DKG møde om Dataintegritet – Part 2

31. januar 2022 kl. 15:30-17:00 online via TEAMS

Agenda

1. Velkommen og kort "bordet rundt"/præsentation af mødedeltagerne

2. Diskussion af indkomne emner og spørgsmål samt erfaringsudveksling vedr. data integritet

    1. Lene Jakobsen, Unilabs
        - *OECD doc.no. 22, page 19-20: 6.2 Manual recording*
          Hvordan løser I udfordringen med at have styr på antallet af "printouts"?
          Vi tænker at kunne gøre det projektvis.
        - Vil vi på baggrund af en risiko vurdering kunne undgå en "change control" side, hvis templates til *"blank forms"* godkendes I vores QMS system?
          Se mere information på næste side (Appendix 1)

    2. Susanne Berg, LEO Pharma
        - *OECD doc.no. 22, page 21: 6.4 Electronic Signatures*
          Hvordan fortolker I teksten: "An inserted image of a signature is not sufficient"?
        - Ser I nogen muligheder for at underskrive papirdokumenter i hånden, hvis de skal indsendes til myndighederne i søgbart format?
          Se mere information på næste side (Appendix 1)

    3. Kim Stenbo Nielsen. Bavarian Nordic
        - *OECD doc.no. 22, page 22: 6.5 Generation of verified copies*
          "True Copies" – må man kasserere et orginalt papir, såfremt man har en valideret proces for at verificere og arkivere kopien (scannet dokument)

    4. Vibeke Klemmed Bjørk og Karen Sejer Gøtzsche, Novo Nordisk:
        - *OECD doc.no. 22, page 17: Data Integrity Risk Assessment*
          How can you integrate data integrity in your setup for Quality Risk Management?
          (This question is meant as a discussion of current practices and ideas for how we can work with "Data Integrity Risk Assessments", for example how can we identify and document "residual risks" for Test Facility Management approval?)
        - *OECD doc.no. 22, page 10: Introduction 'Data flows'*
          How can we ensure that data flows are implemented which makes it possible for the users to understand the data flows they are responsible for/involved in, in order to identify data that are likely to have impact on GLP compliance? We have discussed the level of details needed and how this can be set up in a simple way.

3. Evt. og forslag til emner til kommende DKG møder

Vi håber, at I ALLE har lyst til at deltage i diskussionen, byde ind og dele synspunkter/erfaringer.

Appendix 1

Ad. 2.1 Lene Jakobsen
OECD doc.no. 22: Manual Recording (page 20):

Access to the current version of templates or forms used to record the raw data, should be available at locations where activities take place so that data can be recorded promptly. The number of used templates compared to the number of available copies should be controlled to avoid duplication and to support the identification of data integrity issues, such as the detection of recreation or transcription of a record. If templates or forms to record data are available by printing, the number of printouts should be controlled.

- **Hvordan løser I udfordringen med at have styr på antallet af printouts?**
  Vi tænker på at kunne gøre det projektvis.

The reconciliation between the available sets of blank forms at the beginning and upon completion of all issued forms should be implemented. The use of paginated books can be an appropriate solution, so that the deletion of pages could be detected. Risk assessment should identify the level of control needed and the absence of full control and reconciliation should be justified. Nevertheless, the system implemented for controlling access to forms should allow an easy availability of the proper document to avoid the potential use of improper recording of data on an unapproved form and any subsequent transcription

- **Vil vi på baggrund af en risiko vurdering kunne undgå en "change control" side, hvis templates til "blank forms" godkendes i vores elektroniske QMS system?**
- **Her vil en ændring føre til en ny version, der godkendes. På den måde er der styr på template versioner, men ikke nødvendigvis dokumentation for de enkelte ændringer i en template fra version til version.**

Ad. 2.2 Susanne Berg
OECD doc.no. 22: Section 6.4. Electronic Signatures (page 21):

6.4. Electronic Signatures

An electronic signature should be equivalent to the handwritten signature of the signatory and may be used to signify approval, authorisation or verification of specific data entries.

In order to ensure data integrity, the use of electronic signatures should be appropriately controlled with consideration given to:

- how the signature is attributable to an individual and to the purpose it is being used for (e.g. approval, verification, acknowledgement);
- how the act of signing is recorded within the system so that it cannot be altered or manipulated without invalidating the signature or status of the entry;
- how the time and date of the signature is recorded along with the name of the owner and the meaning of the signature;
- how the record of the signature will be associated with the entry made and how this can be verified; and
- how the security of the electronic signature is ensured i.e. so that it can only be applied by the owner of that signature.

An inserted image of a signature or a footnote indicating that the document has been electronically signed (where this has been entered by a means other than the validated electronic signature process) is not sufficient.

If, in connection with an electronic signature functionality, a traditional authentication consisting of a user ID and a secret password is replaced by biometric authentication (e.g. fingerprint, hand, face or iris scanner), the implemented solution should be thoroughly validated and documented.

Background: Our German GLP CRO got this finding from the German Authorities in Dec 2020:

> The CRO was not allowed to print a report signature page, sign in wet ink, scan the page to PDF and then merge it with the searchable PDF report.
>
> The CRO was, however, allowed to print the entire report (e.g. 50 pages), go to the printer, sign in wet ink and then scan all 50 pages to PDF as an image.
>
> The problem is that scanned reports (PDF as image) cannot be sent to the Authorities who require searchable/copy-pastable documents.

At LEO Pharma, creating a text searchable file of the scanned PDF report via OCR is not the solution:

eCTD Guidance Document (europa.eu)

If the only version of a document available is in paper, then scanning to PDF and using an Optical Character Recognition (OCR) routine is the only way to create searchable text. PDF files created in this way tend to be much larger in size, for the same number of pages (from 10 to 100 times as large), and the quality of the text that is created will almost certainly not be a 100% match to the original text. It is noted that tools for checking and correcting this text tend to be somewhat cumbersome. For these reasons, applicants are recommended to use scanning/OCR only as a last resort.

- **How do you interpret the text "An inserted image of a signature … is not sufficient"?**
- **Do you see any possibilities for signing documents in wet ink if they need to be submitted to health authorities in searchable format?**