(Prepared in August 2018)

DI Compliance Assessment Sheet (Data Integrity Master Plan Attachment 1)

Check Items

1. **Data governance**	2. **Operating procedure for paper media**	3. **Operating procedure for electronic media**
a) Control rules b) Education and training c) Control of computerized systems d) Risk management approach e) Review f) Organization	a) Control of original paper records b) Control and distribution of paper record forms c) Filling out record sheets d) Correction of records e) Verification of manufacturing records f) Maintenance and control of records g) Direct Printout from electronic system h) True copies i) Document storage j) Disposal of original records	a) Validation b) Data transfer between systems c) Security d) Audit trail e) Data collection/entry f) Review of electronic data g) Storage, archiving and disposal of electronic data

Conformance legend (example)

■**:** Conformance

■**:** Partial conformance

■**:** Non-conformance

Assessment unit: Manufacturing site, department

Object of assessment		Evaluation period		
Evaluator	(Position)	(Name)	(Signature)	(Date)
Approver	(Position)	(Name)	(Signature)	(Date)
	(Position)	(Name)	(Signature)	(Date)

Item	Relevant Guidance / Points to Consider	Assessment results (example)	Degree of conformance	Action
1. Data governance				
a) Control rules				
1. Have standard documents defining the data integrity policies and requirements of the manufacturing site been prepared?	PIC/S 5.2, MHRA 5 The data governance system should ensure controls over data lifecycle which are commensurate with the principles of quality risk management. These controls may be: "organizational" and "technical." The standard documents prepared should be reviewed periodically.	"Control rules for records/data" exist, but there is no policy on data integrity.		Revise "Records and Data Management Rules" to define the data integrity policy.
2. Do the standard documents cover the lifecycle from preparation to disposal of data?	PIC/S 5.2, MHRA 5,6	There are provisions covering procedures from data preparation to disposal.		NA
3. Do the standard documents specify responsibilities and involvement of the management?	PIC/S 5.2,5.3,6.1,6.2, MHRA 5 In order to ensure data integrity, it is necessary for senior management to have an	Management responsibilities and involvement have not been defined.		Define management responsibilities

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	awareness and understanding of data integrity.			and involvement in the data integrity policy.
4. If a data integrity failure is observed, is it evaluated as a deviation from the quality management system?	PIC/S 6.7 Not only should it be evaluated as a deviation but corrective and preventive actions should also be taken.	Not specified in the procedure.		
5. Has a control policy been established for data integrity at external laboratories and suppliers?	PIC/S 10 Data integrity plays a key part in ensuring the security and integrity of supply chains In initial qualification and periodic re-qualification of supply chain partners and outsourced activities, data integrity risks and appropriate control measures should be considered. It is necessary to understand the data integrity limitations of the information obtained from the supply chain (e.g., summary records and copies/printouts) and the difficulties of remote monitoring.	Not specified in the procedure.		
6. Is there a quality agreement with external laboratories and suppliers, etc., and are there provisions for data integrity?	PIC/S 10 There should be a quality agreement between the manufacturer and the supplier/CMO, with specific provisions to ensure the integrity of the supply chain data. This sets expectations for data governance and transparent error/deviation reporting from contract acceptor to contract giver. There should also be a requirement stating that the contract giver should be notified of any data integrity deficiencies identified by the contract acceptor.	There is a quality agreement, but there are no provisions for data integrity.		

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b) Education and training				
1. Are new employees and existing employees newly engaged in GMP-related operations given training that provides an overview of data integrity?	PIC/S 5.2, MHRA 5.1, WHO 8.3, FDA16	Training related to data integrity is provided.		
2. Are there provisions for periodic re-education on data integrity (policies and SOPs)?	PIC/S 5.2,6.4, WHO 8.3	There are no provisions for periodic re-training on data integrity.		
3. Have key personnel, including supervisors, managers and quality unit personnel, been trained on how to prevent and detect data integrity issues?	WHO8.2 Key personnel, including managers, supervisors and quality unit personnel, should be trained in measures to prevent and detect data issues. This may require specific training in evaluating the configuration settings and reviewing electronic data and meta data, such as electronic data and audit trails, for individual computerized systems used in the generation, processing and reporting of data.	They have received special education and training covering second-person review of data and review method for audit trails, but they do not have practical skills in file identification and confirmation of configuration settings.		
c) Control of computerized systems				
1. Does the risk assessment for computerized systems take into account differences between human intervention operations such as manual input or data capture from external storage media and the network system in which the exchange is performed automatically between devices?	PIC/S 5.5 Computerised system validation in isolation may not result in low data integrity risk, in particular when the user is able to influence the reporting of data from the validated system.	At the time of risk assessment, consideration was not given to the fact that there could be human intervention in data reporting by the network system.		
d) Risk-based approach				
1. Is there a procedure for evaluating the criticality of data (criticality risk) based on the risk management approach?	PIC/S 5.3,5.4,5.5, WHO 5.3 Risk-based approach enables you to take control measures depending on the risk. The effort and resources allocated to the control	Risk management procedures have been specified, but the criticality of data obtained has not been included in the scope of risk evaluation.		

