Medicines & Healthcare products
Regulatory Agency

MHRA

PHASE I
ACCREDITATION SCHEME
REQUIREMENTS

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1. Background

As detailed in the original implementation of the accreditation scheme in April 2008, one of the recommendations from the Expert Scientific Group on Phase I Clinical Trials (ESG), following the TGN1412 incident in March 2006, was that a voluntary accreditation scheme be established for organisations conducting Phase I trials, in particular for those conducting first in human (FIH) trials and for those trials with risk factors that would require review by the Clinical Trials, Biologicals and Vaccines Expert Advisory Group of the Commission on Human Medicines (EAG) before it may be authorised.

The MHRA GCP Team has routinely inspected organisations conducting Phase I trials in the UK in a cyclical programme since 2006. However, the MHRA only inspects within the scope of the clinical trial regulations and therefore many aspects relating to how these organisations performed Phase I trials at that time could only be made as recommendations.

The original aim of the MHRA Phase I Accreditation Scheme was to increase the scope and depth of inspections in order to provide the MHRA and Research Ethics Committees (REC) with more information about the organisations seeking to conduct these trials, so that approval decisions could be made even more robust.

The scheme was designed to give assurance that organisations within the scheme not only met but surpassed the basic regulatory GCP aspects by having additional 'best practice' procedures that encompassed the highest standards for avoiding harm to trial participants and for handling medical emergencies should they arise. Thus also assuring sponsors that accredited organisations make significant contributions to enhancing the safety of participants and are considered to be centres of excellence for Phase I research.

The original accreditation scheme was formally implemented in April 2008 and the initial scope was for organisations conducting non-therapeutic Phase I trials, including those organisations conducting early phase trials in the 'patient volunteer' populations e.g. asthma sufferers. It was not intended to cover Phase I trials in severely ill patients conducted in a hospital setting (including first time in patient (FTIP) trials such as in oncology), non-interventional drug trials i.e. those that do not require a Clinical Trial Authorisation (CTA) or non-drug trials.

The scheme originally allowed for the classification of organisations into two types: standard accreditation (accredited to carry out all Phase I trials other than FIH trials with risk factors that would require EAG review) and supplementary accreditation (accredited to carry out clinical trials with compounds at all levels of risk, including those that require review of risk factors by the EAG).

2. Scope

The scheme continues to be voluntary for organisations (commercial and non-commercial) conducting Phase I trials i.e. clinical trials to study the pharmacology of an investigational medical product (IMP) when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the participants of the trial (UK Statutory Instrument 2004/1031[1]).

The scheme has a single classification system which is based on the organisation's procedures and facilities, plus the training and experience of the organisation's personnel; thus assessing the ability of the organisation to manage trials, including those with certain risk factors (such as those for FIH trials or trials that would require review by the EAG). Further information on these risk factors can be found on the MHRA website[2] and in the Committee for Medicinal Products for Human Use (CHMP) 'Guideline on Strategies to Identify and Mitigate Risks for First in Human Clinical Trials with Investigational Medicinal Products'[3].

The scope of the scheme encompasses both standalone facilities and named organisations within a hospital or academic setting (i.e. either a commercial organisation's wards/area or a pre-defined non-commercial clinical research facility/ unit, including their named or core staff). The accreditation does not cover the entire hospital and all the wards and staff or trials performed outside the named organisation.

The scheme covers Phase I and other 'early phase' trials in healthy participants, patient participants and patient populations (see definitions in section 7). It is not intended to cover non-interventional drug trials i.e. those that do not require a CTA, non-drug trials or later phase trials (i.e. Phase II to IV).

Serious Adverse Drug Reactions may occur in any trial, regardless of the perceived 'higher risk' of certain compounds and molecules. There are also risks associated with trial procedures (for example, inhalation studies, bronchoscopy etc.) and the possibility of reactions to marketed drugs used as comparators and non-IMPs used as challenge agents. It is therefore vital that all organisations conducting Phase I trials have adequate staff and facilities for dealing with any such emergencies.

