序号	法规/指南名称 版本号/发布时间	所属章节	内容	分类
1	中国-《药品生产质量管理规范》 2010 年修订	第一百六十条	应当尽可能采用生产和检验设备自动打印的记录、图谱和曲线图等，并标明产品或样品的名称、批号和记录设备的信息，操作人应当签注姓名和日期。	I 、II
2	中国-《药品生产质量管理规范》附录：计算机化系统 2015 年	第十八条	对于电子数据和纸质打印文稿同时存在的情况，应当有文件明确规定以电子数据为主数据还是以纸质打印文稿为主数据。	I
		第十九条	以电子数据为主数据时，应当满足以下要求： （一）为满足质量审计的目的，存储的电子数据应当能够打印成清晰易懂的文件。	II
3	中国-《药品记录与数据管理要求（试行）》 2020 年	第二十一条	采用电子记录的计算机（化）系统至少应当满足以下功能要求： （二）能够显示电子记录的所有数据，生成的数据可以阅读并能够打印；	II
4	中国-《疫苗生产检验电子化记录技术指南（试行）》 2022 年	5.2	用于生产区的信息化硬件，如工作站、打印机、扫码枪等应适合洁净区的使用。如需硬件安装，应当平整光滑、无裂缝、接口严密、无颗粒物脱落，避免积尘，便于有效清洁，必要时应当进行消毒。 洁净区内使用的工作站、扫码枪与打印机之间应优先考虑使用无线连接。	III
		5.3.2	建议通过扫描物料标签上编码的方式对物料的称量、配料、转移、接收、贮存和使用进行电 子化记录，辅助进行物料识别，避免混淆和差错。 应当采用信息化手段管理原辅料的称量全过程，包含下列电子记录形式： b) 每次称重作业中生成称重报告。记录称重使用的秤具名称或编号、校准状态、精度，称量结果、使用者和使用时间信息； c) 可根据称重结果自动生成称量标签。称重标签内容至少包含产品名称、产品规格、产品 批号、物料名称、物料批号、称量重量、称量人、称量日期、编码，如特殊情况下称量 标签无法完整显示上述内容，可通过扫描编码后在系统上显示。称量标签可打印后用于物料转移与识别。	IV
		5.5	建议记录空调净化系统和生产区监控数据的报警信息，包括报警发生的时间、位置信息、设备信息、报警内容、处理人和恢复时间等电子数据，并允许查询和打印报警信息。	III
		5.6	建议记录报警发生的时间、设备信息、报警内容、处理人、处理方法和恢复时间等电子数据，并允许查询和打印报警信息。	III
5	FDA-21 CFR Part 11 Electronic Records; Electronic Signatures 2023 年	NA	NA	NA
6	FDA-Data Integrity and Compliance With CGMP Q&A 2018 年	10	Is it acceptable to retain paper printouts or static records instead of original electronic records from stand-alone computerized laboratory instruments, such as an FT-IR instrument? A paper printout or static record may satisfy retention requirements if it is the original record or a true copy of the original record (see §§ 211.68(b), 211.188, 211.194, and 212.60). During data acquisition, for example, pH meters and balances may create a paper printout or static record as the original record. In this case, the paper printout or	II

			static record, or a true copy, must be retained (§ 211.180). However, electronic records from certain types of laboratory instruments—whether stand-alone or networked—are dynamic, and a printout or a static record does not preserve the dynamic record format that is part of the complete original record. For example, the spectral file created by FT-IR (Fourier transform infrared spectroscopy) is dynamic and can be reprocessed. However, a static record or printout is fixed and would not satisfy CGMP requirements to retain original records or true copies (§ 211.180(d)). Also, if the full spectrum is not displayed in the printout, contaminants may be excluded.	