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	of data and records must be commensurate with the product quality risk.			
2. Are there data integrity control procedures for facilities and equipment handling critical data, based on the risk management approach?		Equipment with critical data has been identified, but there are no specific control procedures.		
e) Review				
1. Do you regularly evaluate the effectiveness of data integrity control procedures (established organizational and technical measures)?	PIC/S 5.6, MHRA 5 The effectiveness of data integrity control procedures should be evaluated periodically as part of self-inspection (internal audits) and other periodic review processes. Verify that control measures throughout the data lifecycle are working as intended.	Management review is held once a year to report the results of the internal audit.		
f) Organization				
1. Does management understand the criticality of data integrity?	PIC/S 6.2	It is understood, but the management does not issue specific instructions or take specific actions.		
2. Has management constructed a transparent and open workplace environment (quality culture) in which employees freely communicate about data integrity incidents and errors and take corrective and preventive actions?	PIC/S 6.3, MHRA 6.5, WHO 4.7 A reporting mechanism independent of organizational hierarchy must be provided.	QC circle activities are being carried out. A whistleblowing system has been established.		
3. Does management make personnel aware of the importance of their role in ensuring data integrity and the implications of their activities on assuring product quality and protecting patient safety?	PIC/S 6.2	An external lecturer is invited once a year to hold lecture meetings on quality.		
4. Does management have a good grasp of the current status of data integrity at the manufacturing site and the relevant risks?	WHO8.1 Personnel should be trained in data integrity policies and agree to abide by them.	Management is not sufficiently aware of compliance. Therefore, no specific measures have been taken, and risks related to data integrity are		

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	Management should ensure that personnel are trained to understand and distinguish between proper and improper conduct, including deliberate falsification, and should be made aware of the potential consequences.	not well understood.		

Assessment units: QC area, manufacturing area, packaging area, utilities, warehouse area, quality system (annual review, self-inspection, change control, deviation management, etc.)

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2. Operating procedure for paper media				
a) Control of original paper records				
1. Do paper record forms (originals from which copies are made) have unique identification numbers and identify the author, approver, and date of preparation/approval? And are there specific forms for this purpose?	PIC/S 8.4 Critical data must be properly recorded and controlled to prevent loss and falsification.	Paper record forms (for copying) have a unique identification number. The persons and dates can be identified for both preparation and approval.		N/A
2. Are all forms used to record data (numerical values, letters, etc.) controlled as record forms?	PIC/S 8.4, WHO Appendix1 Temporary recording methods, such as uncontrolled memos, should not be used.	Uncontrolled record forms are used in some cases.		List the record forms that are not controlled, and register and control them as GMP documents.
3. Is there sufficient space for handwritten entries on the record forms?	PIC/S 8.4 Handwritten data should be recorded legibly.	There is sufficient space for handwritten entries.		

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4. Does the format of the form clearly indicate what data should be entered?	If the contents to be entered are unclear, there is a risk that these will result in erroneous and inconsistent records. Care should be taken to ensure that data entry is clear, contemporaneous and indelible/durable.	On the other hand, there are formats with fields where it is unclear what sort of data should be entered.		
5. Have procedures been established for distribution of the latest version and collection/retirement of obsolete versions? In addition, is the original record form (original from which copies are made) stored by a method that appropriately manages the version number?	PIC/S 8.4 Ensure that obsolete versions are not used. Improper storage conditions can result in inappropriate changes, use of expired documents and/or drafts, loss of original record forms, etc.	Distribution of the latest version and disposal of the old version are performed appropriately.		
6. Does the person in charge of document control in the quality control unit perform ledger control for all paper record forms (originals from which copies are made)?	PIC/S 8.4 At least the following information should be entered in the control ledger for each type of paper record form (original from which copies are made); title, reference number including version number, storage location (e.g., documentation database), effective date, date of next review, etc.	All paper record forms (originals from which copies are made) are controlled by ledger.		
7. Are paper record forms (originals from which copies are made) appropriately controlled to protect them from unauthorized or inadvertent changes?	PIC/S 8.4, MHRA 5.1 They must be protected from unrestricted use by unauthorized persons and from unapproved modification.	The paper record forms (originals from which copies are made) are controlled by the document control manager, and unauthorized persons cannot access them.		
b) Control and distribution of paper record forms				
1. Does the person in charge of document control in the quality unit affix a unique identification code (example: serial number) to each record form to be issued, and control the records of	PIC/S 8.4	Records of record form issuance are not controlled.		