Where a sponsor selects a Phase I accredited organisation, it will be because they have decided to have their trial conducted at an organisation that surpasses basic regulatory requirements, as the accreditation scheme is concerned with the quality systems and operation of the organisation. The sponsor must remember that it is the organisation (i.e. the organisation's procedures and systems) that is inspected and receives accreditation. However some aspects relevant to the accreditation scheme are the responsibility of the sponsor (e.g. the collection, analysis and quality of the pre-clinical data) or may be retained by the sponsor (e.g. collection, analysis and quality of data for the decisions to continue the Phase I trial/dose escalate). Therefore, where the sponsor requires their trial(s) to be carried out in compliance with the accreditation scheme, the sponsor also needs to adhere to any requirements specified by the accredited organisation and any activities they retain should be performed to a similar standard to that required by the accredited organisation's procedures. Also, sponsors should already be aware of all the potential risks in the clinical trial and take steps to mitigate these risks[3].

MHRA statutory GCP Inspections have been in place since May 2004. Those organisations that are part of the voluntary Phase I Accreditation Scheme do not routinely receive additional routine statutory GCP systems inspections but the MHRA reserves the right to perform a routine inspection of additional systems or triggered inspection of the organisation if concerns arise or if important information comes to light that requires investigation. Organisations may also be inspected by other MHRA GXP teams, regulatory authorities or as an investigator site as part of a sponsor inspection.

Organisations that are not accredited are not excluded from conducting Phase I clinical trials, since the scheme is voluntary. However, RECs/Research and Development

(R&D) Departments (where applicable) will take the absence of accreditation into account when considering the trial site and may consider conducting their own site assessment or evaluation.

3. Accreditation of Organisations

Potential applicants will submit a completed Phase 1 Accreditation Compliance Checklist and associated Declaration Form (available from the MHRA website[2]) and any associated documents (the current clinical floor plans, CVs and job descriptions for key personnel and all Standard Operating Procedures (SOPs) referenced in the checklist) to the MHRA GCP Team. This will be reviewed and, on completion of a successful inspection verifying that all the requirements have been met, the organisation will be recommended for accreditation.

An organisation must be able to demonstrate that it is able to carry out clinical trials with compounds at all levels of risk, including those that have never been tested in humans (FIH) and those that require review of risk factors by the EAG. This means they must have formal procedures in place and appropriately trained and experienced staff available to cover all the requirements stated in Appendix 1.

Accredited organisations will be required to complete and submit an updated Phase I Accreditation Compliance Checklist in advance of each subsequent re-accreditation inspection.

4. Operation of the Accreditation Scheme

The scheme is operated on a voluntary basis. The inspections conducted for the accreditation scheme encompass a wider scope than standard GCP inspections and includes a detailed review of the organisation's systems and procedures relevant to the accreditation scheme requirements.

When organisations apply for accreditation, an inspection will be carried out accordingly with an appropriate fee. Fees are consistent with current inspection fees. In addition, there will be an initial set-up fee, plus a small fee for issue of the accreditation certificate. Any variations to the certification requested at a later date may require a further inspection (and an additional fee) as an inspection may be required to assess the criteria or facilities not previously reviewed.

Once an inspection has demonstrated that the requirements of the scheme are met, the organisation will be accredited accordingly, and an accreditation certificate issued. The certificate will not include an expiry date and the current status of accreditation will be as per the list of accredited Phase 1 organisation on the MHRA website[2].

Organisations are required to submit to the MHRA GCP Team any significant changes or variations after accreditation. Significant changes or variations are those that affect the basis upon which the accreditation is granted as outlined in Appendix I. For example, these may include:

- Relocation of the organisation or addition/change to facilities (e.g. extension of an existing organisation or the permanent use of facilities at another location).

- Significant changes to procedures that impact on key aspects of the accreditation scheme (e.g. changes to procedures relating to medical emergencies, participant recruitment, resourcing and staffing, minimum staffing requirements, risk assessment etc.)
- Changes in key personnel (titles used for key personnel will differ between organisations and organisations will need to review the requirements in the accreditation scheme and determine which personnel are key to attaining and maintaining those requirements. However, in general, these will be the medical doctors (including the Medical Director or the medical doctor who has overall responsibility for medical aspects), any PIs authorised for FIH trials (or the person responsible for assessing the PI for a clinical trial), Senior Nurses, Clinic Manager (i.e. the person who has overall responsibility for the day to day running of the clinic and the clinic equipment e.g. emergency trolley), the Pharmacist (or individual responsible for the emergency drugs) and also the person responsible for maintaining the organisation's quality system.
- Significant contractual changes in agreements with local hospitals.
- Significant changes in the organisation's systems, for example, implementation of an electronic source data capture system which changes how data is collected, stored, used across numerous processes including Phase I accredited processes, dose escalation, Investigator review of volunteer safety data, changes to the Quality Management System resulting in different SOP structure, names and references etc.

