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GDDP & Data Integrity

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| **Across****2.** Data as the file or format in which it was originally generated, preserving the integrity (accuracy, completeness, content and meaning) of the record, e.g. original paper record of manual observation, or electronic raw data file from a validated computerized system.**4.** This signature (or initials) identifies a second individual who: Reviewed a document for accuracy and completeness; confirmed that the document is in compliance with established specifications, parameters and procedures; and agreed with the conclusions presented in the record.**9.** Any system including instruments or equipment that handles electronic data.**10.** Identifies the individual who evaluated the executed work, to ensure it was done and documented accurately, completely and in accordance with internal procedures, and is compliant with regulatory expectations.**11.** The completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate. The extent to which all data are complete, consistent and accurate, throughout the data lifecycle. | **Down****1.** All data with direct impact on product safety, quality, identity, purity, and potency.**3.** A system with a combination of original electronic records and paper records that comprise the total record set that should be reviewed and retained.**5.** A person who performs the activity and documents the required information at the time of performance.**6.** Identifies a second person who confirms the step was completed and the required information has been fully and accurately documented.**7.** Identifies a second person who confirms the step was completed and the required information has been fully and accurately documented.**8.** Original records and documentation, retained in the format in which they were originally generated (e.g. paper or electronic), or as a true copy. |