York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
Pharm/S49

Training of Pharmacy Personnel

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&D Unit's 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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&D Unit 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&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

SOP Reference:	Pharm/S49
Version Number:	4.0
Author:	Poppy Cottrell-Howe
Implementation date of current version:	18th March 2019

Approved by:	Name/Position:	Stuart Parkes, Deputy Chief Pharmacist
	Signature:	Signed copy held by R&D Unit
	Date:	18th February 2019
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	18th February 2019

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	Details of significant changes
1.0	27th February 2012	
2.0	24th October 2013	Removal of references to the North and East Yorkshire R&D Alliance
3.0	19th January 2016	Updated references to the new Pharmacy clinical trials guidance published in October 2013. Removed requirement for Pharmacist trials training every 2 years. Removed references for publishing trial instruction on Q pulse. Removed references to Pharm/T25. Removed references to labels unlimited software.
4.0	18th March 2019	Change of author, reviewed and changed to reflect updated training packages, training packages separated from this SOP added as forms. Change of link to R&D website

Contents

1 Introduction, Background and Purpose

Pharmacy staff within York and Scarborough Teaching Hospitals NHS Foundation Trust, who contribute in providing a pharmacy clinical trials service, must be appropriately qualified, trained and experienced.

The purpose of this SOP is to ensure that the following are achieved and documented accordingly;

1. Any member of the Pharmacy clinical trials team who is involved in dispensing Investigational Medicinal Product (IMP) as part of a clinical trial (or any other role assigned on the delegation log for a trial e.g. drug accountability) is adequately qualified, trained and competent to fulfil this role.

2. Pharmacists and technicians who check clinical trials prescriptions must be appropriately trained and competent to fulfil this role.

3. All staff within the clinical trials team have up to date training records, GCP certificates and CV's available.
4. All staff within the clinical trials team receive study-specific training prior to dispensing of any IMP as part of the trial.
5. Signature logs are maintained for any Pharmacy staff involved in clinical trial activity.

2 Who Should Use This SOP

This procedure applies to all staff working or fulfilling duties within 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 when any new or existing member of staff with roles and responsibilities within pharmacy clinical trials requires training or revalidation of training. This SOP should be used when maintaining accurate training records.

4 Procedure(s)

4.1 Training and education requirements of members of the Pharmacy clinical trials team

All members of the Pharmacy clinical trials team must be qualified by education, training and experience to fulfil their role within the trial. A list of the generic job

specifications for all grades of staff is available on the Pharmacy X:drive and each person specification will indicate the requirements for the role.

4.2 Training packages and competencies

There are two clinical trials training packages available depending on the individual's role with pharmacy clinical trials they should complete and maintain the relevant pack, see details below:

- **Training package & competency workbook (Pharm/F115):** This training package is a comprehensive workbook and the relevant sections must be completed by any member of staff with roles and responsibilities within pharmacy clinical trials. There is a list on page 2 of the training package which indicates which sections must be completed according to an individual's job role.
  A fully trained Senior Pharmacy Technician for clinical trials or the Pharmacy Clinical Trials Manager will train the relevant member of staff alongside the training package; they will assess the member of staff's competence while working through the training pack and will subsequently sign their training pack as evidence that they have successfully completed their training.
  Training packs will be retained within the pharmacy clinical trials department and revalidation documentation can be added to the pack when completed.

- **Introduction to Pharmacy Clinical Trials – Short course training package (Pharm/F116):** A short overview of the pharmacy clinical trials service - this package should be completed by staff who are only with pharmacy clinical trials for a short period of time (less than a month) and will not have the need to perform any roles and responsibilities within pharmacy clinical trials. E.g. work experience students or cross sector pre-registration pharmacists.

Until a member of staff has completed the training relevant to their job role within pharmacy clinical trials, they must work under the direct supervision of a competent Senior Pharmacy Technician for clinical trials or the Pharmacy Clinical Trials Manager.

4.3 Standard operating procedures (SOP's), Good Clinical Practice (GCP) training and Curriculum Vitae (CV)

Standard operating procedures (SOP's)

The latest versions of the Pharmacy clinical trials standard operating procedures are available on the York and Scarborough Teaching Hospitals NHS Foundation Trust Research and Development Unit website (www.research.yorkhospitals.nhs.uk/sops-and-guidance-/). When a new clinical trial SOP or associated form is published, an email from Q-Pulse will be sent to the staff to whom it applies, on receipt of the email, recipients should read and acknowledge the document to confirm they have read and understood it. This should be done prior to the formal implementation date of the document where possible.