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issuance?				
2. Have procedures been established to prevent misuse of paper record forms (originals from which copies are made) and the record sheets made from them?	PIC/S 8.4 It is desirable to make it possible to easily distinguish original paper record forms (originals for copying) from record sheets made from them by using paper or ink with different colors.	There are no procedures for this item.		
3. Have procedures been established for re-issuance of record sheets and is the reason for re-issuance (e.g., defacement of distributed record sheets) documented along with its approval?	PIC/S 8.4 In order to prevent improper rewriting, etc., it is necessary to record the number of sheets issued and the reason for re-issuance while also limiting re-issuance authority to certain persons.	No procedure has been specified for re-issuance.		
4. Are record sheets that were issued but not used collected and disposed of appropriately by the issuer?	PIC/S 8.4 There is a risk of misuse or improper use.	Unused record sheets are not collected.		
5. Is there a system or procedure for issuance of records to prevent inappropriate copying, such as affixing a secure stamp or using paper with a color different from that used in the working area?	PIC/S 8.4	Used are record forms with a color not used in the working area.		
6. Is the number of record sheets distributed controlled by assigning page numbers (serial numbers)? Is the number of sheets used checked against the number issued to confirm the accuracy and completeness of records?	PIC/S 8.4	Page numbers are affixed to record sheets, but no record is made of the number of pages issued, so it cannot be compared with the number used.		
7. Are the distributed record sheets appropriately controlled by the designated person in charge?	PIC/S 8.5 These controls should be carried out to minimize the risk of damage or loss of the records and ensure data integrity. Where	Record sheets are filled out at a specified area free from contamination in the manufacturing area.		

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	necessary, measures must be taken to protect records from being soiled (e.g. getting wet orstained by materials, etc).			
8. Are the control methods for 5 to 7 above specified in the SOP?	PIC/S 8.4 If control methods are not specified in the procedure and they are not implemented as per an SOP, there is a risk of rewriting or falsification of data or misuse of the old version.	Some of the methods are not specified in the SOP.		
c) Filling out record sheets				
1. Are the record sheets filled out by the person who actually performed the operation? (Exceptions are limited to the following cases) - The act of recording places the product or activity at risk e.g. documenting line interventions by sterile operators. - To accommodate cultural or staff literacy / language limitations, for instance where an activity is performed by an operator, but witnessed and recorded by a Supervisor or Officer. .	PIC/S 8.6, MHRA 5.1,5.2 It is necessary to make an accurate record at the time the operation occurs.	The record is made by the operator himself/herself.		
2. Are unused blank fields in the record sheet crossed-out, dated and signed?	PIC/S 8.6	Blanks are crossed-out, but the procedures do not specify that the sheet should be dated and signed.		
3. Are entries made in a clear and legible manner?	PIC/S 8.6 Ambiguous symbols and abbreviations should not be used.	The symbols and abbreviations used are defined in procedures.		
4. Are the date fields filled out in accordance with the rules of the manufacturing site? (e.g.:	PIC/S 8.6 Avoid ambiguous descriptions.	Procedures for entering dates have been established.		

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dd/mm/yyyy or mm/dd/yyyy.)				
5. Are records kept in the area where the operation is performed and filled out at the same time the operation is performed?	PIC/S 8.6, MHRA 5.1 Accurate records should be made at the time the operation occurs, and they should also be made at the location where the activity takes place so as to avoid unnecessary duplication of data recording at the point of operation and subsequent transcription into official records.	Records are made at the same time the operation occurs.		
6. Are records written in indelible ink? Do the records smudge or fade during storage?	PIC/S 8.6, WHO Appendix1 • Pencil records must not be overwritten with a pen. • If heat-sensitive paper is used, the characters may fade over time, rendering the record illegible. • Entries in records must not be covered with opaque correction fluid, etc.	Records are filled out with a ballpoint pen so that the entries cannot be erased. Use of pencil is prohibited by the procedures.		
7. Is the signature of the recording personnel registered?	PIC/S 8.6, WHO Appendix1 • All key entries must be signed and dated. • The use of personal seals is not recommended. • Digital signature images are not acceptable for signing documents.	The signature of the recording personnel is registered. Use of digital images of seals and signatures is prohibited.		
8. When operations that require accurate recording of time are performed, is an appropriately controlled clock used?	MHRA 5.1	Regularly calibrated clocks are used.		
9. When pages are added to a record, is the number of pages to be added clearly noted on a page of the original record, along with the source, and are the pages signed?	PIC/S 8.4 Integrity of records should be ensured.	Procedures for adding pages to records have been specified.		

