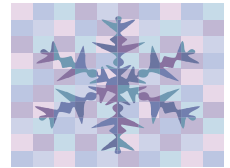




Northern Highlights



President's Outgoing Message

Chris Wubbolt, President, NERCSQA



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

Wow!!! 2013 has come and gone so quickly! What a great year this has been for NERCSQA! As my term as NERCSQA President comes to a close I have to reflect on what we have accomplished in 2013. We have had held four member meetings, the last occurring on December 10 at the John Harvard Brew House in Framingham (see the photo below for some of the members that attended the meeting). NERCSQA held two very successful training sessions on auditing computer systems and CAPA programs. We've updated the NERCSQA website! And with this newsletter we have published four (yes! four!!!!) NERCSQA Newsletters in 2013. NERCSQA has also seen an increase in membership in 2013 by almost 30%. All of these accomplishments are terrific, but for me, our biggest accomplishment has been the increased participation in NERCSQA activities by the NERCSQA membership. Everyone on the NERCSQA board and throughout the membership should be proud of these accomplishments and have 2014 to look forward to bigger and better things.

In my first message for the March 2013 NERCSQA Newsletter I introduced the NERCSQA Board members. As my term closes, I have to thank all of the NERCSQA Board members again for their contributions throughout the year, particularly Aimee Altemus who has diligently managed to publish four NERCSQA

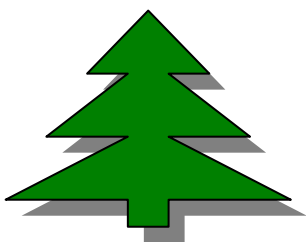
Newsletters this year, Danielle DeOssie, who has worked as Director of Membership, Laura Hoffmann, who – no matter where she is travelling in the world manages to provide NERCSQA with support as Treasurer, and last, but definitely not least, Jennifer Bravo, who as Vice President and Director of the Program Committee has been instrumental in NERCSQA's successes. I am looking forward to 2014 and serving as Past President for NERCSQA. I know Jen and the rest of the NERCSQA Board are going to accomplish even greater things in the coming year.

Happy Holidays!



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FDA Small Business Regulatory Education for Industry (REdI) Conference, Fall 2013



Small Business Success with the FDA

By: Courtney Zielonka, Compliance Specialist, QACV Consulting, LLC

The FDA Small Business Regulatory Education for Industry (REdI) Conference was held September 25 and 26, 2013 in Bethesda, Maryland. This two day event focused on the importance of small businesses, updates on FDA initiatives and regulation approaches, and what we can look forward to in the future. The REdI Conference is an FDA-led forum that brings together the regulatory educators from FDA's Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH). The goal of this conference is to provide direct, relevant, and helpful information on the key aspects of drug and device regulations. Our intended audience is the small manufacturers of drug and/or device medical products who want to learn about how FDA approaches the regulation of drugs and devices. Because the regulatory principles of drugs and devices are both similar and different, the REdI Conference features a cross-cutting plenary addressing Food and Drug Administration Safety and Innovation Act (FDASIA) updates as they impact both drugs and devices, as well as individual break-out sessions which focus on the unique issues of drugs and devices. Common themes include:

- Meetings with FDA
- Clinical Studies and Review
- Site Inspections

Attendees were welcomed with recognition from the FDA presenters for their contributions to the small business side of the pharmaceutical industry. Small businesses are involved in the cutting edge of development and are building and moving important products forward.

Because of small businesses, a total of 87 products were submitted within the last year alone. Their continuous efforts are putting products out there that really matter.

The first day of the conference demonstrated important aspects of the FDASIA, including updates on their progress since the act was first signed into law in July 2012. So far, the Prescription Drug User Fee Act (PDUFA) program has been a great success. Even though it was first enacted in 1992, its exposure is now even greater. The median time to approval has been reduced from 19 months in 1993 to now just 10 months as of 2012. Since 1992, the PDUFA program has also enabled earlier patient access to over 1500 new drugs and biologics with the number of filings and approvals going up. The future of PDUFA V (FDASIA) looks just as promising as the program has initiatives to increase base funding and communication with sponsors, as well as focus on strengthening regulatory science and post-market safety.

The second day of the conference concentrated on a variety of topics including drug imports and exports compliance, postmarketing surveillance, requesting meetings with the CDER, and NDA submissions as well as other important information such as their 21st Century Review Program. One particular topic I would like to highlight is the presentation titled "Overview of Postmarketing Safety Reporting and Pharmacovigilance in CDER" presented by Min Chen, M.S., R.Ph. from the Office of Surveillance and Epidemiology. The presentation provided insight on the components of the post-

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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.

Mary Donohoe (RQAP-GLP) is the 2nd to step up to the plate! THANKS Mary!

