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The **Food and Drug Administration** (FDA) Notice: **Data Integrity and Compliance With Current Good Manufacturing Practice; Draft Guidance for Industry; Availability**

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mochizuki-kiyoshi@xpro-asso.com Email Receipt

Your comment:

Comment:

(1) LINE 100 - 101
"the integration parameters used, and details of a reprocessing"
>>> COMMENT>>>
I don't think that the audit tail includes "the integration parameters used, and details of a reprocessing". These are meta data.

(2) LINE 195 - 196
"If second-person review is not possible, the Agency recommends that the person recheck settings and his or her own work."
>>> COMMENT>>>
By the agency's recommendation, the first person can falsify the data without being revealed. The following is extracted from MHRA's data integrity guidance and would be better.

System administrator access should be restricted to the minimum number of people possible taking account of the size and nature of the organisation. The generic system administrator account should not be available for use. Personnel with system administrator access should log in under unique log-ins that allow actions in the audit trail(s) to be attributed to a specific individual.

System Administrator rights (permitting activities such as data deletion,

database amendment or system configuration changes) should not be assigned to individuals with a direct interest in the data (data generation, data review or approval). Where this is unavoidable in the organisational structure, a similar level of control may be achieved by the use of dual user accounts with different privileges. All changes performed under system administrator access must be visible to, and approved within, the quality system.

The individual should log in using the account with the appropriate access rights for the given task e.g. a laboratory manager performing data checking should not log in as system administrator where a more appropriate level of access exists for that task.

(3) LINE 204
"login credentials "
>>> COMMENT>>>
Is "login credentials " same as "login ID"? If so, please use the familiar term, "login ID" instead of "login credentials "

(4) LINE 266 - 267, 271
"static image" and "static record"
>>> COMMENT>>>
Please explain the difference between "static image" in line 266/267 and "static record" in line 271. If both are the same, "static record" would be better than "static image", since "dynamic record" is used as a opposite term.

(5) LINE 271
"dynamic format"
>>> COMMENT>>>
I think "dynamic data" is better than " dynamic format"

(7) LINE 260 - 276
Discussion on the retention of original record
>>> COMMENT>>>
I like to know if the retention of original electronic record is required in the following case.

1) Measuring the absorbance by the endpoint method using UV.
2) The absorbance is just a number and no dynamic data is required.
3) The measured absorbance and required meta data such as operator information, time/date, wave length and sample ID are printed out, and the printout is retained as a CGMP paper record.
4) Sample IDs are automatically given as consecutive and serial numbers, so that you cannot conceal any testing.
5) However, the electronic data of UV is not backed up. This means that the audit trail is not guaranteed to be retained for years.

I think that the paper record is sufficient and the retention of original electronic record is not required in the above case.

(7) LINE 368
"raw data"
>>> COMMENT>>>

21 CFR part 211 and this guidance have no definition for "raw data". Please define "raw data".

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First Name:
Kiyoshi

Last Name:
Mochizuki

ZIP/Postal Code:
2440801

Email Address:
mochizuki-kiyoshi@xpro-asso.com

Organization Name:
NA