Variations should be emailed to phase1accreditationscheme@mhra.gov.uk using the Variation Form available on the MHRA website[2]. The MHRA GCP Team will assess the changes and decide if an inspection is warranted or if the changes can be accepted based on the documentation provided. The assigned GCP inspector will issue the completed Variation Form (with a new certificate as applicable) once the changes have been approved. If changes at the organisation result in any of the accreditation criteria no longer being met, the MHRA GCP Team must be informed immediately, and could result in a suspension of accreditation (refer to section 6 for further details). If substantial changes occur during a clinical trial, then the REC and MHRA Clinical Trials Team need to be informed where appropriate and in accordance with the legislation.

MHRA keeps the Health Research Authority (HRA) informed of the accreditation status of organisations, including forwarding of relevant documents (e.g. Inspection reports and accreditation certificates or any information on the suspension or termination of an organisation's accreditation status) in order to assist RECs with their responsibility to carry out site-specific assessments. RECs will assess non-NHS organisations, while the R&D department on behalf of the hospital Trust will be responsible for NHS units. However, RECs may request further information to assist with the site-specific assessment, whether or not an organisation participates in the accreditation scheme.

The MHRA GCP Team will maintain a list of accredited organisations; this list will be published on the MHRA website[2].

5. Reporting Accreditation Inspections

Following initial accreditation and routine re-accreditation inspections, which have not resulted in critical findings, an inspection report will usually be produced within the

standard timeframe for routine GCP inspections (this is currently 25 working days). Any major findings, particularly in the area of participant safety (e.g. eligibility, medical cover and participant identification) will need to be resolved prior to accreditation or re-accreditation. Responses will be required as per the standard format for routine GCP inspections; however, for any findings related to the key requirements of the accreditation scheme, evidence of CAPA completion will need to be submitted along with the responses (e.g. the relevant updated SOP or examples of the new/completed forms).

If critical findings are identified during the inspection, the Lead Inspector will promptly inform the MHRA Clinical Trials Team and HRA, as appropriate. Also, the legal entity which the organisation forms part of (e.g. the NHS Trust or University for academic units) will be notified. Critical findings are reviewed by the GCP Compliance Management Team and may be referred to the Inspection Action Group, according to standard MHRA procedures, and a decision will be taken as to what action should be taken, this could include suspension or revocation of the organisation's accreditation (refer to section 6).

Upon adequate resolution of all findings, the inspection will be closed as per the standard format for GCP inspections. At initial accreditation, an accreditation certificate will be issued.

6. Suspension/Revocation of Accreditation

Once accredited, organisations must continue to demonstrate compliance with the requirements of the scheme in order to maintain their accreditation. However, should serious issues be identified, either by themselves or as a result of information received by the MHRA (e.g. through inspection, a complaint, serious breach report or information from HRA), this may then lead to a temporary suspension of the organisation's accreditation status or, ultimately, removal of their accreditation status.

When an organisation is suspended or removed from the accreditation scheme, this does not prevent them from continuing to recruit and treat participants ; however they will be required to inform the sponsors as well as associated RECs/R&D departments of any current and upcoming trials they are conducting of their suspension or removal.

7. Definitions

Phase I (according to Statutory Instrument)	A clinical trial to study the pharmacology of an IMP when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the participants of the trial. Note: It is recognised that this definition is too restrictive to apply to all Phase I trials, for example, in oncology, anaesthesia, genetic disorders, immunological etc.
Early Phase	All types of Phase I trials using either healthy participants, patient participant and/or patients, including FIH, FTIP.