7	EU-GMP Annex 11 Computerised Systems 2011 年	8	Printouts 8.1 It should be possible to obtain clear printed copies of electronically stored data. 8.2 For records supporting batch release it should be possible to generate printouts indicating if any of the data has been changed since the original entry.	II
8	EU-GMP Annex 11 Concept Paper on the Revision of Annex 11 2022 年	17	[8] The section should include an expectation to be able to obtain data in electronic format including the complete audit trail. The requirement to be able to print data may be reconsidered.	II
9	EMA-Data Integrity Q&A 2016 年	7	'Data lifecycle': What risks should be considered when assessing the processing data into usable information? • Does the person processing the data have the ability to influence what data is reported, or how it is presented; Even 'validated systems' which do not permit the user to make any changes to data may be at risk if the user can choose what data is printed, reported or transferred for processing. This includes performing the activity multiple times as separate events and reporting a desired outcome from one of these repeats. Data presentation (e.g. changing scale of graphical reports to enhance or reduce presentation of analytical peaks) can also influence decision making, and therefore impact data integrity.	III
		16	Why is it important to review electronic data? In the case of data generated from an electronic system, electronic data is the original record which must be reviewed and evaluated prior to making batch release decisions and other decisions relating to GMP related activities (e.g. approval of stability results, analytical method validation etc.). In the event that the review is based solely on printouts there is potential for records to be excluded from the review process which may contain un-investigated out of specification data or other data anomalies. The review of the raw electronic data should mitigate risk and enable detection of data deletion, amendment, duplication, reusing and fabrication which are common data integrity failures.	III
10	EMA-Guideline on Computerised Systems and Electronic Data in Clinical Trials 2023 年	NA	NA	NA
11	MHRA-GXP Data Integrity	5.1	Systems and processes should be designed in a way that facilitates compliance with the principles of data integrity.	Ⅰ、III

	Guidance and Definitions 2018 年		Enablers of the desired behaviour include but are not limited to: • User access rights that prevent (or audit trail, if prevention is not possible) unauthorised data amendments. Use of external devices or system interfacing methods that eliminate manual data entries and human interaction with the computerised system, such as barcode scanners, ID card readers, or printers. • Reconciliation of controlled print-outs.	
		6.2.	Raw data (synonymous with 'source data' which is defined in ICH GCP) In the case of basic electronic equipment that does not store electronic data, or provides only a printed data output (e.g. balances or pH meters), then the printout constitutes the raw data. Where the basic electronic equipment does store electronic data permanently and only holds a certain volume before overwriting; this data should be periodically reviewed and where necessary reconciled against paper records and extracted as electronic data where this is supported by the equipment itself.	I
		6.7.	Recording and collection of data The selected method should ensure that data of appropriate accuracy, completeness, content and meaning are collected and retained for their intended use. Where the capability of the electronic system permits dynamic storage, it is not appropriate for static (printed/manual) data to be retained in preference to dynamic (electronic) data.	II
		6.11.1.	Original record A static record format, such as a paper or electronic record, is one that is fixed and allows little or no interaction between the user and the record content. For example, once printed or converted to static electronic format chromatography records lose the capability of being reprocessed or enabling more detailed viewing of baselines.	II
		6.11.2.	True copy Data must be retained in a dynamic form where this is critical to its integrity or later verification. If the computerised system cannot be maintained e.g., if it is no longer supported, then records should be archived according to a documented archiving strategy prior to decommissioning the computerised system. It is conceivable for some data generated by electronic means to be retained in an acceptable paper or electronic format, where it can be justified that a static record maintains the integrity of the original data. However, the data retention process must be shown to include verified copies of all raw data, metadata, relevant audit trail and result files, any variable software/system configuration settings specific to each record, and all data processing runs (including methods and audit trails) necessary for reconstruction of a given raw data set. It would also require a documented means to verify that the printed records were an accurate representation. To enable a GXP compliant record this approach is likely to be demanding in its administration.	II
		6.14.	Electronic signatures For printed copies of electronically signed documents refer to True Copy section.	II
12	ICH-E6(R3)《药物临床试验质量管理规范（草案）》	NA	NA	NA

	2023 年			
13	ISPE-GAMP5 第二版 A Risk-Based Approach to Compliant GxP Computerized Systems 2022 年	4.2.6.1 12.3.3	Life cycle phases Project Practical examples Example of a Standard Product Software products that are used off-the-shelf (i.e., standard and not configurable for a specific business process), are typically classified as GAMP Category 3. This includes off-the-shelf components used for business purposes. It includes both those that cannot be configured to conform to business processes, and those that offer defined ranges of factory-provided values or ranges (also called parameterization, as may be found in process control systems and simple laboratory devices). In both cases, configuration to run in the user's environment is possible and likely (e.g., for printer setup). Regulated companies typically perform the required specification and verification. While the system is not configured for a business process, there may be some limited configuration such as run-time parameters or printer setup.	II
