GLP ASSESSMENT WORKSHEET

Self-assessment

This self-assessment worksheet may be used in preparation for an assessment. It does not need to be returned to NATA.

1. Test Facility Organisation and Personnel

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
1.1	**TFM Responsibilities**	
1.1.1	Overall responsibility for compliance with Principles.	
1.1.2a)	Statement identifying TFM: - documented distribution of responsibilities where TFM more than one person; - delegation of any TFM responsibilities.	
1.1.2b)	Sufficient resources (personnel, facilities, equipment, materials); - including resources to ensure data governance (Doc 22.)	
1.1.2c)	Records of qualifications, experience, training, Job Descriptions (JDs) etc. - records reflecting progression of training for SD (Doc 8).	
1.1.2d)	Ensure staff understand functions and provide training where necessary - including training on data integrity (Doc 22).	
1.1.2e)	SOP approval and availability.	
1.1.2f)	Appoint QA programme. TFM verification of QA Programme (Doc 23, 7.6 12.2) - internal procedure required, cannot rely solely on external or regulatory audits. TFM responsible for ensuring facility and process based audit findings are addressed (Doc 23, 7.8.3). TFM to inform SDs of facility-based inspection outcomes so SD can assess impact on their studies.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
1.1.2g)	Appointment of SD. Replacement of SD/PI in accordance with established procedures and documented (Doc 8). If multiple SD or PI policy for selection and appointment (Doc 8).	
1.1.2h)	Appointment of PI.	
1.1.2i)	Ensure SP approved by SD.	
1.1.2j)	Ensure Study Plan (SP) available to QA.	
1.1.2k)	Historical SOPs.	
1.1.2l)	Designate Archivist.	
1.1.2m)	Master schedule - including type of study, SD, critical dates, study number, test system, test item, and/ or for multi-site studies, PI, test site, test site identifier (GLP GRC).	
1.1.2n)	Supplies.	
1.1.2o)	Multi-site studies: - documented mechanism for communication (Doc 13); - TFM approval of test sites (Doc 13); - documented rationale for use of non GLP test sites (Doc 13).	
1.1.2p)	Characterisation of Test Item (TI) and Reference Item (RI).	
1.1.2q)	Computer systems validated, including functionalities associated with data integrity (Doc 22).	
1.2	**SD Responsibilities**	
1.2.1	Single point of control. Overall responsibility for study and its report.	
1.2.2a)	Approve SP and amendments.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
1.2.2b)	Provide QA with SP and amendments. Respond to inspection reports promptly including correction (Doc 23). Assess impact of facility and process-based audit findings on their studies (Doc 23).	
1.2.2c)	Ensure SP, amendments & SOPs are available to study personnel.	
1.2.2d)	For multi-site, ensure SP and final report (FR) identifies PI, TF and TS.	
1.2.2e)	Assess impact of SP deviations. Acknowledge SOP deviations. Take corrective action where necessary.	
1.2.2f)	Ensure raw data is fully documented.	
1.2.2g)	Ensure computerised systems to be used on study are validated.	
1.2.2h)	Sign and date report.	
1.2.2i)	Ensure archiving on study completion.	
1.3	**PI Responsibilities**	
1.3	Ensure that delegated phases are conducted in accordance with GLP.	
Doc 13	Documented agreement that the PI will conduct their phase in accordance with the SP and GLP (Doc 13).	
1.4	**Study Personnel Responsibilities**	
1.4.1	Knowledge of Principles as applicable to involvement in study.	
1.4.2	Access to SP and SOPs as applicable to involvement in study. Document and communicate deviations to SD/PI.	
1.4.3	Prompt and accurate recording of raw data.	
1.4.4	OH&S.	

