Data Integrity Event Decision Tree Event **Event Notification** Issue is due to a GxP related to Not a Data Integrity electronic data/ paper data (it includes audit trail, raw data, Event metadata, true copy? Considerations and Examples: **Attributable** Record is signed, it indicates who did the action? Data Is not attributable to who generated data A generic account was used to record activity? There is no Attributable Attribution of actions records should possibility to identify who did the actions? occur, as appropriate, through the use of: Audit trail did not track who execute the action? • initials (user ID in Computer Systems); There is no link between paper record and esign handwritten signature (eSign when applicable) Activity was recorded by a different person with respect to the action and/or there is no SOP that manages this aspect. Legible (Enduring) **Considerations and Examples** Corrections have been made on the document without justifications or It is not possible to read the data, data made in a non-compliant manner (obliteration, whiteout, etc.), missing have been manipulated/deleted/ signature/date that cannot be reconciled. disrupted/lost. Data cannot be considered Document missing pages or is not complete (i.e. Batch Record does not contain all the requested attachments) legible. It is not possible to reconstruct the Data is not legible or not preserved (i.e. faded thermal paper and a true activity executed. The reviewer cannot copy was not executed) reconstruct the whole history. Audit Trail does not exist, it is not possible to reconstruct the whole history Back up of data does not exist, nor a mitigation action Original data it is not retrievable from the computer system Electronic data were deleted/overwritten/lost, a back up is not available Considerations and Examples: Contemporaneous Procedures do not describe in a clear way how to record data and make Data was recorded in another It is not possible to have a time-stamp from the system timeframe so that it cannot be Original Data is saved in temporary memory, not in a permanent way considered contemporaneous? Data is Date & Time can be changed by a user with generic profile not original, there is no possibility to Date & Time have to be synchronized with the server time reconstruct the whole history? Nor is a An SOP should be available on how to execute a true Copy from an original True copy available of the original record document document/record; Date & Time change The file is a copy that does not preserve the dynamic nature of the on the Computer System is notelectronic record Audit Trail is not activated on the System protected Audit Trail is missing for a timeframe Considerations and Examples: Systems are qualified/ periodically maintained, Validated, Calibrated? Was there data loss? Systems undergo a periodic review? Is there in place a validation package for the Computer Systems that tracks Data is not retrievable anymore? the processing, storing, archiving, and generation of data? Systems not validated/calibrated/ Computer Systems are validated in order to ensure that data are valid, qualified were used to produce data? consistent? SOP Instructions were not followed so If there is an interface between systems to transfer data, was this interface that it is not possible to reconstruct the part of the validation effort? whole history Analytical Methods were validated? GxP data and record undergo a routine review which includes meta data? Data Integrity Event