		8.5.3	Secondary Test Evidence The generation and retention of secondary supporting hard copy or image evidence such as screenshots, in addition to the primary test result or output, is unnecessary in most cases and does not add value. It often adds significant cost without associated benefit, as well as adding unnecessary complexity. Such additional evidence should be generated and maintained only where value-added and necessary for effective testing. Examples where additional test evidence may be useful include: • Complex results, which may be difficult or time consuming to record manually, or where printouts are more efficient than manual recording Also, systems may also have data audit trails or other system logs that capture much of the information that may have been traditionally captured by screen prints.	II
		16.3.2	Appendix M8 – Project Change and Configuration Management Change Management All deliverables should be identified so that the controlled items subject to change management may be defined. These may include: • Hardware (e.g., Programmable Logic Controllers (PLCs), Personal Computers (PCs), minicomputers, servers, communication interfaces, printers)	II
		35.4.3	Appendix O3 – System Monitoring System Monitoring Considerations System monitoring should consider the following: • Printer queue failures	III
		48.2.1	Appendix S3 – End User Applications Including Spreadsheets	IV

			Application Types Disposable Spreadsheets Spreadsheets may be used in the same way as a hand calculator. For example, 10 output values from a laboratory test are input for the purpose of calculating a mean and standard deviation. In this scenario, the electronic copy is not retained. This should be documented in the same way the use of a non-printing calculator would be documented, i.e., the values and result are recorded and signed. The results can be printed, labeled, and signed. Alternatively, they may be saved to a static format and signed via an external electronic signature tool. In either case, these are now documents, and the guidance in Section 48.2.2 applies. It should be clear on the page exactly what arithmetic manipulation was done. This can be facilitated in most spreadsheet tools by printing a copy of the spreadsheet displaying the cell formulas. Calculations used to process GxP data should be verified. This does not mean that algorithms used by native functions of the spreadsheet need to be checked for accuracy every time the sheet is run, but rather to demonstrate that they are the correct calculations during the verification stage. For example, (a+b)îc is a very different expression from a+(bîc), and errors like this are easily made. Verification of the calculations can be accomplished by printing the cell formulas, or by a third-party review. Such calculation verification is appropriate for any GxP spreadsheet.	
		48.2.4	Template Applications • Will output be saved to a file or only printed? Electronic record controls may be necessary if the document is retained electronically.	IV
14	WHO-TRS 1033 Annex 4 Guideline on Data Integrity 2021 年	4.15.	Data governance Records (paper and electronic) should be kept in a manner that ensures compliance with the principles of this guideline. These include but are not limited to: ■ having automated data capture systems and printers connected to equipment and instruments in production (such as Supervisory Control and Data Acquisition (SCADA), Human Machine Interface (HMI) and Programme Logic Control (PLCs) systems), in, quality control, and in clinical research (such as Clinical Data Management (CDM) systems), where possible;	I
		Appendix 1	Examples in data integrity management Example 1: Quality risk management and data integrity risk assessment For example, if during the weighing of a sample, the entry of the date was not contemporaneously recorded on the worksheet but the date is available on the print-out from a weighing balance and log book for the balance for that particular activity. The fact that the date was not recorded on the worksheet may be considered a lapse in data integrity expectations. When assessing the risk relating to the lack of the date in the data, the risk may be considered different (lower) in this case as opposed to a situation when there is no other means of traceability for the activity (e.g. no print-out from the balance). When assessing the risk relating to the lapse in data integrity, the severity could be classified as “low” (the data is available on the print-out); it does not happen on a regular basis	II 、IV

			(occurrence is “low”), and it could easily be detected by the reviewer (detection is “high”) – therefore the overall risk factor may be considered low. The root cause as to why the record was not made in the analytical report at the time of weighing should still be identified and the appropriate action taken to prevent this from happening again. Example 10: Controls Based on the outcome of risk assessment which should cover all areas of data governance and data management, appropriate and effective controls should be identified and implemented in order to assure that all data, whether in paper records or electronic records, will meet GxP requirements and ALCOA+ principles. Examples of controls may include, but are not limited to: ■ the qualification, calibration and maintenance of equipment, such as balances and pH meters, that generate printouts; Example 11: Accuracy Points to consider for assuring accurate GxP records: ■ when the activity is time-critical, printed records should display the date and time stamp.	
