# Quality Parameters

# Q1 There should be a validated quality driven process for document scanning and uploading into an Electronic Content Management System (ECMS).

**INTERPRETATION:**

**Steps for consideration:**

A scanner should be selected that can produce scanned images in a way that meets the technology requirements previously identified, including but not limited to scanner settings.

The minimum resolution of 300 dpi as identified under the Technology parameters T1 is recommended to balance legibility with file size. Documents scanned should provide adequate legibility both on a computer screen and printed copy while at the same time, producing a minimal file size.

The use of grayscale and color significantly increases the file size and it is only recommended when these features improve the readability of the material. It is recommended that documents with color also be scanned in color (egg: color seal, color-coded data outputs, etc.). After scanning, avoid re-sampling to a lower resolution. A captured image should not be subjected to non- uniform scaling (i.e. sizing).

Digitized documents should be PDFs. Refer to Technology parameters for version recommended. No additional software must be needed to read and navigate the PDF files.

Preparation Steps for Scanning Documents:

* Removal of wallets/staples/binding/paperclips
* A QC check of original paper documents to determine whether simplex or duplex scanning settings are required. Duplex scanning settings are required for documents with information on back pages

There are 2 scenarios for consideration depending on scanning process:

* Individual document scanning
* Batch scanning

Documents can be batched for ease of scanning and to facilitate scanning in bulk.
If scanning in batches, document separator/cover sheets can be used, to distinguish each document within the batch. Metadata for indexing should be considered in the process.

**BIBLIOGRAPHY/REFERENCES:**

1. "BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically." British Standards Institution (BSI). <http://shop.bsigroup.com/en/ ProductDetail/?pid=000000000030186227>
2. United States. Food and Drug Administration. Portable Document Specifications. <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163179.pdf>
3. United States. Food and Drug Administration. Guidance for Industry Providing Regulatory Submissions in Electronic Format —General Considerations. <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm124751.pdf>
4. United States. Food and Drug Administration. Guidance for Industry: Computerized Systems Used in Clinical Investigations. <www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf>
5. Industry opinion: various documents compiled by quality topic team members outlining process and quality control checks, including scanning settings, pdf version required for scanning (PDF/A is an ISO Standard for using PDF format for the long-term archiving of electronic documents), batch scanning, indexing, QC of scanned documents and importing to an ECMS

**PROCESS STEPS:** 306,307

# Q2 The authenticity of scanned images as certified copies must be established.

A QC process should be defined to review the scanned document(s), whether they are bar-coded or routed directly to indexed files.

 A quality-driven process should be established for image quality, indexing quality, and verification of certified copy. Completion of QC processes must be documented including a signature to attest for accuracy and completeness. If completion of QC steps is being documented electronically, then audit trail and/or electronic signature functionality should be implemented and validated as part of the overall validation of the computerized system. All QC may be done at individual document level or at a batch level, as per company process.

**INTERPRETATION:**

CRITERIA FOR QC: IMAGE QUALITY(NOT IN ORDER OF PRIORITY)
The following are considerations for companies to assess, to best define their own company-specific requirements for image quality (QC):

* Are all pages present? Are there any double feeds?
* Is everything in paper present in the electronic image? i.e. information such as headers/footers is not cut off? Pages with only header and footer information are not to be considered as blank pages.
* If scanning duplex, does the image contain all of the information?
* If scanner settings are duplex, are true blank pages removed?
* Is the document the right size and orientation (e.g., US Letter A4; landscape)? Are all pages rotated the right way?
* Is the image too light/too dark?
* Are pages skewed?
* Any post it notes inadvertently scanned?
* Is all content legible?
* Are all signatures legible?
* Are pages in the correct sequence?
* Are there any bent corners blocking document content?
* Removal of hole punches on images is not recommended.
* Removal of any content from the original document is not permitted (e.g. fax header
information).
* De-speckling capabilities were not used.

The quality of the image should be a true reproduction of the quality of the original. It is not recommended that images be enhanced. If an image is too light/ dark, retention of the paper original should be considered.