2. Quality Assurance Program

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
2.1	**General**	
2.1.1	Documented QA program. Risk based QA program (refer to Doc 23, clause 7.2): - risk assessment approved by TFM; - risk mitigation and detection; - periodic review of risk assessment. Information from the risk assessment used to dictate and justify the frequency and scope of QA inspections for each activity.	
2.1.2	QA personnel designated by and directly responsible to TFM. Familiar with test procedures (Doc 23), training and competence of QA staff (Doc 23).	
2.1.3	Independent . If QA personnel assume additional responsibilities other than the QAP these activities should be inspected by appropriately trained, independent person appointed by TFM not involved in these activities and reporting directly to TFM (See Doc 23, 11.1 - 11.8).	
2.2	**QA Responsibilities**	
2.2.1a)	Access to SPs, SOPs and Master Schedule (MS).	
2.2.1b)	Verify SP (documented) as well as any amendments (Doc 23, 7.3).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
2.2.1c)	Conduct inspections: *Study Based audits* (Doc 23, 7.4.1) - inspection of *experimental phases* based on risk; - critical phase inspections - the phase that must be correctly executed to ensure study validity should be inspected for each study (unless justified by risk assessment; - novel or infrequent activities inspected for each study. *Facility based audits* (Doc 23, 7.5.2)	
	- scheduling / frequency of inspections risk based; - verification of QA programme (Doc 23, 7.6). *Process based audits* (Doc 23, 7.5.1) - all experimental phases inspected within a defined period - See Doc 23, 7.4.1; - justification for the frequency of inspection of each process documented. QA physically onsite for inspections (remote alternative for exceptional circumstances only) - use of remote observation methods fully risk assessed (Doc 23).	
2.2.1d)	Inspect final report. Process to ensure QA is aware of all additions or changes to report after the inspection (Doc 23, 7.4.2).	
2.2.1e)	Report inspection results to SD/PI, TSM/TFM: - facility based audits reported to TFM; - study based audits reported to TFM/SD; - process based audits reported to TFM and all applicable SDs; - reporting to TFM where more than one person as TFM.	
2.2.1e)	For multi-site, TSQA report inspection results to SD, TFM and Lead QA. (Doc 23,8).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
2.2.1e)	Records of inspections: - level of detail in inspection reports to provide for an accurate record of the inspection performed (Doc 23, 7.8.1); - QA to verify all outcomes of inspections are addressed (by TFM or SD as appropriate) (Doc 23, 7.8.3).	
2.2.1f)	QA statement confirming final report reflects raw data: - date of inspection and date reported to TFM/SD/PI; - QA statement to demonstrate adequate QA coverage, taking into account process and facility based inspections (Doc 23, 7.9); - reference to TS QA statement (Doc 23 8.44).	
Doc 17	QA involvement throughout the system life cycle (Ref 29, 17) and QA inspections throughout the life cycle including periodic evaluation.	
Doc 22	Surveillance activities of critical transactions to be considered as part of the QA programme (Ref 6.12).	

3. Facilities

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
3.1	**General**	
3.1.1	Suitable size, construction and location: - floor plans (Doc 15), GLP areas identified.	
3.1.2	Separation of different activities to assure proper conduct of study.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
3.2	**Test System Facilities**	
3.2.1	Isolation of TS, and isolation of studies involving biohazardous substances.	
3.2.2	Rooms/areas for diagnosis, treatment and control of diseases.	
3.2.3	Storage rooms/areas, separate to that used to house test system.	
3.3	**Facilities for Handling Test and Reference Items**	
3.3.1	Separate rooms/areas for receipt and storage of TI/RI, and preparation of TI. Handling and storage facilities designed to ensure integrity of TI (Doc 19, Ref 29).	
3.3.2	TI storage area separate to that containing TS. TIs received, stored and prepared in separate rooms / areas to the Test System (Doc 19, Ref 30 & 31).	
3.4	Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.	
3.5	Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.	

