

Skipping the Search for a Needle in a Haystack during an Inspection

Organizing Your Digital Data and Documents

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Overall Agenda

- primary goals
- saving for long-term retrievability
- handling photos and videos
- scanning to make true copies
- forcing documents out of email
- miscellaneous tips and tricks

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About Your Presenter

John Avellanet



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Trainer for US FDA and Health Canada inspectors and district officers on advanced data integrity inspection techniques and detecting data fraud

Served on behalf of the US Department of Justice as the independent overseer for the five-year, multi-million dollar Dr. Comfort Corporate Integrity Agreement

Industry reviewer for the international standard, BSI 10008 *Evidential Weight and Legal Admissibility of Electronic Information* (2015)

Former lead expert for the ISPE GAMP Data Integrity Working Group

Author of [Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine](#) (2010); co-author of [Pharmaceutical Regulatory Inspections](#) (2014)

Prior to founding Cerulean, John spent more than 15 years designing, implementing, and being accountable for quality systems and data compliance programs for FDA, DEA, BIS, ICH, IMDRF, and ISO

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Primary Goals

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Permit “beyond easy” retrieval

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Ensure compliance

3

Stay practical

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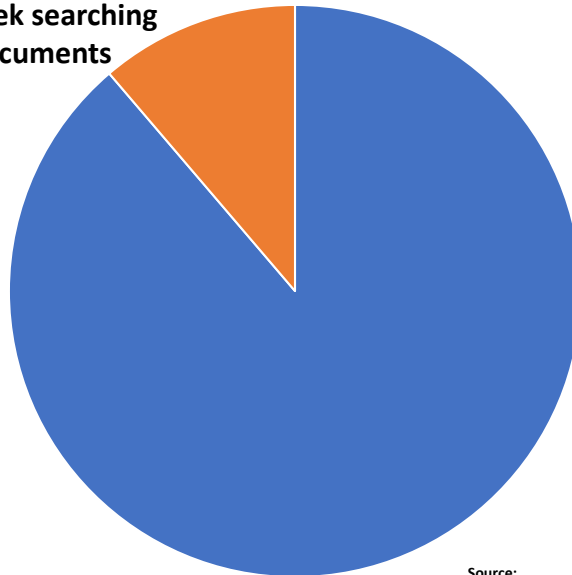
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Personnel spend, on average, **38 minutes searching for one document** -- whether that's on their own computers or their organization's networks, databases or intranet.

- CIO Magazine, *Have You Ever Spent 38 Minutes Looking for a Document?* May 2009 (online: <https://www.cio.com/article/2428183/have-you-ever-spent-38-minutes-looking-for-a-document-.html>)

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4.5 hours a week searching for files and documents



Source:
IDC's Information Worker Survey, June 2012 (online: https://medium.com/@diamond_io/productivity-lost-time-and-the-power-of-ai-to-make-search-easier-a59d4cd85a26)

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High Keyword Searchable File Names

A) “Metal Analysis Preparation”

or

B) “Preparation of Cell Tissue for Metal Analysis”

This almost doubles key words – thus improves chances of finding the file (and reduces time wasted searching)

A) “Corrective and Preventative Action”

or

B) “Corrective and Preventative Action (CAPA)”

This improves chance of finding file because it incorporates an acronym commonly known and used globally

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High Keyword Searchable File Names

Pretend you are an FDA investigator wanting to see a firm’s CAPA SOP – which document do you ask for?
Which one immediately makes you a bit more comfortable you’re going to get what you expect?

