York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Department
Standard Operating Procedure
Pharm/S99

Pharmacy preparation for MHRA GCP Inspection

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&I Department website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&I Department SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&I Department website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Date:	16th June 2026
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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	11th February 2015		
2.0	25th March 2019		Change of author. Change of link to R&D website, inserted sections about mock inspections and peer assessments. Added section about the usability of PSF and the acknowledgment of SOPs on Q-Pulse.
3.0	26th May 2022		Addition of reference document Professional Guidance on Pharmacy Services for Clinical Trials. Change of author.
4.0	16th June 2026	Dominic Burns	Change of author Change in terminology according to new 2026 regulations Addition of inspection checklist

Contents

1 Introduction, Background and Purpose

An introduction to GCP (Good Clinical Practice) Inspections is described in Annex 1 of the Medicines and Healthcare Products Regulatory Agency (MHRA) Good Clinical Practice Guide. This describes the following aspects relating to GCP inspections:

- The Legal Basis for Inspections
- MHRA GCP Inspectors
- Types of GCP Inspections
- Scope of GCP Inspections
- Inspection schedule
- Phases of the Inspection Process

Pharmacy is likely to be involved at each phase of the inspection process as follows;

- Planning
  Input into the GCP inspection dossier that is required to be submitted to the MHRA prior to a statutory inspection of the organisation.
- Conduct
  Investigational Medicinal Product management (IMP) is one of the activities that may be selected for review by the MHRA during an organisation site inspection, and in the case of an Investigator site inspection, Pharmacy may be required to provide documentation relating to IMP accountability, host a tour of GCP Inspectors, or be interviewed as part of the inspection process.
- Reporting
  Pharmacy, if part of the inspection, may have critical, major or minor deficiencies following the inspection which they will need to address as part of the organisations CAPA (Corrective and Preventative Action) plan.

The purpose of this SOP is to describe the process of Pharmacy preparation for MHRA GCP Inspection and to describe the actions that the Pharmacy clinical trials team should take to support the phases of the GCP Inspection process as described above.

2 Who Should Use This SOP

This SOP is applicable to all members of the Pharmacy Clinical Trials Team at York and Scarborough Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used as follows:

- Pharmacy-related preparation for GCP inspection, Sponsor inspection and mock inspections or peer reviews.
- Pharmacy input into the phases of the inspection process.
- Pharmacy reporting and actions following inspection.

4 Procedure(s)

4.1 Preparation for the Inspection

Once notification of GCP inspection has been received by the Organisation, members of the Pharmacy clinical trials team should check compliance with the following points and take action to rectify any issues found (these points are adapted from GCP Considerations: Pharmacy GCP Checklist

Facilities (consideration should also be made for IMP storage areas outside Pharmacy)

1. Is all study medication in an area with restricted access?
2. Are all environmental monitoring records available?
3. Is all study medication segregated from normal hospital stock and clearly marked?
4. Are all returns/used study medication segregated from unused study medication (i.e. that is suitable for dispensing)?
5. Are quarantine areas clearly marked and quarantine records updated and maintained?
6. Are calibrated temperature monitoring systems/devices being used (and records easily available for inspection)?
7. Are all IT systems suitably validated e.g. electronic prescribing/dispensing systems, document management systems?
8. Are records available for fridge and freezer servicing?

Documentation

1. Are all documents version controlled and the latest version being used?
2. Do all Pharmacy files demonstrate a full audit trail of study medication management in Pharmacy?

File maintenance should be performed on a regular basis following the relevant SOPs. Pharmacy files should be presentable and user friendly. Issues and concerns should be resolved, file notes should be used to explain resolutions, and any missing documentation must be filed. Particular attention should be given to those studies selected for inspection or audit. The following are key aspects of the audit trail of study medication management and should form key checks as part of preparation for GCP inspection;

- Study medication receipt documents are present and match entries on relevant accountability logs.
- Environmental monitoring records (for storage and shipments) are present and readily available for inspection.
- Prescriptions are present and match entries on accountability logs.
- Signature logs are in place in each file to identify staff involved in dispensing, checking and other study activities.
- Dispensing and checking procedures are in place and they reflect the latest study protocol.
- Accountability logs are clear and match study medication held at site.
- Returns and destruction records are all up to date.
- Any deviations from SOPs or the trial protocol are documented in clear file notes.
- The following documents (and latest versions thereof) are present;

i. Trial Protocol
ii. Amendments
iii. Investigators Brochure
iv. Technical Agreements
v. Regulatory and Trust approvals i.e. MHRA, Ethics

Standard Operating Procedures

1. Are standard operating procedures in place, and up to date, for all activities being undertaken by the Pharmacy Clinical Trials Team?