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10. Are there procedures for prohibiting the use of uncontrolled documents, the act of temporary record-making, and the disposal of such records?	PIC/S 8.4 Use of uncontrolled documents should be prohibited by local procedures. Temporary recording methods such as memos should be prohibited.	Applicable procedures are specified.		
d) Correction of records				
1. Are records corrected in such a way that the original description before correction is legible?	PIC/S 8.7, WHO 3 The PIC/S Guidance states that "corrections should be made by drawing a single line [through the part to be deleted or changed]." The original data must be legible to maintain traceability.	Changed parts are deleted with a single line in accordance with the procedure, so that the original descriptions can be read.		
2. Is the reason for correction specified? In the case of a critical change, is the appropriateness of the correction confirmed?	PIC/S 8.7 Corrections to records should be made in a manner that ensures full traceability.	The reason for the correction is specified. The validity of the reason for correction is confirmed during the review of records.		
3. Does the person who makes corrections sign and date them in the record?	PIC/S 8.7, WHO Appendix1 • All key entries must be signed and dated. • The use of personal seals is not recommended. • Digital signature images are not acceptable for signing documents.	The person who makes corrections signs and dates them in the records.		
4. Are records corrected indelible ink? Do the records smudge or fade during storage?	PIC/S 8.7 • Pencil records must not be overwritten with a pen.	The procedures specify what writing implements can be used.		
e) Verification of manufacturing records				
1. Is the designated person in charge (e.g., process control manager) present at the time the operation is performed to confirm the manufacturing record for critical process?	PIC/S 8.8	The process control manager is present and confirms the record.		

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2. Are manufacturing records for critical processes reviewed by authorized personnel in the manufacturing unit before they are sent to the quality unit?	PIC/S 8.8	They are reviewed by the Manufacturing Unit Manager before being sent to the quality unit.		
3. Are manufacturing records for critical processes reviewed and approved by the quality assurance unit (e.g., an authorized person/a person duly qualified) before the manufactured batches are released/distributed?	PIC/S 8.8	They are reviewed and approved by Quality Assurance prior to batch release.		
4. Are manufacturing records on matters other than critical processes usually reviewed by the person in charge of manufacture in accordance with the approved procedure?	PIC/S 8.8	Manufacturing records are reviewed by manufacturing personnel.		
5. Is confirmation for 1 to 4 above performed after the manufacturing operations and recordkeeping have been performed? Are the records signed and dated by the person who performed the confirmation?	PIC/S 8.8, WHO Appendix1 • All key entries must be signed and dated. • The use of personal seals is not recommended. • Digital signature images are not acceptable for signing documents.	Confirmation is performed after manufacturing operations and recordkeeping. Registered signatures are used.		
6. Are the latest versions of written procedures specifying how to confirm/review records kept on the place of operation?	PIC/S 8.8	Although there is a written procedure specifying confirmation/review of records, it is not kept on the place of operation.		
7. Is it confirmed that all fields have been completed correctly using the latest approved record form, and that the data have been compared with the acceptance criteria?	PIC/S 8.8	It is confirmed, but the content of confirmation is not specified.		
8. Does the review of records confirm the appropriateness of entry and correction of records?	PIC/S 8.8	It is confirmed, but the content of confirmation is not specified.		
9. Does the review of records confirm that the	PIC/S 8.8	It is confirmed, but the content of		

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calculation formulae used and the data transferred for calculation are accurate?		confirmation is not specified.		
f) Maintenance and control of records				
1. Have procedures been established for storage and retrieval of records?	PIC/S 8.9	Applicable procedures are specified.		
2. Are records stored so that they can be read out easily? (e.g., stored in sequence or with creation of a master list to control the retrieval status)	PIC/S 8.9	They are controlled by means of a master list.		
3. Are all records stored in a specified location?	PIC/S 8.9	Records are stored in the locations specified by written procedures.		
4. Does the procedure specify that all GMP records are retained for the periods that meet GMP requirements?	PIC/S 8.9, MHRA 6.17	The retention period is not specified in the SOP.		
5. Is there a system to protect records from fire, insects, rodents, liquids, humidity, etc. (e.g. pest control, fire extinguishing equipment, etc.)? Is there a system to prevent unauthorized access?	PIC/S 8.9, MHRA 6.17 Records must be protected from falsification, exchange, and damage/destruction. If sprinklers are used, consider protecting documents from water.	A fireproof cabinet is used. An initial fire extinguishing system is used. The library is locked and only designated persons can access it.		
6. Do you have an established procedure for recovery of records in a disaster?	PIC/S 8.9	A procedure has been established for recovery of records in a disaster.		
g) Direct print-out from electronic system				
1. For paper records created by a very simple electronic system (simple processing devices that do not store data such as a balance or pH meter), does the person who creates the record sign and date the original record and attach the	PIC/S 8.10, MHRA 6.2 Paper records generated by very simple electronic systems, e.g. balances, pH meters or simple processing equipment	The original chart from the balance or pH meter is attached to the manufacturing (or testing) record, and the signature and date are entered. A tally signature method is		

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original record to the manufacturing/test record?	which do not store data provide limited opportunity to influence the presentation of data by (re-)processing, changing of electronic date/time stamps..	adopted at the time of attachment so that it can be reproduced in case of peeling after application. If the chart is printed on heat-sensitive paper, a copy of the signed and dated chart is made and kept in case the part with characters is lost (fades) over time.		
h) True copies				
1. Are records controlled to ensure, during their life cycle, that the data received from a contractor are maintained as “true copies”, or, where the requirements of a “true copy” are not met, used as a “summary report”.	PIC/S 8.11 Summary report: E.g., a summary of complex analytical data	Control procedures for "true copy" or "summary report" have been established.		
2. When raw data generated by electronic means are stored as static records (paper or electronic format (e.g. PDF file)), is all information displayed to maintain the integrity of original data, such as setting conditions?	PIC/S 8.11 • - The data retention process must be shown to include verified copies of all 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. • - Many electronic records are important to retain in their dynamic (electronic)	Electronic raw data are not stored as static records.		