4. Apparatus, Materials, Reagents

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.1	Suitably located and of appropriate design and capacity.	
4.2	Periodically inspected, cleaned, maintained and calibrated, with records retained. Calibration traceable to SI units.	
4.3	Apparatus/materials are not to interfere with TS.	
4.4	Chemicals, reagents and solutions labelled to indicate identity, concentration (if appropriate), expiry date and storage instructions. Information on source, preparation date and stability to be available.	
	Equipment inventory.	
Doc 17	**Computerised Systems.**	
Doc 17	Risk management to be applied throughout life cycle and documented (Ref 13 - 15).	
Doc 17	<u>Responsibilities</u> - defined tasks and responsibilities throughout life cycle (Ref 16 - 30); - conflicts of interest (Ref 27, 98) - IT personnel reporting line to TFM (Ref 40) (e.g., org chart); - IT qualifications and training records (Ref 17, 19).	
Doc 17	<u>Inventory</u> - includes all systems (Ref 33); - includes functionality, validation status, make, model or version, system owner (Ref 33); - traceable from the study plan (or relevant SOP) to the inventory (Ref 33).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
Doc 17	Validation (Ref 51 - 69)	
	User Requirement Specifications: - documented for all systems regardless of complexity (Ref 57); - URS to cover data integrity requirements. Acceptance Testing (IQ/OQ/PQ): - predefined requirements (test scripts and expected outcome) (Ref 63); - (documented evidence of all testing procedures, test data, test results) (Ref 52 & 63); - documentation to include test records, (Ref 63), formal summary of testing (Ref 52), formal record of acceptance (Ref 52); - test documentation traceable to the URS (Ref 57).	
Doc 17	Change control / configuration management (Ref 84 - 88) - documentation of changes and evaluation of impact; - approval / authorisation of changes; - may require partial or full re-validation; - change control for modifications implemented by routine automation (e.g. operating system patches) (Ref 88).	
Doc 17	Suppliers (Ref 34 - 40) - includes vendor, third parties, service providers, hosted services and internal IT departments (Ref 34); - agreements outlining responsibilities and data ownership (Ref 34); - TFM evaluation of vendor quality system acceptable by TFM (Ref 59); - commercial off-the shelf software, User Requirement Specifications; - defined, and validation/verification depending on risk and complexity of system (Ref 41 - 43).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
Doc 17	<u>Cloud Based systems (Section 5.3)</u> - detailed risk assessments for each Cloud based system; - provider assessments for each cloud service, including audits when relevant, prior to use and periodic review; - clearly defined service level agreements with providers directly related to the operational activities and services	
Doc 17	<u>Data (Ref 73 - 78)</u> - raw data to be identified for each system (Ref 76.a); - security (physical and electronic) of stored data (Ref 74); - stored data verified for restorability, accessibility, readability (Ref 74); - long term storage, continued access (Ref 75); - back-up (validated) (Ref 77); - exchange of data (Ref 70); - data migration and transfer (Ref 66 - 69); - where electronic equipment stores data which maybe overwritten due to size must try to extract and control the data and metadata as electronic data (Doc 22, Ref 6.2).	
Doc 17	<u>Physical, logical security and data integrity</u> (Ref 91 - 98).	
	<u>User access rights:</u> - access controls applied at both the operating system and application levels (Doc 22); - records of the creation, change and cancellation of access rights (Ref 92); - periodic review of authorisation records (Ref 92); - where systems support only a single user login or limited numbers of user logins, equivalent control may be provided by alternate means (Doc 22, Ref 8.2).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	Administrator rights: - administrator rights should not be given to a person with a potential interest in the data (Ref 98); - unique credentials for system administrator allowing actions to be attributed to a specific individual (Doc 22, ref 8.2); - control over introduction of software / data (Ref 95).	
Doc 17	Printouts (Ref 79) - regulatory record: need to define when both electronic and hard copy raw data are maintained (Ref 107); - if printouts (e.g. of chromatograms) used as "regulatory record" all electronic data (metadata, derived data) must also be printed, or alternatively, verifiable on screen in human readable format and retained; - any printouts should comprise all associated available metadata and should keep the link that binds them to the raw data. For example, if the associated metadata are printed in another page from the raw data (Doc 22, Ref 6.14).	
Doc 17	Electronic signatures (Ref 102 - 107) - system validated (Ref 103); - traceable to individual by name and their role in the study (Ref 102, 104); - password re-entry required (Ref 105); - include date, time, identification of signatory and meaning of the signature (Ref 102); - changes to electronically signed data must not change the originally applied eSig or its metadata (Ref 106); - authenticity verified (Ref 1.5).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
Doc 17	Audit trails (Ref 80 - 83) - enabled, in human readable (Ref 80); - personnel with a direct interest in the data must not be able to amend or switch off the audit trail (Ref 81, see also Doc 22); - review of audit trail (Ref 82) as determined by risk assessment identifying the criticality of the data subject and the criticality of transactions identified through the data flow (Doc 22 Ref 7.2).	
Doc 17	Electronic archiving (Ref 109 - 118) - archiving process to be validated (Ref 113); - readability, integrity and retrievability throughout retention period (Ref 114); - information that is captured in a dynamic state to remain available in that state (Doc 22); - migration or conversion of data to different format to include raw data, meta data, audit trails, etc. (Ref 114); - where migration with full original record functionality is not possible, the migration file format should be selected taking into account the balance of risk betweenlong-term accessibility versus the possibility of reduced dynamic data functionality. It is recognised that the need to maintain accessibility may require migration to a file format that loses some attributes and/or dynamic data functionality. It is the TFM's responsibility to assess the impact of such lossesand maintain the link between the readable audit trail or electronic signatures and the audited data to an acceptable level. (Doc 22).	
	Disaster recovery (Ref 119 - 122) - disaster recovery provisions tested and validated; - availability of software necessary for recovery; - may necessitate re-validation; - verification of each back-up to ensure it has functioned correctly (Doc 22).	