15	PDA-No.80 Data Integrity Management System for Pharmaceutical Laboratories 2018 年	4.1	Original Records Original records include source data and all metadata needed to be "complete" and to allow for full reconstruction of conduct of the GXP activity. Original records for most laboratory systems include source electronic data and any subsets that are printed. Some equipment, such as pH meters and balances, may create a paper printout or static image of electronic reading during data acquisition as the original record. However, electronic records from certain types of laboratory instruments are dynamic records, and a printout or a static record does not preserve the dynamic format that is part of the complete original record. A firm must justify the choice of record (paper or electronic) based on whether the data is static or dynamic. In the case of dynamic data, it is required to maintain electronic records.	Ⅰ、Ⅱ
		5.1.1	Interviewing Analysts One critical element in conducting an audit for data integrity problems in a microbiological laboratory is interviewing the individuals who perform the QA/QC tests, in particular, the laboratory analysts or technicians. When reviewing analytical results recorded on worksheets or data printouts form the LIMS, for example, it is extremely difficult to detect data that should have been recorded but was not. Much of what analysts learn comes &om on-the-job training, yet unofficial dialogue with coworkers or supervisors is rarely captured or documented. For instance, when a senior analyst instructs a junior analyst on how to handle the appearance of "unwanted" microorganisms found growing on analytical petri plates (such as, "Write the numerical count of the suspected colonies on the lid of the petri dish but don't record it on the official worksheet until the supervisor has a chance to review it."), this "unofficial" practice will not be found in the company's standard operating procedures (SOPs).	Ⅲ

			An auditor can best assess the potential fur inappropriate practices, first, by verifying the acceptance criteria described in SOPs and, then, by inquiring of the analysts or technicians if they have been instructed to adjust or modify data or divert from the laboratory SOPs in any form. Without conducting such face-to-face interviews, this kind of microbiological data manipulation would be extremely difficult to detect.	
		5.1.4	Contract Laboratories Two laboratory areas that the sponsor or owner company must carefully oversee are: (a) monitoring of source data, including electronic data and metadata, at the contract site, and (b) establishing contractual provisions to ensure the contract site does not delay, deny, refuse, or limit the ability of the sponsor or owner company to inspect their source data. As observed by experienced consultants, some contract sites only allow the sponsor company to review printouts, refusing access to their source electronic data and metadata. Risk-based reviews of critical source data and metadata and reconciliation of source data with reported information is essential for a meaningful data integrity audit.	III
		6.2.1	Hybrid Systems — Associated Risks • Testing into compliance or duplicate prints of the same record • Lack of adequate second-person verification that printed data is a true copy of original data electronic data or a representative summary of the source electronic data, including all metadata and results	II、III
		6.2.2	Hybrid Systems — Qualification • Cross-platform data capabilities. The requirements for viewing, printing, or analyzing data on a computer should be known and tested, e.g., if the data is stored in CSV text or PDF format, it may be viewed directly. Most data (such as Karl Fischer equipment for measuring moisture) may require installation of a specific software program to store and interpret this data; in that case, software validation may be required, and the software should be checked for additional features, such as data compatibility with commonly used software (e.g., PDF generators and spreadsheets). • Data Integrity when copied to computer. If data or results are being copied to a computer, the possibility of data manipulation must be tested to define the controls and limitations fur data copying and printing; for example, if the data is stored in spreadsheet format, the date and time of acquisition, identity, result, etc., might be open to manipulation. • Data handling. If an analytical instrument (e.g., balance) does not have the functional capability to store and manage the data or the critical metadata, the printed data may be considered as the original record, only when that record is a complete and accurate copy of the complete data and metadata generated by the instrument. Firms engaged in the manufacture and testing of pharmaceutical products who process information electronically should have laboratory equipment that meets CGMP standards for the processing and maintenance of electronic data. The entire end to-end data handling process, fi-om the point of generation of the electronic signal in the source system through to final decision-making based upon this source data, needs to be assessed for data integrity risks and designed to reduce these risks through a combination of appropriate technical and procedural	II

			controls. The Quality Unit is ultimately responsible for ensuring that appropriate procedures are in place for storing and protecting electronic records and restricting access to those files. One best practice is to identify an independent system administrator with specialized expertise to be responsible for storing and protecting electronic records. • Results output. The results from hybrid systems (pH meters, balances, and titrators) should be printed with date-and-rime stamp, raw data, metadata, measurement values, sample identity, batch number, file names, and calculated values. • Backup and data review. For hybrid systems that are not connected to computers, ideally a report (event log) can be printed (meaning published in PDF) with every analysis or, at least, printed periodically. Publishing or viewing event logs may not always be possible on hybrid analytical equipment; therefore, data integrity should be ensured by periodic Quality Unit checks for date and rime breaches, data breaches, weights-on-results calculations vs. analytical scale printouts, checks against the riming of other instruments, and periodic data reconciliation (results stored on the instrument vs. recorded in an equipment logbook). Any breach in data or of established laboratory criteria should be investigated according to laboratory SOPs and applicable regulatory guidance.	