The SOP controller will be asked to send any relevant SOP's to new members of staff when they join the clinical trials team.

GCP Training

Any Senior Pharmacy Technician, Senior Assistant Technical Officer, Pharmacy Clinical Trials Manager or Pharmacist who is a member of the Clinical trials team (or any other staff who are trained in dispensing clinical trials) and are delegated responsibilities as part of a clinical trial (as recorded on the delegation log), must complete training in Good Clinical Practice (GCP).

Once completed, a copy of the relevant GCP training certificate must be retained in the pharmacy clinical trials department. Copies of the certificates can be provided to Trial Sponsors upon request. GCP certificates may not be filed in the individual Pharmacy trial files, in accordance with the Pharmacy Clinical Trial File Contents SOP (Pharm/F52), and may be referenced as being stored centrally through an appropriate file note.

If a member of staff is new to research it is recommended that they attend a face to face GCP training session, however eLearning is also available.

GCP must be completed every 2 years.

Curriculum Vitae

Every member of the Pharmacy clinical trials team must be able to demonstrate their training and experience to carry out their role as part of the Pharmacy Clinical Trials team through their Curriculum Vitae (CV).

Once completed, a copy of the relevant CV for every member of the clinical trials team must be retained in the pharmacy clinical trials department. Copies can be provided to Trial Sponsors on request.

CVs do not have to filed in the individual Pharmacy trial files, in accordance with the Pharmacy Clinical Trial File Contents SOP (Pharm/F52), and may be referenced as being stored centrally through an appropriate file note.

It is the responsibility of each member of the pharmacy clinical trials team to maintain their own CV following any training courses attended or review of their relevant experience. This should be done on an annual basis as a minimum.

4.4 Trial specific Instructions/dispensing and checking procedures training

Every member of the Pharmacy clinical trials team must receive training in the Pharmacy Trial Instructions (or procedures relating to handling of the IMP in Pharmacy, including the dispensing instructions) prior to Pharmacy readiness being issued to the R&D department and subsequent commencement of the trial where possible. As a minimum, this training will consist of communication of the Pharmacy Trial Instructions relating to that trial. The training given and details of who has received it should be recorded on Pharm/F61 (Pharmacy clinical trials

training record) and a copy of this kept within the relevant Pharmacy clinical trial site file.

Any member of the pharmacy clinical trials team who is involved in dispensing IMP as part of a clinical trial (or any other role assigned on the delegation log for a trial e.g. drug accountability) must be adequately qualified, trained and competent to fulfil this role.

New members of the Pharmacy clinical trials team should also receive study-specific training prior to dispensing the trial alone. This may involve shadowing a trained and competent member of staff, when dispensing a prescription for a new trial for the first time.

4.5 Accuracy checking training in clinical trials

Any pharmacist or pharmacy technician involved in accuracy checking dispensed IMP must be appropriately qualified and trained to fulfil this role. They are required to have read the Clinical trial summary and the checking procedure found within each Pharmacy clinical trial file.

They should sign the Pharmacy signature log (present in every clinical trial file) prior to checking the clinical trial prescription to indicate that they agree to follow the written procedures for the study. The checking procedure must be followed at each dispensing episode as the procedure may have been amended and a new version implemented.

As part of the pharmacy department's local induction, any new pharmacists will be given a brief overview of the clinical trials service by a member of the pharmacy clinical trials team. During this overview they will be informed about the unblinding/code breaking procedures which they may be involved in while performing out of hours duties. It is then the responsibility of the individual to read and acknowledge the corresponding SOP's on Q-Pulse.

4.6 Tracking of Training

Records of the following dates for all relevant individuals (Pharmacists and members of the Pharmacy clinical trials team) will be tracked on a spreadsheet for the purpose of ensuring compliance with the mandated timescales for completion:

- Clinical trials competency pack completion
- Completion of initial and subsequent GCP training every 2 years
- Production of an amended CV on a yearly basis

This information will be stored on the Pharmacy X: drive. The pharmacy clinical trials manager will review the spreadsheet periodically and send email reminders to staff whom further or refresher training is needed in order to maintain competence.

5 Related SOPs and Documents

Pharm/F61 – Pharmacy Training Record

Pharm/F115 - Training package & competency workbook

Pharm/F116 - Introduction to Pharmacy Clinical Trials – Short course training package