5. Test Systems

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.1	**Physical/Chemical**	
5.1.1	Suitably located, appropriate design and adequate capacity.	
5.1.2	Integrity of system to be ensured.	
5.2	**Biological**	
5.2.1	Conditions for storage, housing, handling and care: - separation; - temperature parameters; - humidity parameters; - light/dark cycle (verified).	
5.2.2	Isolated on arrival until health status evaluated. At start of study, test systems to be free from disease or condition that may interfere with study. Test systems becoming diseased or injured during course of study to be isolated. Records of diagnosis and treatment of any disease. Withholding period if used on previous studies.	
5.2.3	Records of source, date of arrival, arrival conditions.	
5.2.4	Acclimatised prior to TI administration.	
5.2.5	ID of test system. Housing identified. ID of test systems if removed from housing containers. Test systems as stated in SP.	
5.2.6	Any material in contact with test system free from contaminants at levels that would interfere with the study (Testing of feed, water, bedding). Husbandry - cleaning of housing, changing of bedding. Pest control agents documented.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.2.7	Test systems in field sites: - location maps; - ID of plots; - potential for contamination of test site; - details of previous sprayings.	

6. Test and Reference Items

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.1	**Receipt, Handling, Sampling and Storage**	
6.1.1	Records of characterisation, receipt and quantities received and used. Transport conditions established in advance and monitored if appropriate (Doc 19 Ref 21). Documented assessment of integrity on arrival (including review of transport conditions, physical condition of TI and container) (Doc 19, Ref 22). Identity of TI should be verified upon receipt. Information on the container labelling versus CoA (Doc 19, Ref 24). Reconciliation between amounts received, amount used and amount remaining, with any discrepancies investigated and justified (Doc 19, Ref 32).	
6.1.2	Handling, sampling and storage procedures to assure homogeneity and stability and to minimise potential for contamination or mix up.	
6.1.3	Labelling of storage containers to carry unique identification information, expiry date and specific storage instructions (Doc 19, Ref 26).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2	**Characterisation**	
6.2.1	TI and RI must be characterized Docunented check of physical characteristics agains CoA on receipt (or first opening) (Doc 19, Ref 25).	
6.2.2	The identity, including batch number, purity, composition, concentrations, or other characteristics required to define each batch of TI/RI must be known. CoA must contain details of identity, biological parameters, batch number, purity, composition, concentration. Stability information must also be available. If CoA is inadequate, this constitutes a deviation (Doc 19, Ref 34, 35, 42 & 44). TI usage should only occur when sufficient information is available to confirm identity. Characterisation (including stability) must be complete by the end of the study. If not, this is a deviation. (Doc 19, Ref 37 & 38.) Lack of characterisation data should be justified (Doc 19, Ref 46 & 47). Verification of the quality and integrity of the characterisation information provided on the CoA, e.g. what quality system was the data generated under (Doc 19, Ref 40).	
6.2.3	Where supplied by Sponsor, mechanism in place to verify the ID of the TI.	
6.2.4	Stability under storage and test conditions to be known.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.2.5	Prepared test item: - homogeneity, conc, stab in vehicle must be determined and reported; - expected that this data is generated in compliance with GLP. If not, it needs to be highlighted in the report and the impact on the validity of the study and integrity of the TI assessed (Doc 19, Ref 44, 62, 63 & 64); - for tank mixes, this analysis may be undertaken as a separate laboratory experiment; - use of pre-existing data acceptable if justified by documented risk assessment provided that this data is available and there are records to demonstrate that equivalent preparation processes were used.	
6.2.6	Retention/archiving of TI (for all studies except for short term): - sample from each batch should be retained and archived (either immediately after receipt or on first opening of container), under appropriate storage conditions, for as long as its quality permits evaluation (Doc 19 Ref 28, 70, 71, 72).	