1. Current Company: Biogen IDEC Cambridge, MA
2. Current position: Manager R&D Compliance
3. How long have you been in your current position and how long have you been a Quality Assurance professional? I have been in my current position for 4 years. I have been a QA professional for 13 years.
4. How long have you been a member of NERCSQA / SQA? I have been a member of NERCSQA/SQA for 10 years.
5. How has NERCSQA or SQA helped you develop professionally? NERCSQA and SQA trainings have helped me develop my skill set in order to advance in my career. The great thing about NERCSQA is that they illicit feedback on what QA professionals want to be trained on. Also, the trainings are opportunities for networking with other QA professionals. I became a Registered Quality Assurance Professional through SQA.
6. What types of activities do you find most rewarding at your job? I like doing critical phase audits and process audits. You can identify issues that can help improve processes. I also like managing the vendor audits.
7. Have you had any mentors or teachers that have helped you develop professionally? I would say that my "teachers" have been the other auditors whom I have worked with and currently work with.
8. What advice would you give to someone new to the Quality Assurance field? I found it helpful to have worked in a laboratory/clinical setting before becoming an auditor. Become a member of SQA and NERCSQA. The trainings will help you along on your career path and you will be able to network with other QA professionals. SQA offers a mentor program to help give guidance.
9. What types of activities do you find most challenging? I find Process Audits challenging as you are going quite in depth into a particular process.
10. What educational opportunities would you like to see offered by NERCSQA in the future? Auditing aspects of Clinical Trials for compliance with Good Clinical Practices; Auditing Vendors; Introduction into CLIA
11. What do you enjoy doing outside of work? I quilt. I am on my third quilt. I also do needlepoint and crosstitch. I enjoy traveling. My most recent trip was to Italy. Umbria is especially scenic.
12. What is your favorite vacation spot? My favorite vacation spot is Bermuda. The crystal caves are fascinating.

(continued on page 4)



Meet
Mary
Donohoe

YOU COULD BE NEXT!

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

Danielle DeOssie,
DirectorM@nercsqa.org



NERCSQA Member Profile Corner (continued from Page 3)

13. What is your favorite North American city? Why? My favorite city is New Orleans. The food is amazing, the people are friendly, and there is jazz music on practically every corner. A short trolley ride away and you will find yourself admiring the antebellum homes.
14. What are your favorite restaurants in the New England area? Towne next to the Prudential Center for American, Atlantic Fish Company, and Kashmir for Indian
15. What is your favorite season? Why? My favorite season is the summer. I like to go to Cape Cod. The hydrangeas are in full bloom.
16. Have you read any (non-QA) books lately? Do you have any you would recommend? The last book I read was "The Paris Wife" by Paula McLain. It is a story of Ernest Hemingway and his wife Hadley. It is a "heartbreaking story of love and torn loyalty". I would rate it 5 stars.
17. Do you have any pets? I have a cat "Pounce". I got her from the Animal Rescue League. Now I know why she was called Pounce. She likes to jump on top of me from heights.
18. What is your philosophy of life or work? Philosophy of work is strive to be a lifelong learner. Mentor those coming behind you. Take advantage of all trainings and opportunities NERCSQA/SQA has to offer.

Small Business Success with the FDA

(continued from Page 2)

market drug safety system, safety reporting for combination products and lastly, how those reports are handled. Also referenced was an overview of what you need to know when reporting Serious Adverse Events (SAEs) and medication errors. This included the FDA Adverse Event Reporting System (FAERS) which holds over 7 million records. Data sources are both on a national and international level which allows the FDA to evaluate cases from all sources and assess all safety signals, regulatory actions, and communication of safety information. To learn more about post-marketing surveillance, visit the section on the FDA website.

Although this was just a brief overview of some of the information provided at this year's FDA Small Business REI Conference, further information is accessible at the conference's website. Also, the FDA provides other valuable links for those representing the small business sector including general information and an education series. As always, please visit www.fda.gov for all resources and additional information.



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

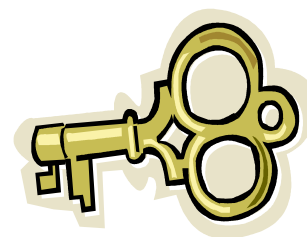
NERCSQA Member Companies Word Search Puzzle

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ABBVIE
 ACTION
 ADVANCEDCELL
 AGILUX
 ALEXION
 ARIAD
 BIOGENIDEC
 BOEHRINGER
 BOSTONSCIENTIFIC
 CAMBRIDGEBIOMEDICAL
 CBSET
 CHARLESRIVER
 CIMCON
 COGMEDIX
 CONCERT
 CUBIST
 EMDSERONO
 FOSTER
 GENZYME
 GMQA
 GXP
 HAEMONETICS
 HCRI
 IMMUNETICS
 INGELHEIM

HCRI
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 INGELHEIM
 IRONWOOD
 LUDWIGCENTER
 MEDIVECTOR
 MILLENIUM
 NOVARTIS
 NSF
 PAREXEL
 PFIZER
 PURDUE
 PUTNEY
 QACV
 QUALITYSYSTEMS
 SHIRE
 SMITHERSVISCIENT
 STELLAR
 SYNTA
 TOXIKON
 TUFTSCUMMINGS
 VERTEX
 WILRESEARCH

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



**Answer key
for Sep 2013
NERCSQA
Word Search
on next page!**