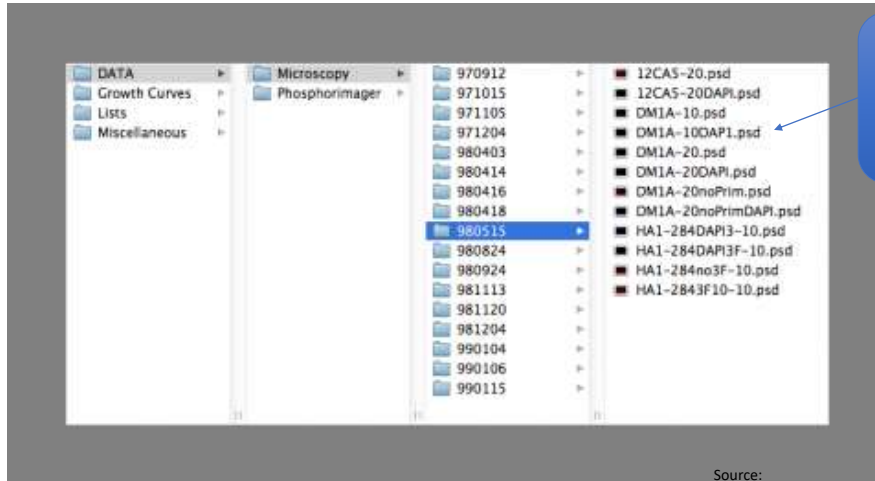
A) “是正および予防措置”

or

B) “是正および予防措置 (CAPA)”

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Concise Descriptive File Names



Source:

Stanford University Library (online:
<https://library.stanford.edu/research/data-management-services/case-studies/case-study-file-naming>)

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Concise Descriptive File Names

1) Be **descriptive enough** to give a typical person *conversant in your industry* (not just you) an idea of what the file contains:

- Elec_Microscope_12_Cell_Culture_109A_Oct2018
- Investigator_Site_Tanaka_Trip_Report_Trial_3104_Sept2016

Allows for
precision file
retrieval

2) Keep the **file name to 12 words or less** (ideally 25 characters or less)

- Helps keep entire file name visible in window or screen

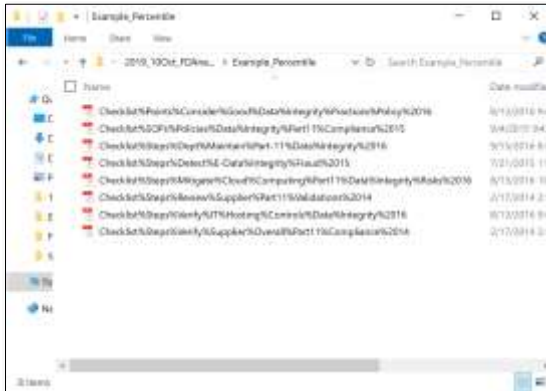
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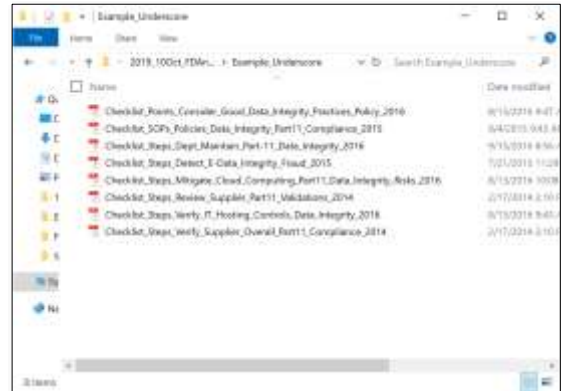
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Which is Easier to Quickly Scan Through?



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Web-Friendly File Names

- 1) Separate words with “_” or “-” to ensure that as the files move from system to system across their lifespan, the “ ” is not replaced with unwieldy special characters or inadvertently truncated or links lost

SOP Corrective and Preventative Action =>
SOP%Corrective%and%Preventative>Action

- 2) With “()” words, either use a “_” or a “-”

SOP_Corrective_and_Preventative_Action_CAPA

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Make Retention and Disposal Easy

1) Save filename with the year (YYYY) at minimum

- SOP_Corrective_Preventative_Action_CAPA_2019

2) Ideally, use the date (such as MMDDYYYY)

- SOP_Corrective_Preventative_Action_CAPA_10222019

Easier and simpler to use approval date for SOPs because effective dates can change....

