STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_026

SOP Title: Pharmacy documents control

Role	Name	Signature	Date
SOP Author	Alex Weston – Principal Pharmacist R&D		05/03/18
SOP Reviewer	Victoria Croome – Clinical Trials Technician		08-Mar-2018
SOP Authoriser	Raj Parekh – Interim Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**		Effective date varies

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	02-Aug-2016	V.1- Initial Version	01-Aug-2016
2	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_026

SOP Title: Pharmacy documents control

1. PURPOSE AND CONTEXT

1.1. To ensure that all pharmacy produced documents are version controlled and accounted for.

2. DEFINITIONS

2.1. Document control: managing documents through their life cycle to a high degree for security, version control, review cycle, visibility and for a controlled reliable audit trail.

3. PROCEDURE and RESPONSIBILITIES

3.1. Overall document control for trial produced instructions

3.1.1. All electronic pharmacy documents relating to a particular trial will be saved in: **R:\Medicines Management\Clinical trials resources\Trials** under the appropriate trial file.

3.1.2. All documents will be saved in one of the following folders:

- Approval documents (e.g. MHRA, REC, ethics committee approval, pharmacy review and approval)
- Current pharmacy produced documents (e.g. dispensing instructions, receipt instructions etc.)
- Current protocol and amendments
- Archived protocol and amendments
- Other (e.g QP certificates, SIV information)

3.2. Pharmacy produced instructions, initial production

3.2.1. Where possible, all pharmacy produced instructions will be reviewed by a second checker (either the clinical trials pharmacist or technician, depending on the author). Instructions awaiting approval will be saved in the "Draft" subfolder of "Current pharmacy produced documents" for that trial until approved.

3.2.2. Once a draft has been approved:

- Print a copy to go in the relevant section of the Pharmacy Documents control file.
- Move the original Word file from the drafts folder to the "Current pharmacy produced documents" folder for that trial.

3.3. Pharmacy produced labels, initial production

3.3.1. See SOP CP/R&D_016 for instructions on printing labels

3.3.2. All pharmacy produced labels must be reviewed by a second checker (either the clinical trials pharmacist or technician, depending on the author). Labels awaiting approval will be saved in the "Draft" subfolder of "Current pharmacy produced documents" for that trial until approved.

3.3.3. Once a draft has been approved:

- Print out labels, and complete Form 15 (printing labels worksheet). Form 15 will be kept in the relevant "Pharmacy document control" file as a record of label approval.
- Move the original Word file to the relevant folder on the computer.
- Put printed labels in the pharmacy working documents folder.

3.4. Pharmacy produced instructions, update

3.4.1. Complete the relevant Document Control Form (Form 16). Note the trial, document needing updating and the reason for this.

3.4.2. Move the Word copy of the instructions into the Draft folder for update.

3.4.3. Once the document has been updated, sign the Document Control Form (Form 16).

3.4.4. The document will be approved.

3.4.5. Once the document has been approved:

- Move the original Word file from the drafts folder to the "Current pharmacy produced documents" folder for that trial.
- Sign the document control form to show that the document has been approved.
- Cross through the old copy of the instruction in the working documents folder and mark as "superseded", sign and date. Remove from the working documents folder and staple in front of the counterpart version in the Pharmacy Document Control file.
- Print two copies of the new instruction. File one copy in the relevant working documents folder and another copy in the relevant section of the Pharmacy Documents control file.
- Sign the Document Control Form (Form 16) to show that the obsolete version of the document has been removed from the working documents file and the new updates have been put in the working documents file.

3.5. Pharmacy produced labels, update

3.5.1. Complete the relevant Document Control Form (Form 16). Note the trial, labels needing updating and the reason for this.

3.5.2. Move the Word copy of the labels into the Draft folder for update.

3.5.3. Once the labels have been updated, sign the Document Control Form (Form 16).

3.5.4. The labels will be approved.

3.5.5. Once the labels are approved:

- Sign the document control form to show that the labels have been approved.
- Cross through any obsolete labels in the working documents folder and mark as "superseded", sign and date. Remove from the working documents folder and put in a plastic wallet with the printing labels worksheet (Form 15) corresponding to those labels. Cross through the obsolete printing labels worksheet (Form 15), mark as superseded, sign and date. File the obsolete labels and Form 15 in the relevant section of the Pharmacy Documents control file.
- Print out the new labels, and complete Form 15 (printing labels worksheet). Form 15 will be kept in the relevant "Pharmacy document control" file as a record of label approval.
- Move the original Word file to the relevant folder on the computer.
- Put printed labels in the pharmacy working documents folder.
- Sign the Document Control Form (Form 16) to show that the obsolete version of the labels have been removed from the working documents file and the new updates have been put in the working documents file.

3.6. Pharmacy SOPs

3.6.1. Electronic copies of pharmacy SOPs are maintained by the R&D department.

3.6.2. Paper copies of all current versions of all pharmacy SOPs are kept in a folder in MARC and R&D. The master, wet-ink signed copies are held in the pharmacy office.

3.6.3. Paper copies of obsolete SOPs are removed from the pharmacy SOP files in MARC and R&D, and will be crossed through and marked "superseded", signed and dated. Store obsolete SOPs in the SOP sections for both the MARC and R&D Document Control Files.

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical Trials Pharmacist	Maintaining document control processes
2	Clinical trials pharmacist	Clinical trials pharmacist, clinical trials technician	Responsible for ensuring that document control processes are followed
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Form 15 (Printing labels worksheet)
- Form 16 (Documents Control Form)
- SH CP 1 Medicines Control, Administration and Prescribing Policy

- SOP CP/R&D_016 Printing labels

5. TRAINING

- ICH-GCP guidelines

6. REFERENCES