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	format, to enable interaction with the data. -Creating pdf versions of electronic data should be discouraged, as this is equivalent to a printout from the electronic system, which risks loss of metadata.			
3. Has a procedure for issuing paper "true copies" s been established?	PIC/S 8.11 The procedure should include the following contents. - Photocopy the original document ensuring that no information from the original copy is lost; - Verify the authenticity of the copied document and sign and date the new hardcopy as a “true copy”; - After this, the “True Copy” may be sent to the intended recipient. After verifying creation of a ‘true copy’, it may be possible to permit destruction of the original documents such as heat-sensitive papers. There should be a documented approval process for this destruction.	The procedure for issuing "true copies" has been established.		
4. Are scanned/saved records protected in the	PIC/S 8.11	No special tamper-evident measures		

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creation of "true copies"?	Data integrity cannot be ensured if scanned images are altered.	have been taken for scanned images.		
5. Has a procedure for issuing "true copies" of electronic documents been established? Does the procedure specify that the true copy should be created by electronic means (electronic file copy), including all required meta data?	PIC/S 8.11 Creating pdf versions of electronic data should be discouraged, as this is equivalent to a printout from the electronic system, which risks loss of metadata	Electronic raw data are not stored as static records.		
6. Is a distribution list of "true copies" (paper documents/electronic documents) controlled?	PIC/S 8.11	A distribution list of "true copies" is controlled for both paper and electronic documents.		
7. Are received "true copies" (paper or electronic forms (e.g. PDF files)) controlled in accordance with procedures approved by QA? Does the document specify that it is a true copy and not an original record?	PIC/S 8.11 The "true copy" received should be reviewed and retained in accordance with the appropriate document control process.	It is controlled in accordance with the procedure approved by QA. It is clearly stated in the document that it is a "true copy," and this is specified in the procedure.		
8. Have quality agreements been established between the contract giver and the contract acceptor that address the responsibilities for creation and transfer of "true copies" and control of data integrity?	PIC/S 8.11 The contract giver and receiver should audit the system for the issuance and control of "true copies" to ensure that the process is robust and meets the principles of data integrity.	There is an agreement but it does not refer to the responsibility for creation and transfer of "true copies" and control of data integrity.		
i) Document storage				
1. Does the retention period of each type of records satisfy the period specified in the GMP requirements (at least)? (Consider local or national regulations that specify longer retention periods.)	PIC/S 8.13	The retention periods specified in the procedure satisfy the period required by GMP.		
2. Is risk assessment performed if documents are stored using external storage services? Has a quality agreement been concluded? Are storage areas audited?	PIC/S 8.13 It should be demonstrated that the retention system/facility/service is adequate and that residual risks are known.	The outside storage service selected after risk assessment is used. There is an agreement, but no audit is performed.		

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3. Are the identification of the storage cabinet, list of records for each storage cabinet, storage period, storage place, etc. specified in the procedure for record storage?	PIC/S 8.13 Archived records should be retrievable.	The procedure for record storage is specified.		
4. Is access to archived documents limited to authorized personnel?	PIC/S 8.13 Integrity of archived records should be ensured.	Access to archived documents is restricted.		
5. Are all paper documents stored under the following conditions? - Secure locations to prevent damage or loss - It is easy retrievable. - Records are likely durable for their archived life.	PIC/S 8.13	Risk assessment is performed and records are controlled under such conditions.		
j) Disposal of original records				
1. Is there an established procedure for disposal of original records past their retention period?	PIC/S 8.14 Procedures should be in place to ensure that current records are not destroyed by accident and historical records are not mixed with existing records..	The procedure for disposal has been specified.		
2. Are destruction records prepared in accordance with the disposal procedure?	PIC/S 8.14 A record/register should be available to demonstrate appropriate and timely destruction of retired records.	Destruction records are prepared.		
3. Are measures in place to reduce the risk of deleting the wrong documents?	PIC/S 8.14 For example, the access rights allowing deletion of records should be limited to a few persons.	The destruction rights are not restricted.		The destruction procedure will be revised to specify the person responsible for destruction and his/her

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				authority.

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3. Operating procedure for electronic media				
a) Validation				
1. Has a master list of computerized systems used at the manufacturing site been prepared?	PIC/S 9.2 If it not in place, there is a risk of overlooking the criticality of the system and creating vulnerabilities within the data lifecycle.	The computerized system is controlled by a master list.		N/A
2. Are validation documents in place for each system?	PIC/S 9.2, MHRA 6.19 Unvalidated systems may present a significant vulnerability regarding data integrity as user access and system configuration may allow data amendment Computerized system validation shall be	Validation according to category is performed in accordance with the Guideline on Proper Management of Computerized Systems. Some of it is planned to be implemented retrospectively.		We will perform the validation retrospectively and review and revise the validation documents.