3) Choose the date based on final iteration of that version

Video and Photo Retention

• **Prioritize long-term readability** over edibility

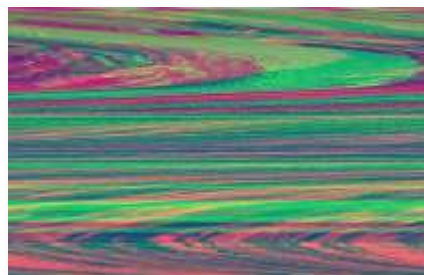
• Photos:

- JPEG
- TIFF

Best practice is to always save 2 copies – one JPEG and one TIFF (both uncompressed)

• Videos:

- Evolving
- MPEG-2 (.mp2) and MPEG-4 (.mp4) are best bets now



Corrupted Photo from July 2014 GMP Tablet Release Camera

Practically Speaking

If you use videos in clinical trials,
in product QC testing, etc.

Archiving Video for cGXP/QSR Compliance and Retention

- *IDEALLY*, store in lossless .mp2 (MPEG-2) and .mp4 (MPEG-4) format
- Space constraints may dictate only archiving one format (*consider .mp4 only ...not .m4a or .m4p*)
- [if you use video/picture product release] You will **NOT** be able to store all the video or pictures, so you will need to store samples
 - use scientific sampling to identify number of snippets (ANSI z1.4, c=0, or your validated sampling method)
 - spell out this rationale in your record keeping policy
 - have a written SOP to cover the action steps required to cut, create, and store the sample frames (rather than archiving the entire video stream)
 - may need to validate the overall process b/c regulators are just learning about the realities of trying to store ALL the raw data (e.g., all the video)....

Filenames for Videos and Photos

- 1) Put year (or full date) first to help sorting
- 2) Consider saving by one of three methods – by project/product, by modification, or by location/purpose analysis
 - 2018_Ibuprofen_Line04_Lot-4122A
 - or
 - 2018_Ibuprofen_Line04_Lot-4122A_original
 - 2018_Ibuprofen_Line04_Lot-4122A_cropped
 - or
 - 2018_Ibuprofen_Berkeley_Plant_Line04_Lot4122A

Scanning, True Copies and FDA

Q: If we use a validated process to create a “true copy” of a document, can we destroy the original paper record?

A: YES, if you make a true copy with appropriate quality control checks in place or have otherwise validated the process to show a high degree of confidence (note: MHRA and EMA require validating your true copy process).

Options for Making a True Copy

Option A) Follow BS 10008:2014 to the letter (all three books)

OR

Option B) Follow these four guidances:

- EMA draft *Guideline on GCP compliance in relation to trial master file (paper and/or electronic) for content, management, archiving, audit and inspection of clinical trials* (see §5, pages 10-11 for various QC checks)
- PIC/S draft *Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments* (see pages 22-23 for things that the inspector should look for during an inspection)
- WHO final *Annex 5, Guidance on Good Data and Records Management Practices* (TRS-996) (see page 205 or page 41 in the stand-alone PDF)
- NHS *Information Governance: Records Management Guidance: Digital Document Scanning*, November 2011

Sample Inspection Questions

- Does the firm have a written procedure on making true copies?
- When scanning a document, does the firm make the scan into an image (or an imaged PDF) OR does the firm make a searchable PDF?
- Does the firm use the scans strictly for disaster recovery (DR) purposes OR does the firm use the scans for making decisions, during production, etc.?
- Are there specific quality control checks that the firm undertakes of document scans (e.g., for blurred numbers, for light typefaces, etc.)?
- Does the SOP specify how to handle situations where some information on the original paper document is obscured (such as with a sticky note, etc.)?

