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Northern Highlights

President's Message

Cheryl McCarthy, President, NERCSQA

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2011 is almost here!

As I put together the final president's message for this year, I reflect back on where we started. Many of the messages are still as valid in December as they were in March:

- This past year saw some challenges in our industry and local economy that most likely affected you personally in some way.
- NERCSQA is looking to identify ways to help our membership network to facilitate education opportunities, awareness of job openings and peer support.

We have collaborated with other area quality professionals (NEPDA in September). We hope those that got to attend that session had an opportunity to network with the NERCSQA and NEPDA members and benefited from the information provided during the session.

Speaking of networking opportunities, please join us for our annual members meeting to be held January 19, 2011 – see page 4 for additional details.

2011 will bring some new board members onto our team. We are currently accepting nominations for many of our board positions – please see page 4 for additional information on this.

As part of our benefits to our members, we make available a scholarship for one of our members to utilize in attending the annual SQA conference or a NERCSQA training event. We are currently accepting applications for the 2010 Ging Lee Scholarship.

Like many associations, NERCSQA is a volunteer organization. While it is recognized that our personal and professional lives keep us busy, organizations like ours benefit from any time you can offer to participate on our board or program committee, as a presenter at a NERCSQA session, as a host of a NERCSQA session, as a contributor to our Northern Highlights newsletter, and as an attendee at one our events. I have truly enjoyed the many opportunities, friendships and peer support I've had as a result of volunteering for NERCSQA and SQA activities and look forward to what 2011 will bring!

I would like to thank the outgoing board members for their time to NERCSQA - Patience Miller (Past President) – your efforts are greatly appreciated!

We hope you can join us in 2011!

Inside this issue:

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 Jen Bravo at DirectorP@nercsqa.org.

PRACTICAL COMPLIANCE SERIES

The article below is the first in a series of short articles related to various compliance topics. The articles will address best practice and considerations in areas such as auditing, backups, electronic signatures, review of records, etc. Each issue of the newsletter will address a different aspect of compliance. If you would like to see a particular topic addressed in one of the issues, please feel free to contact Jen Bravo at jbravo@agiluxlabs.com.

Certified Electronic Copies of Paper Records

By Chris Wubbolt, Director Compliance Services, Accuex, Inc. and Jennifer Bravo, QA Manager, Agilux Labsoratories.

The certification process should require verification at the time of creation that the scanned copy is complete (i.e. all pages are present), legible, and accurate. The scanned document must also preserve the content and meaning of the source record.

Introduction

The definition of 'raw data', as described in 21 CFR Part 58.3 (k), allows certified 'exact copies' to be substituted for the original source as raw data. The ability to generate 'exact copies' of raw data provides companies with a certain degree of flexibility in the way the data is collected and maintained. For example, some instruments print out results in thermo paper, which deteriorates over time. Being able to make a copy of the thermo paper provides a means of preserving the information without having to make costly modifications to the way the data is recorded. Another example involves contract research organizations (CROs). In the course of doing business, CROs prepare a large number of laboratory solutions. Some solutions may be study specific (*e.g.* calibration standards) while other solutions may be for general laboratory consumption, such as 50:50 methanol:water, and are used across multiple studies. In the latter case, the ability to create exact copies of the original data enables the CRO to include copies of the preparation sheets with each study in which the solution was used. Without the ability for generating exact copies, the CRO may need to prepare the 'general solution' for each study in order to archive all the information necessary for study reconstruction.

The manner in which 'exact copies' are made and authenticated must be defined in a standard operating procedure (SOP). In a paper-based system, copies of raw data can be made through the use of a photocopier. The resultant copy may be certified as an 'exact copy' via a copy stamp and the dated initials of the individual making the copy. But what if you want to scan the paper document into an electronic format, such as PDF? Can the scanned document be considered an 'exact copy' of the source data? The answer is yes. But, and this is a big but, controls need to be established to ensure the record's authenticity and protection from alteration after it is created.

Certifying an Electronic Record as an 'Exact Copy'

As with other activities in a regulated environment, if you plan on scanning paper into an electronic format as an 'exact copy', you will need to update any relevant SOPs to indicate how the electronic record will be certified as a true reproduction of the original source record. The process should require verification at the time of creation that the scanned copy is complete (*i.e.* all pages are present), legible, and accurate. The scanned document must also preserve the content and meaning of the source record. For example, if the source data utilizes color codes to differentiate certain items within the document, the scanned file will also need to be in color in order to preserve the meaning of the original record.