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	conducted in accordance with PIC/S Good Practices for Computerized Systems in Regulated "GxP" Environments (PI 011).			
3. Is a validation summary report prepared for each computerized system and approved by the quality unit?	PIC/S 9.2 A Validation Summary Report for each computerized system written by the Quality Unit should be in place and state at least the following items: - Critical system configuration details and controls for restricting access to configuration and any changes (change control). - A list of currently approved users, specifying the users name and surname, and any specific usernames. - Identity and permitted activities (privileges) for each user of the system. - Identity and role of the System Administrator. - Frequency of review of audit trails and system logs. - Procedures for: o how a new system user is created; o the process for the modification	No validation summary report has been prepared.		

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	(change of privileges) for an existing user; o the process of deleting users o arrangements for backup and frequency; o A description of the recovery process in case of an incident; o Process and responsibilities for data archiving; o Approved locations for data storage. - It should be clearly stated that the original data are retained with relevant metadata in a form that permits the reconstruction of the manufacturing process or the analytical activity.			
4. Does the computerized system validation master plan contain specific provisions for data integrity?	PIC/S 9.2	The validation master plan does not contain any specific provisions for data integrity.		
5. Is the computerized system periodically re-evaluated at a frequency based on the risk assessment and is the result documented?	PIC/S 9.2 Computerized systems should be evaluated periodically in order to confirm they maintain the validated status and are GMP compliant.	Periodic re-evaluation is done but is not comprehensive.		We will draw up a plan and perform re-evaluation at a fixed interval.
b) Data transfer between systems				
1. Are interfaces (standards and specifications for	PIC/S 9.2, MHRA 6.8	Interfaces are also evaluated.		

Item	Relevant Guidance / Points to Consider	Assessment results (example)	Degree of conformance	Action
inter-device connections) evaluated during validation to ensure accurate and complete transfer of data?				
2. Is it confirmed that archived (stored) data can be read with the new software at the time of software update?	PIC/S 9.2, MHRA 6.17.1 It is important to read the original format throughout the data lifecycle, and both the readability of the data and access to old software must be maintained.	No special verification is performed at the time of software update.		
3. Are there any provisions to maintain a PC installed with the old software in case the data stored cannot be read with the new software? Alternatively, are hard copies (installation CDs) available?	PIC/S 9.2 It is important to read the original format throughout the data lifecycle, and both the readability of the data and access to old software must be maintained.	CDs for old software installation are maintained and available for use.		
c) Security				
1. Have both physical and electronic control methods for user access to computerized systems been established, and are they executed as described in 2 to 9 below?	PIC/S 9.3, MHRA 6.16			
2. Have individual login IDs and passwords been set?	PIC/S 9.3 Shared login credentials do not allow for traceability to the individual who performed the activity. For this reason, shared passwords, even for reasons of financial savings, must be prohibited.	Individual login IDs and passwords have been set.		
3. Are data input and changes to computer records made only by authorized personnel?	PIC/S 9.3	Authorizations have not been set.		
4. Has a list of authorized persons and their access	PIC/S 9.3	No list has been created, since		

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rights been prepared for each electronic system used?		authorizations have not been set.		
5. Do you restrict general users' access to critical software functions such as system clocks and file deletion functions?	PIC/S 9.3	Access is not restricted for general users.		
6. Is the system administrator uninvolved in manufacturing/testing operations, normally independent from the users engaged in the manufacturing/testing operations, and uninvolved or disinterested in the data created or available in the electronic system?	PIC/S 9.3	An independent person is appointed as the system administrator. The system administrator is uninvolved in the results presented, and there is no conflict of interest.		
7. Is the system designed to prevent accidental change in or deliberate manipulation of the computerized system? For example, are computerized systems evaluated for physical security of hardware, vulnerabilities of networked systems from local and external attack, and remote updates of networked systems by the vendor?	PIC/S 9.3 Unauthorized changes to validated settings may ultimately affect data integrity.	Physical security has not been evaluated. To address vulnerabilities of networked systems, measures are taken by installing anti-virus software.		
8. Are the electronic signatures used in place of handwritten signatures appropriately validated, issued and controlled, and can individuals be identified?	PIC/S 9.3, MHRA 6.14, FDA 11 The authenticity and traceability of the person electronically signing the record must be ensured.	The registered electronic signatures are used.		
d) Audit trail				
1. Does the electronic system have an audit trail function?	PIC/S 9.4, MHRA 6.13 It is necessary to be able to properly to capture general system events as well as any activities relating to the acquisition, deletion, overwriting of and changes to data for audit purposes. Users should not be able to amend or switch	Some devices have an audit trail function.		