CRITERIA FOR QC: INDEXING QUALITY
Indexing document attributes or metadata may be completed prior to or after scanning, depending on company processes, but all attributes should be checked for accuracy before QC signatures are applied and the images uploaded into an ECM system .

Considerations for QC TO VERIFY A CERTIFIED COPY - Process to be defined or approved by Sponsor

A certified copy means a copy of original information that has been verified through a
validated process (i.e. as indicated by dated signature, audit trial, and/or e-signature), as an exact copy having all of the same attributes and information as the original.

* QC process to document the chain of custody and process through the life of the original and electronic document.
	+ Tracks how the document came in, who scanned documents and reviewed the image; capabilities exist to capture scanning parameters.
	+ Tracks quantity and quality.
	+ Tracks who has uploaded and approved the document.
* If companies wish to use scanned copies in lieu of the scanned paper, (i.e. destroy the paper) the scanned copies must meet the definition of a certified copy.
* Any protected documents not to be destroyed should be defined or approved by the Sponsor, listed and maintained through the life of the study. *(Refer to Glossary for definition of “protected document”)*
* It is recommended that where the paper will be destroyed, that all documents are fully QC’d against the electronic images to show they are verified as certified copies. Company records management policies must be followed.
* If companies will not be destroying paper, an acceptable quality level can be applied to QC (i.e. algorithm for QC), including identifying the authoritative document (i.e., the paper – by electronic attribute in the ECMS) if it the image does not pass QC.
* If companies are following a hybrid document management process (i.e. paper and ECMS), requirements for maintaining historical documents must be considered.
* It is recommended that QC steps are performed by a different person than the person that performed the scanning and indexing.

**BIBLIOGRAPHY/REFERENCES:**

1. "BS 6498:2002 Guide to preparation of microfilm and other microforms that may be required as evidence" British Standards Institution (BSI) <http://shop.bsigroup.com/en/ProductDetail/ ?pid=000000000019998064>United States. Food and Drug Administration.
2. "BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically." British Standards Institution (BSI). <http://shop.bsigroup.com/en/ ProductDetail/?pid=000000000030186227>
3. Draft Guidance: Electronic Source Documentation in Clinical Investigations. Dec. 2010. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM239052.pdf> United States. National Archives and Records Administration (NARA).
4. Technical Guidelines for Digitizing Archival Materials for Electronic Access: Creation of Production Master Files – Raster Images. June. 2004. <http://www.archives.gov/preservation/ technical/guidelines.pdf> Page 43 Industry opinion and practice though not formally cited in the public domain

**PROCESS STEPS:** 308,309,310,311

# Q3 There must be a documented quality driven process for destruction of paper documents and maintaining certified copies in an ECMS; in compliance with regulations and legal requirements.

**INTERPRETATION:**
ECM systems
If companies wish to retain the electronic copies in an ECMS in lieu of paper, the ECMS must comply with FDA 21 CFR part 11 and Section 5.5 of the Note for Guidance on Good Clinical Practice (CPMP/ICH/GCP/135/95)1. These references include the following additional requirements:

* Computerized system validation
* Maintenance of SOPs for the use of the system
* Maintenance of an audit trail of data changes ensuring that there is no deletion of entered data or scanned documents
* Maintenance of a security system to protect against unauthorized access
* Maintenance of list of the individuals authorized to make data changes
* Maintenance of adequate backup of the data, safeguard the blinding of the study and archiving of any source data (i.e. hard copy and electronic). Minimum standards for back up should be company specific.
* Appropriate training records for those involved in the scanning and uploading processes. Documents being easily located and traceable in the system