		6.3.7	Data Processing and Peak Integration Printed chromatograms should be presented in visible scale as per the respective analysis (peak top visible for assay or single analysis, peak base clearly visible for purity analysis). After integration, results may be published or electronically stored. If results are reprocessed, permission from a supervisor is required. Those types of events may be noted in a log (paper or electronic) for quick reference.	IV
		6.3.8	Results Printing or Publishing Some software packages use the term "printing" to generate a final result; in this case, printing does not mean output to paper form. Printing, or "publishing," refers to the next step in generating output once testing is complete. In a well-configured system, the results after this step are final and may not be changed without reprocessing. Reprocessing must be governed by procedures and software that is correctly configured and should require a comment or justification. Before publishing, the supervisor or Quality Unit should review the results, according to established laboratory procedures. Though printing results on paper is not an ideal practice, some firms still use this approach, often due to limited software functionality or limited resources. The following items or reports should be generated, through publishing or software functionality, after each analysis and made available in the system for review: • Sample sequence • Instrument method • Integration events/processing method • Results (chromatograms) • Results audit trail (if available) • Sequence audit trail (if available) • Method audit trail (if available) The results should include the following criteria: • Analyst's name and signature • Date and time results were processed • Results audit trail, method audit trail, and sequence audit trail • Chromatograms presented in visible scale per respective analysis (peak top fur assay or single-analyte analysis, peak base for purity analysis)	IV

		6.3.9.4	Results Audit Trail Chromatograms or reports can serve as a results audit trail. Figure 6.3.9.4-1 is a model results audit trail report that presents integration type, date acquired, date processed and by whom, and if the chromatogram was altered after generating data. Typically, chromatograms should contain: • Sample description • Date and time of sample acquisition • Date and time of results processed, if possible • Minimum method parameters, i.e., wave length, injection volume, and method name/ID • Integration type • Retention time (any other system suit parameters) • Time printed, published, or saved • Integration events • Sample name change after execution Filters can also be used to search the requirement from huge amounts of data. Figure 6.3.9.4-2 represents a filter to search whether the sample has been injected in multiple projects. For older systems with limited functionality, the reviewer should sign and stamp results printed on paper and review the electronic data according to the Quality Unit policy. If the results are published electronically, the reviewer should e-sign the results after reviewing and lock the signed file. If it will be used for any investigational purpose, the Quality Unit must review the electronic data per the firm's policy, as electronic data is deemed to be final. Once the printed data is audited, original electronic data should be available for reference and should not be altered. Any modification to the approved data needs to be justified.	II 、IV
		6.5	Laboratory Data Management Software Laboratory data management software typically is validated using the following steps (not necessarily in this order): • Set up controls and traceability of printouts and define number of printouts allowed	II 、 III
16	PIC/S 041-1-Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments 2021 年	7.7.2	It is conceivable for raw data generated by electronic means to be retained in an acceptable paper or pdf format, where it can be justified that a static record maintains the integrity of the original data. However, the data retention process should record all data, (including metadata) for all activities which directly or indirectly impact on all aspects of the quality of medicinal products, (e.g. for records of analysis this may include: raw data, metadata, relevant audit trail and result files, software / system configuration settings specific to each analytical run, and all data processing runs (including methods and audit trails) necessary for reconstruction of a given raw data set). It would also require a documented means to verify that the printed records were an accurate representation. This approach is likely to be onerous in its administration to enable a GMP/GDP compliant record.	II
		8.6.1	Filling out records The items listed in the table below should be controlled to assure that a record is properly filled out. 3. Expectation Records should be enduring (indelible). Potential risk of not meeting expectations/items to be checked • Note that some paper printouts from systems may fade over time, e.g. thermal paper. Indelible signed and dated true copies of these should be produced and kept.	II
		8.9.1	Direct print-outs from electronic systems	II

			Some very simple electronic systems, e.g. balances, pH meters or simple processing equipment which do not store data, generate directly-printed paper records. These types of systems and records provide limited opportunity to influence the presentation of data by (re-)processing, changing of electronic date/time stamps. In these circumstances, the original record should be signed and dated by the person generating the record and information to ensure traceability, such as sample ID, batch number, etc. should be recorded on the record. These original records should be attached to batch processing or testing records.	