First in Human (FIH)	IMP is administered to a human for the first time.
First Time in Patient (FTIP)	This is a subset of FIH, where it would be unethical or not possible to administer the IMP to a healthy participant so the IMP is administered to a patient. It does not refer to a Phase II trial where the IMP was previously given to a healthy participant.
Healthy Participant	A well (generally healthy, not sick) person who agrees to participate in a clinical trial for a reason other than medical purposes and receives no direct health benefit from participating.
Patient Participant	A person who has a specific medical condition (e.g. asthma or diabetes etc.) relevant to the clinical trial, that agrees to participate in a clinical trial for reason other than medical purposes and is unlikely to receive a direct health benefit from participating.
Patient	A person being treated for a specific medical condition who may have been invited or referred by the GP/consultant to participate in a clinical trial. Patients may receive a therapeutic benefit from the trial.
Clinical Trials, Biologicals and Vaccines Expert Advisory Group (EAG)	The Commissions on Human Medicines (CHMP) group of experts available to regulatory authorities to seek an opinion for those trials with risk factors that would require review before it is authorised.

8. References

1. The Medicines for Human Use (Clinical Trials) Regulations (SI 2004/1031), as amended.

2. MHRA GCP – Phase I Accreditation Scheme Page: https://www.gov.uk/guidance/mhra-phase-i-accreditation-scheme

3. EMA Guideline on Strategies to Identify and Mitigate Risks for First in Human Clinical Trials with Investigational Medicinal Products (EMEA/CHMP/SWP/28367/07 Rev01): https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational_en.pdf

4. MHRA Phase I Accreditation Scheme Guidance Document.

9. Revisions

The accreditation scheme was revised in October 2013 after 5 years to:

- accommodate a single classification system.

- expand the scope to include units that function differently to the traditional commercial Phase I unit, for example, those units in an academic setting.
- include more types of trials that can be covered by the scheme, for example, FTIP and patient volunteer (PV) trials that may be performed in the accredited unit.

The accreditation scheme was revised in October 2015:

- section 4: increase in the scheme certification to a 3 year period, in line with the risk based inspection programme, unless there is justification for a reduced certificate period.
- appendix 1, point 11: clarification that scenarios are in addition to those undertaken for life support certification.
- appendix 1 point 12: Clarification regarding Diploma in Pharmaceutical Medicine (for consistency with the Accreditation Scheme Guidance Document, version 2).
- appendix 1 point 15: clarification that this includes any paediatric life support training.

The accreditation scheme was revised in April 2021:

- section 3: Units will now be required to completed and submit a completed Phase I accreditation compliance checklist on initial application and in advance of each subsequent reaccreditation inspection.
- section 4: Variations should now be submitted using the variation form available on the Phase I accreditation scheme website.
- appendix 1, requirements for Staff, point 12.
- appendix 1, requirements for QA and QS formalised in points 20 m and n, 21 and 22.

The accreditation scheme was revised in August 2022:

- Administrative updates only: MHRA branding, formatting and staff titles.

This revision amends:

- Change in procedure to remove expiry dates from accreditation certificates and therefore the requirement to update these after a re-accreditation inspection.
- Clarification around requirements for a variation.
- Other minor updates/improvements made in wording throughout.

Appendix 1: Requirements

In addition to there being no unresolved critical and major findings in GCP at the organisation, particularly in the area of participant safety (e.g. eligibility, medical cover, participant identification etc.), the following **must** be in place for all organisations that wish to be accredited to carry out clinical trials with compounds at **all levels of risk**, including those that have never been tested in humans (i.e. FIH) and those that require review of risk factors by the EAG:

Clinical Trial Design and Set-Up

1. An agreement with sponsors (or internal memorandum of understanding for in-house units) detailing procedures and responsibilities for notifying the investigator immediately if/when new safety/toxicology data come to light.
2. A formal risk assessment and risk management/mitigation strategy. This must be able to demonstrate that the organisation (independently of the sponsor) continuously verifies and assesses all aspects of the trial, including any pre-clinical data and pharmacology. For example (but not limited to), trial design, starting dose calculations, dose escalation proposals, stopping criteria, exposure, predictable reactions/adverse events, availability of any specific antidotes or emergency treatments and any additional and/or specialist staffing and/or training.