7. SOPs

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.1	SOPs & revisions approved by TFM/TSM.	
Doc 22	Forms (Ref 6.2): - the number of used templates compared to the number of available copies to be controlled; - if templates or forms are available by printing, the number of printouts to be controlled.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.2	Access to SOPs: - immediately available; - hard copy/electronic; - current versions available only (version control); - access to textbooks, analytical methods, manuals used as supplements to SOPs.	
7.3	Deviations from SOPs documented and acknowledged by SD/PI.	
7.4	**SOPs available for following:**	
7.4.1	Test and reference items covering: - transport, receipt, identification, labelling, sampling, handling, storage, characterisation, archiving and disposal (Refer to Doc 19 Ref 16).	
7.4.2a)	Equipment/apparatus covering: - use, maintenance, cleaning and calibration.	
7.4.2b)	Computerised systems covering: - validation; - acceptance testing; - operation; - maintenance, fault repair; - security; - change control; - back-up and business continuity, disaster recovery; - periodic evaluation; - responsibilities; - archiving and retrieval; - monitoring and auditing of systems; - system retirement. (Refer to Doc 17, Ref 47)	
7.4.2c)	Reagents and solutions covering preparation and labelling	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.4.3	Record keeping, reporting, archiving covering: - coding of studies, data collection, preparation of reports, handling of data.	
Doc 15	Archiving SOPs to include: - responsibilities of the archivist and archiving staff; - storage conditions / environmental contro;l - security / access control; - procedures for the receipt of records and materials ; - indexing procedures, including electronic records; - procedures for accessing, removal and return of records and materials; - retention period; - contract archiving services, if applicable; - disaster recovery (archive contents); - disposal of archived records and materials; - frequency of archiving non-study specific records; - where hybrid systems are required to be used, this should be clearly documented as to what constitutes the whole data set and SOP should define which records should be retained. (Doc 22). Refer to Document No 15 (ref 7.1).	
Doc 22	Data integrity SOPs to cover: - data governance (Ref 5.1.5); - scribe documentation (Ref 6.2); - processing data rules (Ref 6.9); - process for data review including actions to be taken if deviations identified. This procedure should enable data corrections or clarifications to provide visibility of the original record, and audit trailed traceability of the correction (Ref 7.1).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
7.4.4	Test System SOPs	
7.4.4a)	Room preparation and environmental room conditions;	
7.4.4b)	Receipt, transfer, proper placement, characterisation, identification and care of test system;	
7.4.4c)	Test system preparation, observations and examinations before, during and at conclusion of study;	
7.4.4d)	Handling test system individuals found moribund or dead during study;	
7.4.4e)	Collection, identification and handling of specimens;	
7.4.4f)	Test systems in field plots;	
7.4.5	QA SOPs to cover: - planning, scheduling, performing, documenting and reporting inspections; - QA inspection of raw data (Doc 23, 7.4.2); - QA statement, including responsibility for signing (Doc 23, 7.9); - risk assessment process (if facility adopts risk based audit schedule) (Doc 23, 7.2.1).	
Doc 13	Multi-site SOPs to cover: - selection and monitoring of test sites; - appointment and replacement of PI; - transfer of data. specimens and samples between sites; - storage, return or disposal of TI and RI being used at remote TS.	

