



Northern Highlights



October NERCSQA Training Summary: Implementation of CAPA in a GLP Facility

By Lisa Kennedy

On October 24th twenty Quality Assurance and Bioanalytical professionals of NERCSQA met at the Sheraton Hotel and Conference Center of Framingham, MA for a day long training event on the implementation of CAPA in a GLP Facility. If you are from a GMP background as I am, you might be thinking how in GLP could we use a program like CAPA to make our daily professional roles more efficient, more useful, and maybe just a little less crazy (not crazier, not more deviations)? Through a series of three speakers expanding on and tackling the issue through different approaches and perspectives, we broached this quandary.

What is CAPA you ask? Like some of this century's great poets, our speakers explained that the meaning of terms can change, depending on how one intends to use the terms and thus define them. The first part of the term, "CA", stands for "corrective action" or the action one would take retroactively in response to a non-conformance. To compliment, of course, "PA" stands for "preventive action" or a proactive measure taken to prevent future occurrences of similar issues. Our first speaker, Rich Streeton, a long standing NERCSQA member and QA professional gave us this definition to start us thinking about the fundamentals of a CAPA program, and how they are used and regulated in the GMP environment. Rich drew upon his experience as a QA consultant to illustrate what concepts from CAPA may or may not be useful in a GLP setting.

Paula Picton took the floor after Rich to share her experience of creating a CAPA program for use in a GLP facility at Boehringer Ingelheim. In the creation of her CAPA program, Paula chose to define CAPA differently, in a way many of us in GLP might relate to; for Paula's use, the term "corrective action" refers to a study dependent action, like a protocol deviation, and the term "preventive action" refers to a study independent



action like an SOP defined process that has proved ineffective. Again, stress was placed on the importance of the definitions we use when creating a CAPA program. Paula designed her program to collect specific information for defined uses, such as dates, locations, and a designated responsible person who follows through with the resolution.

Magnus, our third speaker added to our CAPA repertoire by introducing us to the Lean Six Sigma managerial concept. Magnus, also of BI and currently a Lean Six Sigma Black Belt, gave us more terminology and concepts to allow us to thoroughly examine and expand upon some of the terms we had already encountered. Sound confusing? Surprisingly, it's not.

Magnus spent his time discussing root cause analysis or the process by which one determines what action or occurrence is truly causing a non-compliance. He showed us that unless the root cause of a problem is remedied, that problem can keep occurring, even if we think remedial actions have already been taken; if the problem re-occurs, the root cause was not addressed. To unravel the root cause, one should not seek the "obvious answer" or rely upon preconceived notions regarding a problem; instead, fact-finding, un-biased questions must be asked to gain pertinent and sufficient information. If as a profession, QA can utilize the Six Sigma concept in our conception of a CAPA program, solutions or corrective actions, could eventually eliminate the root cause of the offending non-compliance, and in time, lead to the prevention of that problem.

A big thank you to all of our CAPA training event speakers, on behalf of myself and everyone at NERCSQA.



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

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 event? Please contact Jen Bravo at jbravo@agiluxlabs.com.

| Date | Time | Location | Topic |
|----------------------------------|--------------------|---|--|
| Tuesday, December 10, 2013 | 5:30 to 9:00 pm | John Harvard's Brewery & Ale House One Worcester Road Framingham, MA 01701 | NERCSQA Annual Meeting Networking reception NERCSQA Organization Update |

FREE for Members!

**Calling all presenters!
2014**

Interested in brushing up on those presentation skills and sharing your professional knowledge?
Contact Jen Bravo (email above)

Check out the
NERCSQA website!
<http://nercsqa.org/>



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

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