Medical Emergencies and Facilities

3. An agreement with a local hospital for supporting emergencies arising from the clinical trials performed by the organisation *or* the ability to demonstrate communication and notification of trial information (e.g. dosing times) with the hospital's emergency teams. The hospital resuscitation committee, emergency response team and the Intensive Care Unit (ICU) staff (as applicable) must be aware of the accredited organisation, the nature of the research (e.g. FIH, biologicals etc.) and that they could be referred participants from the organisation at any time.
4. An emergency trolley must be available that is easily and rapidly accessible. There must be a trolley in each main area, which can be moved quickly to where it is needed. The emergency trolley must be stocked as per the current Resuscitation Council UK guidelines and carry as a minimum:
    a. Oxygen and delivery apparatus.
    b. Equipment for procedures such as cannulation and suitable fluids for intravenous (IV) infusion.
    c. Supraglottic airway devices (e.g. Laryngeal Mask Airways (LMA) or I-Gel®).
    d. Self-inflating bag, or equivalent, for assisted ventilation.
    e. Suction equipment.
    f. Defibrillator (this should be an automated external defibrillator (AED) defibrillator with a manual override).

g. Equipment for tracheal intubation and emergency cricothyroidotomy should be available for use by appropriately experienced personnel or a responding emergency team only.

5. There must be a documented weekly check of the contents of the emergency trolley, including regular checks of the expiry dates for medication and equipment. If the emergency trolley or the emergency drug box is sealed then the tamper-proof seal should be checked weekly.
6. Continuous monitoring equipment must be available to include ECG, pulse oximetry, vital signs such as blood pressure, heart rate and temperature.
7. Beds used for dosing days must be able to be tilted and adjusted for height.
8. Alarms must be placed in any areas likely to be occupied by participants (e.g. showers, toilets, ward(s) and recreational areas(s)) and these must be regularly tested (and the testing documented).
9. Staff must be able to open the toilet/bathroom doors from the outside in an emergency.
10. A robust (and tested) arrangement for immediate maintenance of life support (i.e. resuscitation and stabilisation of participants in an acute emergency) and onward transfer of participants to hospital, where necessary.
11. All staff must undergo periodic testing of emergency scenarios within the organisation. This testing must be documented. For those staff in contact with participants, they must attend at least one scenario a year in addition to any scenarios conducted as part of a staff members life support certification (e.g. Advanced, Immediate or Basic Life Support (ALS/ILS/BLS) or equivalent).

Staff

12. Documentation that demonstrates that medical doctors are authorised to act as principal investigator – for example, as described by their job description (or other formal documentation approved by appropriately appointed personnel, such as the risk assessment, an authorisation statement etc.), and supported by a curriculum vitae and training record. It is expected that Principal Investigators have relevant qualifications, training and clinical experience.

    For medical doctors that wish to undertake FIH trials, in addition to the above it is expected that PIs for FIH trials have relevant clinical experience in running Phase I trials, plus a post-graduate qualification, such as a Diploma in Human Pharmacology, MSc in Clinical Pharmacology, completion of Speciality Training in Clinical Pharmacology or equivalent. Qualifications such as Member of the Royal College of Physicians (MRCP) and Completion of Specialty Training in Pharmaceutical Medicine (PMST) are highly desirable but are not considered to be sufficient. The Diploma in Pharmaceutical Medicine would only be considered acceptable where it is supported by experience in FIH trials.

    Where the organisation does directly employ the PI or the trial is FIH in patients or patient participants, yet the proposed PI does not have the relevant post-graduate qualification, a Sub-Investigator that is authorised as a FIH PI (as per the above) could be formally delegated responsibility for those tasks that require clinical pharmacology expertise (see associated guidance[4]).

There must be a mechanism for the organisation to assess the trial and the suitability of the PI, plus their research team (as applicable) and ensure there is responsibility formally assigned that meets the above qualifications, training and experience where gaps are identified (e.g. use of a Phase I review committee and expert advisor and information is available on expectations in the associated guidance[4]).

13. Documentation that demonstrates that appropriately trained and experienced staff are available on dosing days. During the conduct of EAG type trials, medical doctors trained to ALS standards and experienced in handling medical emergencies must be present during and following dosing for a defined period. In addition to theoretical knowledge, the medical doctors must have relevant and recent experience of handling medical emergencies. Organisations may approach this in a number of ways, for example:

    - The organisation's employed (or core staff) medical doctors are ALS trained[A] and may participate on an ongoing basis in periodic clinical attachments involving participation in a hospital resuscitation team rota to ensure continued exposure to identifying and handling real medical emergencies[B].