8. Performance of the Study

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.1	**Study Plan**	
8.1.1	Plan approved by dated signature of the SD prior to the initiation of the study.	
8.1.2a)	Amendments justified and approved by SD and maintained with SP. Amendment verified by QA in same manner as SP (Doc 23, 7.3).	
8.1.2b)	Deviations described, explained, acknowledged and dated in a timely fashion.	
8.1.3	For short term studies, a general SP accompanied by a study specific supplement may be used.	
8.2	**Content of the Study Plan**	
8.2.1a)	Title.	
8.2.1b)	Nature and purpose.	
8.2.1c)	ID of TI.	
8.2.1d)	Ref item.	
8.2.2a)	Sponsor.	
8.2.2b)	TF and TS.	
8.2.2c)	SD.	
8.2.2d)	PI and phases delegated.	
8.2.3a)	Date of approval by SD.	
8.2.3b)	Proposed experimental start and finish dates.	
8.2.4	Reference to the OECD test guideline (TG), other test guideline or method to be used.	
8.2.5a)	Justification for selection of test system.	
8.2.5b)	Characterisation of test system (species, strain, source, weight range, age, sex, etc.).	
8.2.5c)	Administration method.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.2.5d)	Dose levels, concentration, frequency, duration of application/administration.	
8.2.5e)	Experimental design including description of chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations, examinations to be performed and statistical methods to be used.	
Doc 22	Data transfer protocol or agreement with mechanisms in place to ensure that the received data have the same attributes as the sent data. (Ref 6.10).	
8.2.6	List of records to be retained.	
8.3	**Conduct of the Study**	
8.3.1	Unique ID, with all items concerning the study carrying this identification.	
8.3.2	Study conducted in accordance with SP.	
8.3.3	Data to be recorded directly, promptly, accurately, legibly, with all entries signed or initialled and dated. Data to be complete, consistent, enduring and available throughout the lifecycle (Doc 22).	
8.3.4	Corrections to data made so as not to obscure previous entry, indicate the reason for the change, and be dated or initialled and signed by the individual making the change.	
8.3.5	Computer data.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	Data Integrity	
Doc 22	Data governance (Ref 5.1.5) - data governance applied across the whole data life cycle addressing data ownership and accountability and considering the design, operation and monitoring of processes/systems, including control over all changes to data; - risk management techniques to detect risks for data integrity failures, to minimise the potential risk to data integrity and to identify any residual risk; - effectiveness of the data governance approach to be monitored and assessed on a regular basis as defined by TFM.	
Doc 22	Risk assessment (or equivalent) - implementation of a fully documented system with supporting rationale thatprovides an acceptable state of control based on the data integrity risk. Requires a documented risk assessment (or equivalent) (Ref 5.1.2); - risk mitigation (Ref 5.1.2); - prioritisation of areas for remediation, including acceptance of an appropriate level of residual risk, to be documented and approved by TFM (Ref 5.1.9); - periodic reviews of the risk assessment (Ref 5.1.9); - where long-term remediation actions are identified, risk-reducing short-term measures to be identified, documented, and approved by TFM until a more permanent solution is implemented (Ref 5.1.9); - access rights to data and records should be always set up based on the risk assessment of each phase of the data lifecycle (Ref 8.1).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
Doc 22	Invalidating or excluding data (Ref 6.8) - documented justification for any data invalidated or excluded; - invalidated or excluded data to be considered during data review and reporting; - investigations to find the cause of the generation of data that must be invalidated or excluded are essential; - for common cases (e.g. failure to meet acceptance criteria), therules to exclude or invalidate data should be defined in advance in the study plan or in SOPs; - all data (even if invalidated) should be retained with the data set and be available for review in a format that allows the validity of the decision to invalidate or exclude the data to be confirmed.	
Doc 22	Data processing (Ref 6.9) - records to allow reconstruction of all data processing activities regardless of whether the output of that processing is subsequently reported. - repeat data processing with progressive modification of processing parameters, to be visible with documented justification.	
Doc 22	Data review (Ref 7.1) - the level and scope of data review defined by a risk assessment with critical data to be reviewed through the critical steps of their data life; - data review to include a review of relevant metadata, including audit trails or elements of them; - records of data review to include any deviationsdetected by the review, the date that reviewwas performed and the signatures of those performing the review; - review of manual data entry (Doc 17, Ref 72); - review of datafrom hybrid systems - actual data sources reviewed should be able to determined (Doc 22 Ref 7.3).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
Doc 22	Computerised system transactions (Ref 6.12) - critical transactions defined during development (e.g. via the URS) based on the functionalityand the level of risk associated with the system; - process controls for critical transactions to consider system design (prevention), together with monitoring and review processes; - oversight of activities to alert to failures that are not addressedby the process design; - Computerised system transactions recorded contemporaneously; - Where transactional systems are used, the combination of multiple unit operations into a combined single transaction is to be avoided (e.g. multiple data entry before saving), and the time intervals before saving of data should be minimised. Systems designed to require saving data to permanent memory before prompting users to make changes. Exceptions to these requirements to be justified.	