Item	Relevant Guidance / Points to Consider	Assessment results (example)	Degree of conformance	Action
	off the audit trail.			
2. Is the audit trail function verified during validation for the electronic system?	PIC/S 9.4			
3. For simple systems with no audit trail, are alternative arrangements to verify the veracity of data implemented, such as administrative procedures, secondary checks and controls?	PIC/S 9.4, MHRA 6.13	Data accuracy is ensured by secondary checks.		
4. Are the audit trails linked with each batch reviewed independently (by a person other than personnel who perform operations or review records) at appropriate timing before batch release, together with other records related to the batch?	PIC/S 9.4, MHRA 6.13	Audit trails related to manufacturing of each batch are checked, but the timing is not before batch release.		
5. Does the quality unit establish and implement a program and schedule for routine review of audit trails based on the criticality of audit trails and system's complexity?	PIC/S 9.4, MHRA 6.13 Failure to properly review the audit trail may result in erroneous acceptance of manipulated or erroneous data by the quality unit or authorized personnel.	Routine reviews are performed according to the schedule.		
e) Data collection/entry				
1. Is the system designed to ensure correct collection of data regardless of whether the collection method is manual or automated?	PIC/S 9.5	It is confirmed by system validation.		
2. For 1 above, are (1) to (4) below performed in the case of manual input?	PIC/S 9.5 Ensure that manual entries made into computerized systems are subject to an appropriate secondary check.			
(1) Is the entry of data only made by authorized	PIC/S 9.5	Recording in the system is limited to authorized persons.		

Item	Relevant Guidance / Points to Consider	Assessment results (example)	Degree of conformance	Action
individuals, and does the system record details of the entry, the individual making the entry and the date when the entry was made?				
(2) Can data be entered only in a specified format? Did validation activities verify that invalid data formats are not accepted by the system?	PIC/S 9.5	It has been verified that invalid forms are not accepted.		
(3) Are manual data entries verified by a secondary operator or a validated computer	PIC/S 9.5	Manual data entry is verified by a secondary operator.		
(4) Are changes to entries captured in the audit trails and reviewed by an appropriately authorized and independent person?	PIC/S 9.5	The audit trail is reviewed by the manager of each department.		
3. For 1 above, are (1) to (3) below performed in the case of manual input?	PIC/S 9.5 For systems using automated data collection methods, validation records should be reviewed.			
(1) Are the interfaces between the originating system, data acquisition, and recording system (standards and specifications for connection between devices) validated to ensure the accuracy of data?	PIC/S 9.5	Intersystem interfaces are also validated.		
(2) Is data captured by the system saved into memory in a format that is not vulnerable to manipulation, loss or change?	PIC/S 9.5	It is stored on the hard disk in the system. Changes can be made with access.		

Item	Relevant Guidance / Points to Consider	Assessment results (example)	Degree of conformance	Action
(3) Does the system software incorporate validated checks to ensure the completeness of data acquired, as well as any metadata associated with the data?	PIC/S 9.5	The system has a checking function, but it has not been validated.		
4. Are changes that need to be made in data permitted and controlled in accordance with approved procedures?	PIC/S 9.5 Any and all changes and modifications to original data must be fully documented and should be reviewed and approved by at least one appropriately trained and qualified individual.	Data are changed in accordance with the change procedure.		
f) Review of electronic data				
1. Do you review electronic data related to GMP prepared by the computerized system?	PIC/S 9.6 The frequency, roles and responsibilities of audit trails review should be based on a risk assessment	Electronic GMP data are also subject to review.		
2. Have you established written procedures that describe the audit trail review method in detail?	PIC/S 9.6, MHRA 6.15 A procedure should describe the actions to be taken if a review of audit trails identifies serious issues that can impact the quality of the medicinal products.	Written procedures that describe the audit trail review method in detail have been established.		
3. Does the procedure include a meta data review policy?	WHO Appendix1	Policy on meta data review is not described.		
4. Have the personnel performing the review received sufficient and appropriate training on the review method and the software system containing the data to be reviewed?	WHO Appendix1	They have received training on the review method and target software system.		

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5. Does the quality unit review samples from the audit trail in self-inspections?	PIC/S 9.6, WHO Appendix1, FDA 8	Audit trail records are not subject to self-inspection.		
6. Are audit trail review records stored with other GMP related records?	PIC/S 9.6, MHRA 6.15	Records of audit trail review are retained with other records.		
g) Storage, archiving and disposal of electronic data				
1. Are data storage, backup and archive systems designed to collect all data, including meta data?	PIC/S 9.7	In some systems, collection of meta data is not considered.		
2. Is there documented evidence showing that the data storage, backup and archive systems have been validated and certified?	PIC/S 9.7	A validation report has been prepared for each computerized system.		
3. If data are backed up or copied, are the backups and copies controlled at the same appropriate level to prevent unauthorized access, data change or deletion, and falsification?	PIC/S 9.7, MHRA 6.17	Backup is not controlled to protect against unauthorized access.		
4. Are routine backup copies stored remotely (in physically remote locations) in the event of disasters?	PIC/S 9.7	Backup copies are stored in the same location as the equipment.		
5. Are backup copies controlled so as to make them accessible and readable and to maintain the integrity throughout the retention period?	PIC/S 9.7 There is a risk with archived data that access and readability of the data may be lost due to software application updates or superseded equipment.	For backup copies, no control method for maintaining integrity is specified.		
6. Does the record retention procedure specify the retention of meta data?	PIC/S 9.7 The record retention procedures must include provisions for retaining the metadata. This allows for future queries or	Storage of meta data is specified.		

