21 CFR Part 11 GAP Assessment Guide

Line Item	Procedural/Technical Solution	Gap Analysis Questions	Interpretation
Electronic Records Requirements – Validation			
1	P	Is the system validated per FDA and company policies and procedures?	Systems must be validated in accordance with FDA and company guidelines
2	P	Is the system's Part 11 functionality (e.g. audit trail mechanisms, detection of invalid/altered records) validated and has a vendor assessment been done, applicable?	Audit trail mechanisms must be validated. Validation must demonstrate that invalid or altered records can be detected. The implementation of vendor software must follow validation procedures. This should include a vendor assessment.
3	T	Can at least one validated, accurate, and complete representation of the electronic record be made available for transmission or presentation to the FDA?	It must be possible to copy records for transmission or presentation to the FDA in an accurate and complete manner. At least one validated, complete representation of the electronic record will be provided on a record by record basis at a minimum. This may require access to the record in its normal state and native application and database, without additional human intervention. It may be necessary to include metadata with copies of records. Annotation **Further requests for multiple record views can be fulfilled, ad hoc, using standard reporting tools if other previously developed business reports do not satisfy the requests.** Best Practices 1 Records- Complete Copy for Audit It is likely that a structured query would need to be created to extract the requested records into a format they can work with, e.g. comma delimited file. Under these circumstances be prepared to provide the FDA with data definitions, meaning of data fields, query statements, etc. Wherever practical, standard validated software should be used to extract the information. **Best Practices 2 Records- Complete Copy for Submission** **For submissions to the FDA, the preamble states that the agency wants to provide maximum flexibility on the use of formats. In many cases, the FDA has put together detailed specifications on submission formats, which now reside on their web pages for submissions.**
Electronic Records Requirements – Retention			

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4	T	Is information content or interpretation, retrievable and/or reproducible and unaltered for the retention period of the record?	Exact format of record, data or information does not need to be preserved so long as information content or interpretation is not altered (e.g. a picture or chart must still produce/present information clearly). Metadata must also be preserved. Annotation -Obsolescence Obsolete equipment need not be retained in order to create accurate and complete copies with respect to format and computer systems as long as the following conditions are satisfied. A validated, verifiable method to migrate the electronic records to current electronic format is required. The records must be searchable, retrievable, viewable, readable, printable, complete, accurate, and authentic. Tools used for the analysis of raw data that are capable of producing the same result must be maintained. Annotation Sortability For migrated data, when the original system had search and sort capability, FDA would expect to be able to conduct searches and sorts of electronic records provided from the migrated system. If the original system in question had no sort capability, then there is no requirement in Part 11 to provide this capability solely for FDA's use. Best Practices **Migrations of data may occur due to changes in hardware, new software releases or upgrades, media changes (e.g. from tape to cdrom) or other reasons.** If you are not preserving the exact format of electronic records, whatever process you use to migrate them to a new electronic form must be validated. The initial and subsequent migration of electronic records must be validated and approved by the owner of the data. Migration to non-electronic media (e.g. paper, microfiche, etc.) is not acceptable.
5	T	Are controls in place to ensure metadata, data attributes, or parameters that are integral to the content or meaning of an electronic record retrievable and/or reproducible for the retention period of the record?	Interpretation Where metadata, data attributes or parameters exist that describe data and are integral to the content or meaning of an electronic record, the metadata must be retrievable and/or reproducible for the retention period of the records.
6	T	Are controls in place to ensure processed or reduced data is retrievable and/or reproducible, and unaltered for the retention period of the record?	Processed/reduced data must be retained and accurately reproducible throughout the record retention period. Best Practices You must save the raw data and the processed/reduced data. The ability to reprocess the raw data and accurately reproduce the results throughout the record retention period must also be preserved.

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7	T	Are controls in place to ensure that electronically captured raw data is retained in electronic form for the retention period of the record?	All raw data captured electronically must be retained in electronic form (original form whether binary or otherwise).
8	PT	For retained raw data, are controls in place to ensure that the ability to derive original results is retained for the retention period of the record?	Raw data, whether or not in human readable format, must be retained with the ability to derive the original results throughout the retention period.
9	P T	Are controls in place to assure that associated signatures (electronic or handwritten captured electronically) are retrievable and/or reproducible, and unaltered for the retention period of the record?	Electronic records with any associated signatures and audit trails, must be maintained electronically to preserve record content, structure, context, and metadata throughout the record retention period. Best Practices Options for maintaining the record electronically would include (1) keeping the record in active storage through its retention, or (2) archiving the record to a long term storage system. When archiving records electronically, periodic checks of the archived material must be performed to ensure its accessibility and process-ability (in terms of viewing and analyzing). At a minimum the following needs to be established: Rules for transferring the record from active storage to archival storage. File and media formats accessible for the retention period (expected to be easily read by tools over the retention period). Rules for media audit review and approval. Media audits will include accessibility and process-ability in terms of viewing and analyzing and a CRC or equivalent performed. Documentation on the audit must be maintained. Retention of system documentation in support of the computer system that created the data including the audit trails.
10	T	Are controls in place to assure that audit trails are retrievable and/or reproducible, and unaltered for the retention period of the record?	