		8.10.2	Document retention (Identifying record retention requirements and archiving records) Expectation All hardcopy quality records should be archived in: - secure locations to prevent damage or loss, - such a manner that it is easily traceable and retrievable, and - a manner that ensures that records are durable for their archived life. Specific elements that should be checked when reviewing records: • In case of printouts which are not permanent (e.g. thermal transfer paper) a verified ('true') copy should be retained.	II
		9.9	Storage, archival and disposal of electronic data Expectation It should be possible to print out a legible and meaningful record of all the data generated by a computerised system (including metadata). If a change is performed to records, it should be possible to also print out the change of the record, indicating when and how the original data was changed. Potential risk of not meeting expectations/items to be checked • Samples of print-outs may be verified.	I、II
		9.10	Management of Hybrid Systems Procedures and records should be available to manage and appropriately control the interface between manual and automated systems, particularly steps associated with: - manual input of manually generated data into computerised systems; - transcription (including manual) of data generated by automated systems onto paper records; and - automated detection and transcription of printed data into computerised systems.	I
		10.1.4	DATA INTEGRITY CONSIDERATIONS FOR OUTSOURCED ACTIVITIES General supply chain considerations It is important for an organisation to understand the data integrity limitations of information obtained from the supply chain (e.g. summary records and copies / printouts) and the challenges of remote supervision. These limitations are similar to those discussed in section 8.11 of this guidance. This will help to focus resources towards data integrity verification and supervision using a quality risk management approach.	III

17	APIC-Practical Risk-Based Guide for Managing Data Integrity 2022 年	4.2.1	System Profiling System categorization The following 6 categories are proposed. Category 3: An electronic system with some limited manual adjustable input data and the generated CGxP data is not stored but printed out. Typical examples could be potentiometric titrators not connected to a PC, balances with printer.	I
		Table 2a	Detailed data integrity checklist Data lifecycle management- Dynamic data 20. Is dynamic CGxP data kept in its dynamic state?(6) Acceptance criteria: Raw CGxP data that is generated electronically should remain in its dynamic (electronic) state if the ability to interact with the CGxP data is critical to its integrity or later verification. Where the capability of the electronic system permits dynamic storage, it is not appropriate for low resolution or static (printed / manual) CGxP data to be collected in preference to high resolution or dynamic (electronic) CGxP data. For Example, Chromatography data for additional processing. Time Stamps-Daylight savings 43. Is the system capable of taking a daylight-saving time switch to correct for summer or winter time? (3/4/5/6) Acceptance criteria: When the system is technically not capable to take daylight-saving time switch into account automatically, specific arrangements need to be implemented and defined in a procedure for that system. These arrangements shall make sure that no CGxP data are lost or overwritten. Additional notation may be required for clarity for those two-time definitions whenever displayed or printed.	II
18	ECA-GMP, GCP and GDP Data Governance and Data Integrity 2022 年	2.5.1	Poor Practices versus Falsification Data Falsification Data falsification and fraud in the laboratory is essentially testing into compliance and is a practice that is intended to deceive: batches or material are passed as within specification with a combination of the following activities: • Performing “chromatographic analysis” without any physical chromatographs, merely reintegrating and printing the same sets of data using a chromatography data system	II 、 III
		2.5.2	Poor Data Management Practices The remaining 95% of data integrity citations are due to poor data management practices. For example, these can include: Original/Accurate: • Using an analytical balance without an attached printer and just recording measurements by observation	I
		4.8.4	Second Person Reviewer Reviewers need to be trained to detect falsification and therefore processes and transfers need to be as transparent and automated as possible. The scope of the second person review should cover the whole analytical process from	II

			sample storage to reportable result and must not be confined to the boundaries of a specific system. Scope of the review: • In case of hybrid and "mixed" records (e.g. electronic records with signatures on the associated paper printouts) is has to be ensured that the paper record is linked to the ER (example see 8.8 Spreadsheets). For media change see 8.7.6 Media Change.	