SOP to Consider

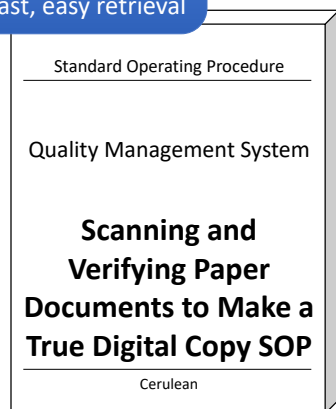
Remember: I'm saving my scanned file using the techniques already discussed to allow for fast, easy retrieval

Procedure elements:

- Layout scanning process examples
 - Make searchable PDF using OCR or text-capable scan
 - reset for drawings and colors (300 dpi for text v 600 dpi for photos, line drawings, etc.)
- Identify specific visual points or data values to verify scan was good
- Final step should be documenting date and initials of scanner (logbook or attached cover page or some other method)

Records produced:

- Scanned record
- As appropriate, logbook
- Scanner calibration record



Forcing Documents Out of Email

Goal

Get knowledgeable person to be in the habit of saving file attachments (and even emails) OUT of their email and into shared file storage to **allow for future easy and speedy file retrieval**



Forcing Documents Out of Email

This has been repeatedly demonstrated to not achieve our objective – getting the knowledgeable person to move records out of email into file storage to allow for easy and quick retrieval

Option 1: Auto-Deletion to Encourage End-Users to Use Restraint

Pros: Easy (set it and forget it)

Cons:

- 1) The IT department (unwittingly) assumes responsibility for retention of necessary files attached to emails
- 2) This policy has historically resulted in multi-million dollar penalties during litigation since 2004 because firms cannot prove have not lost relevant records (in fact, it becomes relatively easy to prove that firm **did lose** relevant data):
<https://www.nytimes.com/2004/07/22/business/judge-fines-philip-morris-for-e-mail-loss.html>

Forcing Documents Out of Email

So this also has a track record of not working very successfully as it can cause resentment and disgruntled behavior patterns

Option 2: One-Size Fits All Mailbox Limits

Pros: Easy (set it and forget it), helps improve email speed, reduces mail technology infrastructure costs for firm

Cons:

- 1) There is **never** a one-size fits all in the real-world (there are always reasons why to expand, increase, etc.)
- 2) Experience shows that this can engender **lowered morale** as people become aware of who is “special” (e.g., prized by organization) and who isn’t
- 3) As a result, this can actually **decrease compliance and retention** of the right records

Forcing Documents Out of Email

Since 2010, this has a very strong track record of success

Option 3: Mailbox Sending Limits

Pros: Improves email speed, reduces mail technology infrastructure costs for firm, allows significant flexibility, and encourages end-user ownership of his/her mail and attachment retention (“pushes self-regulation, nicely”)

Cons:

- 1) Personnel will get annoyed at first because this is creating a new habit (takes approximately 6 weeks for this to be “business as usual”)
- 2) Does take some work on behalf of the IT department to determine reasonable levels and to initially set up

Be Alert to These **Red** Flags

- FDA and other regulators look for places in SOPs and Quality Agreements wherein firms instruct personnel or suppliers to store long-term records on CD/DVD
 - It's *not* wrong per se, it's simply going to invite questions
- Be aware:
 - CDs\DVDs you make have a typical lifespan of 7 years before they start to degrade and you lose data (disc-rot)
 - 60% of computers sold today do NOT come with CD or DVD drives (how will you open files for inspection years from now?)



disc-rot
(chemical degradation)

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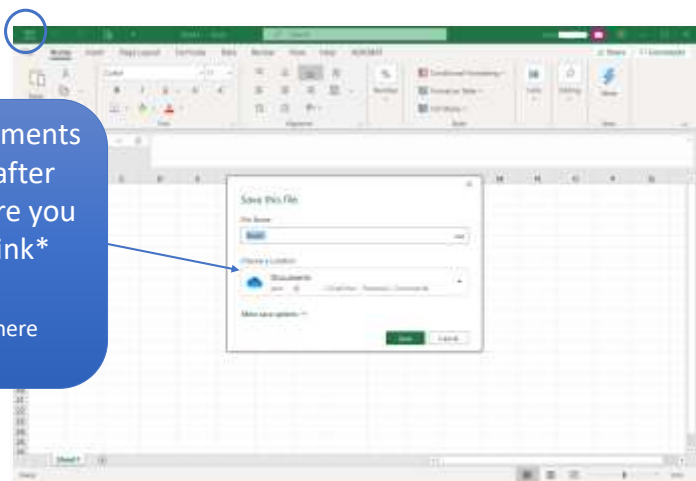
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Be Alert to These **Red** Flags

Office 365 defaults to saving documents on Microsoft's OneDrive Cloud after every update to Office 365 – so are you saving your files where you **think** you're saving them...?

