PROPOSED GLP QUALITY SYSTEM DATA QUALITY AND INTEGRITY

AS THE PROCESS OF REVIEWING THE FDA PROPOSED GLP QUALITY SYSTEM CHANGES CONTINUES, WE WANTED TO BREAK DOWN THE PROPOSED CHANGES, RATIONALE, AND INDUSTRY IMPACTS IN MORE DETAIL.

With regards to data quality and integrity, the proposed FDA GLP changes aim to produce better data with less chance of bias. Many of these changes reflect what most companies in the industry should already be doing. These proposed changes include the introduction of "ALCOA" and compliance with 21 CFR part 11. The main point of potential impact on companies is the addition of the requirement for all data to be in reports. Below are the FDA proposed changes, reason for the changes, and potential industry impacts in more detail.

THE PROPOSED CHANGE

Addition of § 58.180 Data quality and integrity.

(a) All data generated during the conduct of a nonclinical laboratory study must be accurate, legible, contemporaneous, original, and attributable (ALCOA). Also, data must be credible, internally consistent, and corroborated.

(b) All data must be recorded indelibly, directly, and promptly to a permanent medium at the time of observation and must identify unambiguously the person entering the data. Any change to any entry must be made so as not to obscure the original entry, must indicate the reason for such change, must indicate when the change was made, and must identify who made the change. When data are either captured or maintained, or both captured and maintained electronically, these requirements are fulfilled by the use of an electronic records system fully compliant with applicable regulations.

(c) All data accrued as required in paragraphs (a) and (b) of this section must be included in the final study report.

REASON FOR CHANGE AS DISCUSSED IN THE PREAMBLE OF PROPOSED FDA REGULATIONS

"We propose adding a new § 58.180 for data quality and integrity. Ensuring data quality and integrity in a nonclinical laboratory study is one of our critical goals in this part 58 proposal. Therefore, we propose adding this separate § 58.180 to clearly identify requirements for data quality and integrity. We propose this new section in subpart J because data are part of study records and reports. We propose moving to this new section, and revising, the requirements in current § 58.130(e). In § 58.180(a), we propose creating the acronym ''ALCOA''. This is a mnemonic that signifies quality data to stakeholders that conduct clinical and nonclinical studies. We propose therefore that all nonclinical laboratory study data are ''accurate, legible, contemporaneous, original, and attributable''.

"In § 58.180(b), we propose modifying and updating the provisions currently in § 58.130(e) to address electronic data capture and maintenance. Numerous comments to the December 2010 ANPRM note that part 11 (21 CFR part 11, ''Electronic Records; Electronic Signatures'') is applicable to part 58 and therefore parts 11 and 58 should be consistent. We agree, and do not intend to duplicate in part 58 the requirements in part 11. As a result, we propose that electronic records systems need to be compliant with applicable regulations. In § 58.180(c), we propose adding that the final study report must contain all data accrued during the study. This proposed requirement is consistent with our proposal in § 58.120(b)(6) requiring that the protocol describe methods for controlling bias. We propose this requirement because selective data inclusion in the study analysis could introduce bias into the final study report."

Potential Impact of the Proposed Change

This section of the proposed changes is largely self-explanatory. It is important that companies do everything possible to have the most accurate and complete data so that studies are reproducible and conclusions are deemed valid. Though the wording is proposed to change some, the specifics in this section are straightforward and should already be in practice. The expected impact will be in terminology, SOPs, and reporting practices.

Terminology such as “accurate,” “original,” “credible,” “internally consistent,” and “corroborated” has been added in the proposed rules. Though these are new proposed terms, these ideals, as well as 21 CFR part 11 compliance, are all something companies should already be abiding by. If these changes are accepted, company SOPs will need to be updated with the appropriate terminology and any needed specifications.

One notable change that may affect day to day business is the proposed change to include the specification that ALL data should be reported. This seems like a fairly simple idea but in an effort to comply, it may be reasonably expected that processes may change for efficiency so that data is more easily compiled and available to be placed into reports. This could look like more automated data capture or possibly scanning in additional documents. There is still some discussion on what the extent of this proposed change will be. For example, will laboratory notebooks need to be scanned in and added to the report? What about temperature data for a study lasting two years? As the full extent of this proposed change is likely unreasonable, there is hope for some additional clarification through the comments to be submitted to the FDA.

Overall, this section is in line with the overarching goals of the regulations- a better quality, more robust study that can be used to draw conclusions on the safety and efficacy of drugs that will be taken by end users. It takes the bias out of the end results which is vital when it may not be known what the important details are at the time of the study.

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