Item	Relevant Guidance / Points to Consider	Assessment results (example)	Degree of conformance	Action
	investigations to reconstruct the activities that occurred related to a batch.			
7. Are data archived periodically according to written procedures?	PIC/S 9.7	Data are archived periodically according to written procedures.		
8. Are records indexed?	WHO Appendix1 Immediate readouts should be available.	Records are indexed and stored.		
9. Are archive copies stored in a separate location from where backup data are stored?	PIC/S 9.7	Archive copies are stored in a separate location from backup data.		
10. Are archived data controlled so as to make them accessible and readable and to maintain the integrity throughout the retention period?	PIC/S 9.7 There is a risk with archived data that access and readability of the data may be lost due to software application updates or superseded equipment.	There are provisions to maintain the software before updating.		
11. Are procedures in place for restoring archived data where an investigation is required? Is the procedure for restoring archived data periodically tested?	PIC/S 9.7, MHRA 6.17.2	There is no procedure for restoring the archive at the site. So it is not checked periodically.		We will create a procedure for periodically restoring archived data and distribute it to the site.
12. Can the data (including meta data) prepared by the computerized system be printed out as easy-to-read and meaningful records?	PIC/S 9.7	Printed data, including meta data, from some devices cannot be easily understood.		
13. If a record is changed, can a change record be printed indicating when and how the original data were changed?	PIC/S 9.7	It has been confirmed that change records are also printed.		
14. Is there a procedure for disposal of electronically stored data?	PIC/S 9.7 Check that the procedures clearly stipulate the conditions for the disposal of data, and	No procedure for disposing of electronic data is specified.		A procedure for disposing of electronic data will be prepared.

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	that care is taken to avoid the inadvertent disposal of required data during its lifecycle.			

Glossary

Data

Facts, figures and statistics collected together for reference or analysis.

Data governance

The sum total of arrangements to ensure that data, irrespective of the format in which it is generated, is recorded, processed, retained and used to ensure a complete, consistent and accurate record throughout the data lifecycle.

Data Integrity

The extent to which all data are complete, consistent and accurate throughout the data lifecycle

Data Lifecycle

All phases in the life of the data (including raw data) from initial generation and recording through processing (including transformation or migration), use, data retention, archive / retrieval and destruction.

True copies

An accurate and complete copy of the original record that has been verified to have the same information as the original record

Meta data

Data that describe the characteristics of other data and give context and meaning

Audit trail

Records of input, change, and deletion of records to ensure the authenticity of electromagnetic records. Critical GMP information (e.g., change or deletion of GMP-related data) and meta data that make it possible to reconstruct GMP activities.

Raw data

Records including the source data used to obtain the final results and the process of obtaining the same. It is necessary to be able to verify that the final result has been issued correctly.

Backup

A copy of current (editable) data, meta data and system configuration settings (e.g. variable settings which relate to an analytical run) maintained for the purpose of disaster recovery.

Archiving

Long-term, permanent retention of completed data and relevant meta data in the final form for reconstruction of processes and operations

Restoration

Restoring, by re-loading, the programs, parameters, data etc. backed-up in appropriate media beforehand, to the state at the time of system back-up.

Guidance

- **DRAFT PIC/S GUIDANCE: GOOD PRACTICES FOR DATA MANAGEMENT AND INTEGRITY IN REGULATED GMP/GDP ENVIRONMENTS (PI041-1(Draft 2) 10 August 2016):**
  A guidance prepared to assist inspectors; which describes specific items and potential risks to be confirmed by inspectors during inspections.
- **MHRA 'GXP' Data Integrity Guidance and Definitions (March 2018):**
  Consists of definitions of terms and explanations (expectations/guidance).
- **WHO Annex 5: Guidance on good data and record management practices (WHO Technical Report Series No.996, 2016):**
  Describes what each requirement means and provides expectations.
- **FDA: Data Integrity and Compliance With CGMP (Guidance for Industry) (DRAFT GUIDANCE, April 2016):**
  Q&A prepared for the industry in response to the fact that quite a few violations related to data integrity had been detected during inspections by the FDA in recent years, leading to regulatory actions such as WL and Import Alert. There are 18 questions and answers.
- **EMA: Questions and answers: Good manufacturing practice: DATA INTEGRITY (August 2016):**
  A guidance provided by the authorities to minimize risks through appropriate data management by the manufacturer. There are 23 questions and answers.