**BIBLIOGRAPHY/REFERENCES:**

1. European Medicines Agency. Q&A: Good Clinical Practice (GCP). Expectations of EU competent authorities on the use of electronic Trial Master Files. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q\_and\_a/q\_and\_a\_detail\_000016.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800296c5&jsenabled=true
2. United States. Food and Drug Administration. FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations Guidance for Industry: Part 11; Electronic Records; Electronic Signatures- Scope and Application.www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf
3. "BIP 0008. Code of Practice on Legal Admissibility and Evidential Weight of Information Stored Electronically." British Standards Institution (BSI). <http://shop.bsigroup.com/en/ ProductDetail/?pid=000000000030186227>

**PROCESS STEPS:** 308,309,311,501, 502

# Q4 All training must be completed and documented.

**INTERPRETATION:**

All personnel involved in the scanning, uploading, and QC processes, including sign-off, should have appropriate training to enable that person to perform the assigned functions. All training must be documented, and training records must be maintained. Competency levels checked and assessed, and personnel certification documentation should be maintained

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**BIBLIOGRAPHY/REFERENCES:**

1. United States. Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 4. Revised as of April 1, 2011. Sec. 211.25 Personnel qualifications.
2. European Commission. Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use Eudralex, Vol 4, Chapter 2 Personnel. http://ec.europa.eu/health/files/eudralex/vol-4/2011-7\_gdpguidline\_publicconsultation.pdf

# Q5 Third party requirements must be specified for when activities transferred to consultants and vendors.

**INTERPRETATION:**

Any trial-related duty or function that is transferred to a third party (e.g., CRO, consultants, vendors) must be specified in writing. Consultants, Vendors and CROs must have training to advise on the subject for which they are retained. Records must be maintained stating the name, address, and qualifications of any consultants and the type of service they provide. It is recommended that the standards described in this document are included in vendor contracts, agreements, oversight plans, etc., as appropriate.

**BIBLIOGRAPHY/REFERENCES:**

1. Guideline for Good Clinical Practice E6. ICH Harmonized Tripartite. Section 5.2, Contract Research Organization
2. United States. Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 4. Revised as of April 1, 2011. Sec. 211.34 Consultants.

**PROCESS STEPS:** 104,105

# Q6 Monitoring of quality must take place.

**INTERPRETATION:**

It is recommended to continuous review or conduct routine monitoring and/or audits of systems to ensure validation processes and specified requirements are being met and maintained.

**BIBLIOGRAPHY/REFERENCES:**

1. United States. Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 4. Revised as of April 1, 2011. Sec. 21 CFR 820.22 Quality Systems.
2. *United States. Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 4. Revised as* of April 1, 2011. Sec. 21 CFR 820.75b Process Validation.

**PROCESS STEP:** 112, 106

# Q7 It is critical to Perform a Risk Assessment

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**INTERPRETATION:**

A Risk Management and Mitigation plan should be established in a Paper Destruction pilot process.

* Milestones and considerations throughout the pilot, as well as at the end of the pilot to
determine how to proceed with a Paper Destruction process are recommended.

This Risk Management and Mitigation Plan must align with company’s risk management policies.

**BIBLIOGRAPHY/REFERENCES:**

1. "SO 31000:2009. Risk Management- Principles and Guidelines." International Organisation for Standardization <http://www.iso.org/iso/catalogue\_detail?csnumber=43170>
Industry opinion and practice though not formally cited in the public domain

**PROCESS STEPS:** 112,201

# Q8 The paper destruction process and certification of destruction requirements need to be defined by the company.

**INTERPRETATION:**

Companies must develop a destruction policy and a certificate of destruction should be maintained, if a certified copy is verified and original paper is destroyed.

* The destruction process should be defined by the Sponsor Company. (For example, how a certificate of destruction should be maintained and at what level: batch level or individual document level, etc.)
* Certificates of Destruction demonstrate that destruction was conducted per process and regulations. Note that local regulation and statutory requirements should also be considered.
* The timing of paper destruction needs to be considered in line with country specific regulations and company retention policies.

**BIBLIOGRAPHY/REFERENCES:**

1. "BS EN15713:2009.Secure Destruction of Confidential Material; Code of Practice."
British Standards Institution (BSI).

**PROCESS STEP:** 1, 10, 111, 108, 112, 105, 504, 505