(note: this screenshot is from laptop where OneDrive is set to "disabled")



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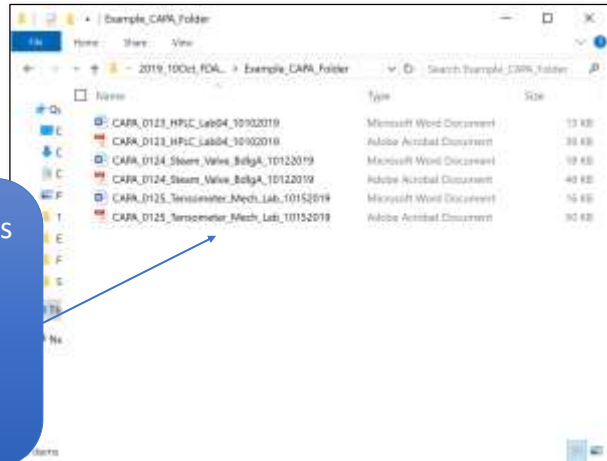
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Be Alert to These **Red** Flags

How do you think FDA investigator is going to react when you open up your file folder of CAPAs (or other controlled docs) and there is the Word version right next to the final PDF version...?



Some Additional **DO's**

- **DO** use commonly known abbreviations (“Jan” = January, “Corp” = corporation)
 - <https://www.abbreviations.com/>
 - <https://public.oed.com/how-to-use-the-oed/abbreviations/#>
- **DO** use sequential numbering (01, 02, 03, 04, etc.) in filenames if the order of viewing is important
 - 01_Welcome_Introductions
 - 02_Agenda_Overview
 - 03_Discussion_Topics
 - 04_Next_Steps

Some Quick **DON'T's**

- Do **NOT** assume you will be the one searching for the file in the future
- Do **NOT** assume that you will need to search for the file within six months of creating it (instead, think: 4 years from now)
- Do **NOT** use initials or acronyms in filenames unless widely known across industry (not just in your company or department...companies and organizations change)
 - SOP_TPS
 - SOP_CA
 - SOP_TO

Quick Personal File Tips



US Library of Congress Personal Digital Archiving Kit
www.digitalpreservation.gov/personalarchiving/padKit/index.html



Nolo Press *Get It Together Organize Your Records*
<https://store.nolo.com/products/get-it-together-get.html>

Key Point Review

- 🔑 Save digital files with highly recognizable key words to allow for future fast and easy searching
- 🔑 File names should be concise and relatively descriptive to allow for successful searching by different people (12 words or 25 characters)
- 🔑 File names should be “web-friendly” to allow for storage and download across a wide variety of systems (use _ or – between words)
- 🔑 Identify the year of the “final” iteration of the file (ideally, use the full date) to allow for easy retention and eventual authorized destruction
- 🔑 If you are not using an EDMS, use simple versioning (v1, v2, v3, etc.)

Key Point Review

- 🔑 Save photos and videos using descriptive, key word filenames with the year and month of photo or video
- 🔑 Save photo and videos in “known good” long-term retention formats (.TIF or .JPG for photos, .MP2 or MP4 for videos)
- 🔑 Scanning paper documents requires making a “true copy” in order to use it for regulatory purposes (EMA/MHRA require validating that process)
- 🔑 Work with your IT department to adopt method to help knowledgeable people save documents out of email into shared file storage
- 🔑 Be aware of three key red flags that can suddenly appear due to evolving technology, services, and new inspection techniques

Questions?



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thank you

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