With a solely paper-based system, certifying that the scanned document is a true copy of the original record can be difficult, but not impossible, to implement. One way to certify the electronic record is to maintain a log where the individual scanning the record can provide a signed attestation indicating what exactly was copied (*e.g.* unique document reference/identification), and that the scan is an exact copy of the original source data. The exact electronic copy must be maintained in a secure repository or file structure, accessible only by authorized personnel.

If your company has an electronic signature

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Certified Electronic Copies of Paper Records

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system, such as a validated electronic document management system (EDMS), in place, the process of certifying the scanned copy would be significantly simpler to implement. Having an e-signature system provides multiple advantages, including the ability to automate the exact copy certification process, eliminating error and human intervention (e.g., forgetting to complete the exact copy log), and making the process more streamlined and efficient.

Controls to Protect the Authenticity of the Certified Copy

Once you decide on a certification process, the next step is to choose a secure location to store the scanned copy to assure its authenticity. Controls must be in place to protect the record from alteration after it has been created and formally certified as a true copy. Without appropriate controls, exact copies of electronic records can be easily modified by adding, replacing or deleting pages. Additionally with the right software, single data points within electronic records (even PDFs) can also be altered.

Certified scanned copies can be managed by using procedural controls and by designating an individual (akin to an Archivist) or group of individuals as responsible for those copies. In order to facilitate searching of the records, a formal procedure for indexing and checking in those copies should be implemented, such as a defined directory structure or file naming convention.

Validating the Process

After the process is established, it will need to be validated according to predefined criteria to ensure the scanned file is a true copy and that the controls put in place meet the applicable predicate rule and 21 CFR Part 11 requirements. While planning the validation activities, one should also keep in mind that the manner in which the scanning device is configured can have an impact on the quality of the copy produced. For instance, one may need to test which resolution provides the best output. Another consideration is whether to scan in black and white or color. The process by which access is provided to directory structures should also be defined. If an EDMS is used, the system should also be validated to meet its intended use and business processes.

Additional Considerations

This article is intended to discuss the process of certifying electronic copies of paper records. The considerations discussed within this article are not intended to be used for generation of paper renditions of electronic records. Typically, paper printouts of electronic records will not include metadata and other attributes to accurately represent an electronic record. FDA's Guidance for Industry, Part 11, Electronic Records; Electronic Signatures – Scope and Application (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072322.pdf) should be considered when making any copies of electronic records in any format. This topic may be the subject of a future article within this series.

Conclusion

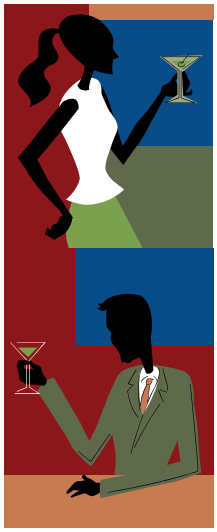
The GLPs allow 'exact copies' to be substituted for the original raw data provided the copy is a complete and accurate representation of the source record. Traditionally, copies of paper records have been made via the use of a photocopier. With the advances in technology, such as faster scanners, some companies may choose to make electronic exact copies. If such an approach is chosen, the certification process must be carefully planned, designed and validated to ensure that the appropriate controls are in place to protect the electronic copy from alteration after it is created and to ensure that the record's authenticity is preserved.

The certification process needs to be validated according to predefined criteria to ensure the scanned file is a true copy and that the controls put in place meet the applicable predicate rule and 21 CFR Part 11 requirements.

Acknowledgements

The authors would like to thank Monica Cahilly of Green Mountain Quality Assurance, LLC. for reviewing the article and providing valuable feedback.

2010 NERCSQA Annual Meeting



Please join NERCSQA board members for a fun evening of socializing and networking. This is a great opportunity to meet the NERCSQA board members and officers, learn more about the organization and socialize with other QA professionals of the region.

WHEN: **Wednesday, January 19, 2011**

WHERE: **Molly Malone's Irish Tavern**
Sheraton Framingham Hotel & Conference Center
1657 Worcester Road
Framingham, MA 01701

TIME: **6 - 8 PM**

COST: **FREE** to members

Appetizers will be served and each person will receive one drink ticket.

If you plan on attending, please send an e-mail to Linda Hook-D'Innocenzo at VP@NERCSQA.org. Please RSVP by Wednesday, January 12, 2011.

Interested in Getting More Involved with NERCSQA? Join the Board of Directors or Become an Officer!