9. Reporting of Study Results

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
9.1	**General**	
9.1.1	Final Report for each study.	
9.1.2	PI to sign and date their reports.	
9.1.3	SD compliance statement.	
9.1.4	Corrections and additions to the report in the form of an amendment. Amendment to clearly specify the reason and be signed and dated by the SD.	
9.1.5	Reformatting to comply with submission requirements of Regulator does not constitute an amendment.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
9.2	**Content of the Final Report**	
9.2.1a)	Title.	
9.2.1b)	ID of TI. If the TI is supplied pre-prepared, the final report should describe where it was prepared and by whom. Characterisation data on the active TI ingredient should also be available and reported (Doc 19, Ref 61).	
9.2.1c)	Reference item.	
9.2.1d)	Characterisation. Final Report must state who was responsible for TI characterisation and who performed it. It may also state other relevant information, e.g. the quality system under which the characterisation was performed. The Final Report should include all available TI data (Doc 19, Ref 41 & 45).	
9.2.2a)	Sponsor.	
9.2.2b)	TF and TS.	
9.2.2c)	SD.	
9.2.2d)	PI and phases.	
9.2.2e)	Name of scientists.	
9.2.3	Exp start and completion dates.	
9.2.4	QA statement.	
9.2.5a)	Methods and materials used.	
9.2.5b)	Reference to OECD guidelines or method.	
9.2.6a)	Results summary.	
9.2.6b)	All info and data required by SP.	
9.2.6c)	Results including calculations and stats.	
9.2.6d)	Evaluation and discussion.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
9.2.7	Location of records. Final report to identify all GLP relevant electronically archived data and the location of the electronic archive (Doc 17).	

10. Storage and Retention of Records and Material

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
1.1.2l)	Archivist (and back-up) appointed. Archivist training records for archivist (1.1.2c). Independence. Archivist confirms archiving with SD.	
3.4	Archive Facilities. Design and archive conditions to protect contents from untimely deterioration. Pest control. Smoke alarms. Temp/humidity controlled.	
1.3	PI to confirm archiving with SD (Doc 15, ref 7.4).	
10.1a)	Archived records: - SP, raw data, final report etc; - where archiving electronic communication (e.g. to allow verification of GLP activities and responsibilities), any attachments should remain associated with the corresponding message and message chains should be preserved (Doc 22).	
	Archived materials: TI/RI, specimens, external data storage devices. Blocks, slides, tissues, etc.	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
10.1b)	QA records.	
10.1c)	Qualifications, training, resume etc.	
10.1d)	Equipment records.	
10.1e)	Computer validations.	
10.1f)	Historical SOPs.	
10.1g)	Environmental monitoring.	
10.2	Indexed and orderly.	
10.3	Access restricted, record in and out. Log of persons accessing archive. Process for retrieval and return (doc 15, ref 7.7).	
10.4	Records to sponsor if TF bust.	
Doc 15	<u>Timeframes:</u> - timeframe for transfer of material from SD/PI to archivist defined (Doc 15, ref 7.4); - timeframe between removal and return of items (Doc 15, ref 7.7); - frequency of archiving facility records defined (Doc 15, ref 7.4); retention times (Doc 15, ref 7.6).	

Clause No.	Requirement	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
Doc 15	<u>Electronic archiving (Doc 15, Ref 8)</u> - discrete area on same system (either physically or logically separated), or dedicated electronic archive system separate to the system that captures the record; - records locked so they cannot be altered or deleted without detection; - migration - all data to be migrated including raw data, metadata, audit trails, e-signatures, etc; - migration to be validated; - validation of electronic archiving processes; - long term storage; - staff involved in management of IT archive (e.g. IT staff) ; - verified copies from electronic dynamic records (generated by migration) should be retained in dynamic state (Doc 22).	
Doc 15	<u>Off-site / contract archiving (Doc 15, Ref 10)</u> - formal agreement; - chain of custody documentation; - access arrangements; - inspected by QA.	
Doc 15	<u>Disposal of records (Doc 15, Ref 7.8)</u> - TFM and sponsor authorisation; - records of disposal, including reasons.	