assurance practices related to Test Strategy, Test Case development for different test types (i.e regression, stress, performance, etc), Test Documentation, bug tracking.
- Experience with various QA related tools such as bug tracking (Jira, Bugzilla), and Test Case Management (Test Director, TestLink) and project management (MSProject, Excel).
- Strong project management skills to manage automation projects with minimal oversight to drive releases that are on-time, feature complete and high quality.
- Strong analytical and troubleshooting skills, as well as excellent written and verbal communication skills.
- Outstanding team player with the motivation and skill to build an automated test framework from the ground up.
- Background in the healthcare industry a plus.

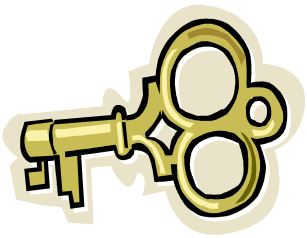
If interested, contact Donna Kirtlink, Human Resource Specialist
650 Ten Rod Road, Suite 12, North Kingstown, RI 02852
Phone: (866) 382-5932 ext. 4067; Fax: (401) 583-4095

NERCSQA Member Name Word Search Puzzle

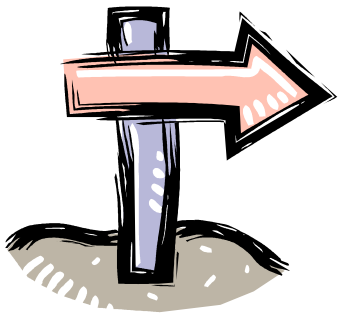
O W M H S C E Z G N O L E D Z B Y V M W A O L H S
F Z E T K I S N E J H N Q O E P N E L A H W X R U
L J N A B E O P O P I Z M U X O R M N D B X E N N
I L D E L H U E O H O N O D K Z S W X E H G O N P
M Y E H C U A D C A P L U J A D U S U M E T L A I
N B S N S O M U R P H Y L L O Y D R I U E W R M C
M Q O O S D N X S U D N A L O N K A R E E K S E T
D V P M F I O N X M P M I L U L J K R D E W N S O
Y H P I L B S A I D A B S V I C J T L R L O A R N
E S C I G A R H S D R N O A A V S I H P S R C M E
D G A O N R E A E I K K N T T N C J S K U R T P B
A D M R A K T L U B C O F A N H H N C F H U P B E
H A L G G U E L R D S O O Y A R M A L O F F J M I
C K P A E I P A D S I C K H T T J R D R O Y A L R
S A E R N N V C R F M S O P S E N I J D S R A A P
K I I E O O V E A L V S K A N N G A N H T I M S F
E C R N D T D T L A U T E T O G O A S I E I R Y K
M U Z R R N R C L R L Z L E C E N Y N A R F A Z S
V L W A A A Y S A O M I L L E R O M L E B N H U E
F Y L L I H A C B M K P Y F E R R A Z Z A A S V A
N E X N C Z N B O X H O F F M A N A Z T I E N D I
O V O L C A U N W B U R G W I N W D T W L S A N W
E R M J I W R B U R T I S D K E L A W I S C S V W
E A A S R E W O B L X I X E E M R M T S Y Y J O V
L G U V N G D Y N V L H L X T B C S D S Q N F W N

ADAMS	DEOSSIE	MARTIN	SCULLLOPEZ
ADUSU	DONEGAN	MENDES	SEMAN
ALTEMUS	DONOHOE	MERZA	SHARMA
ANDERSSON	ENGERRAN	MILLER	SIWALE
ANTONIUK	FERNANDO	MOULAISON	SMITH
APGAR	FERRAZZA	MURPHYLLOYD	SNELL
BALLARD	FOSTER	NAVIN	SOPP
BEEBIE	FURROW	NOLAN	STILES
BELMORE	GARVEY	NOLAND	STREETON
BEURKLIAN	HARRIS	PARKER	SWEENEY
BOWERS	HAUSMANN	PATEL	SZAFRAN
BRATTAN	HEATH	PETERSON	TRAINOR
BRAUDIS	HOFFMAN	PICTON	TWISS
BRAVO	HOOKDINNOCENZO	PRIEBE	TZIPORI
BURGWIN	IORGA	PURDUE	VILAYPHONE
BURTIS	JACKSON	RABIDOU	VONCHONG
CAHILLY	JENSIK	RAMIREZ	WADE
CALLAHAN	KELLY	RANJITKAR	WEDLICH
CARON	KRUEGER	RHODIG	WHALEN
CARUSO	LAMADELEINE	RICCIARDONE	WUBBOLT
CHIN	LARNER	ROYAL	YARMALOFF
CONSTANT	LUCIA	RYAN	ZASLAVSKY
COOK	LYONSHOOK	SANTAANNA	ZISSON
DELONG	MACDONALD	SCHADE	

Answer key for the word search puzzle will be in the next NERCSQA newsletter.



Answer key for March 2013 NERCSQA Word Search on next page!



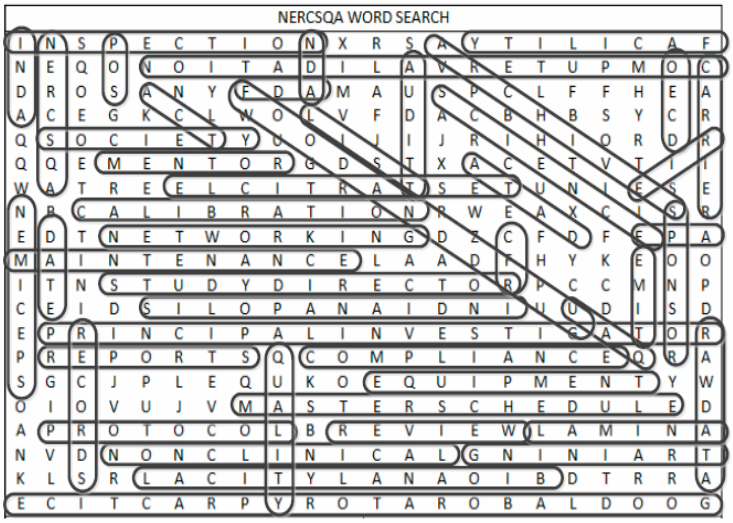
Program Committee Update

By Jennifer Bravo, NERCSQA Vice President

Are you interested in being part of the Program Committee? Do you have suggestions for topics or speakers? Are you interested in presenting or volunteering at one of the NERCSQA events? Please contact Jen Bravo at jbravo@agiluxlabs.com.

Date	Time	Location	Topic
October 24, 2013	9am-3pm	Sheraton Framingham Hotel	Implementation of CAPA in a GLP Facility
November, 2013	TBD	TBD	NERCSQA Annual Meeting

Answer Key for March 2013 NERCSQA Word Search



Check out the NERCSQA website!

http://nercsqa.org/

Chapter Officers for 2013

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

President: Chris Wubbolt, QACV Consulting, President@nercsqa.org

Vice President: Jennifer Bravo, Agilux Laboratories, VP@nersqa.org

Past President: Manish Ranjtkar, Cambridge Biomedical, Inc., PastPresident@nercsqa.org

Secretary: Katherine Connors, Secretary@nercsqa.org

Treasurer: Laura Hoffman, Haemonetics Corporation, Treasurer@nercsqa.org

Director of Publications: Aimee Altemus, Boehringer Ingelheim, DirectorP@nercsqa.org

Director of Membership: Danielle DeOssie, Agilux Laboratories, DirectorM@nercsqa.org

Director of Sponsorship: Chris Braudis, Cambridge Biomedical, Inc., DirectorS@nercsqa.org