		6.3	Validation Validation should address the necessary controls to ensure the integrity of data, including original electronic data and any printouts or electronic reports from the system. In particular, the approach should ensure that Good Documentation Practices will be implemented and that data integrity risks will be properly managed throughout the data lifecycle.	II
		8.4.2	Recording Results from an Analytical Balance Put at its simplest, if you are making a weighing then recording the weight by observation is unacceptable and evidence from an attached printer is essential documented evidence of the weights and the weighing sequence. An alternative is direct data capture by a computerised system e.g. instrument data system, LIMS or ELN, this approach is a better long-term objective as the process is automated and there is no transcription checking to perform.	I
		8.4.4	Observing Results from Simple Instruments In cases such as pH meters, polarimeters and other simple instruments where there is no data system and the only way of recording the result is by observation. Depending on the criticality of the measurement, then their either needs to be a second person to verify the observation or that it is evaluated indirectly by use in an analysis. As a minimum, the investment in a printer if the instrument is capable of being linked is worthwhile and will save much effort; better still is the interfacing to an instrument data system or another informatics application.	I
		8.7.5	Retention of Records The last problem is the retention and archiving of records. What are you going to keep: the paper, the electronic record or both? At the beginning of the Part 11 journey, most companies decided to keep print-outs and destroy (delete) the electronic records. According to FDA, this is only acceptable if the paper printout is a complete copy of the original record, i.e. only acceptable for static records. This approach is not acceptable for dynamic records as the dynamic format, i.e. metadata is not preserved. As discussed on the FDA web site, printouts from a computerised system are not true copies under 21 CFR 211.180(d) and are not exact and complete as required by 21 CFR 211.68(b) [85]. This is also reiterated in the data integrity guidance in Question 10 [2].	II
		8.8	Spreadsheets However, the problem with the spreadsheet is much more complex especially as the end product is hybrid record i.e. the completed template must be stored electronically as the primary E-record and a system must be in place to link any printouts with it. In addition, the development and validation process for the spreadsheet template must	II

<table>
<tr><td></td><td></td><td></td><td>be clearly defined and documented. The most commonly used spreadsheet is Microsoft Excel™ and for the purposes of guideline it will be used to illustrate issues and problems faced when operating within a regulated environment.
In order to use a spreadsheet in a regulated environment it is necessary to;
• Link the primary e-record with the paper printout (record signature linking)
8.8.2 Development and validation of spreadsheet templates
For record signature linking it is important to populate the fields in the spreadsheet margin with appropriate information such as file name, create date/time and print date/time to ensure the linkage between electronic record and paper printout.
8.8.4 Control of completed spreadsheet templates as e-records
Once the completed template has been saved it is the primary record. If a printout is required, then there must be a secure method of record and signature linking and traceability to the e-record.</td><td></td></tr>
<tr><td></td><td></td><td>8.9.10</td><td>Simplify the Business Process
When implementing an electronic system there are three essential design requirements:
• Eliminate transcription error checking: Never print or re-enter data manually into a system, always transfer the data electronically. This also includes elimination of printing and use of spreadsheet files. This also applies to interfacing between applications: validate once and use many the interface times.</td><td>I</td></tr>
<tr><td></td><td></td><td>8.10</td><td>GDP – Good Distribution Practices GDP
The following table provides an overview of the responsibility and checks for the different data types in the GDP area.
<table>
<tr><td>Name of Data</td><td>Temp data from Data Logger / Indicator / Truck Print-out</td></tr>
<tr><td>Data Type</td><td>Dynamic</td></tr>
<tr><td>Critical</td><td>Yes</td></tr>
<tr><td>Process Step</td><td>Distribution Temperature compliance</td></tr>
<tr><td>Description and Purpose</td><td>To record temperature during distribution activities – To verify if product temperature is within acceptable temperature range</td></tr>
<tr><td>Type of Record</td><td>Paper / Electronic</td></tr>
<tr><td>Responsibility</td><td>Warehouse/ Logistics / Quality</td></tr>
<tr><td>Verification</td><td>Double Check</td></tr>
</table></td><td>III</td></tr>
</table>