Training Records

1. Are CV's, GCP certificates and other relevant training records readily available for all staff involved in dispensing or checking clinical trials prescriptions?

4.2 Pharmacy input into the Inspection Process

Planning

Once notification of GCP inspection has been received by the Organisation, members of the Pharmacy clinical trials team should comply with any requests from the local R&I Department for documentation to be included within the GCP inspection dossier.

The following documentation is likely to be requested to be included and therefore should be made available for R&I Department staff;

- Copies of the training records pertaining to each member of the Pharmacy clinical trials team.
- An organisation chart for the Pharmacy department including details of the structure for oversight of clinical trials conduct.
- Copies of standard operating procedures and other policies e.g. Medicines code, relating to the management of study medication by Pharmacy.
- Evidence of corrective and preventative action taken from previous inspections.
- Pharmacy files relating to those studies selected for inspection.
- Acknowledgement from all revenant members of staff for all the SOPs relating to their roles on the relevant Qpulse system (e.g. pharmacy Qpulse or research Qpulse)

Members of the Pharmacy clinical trials team should plan to be available during the inspection, ensure sufficient resources are in place during the inspection schedule to allow attendance at planned Interviews or tours, without impact on the Pharmacy service and plan appropriate facilities to support such events.

Prepare using the following documents and resources:

- Professional Guidance on Pharmacy Services for Clinical Trials
- MHRA Good Clinical Practice Guide
- GCP Considerations: Pharmacy GCP Checklist
- Contact colleagues using the regional and national network groups for findings on their recently conducted inspections

Conduct

Once GCP inspection has commenced in the Organisation, members of the Pharmacy clinical trials team should comply with any requests from the local R&I Department for Pharmacy files or other documentation that is requested by the GCP Inspector.

During any planned interviews or tours of the Pharmacy department by the GCP Inspector, members of the Pharmacy clinical trials team should;

- Be completely open and honest at all times.
- Be clear on their roles and responsibilities.
- Communicate promptly to the inspection team if there are any problems in fulfilling inspection requests.

Other tips for preparing for a competent authority inspection are described in section A1.11 of the MHRA Good Clinical Practice Guide.

Reporting

Following GCP inspection, a member of the Pharmacy clinical trials team (preferably the Overseeing Pharmacist or Clinical Trials Lead) should attend the close out session to understand any deficiencies that may relate to the Pharmacy department.

The Overseeing Pharmacist or Clinical Trials Lead should then liaise with the local R&I Department over the actions to be included in the CAPA plan relating to any deficiencies found in Pharmacy.

Points to consider when responding to inspection findings are contained within section A1.7 of the MHRA Good Clinical Practice Guide.

In general, corrective and preventative action should be completed by the Pharmacy department in a timely manner. Confirmation of actions completed should be sent to the R&I Department.

5 MHRA GCP Inspection Checklist

Planning for inspection

Please make available:

- Copies of training records.
- Organisation chart for Pharmacy including details of oversight structure for Clinical Trials.
- Copies of SOP and other policies.
- Evidence of corrective and preventative action from previous inspections.
- Pharmacy Site Files for those selected for inspection.
- Up to date Q-Pulse acknowledgments.

Documentation

Is all study medication:

- Stored in a restricted area, separated from hospital stock and segregated according to returns/used and quarantined?
- Are quarantine areas clearly marked and records updated?
- Are temperature monitors calibrated and all relevant temperature records and servicing available for inspection?
- Are all relevant IT systems suitably validated?
- Are all documents in use version controlled, up to date and demonstrate full audit trail of IMP management?
- **Particular attention should be paid to:**
    - Receipt documents are present and match entries on relevant accountability logs.
    - Environmental monitoring records.
    - Prescriptions.
    - Signature and delegation logs.
    - Dispensing and checking procedures are in place and they reflect the latest study protocol.
    - Accountability logs are clear and match study medication held at site.
    - Returns and destruction records are all up to date.
    - Any deviations from SOPs or the trial protocol are documented in clear file notes.
    - The following documents (and latest versions thereof) are present;
        - Trial Protocol
        - Amendments
        - Investigators Brochure
        - Technical Agreements
        - Regulatory and Trust approvals i.e. MHRA, Ethics
- SOPs in place and up to date.
- CV, GCP and other relevant training records readily available.

6 Related SOPs and Documents

Professional Guidance on Pharmacy Services for Clinical Trials
Version 2.1, April 2019

GCP Considerations: Pharmacy GCP Checklist Version 1 August 2011

MHRA Good Clinical Practice Guide, 2012.