The NERCSQA Nominating Committee is seeking self nominations and recommendations for candidates for the 2011 open positions listed below. Serving as an officer or as a director is an excellent way to develop professionally, interact with fellow QA professionals, and have a voice in the activities sponsored by the organization. If interested, please contact nominating@nercsqa.org.

- Vice President
  - Primary responsibility: Chair the Program Committee; organize training events
  - Term: 1 year *(Note: The incumbent of this position is also required to serve 1 year as President and 1 year as Past-President)*
- Director of Publications
  - Primary responsibility: Compile and publish NERCSQA's newsletter, *Northern Highlights*
  - Term: 2 years
- Treasurer
  - Primary responsibility: Maintain the society's finances
  - Term: 2 years
- Director of Sponsorship
  - Primary responsibility: Seek sponsors to support NERCSQA's mission and activities
  - Term: 2 years

NERCSQA Welcomes New Members!

NERSQA welcomes the following new members who joined the chapter from January to October

Corrie Bergren, Toxikon
Linda Burns, Toxikon
Linda Carr, Toxikon
Jessica Daley, Charles River Laboratories
Daniel Duran, Springborn Smithers Lab
Ayomi Fernando, Toxikon
Richard Halpern, Overbrook Scientific
Ashley Hedtler, Genzyme
Stacy Hubbard, Toxikon
Rhonda Koska, Genzyme
Jamie Lynn Metzinger, Toxikon
Mathew Panciera, Overbrook Scientific
Priti Patel, Toxikon
Binesh Prabhakar, Vertex Pharmaceuticals
Valerie Ricciardone, ARIAD Pharmaceuticals
Lea Santa Anna, Toxikon
Samantha Erin Scull-Lopez, Genzyme
James Todaro, Alpha Analytical
Lynette Trumbore, Genzyme
Nick Vickers, Toxikon

**** JOB OPPORTUNITIES ****

Compliance Specialist (6 month contract)

Duties: The ideal candidate will be responsible for the review of batch records and manufacturing process documentation to ensure cGMP compliance. Other responsibilities will include performing, visual product inspection, receiving and issuing of packaging materials, product status labeling and lot reconciliation. The candidate will identify compliance issues and provide recommendations for improvements. The candidate will assist in the training of new employees.

Skills:

- Prepare product release documentation
- Review batch records and other documentation for GMP compliance
- Issue and control GMP documentation
- Monitor aseptic filling and finished product inspection; perform AQL inspection
- Identify compliance issues and provide recommendations for improvements
- Knowledge of regulations and standards affecting Pharmaceuticals and Biologics and prior experience in cGMP standards are required
- Experience in QA Compliance Specialist role with background in the following areas:

  - Batch record review
  - Finished lot release
  - SOP authoring, review, approval
  - Deviation and CAPA review/approval
  - COA generation and approval
  - Project support

Education: Bachelor's Degree and 7-10 years of related work experience preferred.
Pay rate on a W-2 contract basis is $35-42/hour based on education and experience.

If interested, contact **Kathleen McTeague, Senior Staffing Consultant, Randstad Life Science Staffing, 617-864-1871, kathleen.mcteague@us.randstad.com.**

**** JOB OPPORTUNITIES ****

Manager of Quality Assurance

Location: Avon. Massachusetts

Description: I am doing a search for a Quality Manager at a very aggressive plant in Avon Mass., they are part of a $3 billion corporation, they employ 300 associates and have Revenue of $100 million they produce "made to order" valves, they seek a strong manager who is hands on, they will hire the right individual now .The salary is in the $150k plus bonus range. You must be an out of the box thinker who coaches and develops teams to deliver on time and at budget. The management team is strong and the Group President who came out of this location is recognized as a get it done person. If this is a fit send your résumé, a list of strengths, the reasons you have left "all" positions and your latest salary plus a one line descriptive of yourself to: **Jack Monahan, Vida Monahan Search, 44 Hawick Dr, Shallotte, NC 28470, *Office* 910-755-2333, *Cell* 477-0129, jackm_nc@vmsearch.com**.

Join Today!!!

CONTACTS:

secretary@NERCSQA.org
VP@NERCSQA.org

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."

As a member of NERCSQA , you will receive:

- *Our newsletter, Northern Highlights*
- *A discount on training sessions*
- *An annual membership directory*
- *End of the year social following the Chapter's Annual Meeting*
- *Opportunity to network with other Quality Assurance professionals*