    Or

    - Appropriately trained clinicians with up-to-date emergency medicine experience may be brought into the organisation on a contract basis during dosing days. These contract staff must also be trained in ALS, the trial protocol, organisational procedures and GCP. The contractor would not be expected to take on the role of the PI so must be appropriately supervised whilst in the organisation. Indemnity arrangements made by the sponsor and/or organisations must also apply to the contractor.

    Or

    - The organisation may be located within a hospital with critical care facilities. The organisation will have 24-hour access to the hospital emergency response team, who can arrive at the organisation within minutes of an emergency.

    [A] *For paediatric Phase I trials an equivalent paediatric life support training (for example, Advanced Paediatric Life Support (APLS) or European Paediatric Advanced Life Support (EPALS).*

    [B] *Where the organisations uses its employed (or core) medical doctors to provide cover in a medical emergency, they must be able to demonstrate appropriate training and experience in handing medical emergencies. A procedure must be in place to address the assessment of continuing competency in this area (e.g. it may be achieved by peer review, audit or other means). This continuing assessment must be documented and countersigned by the assessors. Evidence must be kept to document exposure to medical emergencies in order to demonstrate that they remain experienced and competent to handle such emergencies.*

14. Documentation to demonstrate that there are sufficient numbers of trained and experienced staff employed by or contracted to the organisation for all activities conducted (including appropriate numbers of staff with adequate training to handle medical emergencies). There must be sufficient cover for dosing days and

overnight stays. The organisation must have in place a policy or SOP that stipulates the minimum staffing levels during the clinical conduct of the trial.

15. Staff that are appropriately and currently trained and assessed as competent to perform the activities that they are assigned to undertake. In addition, for clinical staff this must include initiating resuscitation (i.e. basic airway management and ventilation, IV cannulation and fluid therapy, giving adrenaline, CPR and use of an AED). Annual updates are required. At a minimum clinical staff should receive ILS training and annual updates (or equivalent paediatric life support training for organisations that undertake paediatric trials).

Participant Identification

16. A procedure to address 'over-volunteering'.

17. A robust procedure to accurately identify participants. For those unknown to an organisation, this must include utilising photographic identification, thereby verifying the person's identity/existence and ensuring that the person screened is the person dosed. Copies of photographic identification should also be retained.

18. For FIH and EAG type trials, the organisation is required to confirm participants' past medical history. For those unknown to an organisation, this should be received via the participants' GP or other medical doctor (such as hospital consultant for patient trials where they are not recruited by their own consultant, therefore have no access to the medical records for the patient), to provide assurance that inclusion and exclusion criteria are met.

19. The organisation must also hold the contact numbers for participants to ensure that they are able to be contacted when outside the organisation, should the need arise. Participants must also be provided with 24-hour emergency contact numbers for when they are outside the organisation.

Quality System

20. Written SOPs for every aspect of the organisation's activities including all the accreditation requirements. These SOPs must specifically include (but are not limited to):

    a. Procedures for handling common medical emergencies e.g. syncope, hypotension, anaphylaxis and cardiac arrest.

    b. Out-of-hours medical cover and contact with sponsor or IMP responsible person(s).

    c. Procedures for handling immediate maintenance of life support (i.e. resuscitation and stabilisation of participants in an acute emergency).

    d. Transfer of participants to hospital, including the provision of all relevant medical information regarding the trial and the participant(s) in question to the hospital.

    e. Training and refresher training, including competency assessments for all key activities, including emergency resuscitation procedures.

    f. Unblinding in an emergency.

g. Risk assessment and mitigation.

h. Dose escalation.

i. Staffing level/resourcing.

j. Expectation for minimum qualifications, training and experience for key roles and responsibilities (e.g. PIs, nurses, Phase I review committees etc).

k. Minimum staffing requirements.

l. Participant recruitment, including identification, medical history and over-volunteering.

m. Quality control (QC) procedures built into all key procedures to ensure standards are maintained.

n. Quality assurance (QA) procedures requiring audits to be performed against Phase I Accreditation Scheme requirements.

21. QC should be in built across processes with escalation of issues at appropriate points.

22. QA audits should be routinely conducted against Phase I Accreditation Scheme requirements to assess compliance throughout the inspection cycles and to ensure Corrective and Preventative Actions (CAPAs) are implemented in a timely manner.

[Note: This is not an exhaustive list, and organisations should ensure all activities are formalised adequately, especially where these impact on accreditation requirements.]